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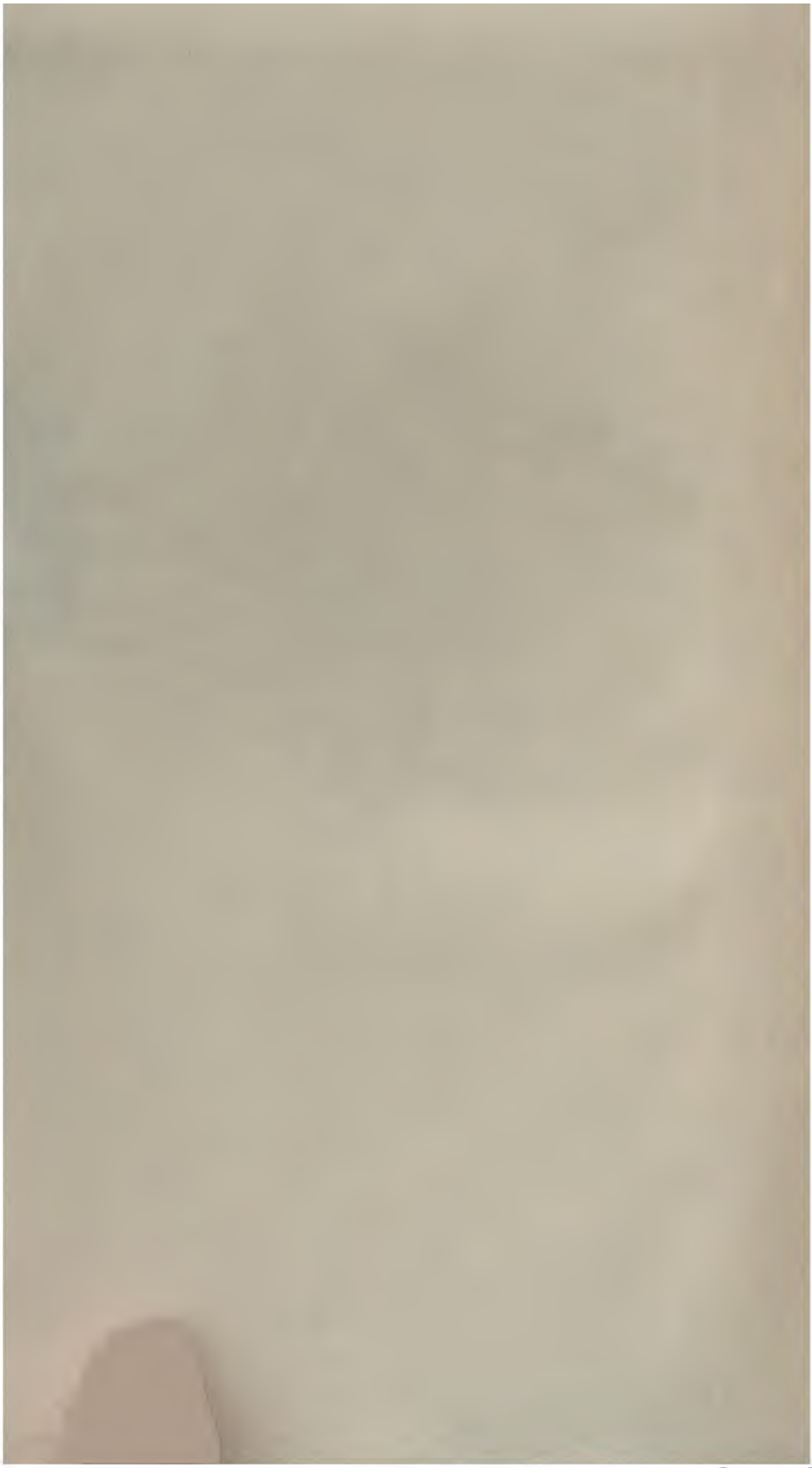

FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT; AND PESTICIDE IMPORT AND EXPORT ACT OF 1985

HEARINGS

BEFORE THE

SUBCOMMITTEE ON DEPARTMENT OPERATIONS, RESEARCH, AND FOREIGN AGRICULTURE

OF THE

COMMITTEE ON AGRICULTURE
HOUSE OF REPRESENTATIVES

NINETY-NINTH CONGRESS

FIRST SESSION

ON

H.R. 1416, H.R. 1910, and H.R. 2482

APRIL 18, 1985
EPA WITNESS
MAY 20, AND 21, 1985

Serial No. 99-7
PART 1

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[1] Effective only for the first session of the Ninety-ninth Congress.

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SUBMITTED MATERIAL

FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

THURSDAY, APRIL 18, 1985

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON DEPARTMENT OPERATIONS,
RESEARCH, AND FOREIGN AGRICULTURE,
COMMITTEE ON AGRICULTURE,
Washington, DC.

The subcommittee met, pursuant to notice, at 9:35 a.m., in room 1300, Longworth House Office Building, Hon. Berkley Bedell (chairman of the subcommittee) presiding.

Present: Representatives Brown, Penny, Volkmer, Roberts, Gunderson, Evans of Iowa, and Combest.

Also present: Representative E (Kika) de la Garza, chairman of the committee.

Staff present: Cristobal P. Aldrete, special counsel; Mark Dungan, minority associate counsel; Glenda L. Temple, clerk; Bernard Brenner, Timothy J. Galvin, and Gary R. Mitchell.

OPENING STATEMENT OF HON. BERKLEY BEDELL, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF IOWA

Mr. BEDELL. The subcommittee will come to order. The Subcommittee on Department Operations, Research, and Foreign Agriculture meets this morning to hear from the Environmental Protection Agency on issues related to the reauthorization of the Federal Insecticide, Fungicide, and Rodenticide Act. The subcommittee scheduled these hearings some weeks ago because we expected that by this date, we would have before us an administration bill proposing some changes in FIFRA. In fact, the hearings were scheduled for April 18 because EPA officials expressed to us their confidence that a bill would be cleared and sent up here by mid-April.

Instead, EPA is coming before us this morning empty handed, although I recognize that this situation is not primarily the fault of officials at the Environmental Protection Agency. It certainly is no surprise to those of us in Agriculture that neither the EPA or USDA has a last word on what this or any other administration sends up here to the Hill.

We could spend a lot of time this morning recounting past pledges of cooperation from former Administrator Ruckelshaus and others in helping the subcommittee to draft legislation that would address issues that EPA either will not or, for some reason, cannot resolve administratively. However, if we sit up here and sling

arrows at you all day long, Dr. Moore, I don't think that would help us to get these outstanding issues resolved and behind us.

Please make no mistake about this subcommittee's intention to move ahead with FIFRA legislation. There are persistent issues which must be faced and I think that we all have a stake in seeing that the Committee on Agriculture succeeds in putting to rest much of the controversy which continues to plague FIFRA. The only outstanding question, as I see it, is whether EPA is going to be a partner in that effort or only an observer. I would certainly rather work with you during this process and I would like to hear from you this morning on the amount of cooperation and assistance which you think you can offer.

The subcommittee had originally scheduled 2 days of public hearings for next week on FIFRA. However, since we want to keep the focus of those hearings on specific legislation, the hearings have been rescheduled for Monday and Tuesday, May 20 and 21. Those hearings would have been scheduled earlier, but a very full farm bill agenda in the committee made an earlier date impossible.

In any event, I fully intend to move ahead with FIFRA this spring and this schedule change should give everyone sufficient time to review various proposals, perhaps even to find areas of agreement, and to prepare their comments.

Mr. Brown, do you have a statement?

Mr. BROWN. Mr. Chairman, I have an excellent statement here, which I would like to insert in the record.

[The prepared statement of Mr. Brown follows:]

STATEMENT OF CONGRESSMAN GEORGE E. BROWN, JR.
APRIL 18, 1985

Mr. Chairman, although the perspective is somewhat different from this chair than it was from your chair, the scene is one which is all too familiar. Just as Persephone rises from Hades to bring Spring to the upper world, FIFRA rises from those same nether regions every year at this time to offset whatever joy I feel at Spring's arrival. My fervent wish is that this be the last Spring that this subcommittee has to spend debating FIFRA for some years to come.

I sense that this time around there is a better chance of achieving consensus and getting a comprehensive reauthorization passed. Faith in EPA has been restored, some of the interest groups are involved in negotiations, and some of the past problems have been settled in court or by administrative action. We have a host of legislative proposals being discussed, a list of which seems to grow by the hour, indicating a keen interest in finding legislative solutions to the remaining, difficult problems with regulating pesticides.

The one chilling element in all of this is the failure of the Administration to come up with a legislative proposal. This failure comes after repeated promises by former Administrator Ruckelshaus to advise the subcommittee of those issues on which EPA needed statutory guidance and assistance. This failure comes after Mr. Ruckelshaus reestablished the EPA pesticide advisory committee, called the Administrator's Pesticide Advisory Committee (APAC), and put that committee through protracted discussions on possible legislative initiatives. This failure comes after extensive EPA discussions and even drafting of legislation only to have this entire effort quashed by those who set Administration policy at the White House and OMB.

I am quite disturbed by the failure of this Administration to develop legislative proposals. Now, I want to make clear that I am not directing my comments at Dr. Moore or his staff, who are not the villains here. Rather I am annoyed by a pattern of avoidance, deception, and downright dishonesty which I have endured from this Administration since this subcommittee began its inquiry into FIFRA in June of 1981. I have tried to be open and forthcoming with all parties involved in this issue and have taken a moderate course during the deliberations over the last four years. I am now in a position of having to question my past course of action.

I want to see this issue settled in a way that adresses the nagging problems in this area and in a way that reassures the public at large that this committee can discharge its responsibility fairly and justly. I am prepared to follow the gyre of this issue one more time in a hope that we can find the center point which will hold and produce a bill at last.

Mr. BROWN. In large part, it supplements what you've already said about my disappointment that EPA has not been forthcoming with a draft of legislation and our desire to address that as effectively as possible.

Mr. BEDELL. Thank you very much. Before I call on Mr. Roberts, I would like to express my appreciation for the work that you have done in the past in chairing this subcommittee. I would also like to express thanks to Mr. Roberts for the help that he's giving me as the new chairman of the subcommittee. I can tell you, as chairman, I rely upon you two to a great extent for what we do with FIFRA.

Mr. Roberts.

Mr. ROBERTS. Mr. Chairman, I want to thank you for your leadership in holding these hearings. Like my colleague from California, Mr. Brown, has indicated, I have an above average statement. [Laughter.]

I would like to ask permission, at this point, to insert the statement in full.

Mr. BEDELL. Without objection, they will both be entered.

OPENING STATEMENT OF HON. PAT ROBERTS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF KANSAS

Mr. ROBERTS. I would like to say we do have a difficult task. We have really wrestled with the FIFRA issue and I would offer the opinion that those efforts could be best described as low calorie, at best. I think the members of the subcommittee will recall that the EPA did agree to take a look at the Pesticide Program and to try to sort out the issues that could be addressed from the standpoint of administration, and then to report back on what was needed to make the program function.

I know we don't have a bill here from EPA and, while I share my colleague's concern in that regard, I want to commend you, Dr. Moore, because you have taken very significant and positive steps from that standpoint that I was talking about in terms of administrating the program to restore confidence in the pesticide regulatory process. I think you should be commended for that. I look forward to hearing from Dr. Moore today on what he believes is needed in terms of legislation to make FIFRA work and to maximize the very limited resources that are available to EPA in the regulation process.

I think, Mr. Chairman, that we also bear part of that responsibility in terms of forming and addressing this legislation. I think it's time for this subcommittee to start to address the issues and concerns raised over the pesticide process. It is time for all concerned to concentrate on a bill, not an issue. I would like to repeat that phrase, if I could, Mr. Chairman, for all present. It is time to concentrate on a bill and not an issue. It's an easy thing to have an issue and headlines and to send out your reports to your mailing list. It's not an easy thing to get a bill. It's time for all concerned in agriculture, industry, Government, special interest groups, to be part of that process, as far as I'm concerned. I have very strong feelings about that.

If that is not the case, it is my opinion that all parties concerned, not just the EPA, will end up in a legislative penalty box. With that, Mr. Chairman, I thank you again for holding these hearings.

[The prepared statement of Mr. Roberts follows:]

STATEMENT OF HONORABLE PAT ROBERTS

MR CHAIRMAN: I COMMEND YOU FOR CALLING THIS HEARING TODAY. THIS SUBCOMMITTEE IS FACED WITH THE TASK THIS YEAR OF REAUTHORIZING THE EXPORT TITLE, RESEARCH AND EXTENSION TITLE OF THE FARM BILL.

HOWEVER, AS DIFFICULT AS THE TASK OF WRITING A FARM BILL MAY SEEM, COMPARED TO THE TASK THIS SUBCOMMITTEE FACES, RE-AUTHORIZING FIFRA, IS EQUALLY DIFFICULT AND IMPORTANT. THIS SUBCOMMITTEE HAS TRULY WRESTLED WITH FIFRA AND THE FRUITS OF THOSE EFFORTS COULD BE BEST DESCRIBED AS A LOW CALORIE AT BEST.

MEMBERS OF THE SUBCOMMITTEE WILL RECALL FORMER ADMINISTRATOR RUCKELSHAUS AGREED TO TAKE A LOOK AT THE PESTICIDE PROGRAM AND SORT OUT THE ISSUES THAT COULD BE ADDRESSED ADMINISTRATIVELY AND TO REPORT BACK ON WHAT WAS NEEDED TO MAKE THE PROGRAM FUNCTION.

TODAY THE EPA, AND MORE SPECIFICALLY, DR. MOORE, ARE TO BE COMMENDED FOR THEIR EFFORTS. THE AGENCY HAS TAKEN SIGNIFICANT AND POSITIVE ADMINISTRATIVE STEPS TO RESTORE CONFIDENCE IN THE PESTICIDE REGULATORY PROCESS.

I LOOK FORWARD TO HEARING FROM DR. MOORE TODAY ON WHAT HE BELIEVES IS NEEDED IN TERMS OF LEGISLATION TO MAKE FIFRA WORK AND TO MAXIMIZE THE LIMITED RESOURCES AVAILABLE TO EPA TO REGULATE PESTICIDES.

IT IS TIME FOR THIS SUBCOMMITTEE TO ADDRESS THE ISSUES AND CONCERNS RAISED OVER THE PESTICIDE PROCESS. IT IS TIME FOR ALL CONCERNED TO CONCENTRATE ON A BILL, NOT AN ISSUE. IT IS TIME FOR ALL CONCERNED--AGRICULTURE, INDUSTRY, GOVERNMENT, AND SPECIAL INTEREST GROUPS TO BE PART OF THAT PROCESS. IF THAT IS NOT THE CASE, IT IS MY OPINION, ALL PARTIES CONCERNED WILL END UP AND DESERVE TO BE IN A LEGISLATIVE PENALTY BOX.

Mr. BEDELL. Thank you very much, Mr. Roberts. We're privileged to have with us the chairman of the full Agriculture Committee, Chairman de la Garza. Mr. de la Garza, do you have any statement to make?

REMARKS OF HON. E (KIKA) de la GARZA, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

The CHAIRMAN. Thank you, Mr. Chairman. I don't have a statement, but would like to associate myself with all the statements made by you three gentlemen. I appreciate your leadership and as chairman of the committee support your efforts. I am particularly supportive of the statement of our colleague, Mr. Roberts, when he said that we need to sit down and work together on this issue. The sooner we do it, the better off all of us will be.

We need patience, charity, and a little bit of sacrifice. Possessing those qualities and working with EPA and the members of this subcommittee, I think we can move forward in a positive, constructive way. I look forward to working with you, Mr. Chairman.

Mr. BEDELL. Thank you, Mr. Chairman. We certainly appreciate your interest in this issue and your contribution toward legislation in this regard.

Mr. Combest.

Mr. COMBEST. I have no comments at this time.

Mr. BEDELL. Thank you very much. We will now hear from you, Dr. Moore, and any of your people you want to have with you.

STATEMENT OF JOHN A. MOORE, ASSISTANT ADMINISTRATOR, PESTICIDES AND TOXIC SUBSTANCES, U.S. ENVIRONMENTAL PROTECTION AGENCY

Mr. MOORE. Thank you, Mr. Chairman. I, too, have an opening statement and I ask, in the consideration of your time, that my full statement be entered into the record, and I will just highlight certain parts of the statement in my opening presentation this morning.

Mr. Chairman, some 18 months ago, in November 1983, EPA's Administrator, William Ruckelshaus, testified before this subcommittee, and he stated that many of the problems with the Pesticide Program could be addressed administratively and pledged that EPA would vigorously pursue improvements without waiting for changes in the law. I can report to you this morning that I think EPA has made good on that promise.

When I became Assistant Administrator for Pesticides and Toxic Substances shortly after Bill testified, the Pesticide Program needed to restore credibility to the regulatory process by improving the timeliness and the scientific quality of its decisions, and by insuring that the decision process itself was conducted in an open and impartial manner.

The last 18 months have been very active ones, and the program has made great strides in accomplishing these goals of timeliness, scientific soundness, and openness of decisionmaking. Permit me to briefly illustrate how progress has been made in these areas.

With respect to timely review and decisions on existing pesticides, reregistration of all previously registered pesticides is the

most complex task that is assigned to EPA under FIFRA. For a number of reasons, the data bases for many of these pesticides are woefully inadequate, and the existing data have not been evaluated by modern standards. Thus, I place the highest priority on getting reregistration moving.

Of the 600-odd pesticide chemicals potentially subject to reregistration, the Agency has reviewed and issued registration standards for 98. Forty-seven of these standards have been completed in the last 2 years. We are now proceeding at a rate of about 25 standards per year and will continue at that pace, giving priority to high volume and food use chemicals and to those which may pose special problems, such as ground water contamination.

To insure that the key data are available when we evaluate a pesticide, we have accelerated the pace of the Data Call-In Program for chronic health effects data on food use chemicals. In addition, a special Data Call-In was issued in 1984 to require environmental fate data on about 100 pesticides preliminarily identified as potential ground water contaminants.

A third major Data Call-In Program is now being developed to ensure that the Agency has precise information on the chemical composition of each registered pesticide; that's somewhere around 49,000 products. We've also initiated a new Data Call-In project in which registrants of 31 nonfood use pesticides are themselves identifying and then filling any significant data gaps.

I'm hopeful that this approach will work so that it could be expanded in the future and we can bring the Data Call-In aspect of reregistration to a rapid close with a minimal amount of manpower required.

We've also begun to closely monitor each registrants progress in meeting their commitments to develop such data when asked. When a registrant makes a commitment to develop needed data by a certain date, we expect that commitment to be kept. When a registrant fails to keep these commitments, we are exercising our authority to suspend their product registration until the data are submitted.

The composite effect of these various efforts will result in submission of a large amount of new data on these old pesticides. The first large influx of data is expected this year. To ensure that the Agency can keep abreast of the most significant of these data, we will be proposing the new rule that requires registrants to highlight those portions of these data which meet certain specified risk criteria.

Special review is that portion of reregistration where there is an intensive risk benefit evaluation on those registered pesticides which may be posing unreasonable risks. In the last 18 months, 25 decisions have been issued—including 10 new special reviews—4 proposed positions issued for review and comment, and 6 final decisions published. Two decisions resulted in returning the pesticide to the regular registration process and there was one voluntary cancellation.

We have just recently published proposed rules to revise the procedures and criteria for special review. These proposed changes reflect my commitment to improving the timeliness of special review decisions by determining up front whether an intensive risk benefit

review is appropriate and by vigorously pursuing the data needed to resolve any outstanding questions.

On the topic of sound scientific basis for decisions, I have placed great emphasis on the importance of insuring the scientific soundness of pesticide regulatory decisions. The Agency has issued good laboratory practices regulations and pesticide assessment guidelines, and has also instituted an effective laboratory and Data Audit Program.

The number of pesticide data audits has been increased from about a dozen in 1982 to a target of 76 in this current fiscal year. Comprehensive standard evaluation procedures for use by EPA staff are also being developed. Various measures to improve internal quality control of data reviews have also been implemented. Our concern for data adequate to support decisions is also reflected in our policy of not granting emergency exemptions under section 18 of FIFRA to allow the use of old chemicals for unregistered uses when the supporting data base for that chemical is inadequate.

This policy has resulted in a significant dropoff in the number of section 18 applications received—from 638 in fiscal year 1983, to 444 in fiscal year 1984—as well as the numbers that have been approved by the Agency—which dropped from 590 to 320 in those same 2 years—this more stringent approach has been incorporated into the proposed rules just published on April 8 which would formally revise the procedures and criteria governing these exemptions.

An adequate basis for regulatory action is also addressed in the recently proposed rule to revise procedures and criteria for conducting special reviews. This proposed rule will improve both the credibility and the efficiency of the process by ensuring that resource intensive reviews undertaken address potential real-world risk situations, for which preliminary exposure estimates are available.

The administration realizes that EPA's regulatory process must provide for participation by all interested parties, including the general public, in order to justify confidence in the complex and far-reaching decisions we are called upon to make. We have taken steps to encourage equitable participation by interested parties in Agency decisions and also to make information on pesticides more widely available.

In particular, we have published a comprehensive description of the data required to register pesticide products. We have made available to any requestor factsheets summarizing the available data and regulatory status of specific pesticide chemicals. We've also published three proposed rules to provide additional opportunities for participation in the registration standards, special review, and section 18 emergency exemption processes.

In summary, the foundation has been laid for a Pesticide Registration and Reregistration Program in which the public can have trust. Our decisions are based on sound science and are made in the open on a timely basis. However, it would be less than candid to suggest that there are no problems to be dealt with or that the job is basically done. Pesticides and other toxic substances are being found with greater frequency in the Nation's water supplies. We are developing a ground water strategy for pesticides as part of

the Agency's overall ground water protection strategy. We are also just now beginning to take a look at inert ingredients in pesticide products, some of which are just as biologically active as pesticide active ingredients, and most of which have not been extensively evaluated. Of course, we have many years of effort still needed to complete review of existing pesticides. In short, we've accomplished much, but these are but the first steps of a very long march.

One of our biggest assets in meeting the challenges is the FIFRA itself. Having now carried out its legislative mandate for a year and a half, I know it is a fundamentally sound environmental law. The FIFRA risk benefit balancing standard gives the Agency the critical flexibility needed to make decisions which can both protect public health and the environment and assure the benefits of pesticide use. FIFRA provides the authority to require data needed to make sound decisions; the authority to take stringent action when necessary to prevent unreasonable risks; the authority to make new pesticides and new pesticide uses available when they're needed; and, the authority to effectively regulate whole new types of pesticides as they are developed.

As you know, the administration did earlier send to Congress a bill which would reauthorize FIFRA in its present form for 2 more years. While the Agency has spent the last 2 years implementing a number of administrative changes in the Pesticide Programs, we have also remained alert to current FIFRA language that may limit our efficiency in implementing our statutory mandate.

No statute is perfect, particularly one as complex as FIFRA. The Agency has sought the advice of various groups on ways that the administration of FIFRA can be changed to provide proper pesticide use while affording the greatest degree of public and environmental protection.

In 1984, the Administrator established a Pesticide Advisory Committee, or APAC, to advise us on major policy issues. One issue raised by APAC was the need to improve the timeliness of the special review process. There was general agreement that the current process should be speeded up. Proposed improvements in regulations notwithstanding, we must find a way to make the process less cumbersome.

The second issue which was discussed with the committee, and on which that group reached general consensus, was that of sharing data with other governmental entities, particularly State governments. The groups agreed that providing EPA the ability to share data with States who have protection for CBI equivalent to that provided under FIFRA, would be a desirable thing.

Another data issue is the need to assure that the data the Agency relies on is of the highest quality. While we have made a start in this area, issues have arisen that we have not yet addressed. Among these is EPA's inability to inspect pesticide testing facilities to insure they are following good laboratory practices. In addition, the violation of GLP regulations is not an unlawful act.

Another issue has arisen over what action the Agency can take where the pesticide data base for an already registered product is found to be of unacceptable scientific quality.

A fourth area where I think legislative attention is merited concerns restricted use pesticides. This is an area that the Pesticide

Advisory Committee considered in depth and is of particular interest to me. One of my key goals in regulation of pesticides is to develop a flexible program in which potential problems are attacked with a scalpel, not a sledgehammer. Classifying a pesticide as restricted use is an essential tool in achieving this goal. We must look to see if anything further can be done to ensure that restricted use pesticides are properly used by persons whose knowledge and qualifications are commensurate with the degree of risk posed by that particular use.

A key element in any regulatory program is the ability to enforce statutory and regulatory requirements. The Agency is looking hard at this area and, in fact, has established a cross-media task force to specify ways to improve the enforcement provisions of all of its environmental statutes.

I also believe EPA needs to find ways of integrating its actions under FIFRA with those of the Occupational Safety and Health Administration.

Another issue the Pesticide Advisory Committee has discussed in depth is inerts. After a long period of neglect, the Agency has begun to focus on inert ingredients used in pesticides, particularly those where we already have some evidence for concern. There are a number of scientific, legal, and economic complexities involving inerts which will take significant time and the best efforts of all of us to resolve. The Agency is now considering the possibility of using labeling to identify inert ingredients which may pose significant risks to human health and the environment.

Finally, I would like to mention two funding issues: First, the current scheme of indemnification and disposal may be flawed. No other environmental statute or health law provides this form of Federal bailout for the manufacturers of chemicals or drugs that are shown to be unsafe. The second funding concern deals with the issue of registration fees. There appears to be considerable sentiment, both within and without the administration, that registrants should be responsible for paying the costs involved in the Federal Pesticide Registration Program. While the administration believes it does have authority to recover all costs, we are currently exploring methods to assess and collect fees in a most efficient manner.

Mr. Chairman and members of the subcommittee, in concluding my testimony this morning, let me assure you that the Agency remains ready to serve you so that FIFRA reauthorization processes can be constructive, taking into account the concerns of all those affected by the regulation of these products. Thank you.

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

Mr. BEDELL. Thank you very much, Dr. Moore. Many of us have a great many questions of you because of the complexity of this issue. Unless there is objection within the subcommittee, we will abide by the 5 minute rule and then we will make as many rounds as we need to under that rule. Is there any disagreement with that proposal?

The CHAIRMAN. Mr. Chairman, I wonder if you would indulge me for one statement and then I won't have to take time for questions.

Mr. BEDELL. We would be glad to give the chairman of the committee whatever time he wishes.

The CHAIRMAN. Thank you very much. I've discussed the issues of pesticides informally with Dr. Moore and have sent the EPA Administrator a letter. Dr. Moore, I would hope that our conversation on this issue will result in some positive information soon.

Mr. MOORE. Congressman, my sense is, in discussing it with some people in the program as well as some of the officials at FDA, that we would hope to be able to have a definitive decision within the next week or so. What data we do have looks good. We can expect setting the tolerance fairly shortly.

The CHAIRMAN. Thank you very much. I thank you for your indulgence, Mr. Chairman.

Mr. BEDELL. Thank you, Mr. Chairman. Mr. Brown.

Mr. BROWN. Thank you, Mr. Chairman. Dr. Moore, it's a pleasure to have you here, of course. Let me just comment first with regard to the matter of a bill and the need to have a framework from the administration. It has been the views of the committee that this was actually for the protection of the administration as much as anything else. The scenario that I foresee is that we could take a straight extension. We're going to find, as a result of the very well known and obvious defects that exist, that there will be efforts to amend the bill on the floor and that it will substantially get out of control of the committee. There may well be amendments offered which are undesirable from the standpoint of the administration and we will not be in a good position to protect ourselves because we have not devoted any efforts to analyzing these things in the committee.

Of course, the legislative process is always uncertain and sometimes flaws can be corrected at subsequent proceedings in the process, but it's far preferable to give acknowledged, necessary changes the thorough consideration that they deserve within the committee before they get out to the floor.

I wanted just to make it clear to you that that's the reasoning behind our putting pressure on you. You are under some restrictions to not present the text of the bill, but I want to commend you because you have laid out here pretty much what the bill should contain. I think if I were to go down the list and ask you about some of these things and ask you to provide language, you could pretty much write a bill for us based on what you've said in your statement.

I won't have time in 5 minutes to do that, but we may want to pursue something along that course as we proceed.

Let me get down to an issue that bothers me a great deal and that is the slow pace of reregistration. I think you are doing a better job now and I want to commend you for that, but I'm still concerned that at the rate at which you are proceeding with reregistration, you've got an agenda that is at least 20 years long. Are you able to suggest any way in which we can do that? Is that strictly a function of your budget? Do you need more staff and resources to speed that process up?

Mr. MOORE. Congressman, the reregistration process and all of its various ramifications is a very labor-intensive effort. Indeed, it is resource responsive.

Mr. BROWN. In other words, given an increase in resources applied to that particular job, you could speed up the timetable. You

are improving the process. You are enhancing the quality of the data and subjecting it to more competent analysis and so forth, so that we are getting a better result out of this. We're just getting it very slowly. Am I correct? You're nodding your head "yes," but say yes for the record.

Mr. MOORE. Yes, sir; I agree with your statement. Something we have done, which I think helps, is that, by accelerating the Data Call-In process for chronic data, we are at least going to be in a position that, as we address a particular active ingredient, we hope we will have a relatively full data set as contrasted to 5 years ago where it was often a codification of what was still missing.

We're still missing things as we get into the standards process, but it's much better. The other thing that is happening as a result of the aggressive Data Call-In is we are finding out up front those registrants who never had any intention of investing the money to develop the necessary data. To the degree that we identify those, we get them off the market faster. There have been some examples of that sort in the last 12 or 15 months; for example, our aggressive Data Call-In for the grain fumigants.

Mr. BROWN. One other thing on this round, at least. Yesterday, before another committee, a representative of the EPA testified that, with regard to the development of biologically engineered organisms, EPA didn't need any new legislation just like they don't on FIFRA, and that they have the situation well under control. There's no threats posed by the possibility of an inundation of applications for biologically engineered organisms used for agricultural purposes, and that you could handle it. How can that possibly be when you're not handling the chemical end of this problem?

Mr. MOORE. Congressman, to the degree that there was an inundation of new applications for products that are developed through biotechnology, I suspect it would stress our system. We have no indication, at this stage in time, that we are going to be inundated with a large proliferation of biotechnology applications of one sort or another.

Mr. BROWN. How many laboratories have you gone into where they are preparing products to come on the market as quickly as possible?

Mr. MOORE. It's a very aggressive area right now within a variety of laboratories in this country.

Mr. BEDELL. Thank you, Mr. Brown. We will go around again for as many times as we need to in order to see that everyone has an adequate opportunity. Mr. Roberts.

Mr. ROBERTS. Yes, thank you, Mr. Chairman. I have a number of questions and some of these questions are repetitive in regards to the testimony you have presented, Dr. Moore. In our efforts to come up with a legislative compromise, I'm going to go ahead and ask some of these specific questions. They are going to be very important to me as we try to pull together.

Over the last several years, this subcommittee has heard many witnesses testify over the problem caused by the misuse of pesticides. Many folks testify over the problems caused by the current statutory language on restricted use pesticides and the interpretation of "under the direct supervision." How can we make sure that

the restricted use pesticides are used only by highly trained and competent applicators?

Mr. MOORE. Congressman, in looking at that issue, there seem to be three things that tie together. One is the possibility of trying to come up with various tiers of restriction of various pesticides as opposed to what we have right now, which is restricted or not restricted, all leading toward the construct that we must come up with a mechanism whereby we can tie one's ability to use that pesticide with demonstrated knowledge.

That infers that one has to have a certification process, or maybe a recertification process, that is aggressive, and, indeed, under some of these restricted use categories, we may change the degree of supervision that is required. The current statute says under the direct supervision, which can infer that the person doesn't have to be present.

If we get into restricted categories, we may say for this particular pesticide for these uses, the person who is supervised must be the only one that can use it, rather than under the general supervision. One way that that could be done is to strike the words "under direct supervision" in the statute, and leave it to the Administrator's discretion to outline a program which may well tie the degree of supervision to the hazard posed by the use of the pesticide.

Mr. BROWN. Would the gentleman yield, just briefly?

Mr. ROBERTS. Yes.

Mr. BROWN. The gentleman's question listed the kind of bill writing that we need to have here and I commend him.

Mr. ROBERTS. Moving right along. [Laughter.]

Are we ready to go to markup on that one, George?

Mr. BROWN. I'm ready.

Mr. ROBERTS. That's what I was afraid of.

Along the same line, if we allow the Administrator the discretion to specify the degree of supervision required to use a restricted use pesticide as you have outlined, I want to know how I can make sure that we won't be placing a very heavy and unfair burden on the family farmer who is going through a very tough time right now, that uses these kind of restricted use pesticides in the normal course of their farming operations. Let me point out—any kind of large scale infestation by any critter that I can dream up at this particular time, is just going to spell havoc in farm country. We are going through a very difficult time, at best, without those kind of problems, and I hope and pray we don't have them, not only from the farmers' standpoint, but from the standpoint of public safety, as well.

Mr. MOORE. Congressman, one thing that we would like to preserve in any change is a distinction between the farm use of particular pesticides and other uses, which can include disinfectants, structural pest control, or commercial applicators which may well be working in the farm environment. We would certainly be sensitive to preserve that area.

Mr. ROBERTS. What is EPA doing to make sure that the various State certification programs are consistent and meet some sort of minimum requirement in regard to training?

Mr. MOORE. We do specify minimum areas of requirement. We have, just in the last several months, gone through and taken a look at five-odd State programs to see what degree of consistency there is or there isn't. As one may expect, there is no consistency across the States. That isn't necessarily all bad. Some of these States have different problems compared to others because of geography and as a result, do have a legitimate approach to this issue that might be different from a sister State.

What we are doing is looking at possibilities of talking with some of the State pesticide applicators, as well as individuals in USDA who often are responsible or are the mechanism for our getting information out as far as training, to see if we can come up with a mechanism that outlines what is the core information needed for the proper use of pesticides.

Mr. ROBERTS. If I might be permitted one more question, Mr. Chairman. One issue that the subcommittee has grappled with for a number of years is the use of the data that has been submitted by a company in the registration package. Some States would like to have access to this information. I understand that the Advisory Committee reached an understanding on the issue of releasing this data to States. Do you have the authority to release the data to State governments and, if not, what would you suggest to clarify this situation?

Mr. MOORE. Our current understanding of the statute is that it does not distinguish between private individuals or corporations or State governments, with respect to access to confidential business information. They are equally restricted. As you know, the States are a key element in making sure there are effective pesticide regulations since they are the ones that are out there with the delegation for enforcement and compliance.

To correct this problem, I think FIFRA could be amended to permit EPA to share data with the States, provided that those States have a comparable authority in place that will protect the legitimate confidential business information. I think it could be as simple as that.

Mr. ROBERTS. I appreciate your testimony, Dr. Moore, and we'll see you during round two.

Mr. BEDELL. Mr. Gunderson.

Mr. GUNDERSON. Thank you, Mr. Chairman. Dr. Moore, on page 12 of your testimony, you indicate that we are developing ground water strategy for pesticides. I assume that means you're in the process of developing a ground water policy. Could you elaborate on exactly what that direction might include?

Mr. MOORE. Congressman, as I've pointed out, we do have in place requirements for the registration of new pesticides that data be provided that gives some sense as to whether or not that chemical has the potential for being a leacher into ground water. We also have required similar data on some of the old pesticides that have been out there, so that we can have this data base.

Once those data are in, we hope to take a look at it in some circumstances, and it may require active monitoring in field circumstances of some of them to make sure that our preliminary information is correct. The long outcome of all of this is going to be that we will end up identifying that, in some circumstances, we just run

a very high probability of this material leaching and possibly getting into ground water. The outcome of that may be that one could end up barring the use of that pesticide in that particular circumstance in a particular geographic locale.

For example, soil type and rainfall and time of the year that a pesticide is applied are all critical to how fast it may well percolate through a soil. In places where we have a sandy soil with a very high water table, certainly that's going to suggest different possible controlled uses as opposed to other soils where the water table is maybe 30 feet down and it's a heavy organic soil and it's applied in the summer months where just the consequence of normal biota in the soil and temperature will speed up its degradation and pose much less of a risk.

What I don't think the Agency ever wants to get into is a circumstance of trying to regulate pesticide use on a county-by-county basis across the United States. I just think that would be an impossible circumstance. I can see, in the long term, that we will have identified what information is needed to make an appropriate determination of use in a particular geographic locale, and make sure that information is available and then have some agency more proximate to the locale where the appropriate factors can be considered in reaching the appropriate conclusion.

Mr. GUNDERSON. For the most part, you're anticipating State or local regulations then, as the result?

Mr. MOORE. Either State or local regulation or State or local application of the information as to its appropriate use.

Mr. GUNDERSON. On page 11, you indicate quite a bit about the disclosure of the data to the public, public participation in the whole process, et cetera. If you were to judge the progress that's been made thus far, do you see this as facilitating the flow of health and safety data? Do you see it as being well received by all parties, or do you see a lot of work yet to do in the area of resolving this controversy as to what data ought to be made public, and how?

Mr. MOORE. I still think, while progress has been made, that there are segments of the American community that feel frustrated in this area. For example, in order to come into possession of health and safety data, they still feel there are long delays associated with their requests being granted, because of the fact that we have to go through in any particular request and make sure that there is no CBI data that are somehow inside of this material. This can be corrected.

The other place, I think, is of greater concern to some people and that is in some of these processes of pesticide review, they still have limited rights and they would like to see those changed.

Mr. GUNDERSON. Has the release of data under section 10, to your knowledge, harmed a registrant?

Mr. MOORE. I'm not aware of any registrant that has been harmed.

Mr. GUNDERSON. You're not aware of any at this point?

Mr. MOORE. No.

Mr. GUNDERSON. I guess I'm about out of time, Mr. Chairman, and I yield back the balance of my time.

Mr. BEDELL. Thank you. Mr. Combest.

Mr. COMBEST. Thank you, Mr. Chairman. Mr. Moore, I know in a lot of States, and certainly in Texas, we are experiencing a lot of concern about the way that the State is also regulating and looking at pesticide uses. What would you recommend we do in the future? We've got a problem, of course, from all sorts of variations and regulations on labels of pesticides relative to reentry time and all this now that EPA has gone through—in the labeling of the product. Are there other things that we can do to try to have some type of cooperative effort so that once a farmer is aware of the fact that we're dealing with a pesticide under a certain way that it is ruled under EPA, that the regulation doesn't change in midstream. I realize that they have their own jurisdictions and authority areas but can we do something to further build that cooperation so that we don't continually have to be concerned about 50 different State rules and regulations regarding the same thing you're ruling on?

Mr. MOORE. Congressman, I think to the degree that we can more easily share data with the States, States may well feel more comfortable in being able to check for themselves whether or not what EPA is suggesting makes sense to them. We also have to be very aggressive in our ability to communicate with the State, to keep them up to date. I think putting together a task force called SFIREG a couple of years ago has gone a long way toward making sure States are fully participatory in many of the issues that are of concern to them or one of concern to the agency.

Couple that with more interaction from an education standpoint, including USDA, I think we can go a long way toward trying to minimize some of these concerns.

Mr. COMBEST. So, your budget is still under what it was in 1980. Do you anticipate that, given additional workloads, with somewhat limited resources and funds, that will curtail or affect your activities? Do you think that you're going to be adequately set up to do those things within the act?

Mr. MOORE. Congressman, our budget for the last couple of years, as you know, is basically level as regards to pesticides. I think Lee Thomas would be upset if I wasn't always bugging him for more resources of one sort or another. On the other hand, I do think we have resources to maintain a credible program. That isn't to say that some people might not argue that certain things should go faster or slower or whatever the case may be. Given the competing priorities of the Agency, I think it's a program that I can live with.

Mr. COMBEST. Currently, regarding the Supreme Court on the *Union Carbide* case, supposedly to be decided some time soon—what could you enlighten us on about what's happening there and what might you guess the outcome to be?

Mr. MOORE. As you know, the Court heard that case just several weeks ago. These suits of this sort not only affect the private party seeking data compensation, but also, in some instances, severely limit the Agency's ability to carry on some of its day to day operations. For example, with the suit that you mentioned, the Agency has no particular interest in whether the arbitration procedures that are being discussed are subject to more extensive review or not.

However, if the Supreme Court could decide that more extensive review is required, it could do it in a way that simply struck the

limitation that they find objectionable in the current statute. There's also a slim possibility that the court could strike the entire provision. If that was to happen, we could end up again with disruption of our current pesticide process.

I think one should watch closely the outcome of that case; the decision, I believe, will probably come out in several months, and, depending on how they rule, be attentive to the need for possibly making a change. FIFRA, for example, could be amended to provide for full judicial review as part of the arbitration process, which is what I understand is the basic complaint of the plaintiffs in this case. They feel that they are being deprived of some of their basic rights: That is, they are being forced to go into arbitration and forced to accept what the arbitrator decides without any ability for seeking relief of that. They feel that's unconstitutional.

Mr. COMBEST. Rather than the elimination of the indemnification fund due to the express purpose of it when it was first put in, do you think it might be wiser to find some other funding mechanism for it so that it really wouldn't interfere with the decisionmaking process of the Agency by removal?

Mr. MOORE. That certainly is an option, Congressman. I will observe that, from my current vantage point, it just doesn't work or isn't setup to work very well. In the circumstances of EDB, there was a suspension of uses whereby there were indemnification claims being filed with the Agency for which we were forced to use existing appropriations to meet those needs. These dollar values that we are talking about are not trivial. They are measured in the millions of dollars, and sometimes it's very difficult to try to come up with several millions of dollars out of existing appropriations and keep on with the management of a program that you've probably worked very hard to craft through the appropriation process.

There isn't a mechanism created to provide for funding when these circumstances come up without disrupting the normal budgetary process. I would suggest we get rid of the whole thing—one or the other. I think it's broken right now; it needs fixing.

Mr. COMBEST. Thank you, Mr. Chairman.

Mr. BEDELL. Thank you, Mr. Combest. Dr. Moore, you say you think it's broken; it needs fixing. With limitations on your budget, I can see where this could be a problem to you. Do you have specific suggestions as to how we should fix it?

Mr. MOORE. We could strike it.

Mr. BEDELL. Is that your recommendation?

Mr. MOORE. I think so. We could just strike the whole process. As I do point out, the indemnification process, as I understand it, is peculiar to FIFRA. We don't provide, with other laws, similar protection in the drug area or things of that sort. So, it's not an implausible suggestion, I think, to strike it.

Mr. BEDELL. I didn't catch exactly your answer to Mr. Roberts' question. You need legislation in order to give States access to the information they need?

Mr. MOORE. Yes, it probably would make sense to do that by clearly identifying that, if a State had the ability to protect the confidentiality claims that are legitimate to the information that we are going to share, we could then share it with them.

Mr. BEDELL. You said that ground water was a serious issue and that States should address the ground water issue. Did I understand you correctly?

Mr. MOORE. We're still in the process of evolving a policy in this regard, Mr. Chairman. In the longer term, I really think that, for a policy to work best, somehow there's got to be a decisionmaker or an adviser closer to the scene making the decision, rather than a bunch of people sitting in Crystal City, across the Potomac.

Mr. BEDELL. I wouldn't have any trouble with that, but I guess the question I would ask you is if one State doesn't do much of anything about ground water contamination and we found massive ground water contamination in a State, would you not expect that that State would come to the Federal Government for financial help in order to help solve their problem?

Mr. MOORE. That's certainly a common outcome of it. There are a couple of things that we certainly could do with some of these pesticides. We can restrict their use. In the process of restricting use, if we state why we've restricted the use it does put the pesticides in the hands of somebody who supposedly is more fully informed of the consequences of misuse.

Some other things that we may well do is to identify geographical restrictions for certain pesticides. What comes to mind is several years ago there was a problem of contamination of the water supplies on Long Island, not because of any peculiar use of the material in that area, but more as a function of the soil type and the high ground water circumstances.

You can look from Long Island into other areas of this country that have similar soil types and high water tables and you can almost predict that there's going to be ground water contamination of a consequence of the use of some of these materials.

Mr. BEDELL. Have you looked at the possibility of what might be included in legislation to make it possible for some type of a cooperative effort in which the States would have the flexibility to better monitor this depending upon the individual problems, but that the Federal Government would have some type of oversight responsibility or authority so that the States did not particularly ignore this responsibility and then come to the Federal Government for money to take care of problems that they had not properly addressed earlier.

Mr. MOORE. Congressman, you identify a very legitimate area and it's an area that we're not as far along with specific solutions to some of the legitimate concerns you raised as we are in maybe some of the other areas that we've looked at. Clearly, I think there is legitimacy to your concern that somehow there still might be a mechanism of oversight retained at a Federal level in some of these ground water concerns.

Mr. BEDELL. Is the reason that you're not further along because of lack of staff and ability and money, or is it just that you haven't bothered to do it?

Mr. MOORE. We work on ground water and it's just a matter of there's just so many hours in the day for these people to focus on certain activities. It's certainly an area that we intend to stay abreast of and it's an area that's of concern in the Agency, not just in the Pesticide Program.

Mr. BEDELL. So, your answer is that you just don't have the staff time and capability to do it. Is that accurate?

Mr. MOORE. Again, it's amenable to resources.

Mr. BEDELL. Thank you very much. Mr. Brown.

Mr. BROWN. Let's pursue the ground water situation a little bit, Dr. Moore. First of all, it's not something that stems exclusively out of the Pesticide Program. It's a major concern in the general toxic waste area. Is that correct?

The fact is that pesticides probably represent the largest volume of chemicals that pose a threat to ground water. I'm trying to get this correct. I understood that, in terms of chemicals into the environment, agricultural chemicals probably represent a large fraction—80 percent—am I somewhere close to correct?

Mr. MOORE. I don't know the percent. I certainly will agree with you that pesticides represented in agricultural chemicals are used in great volume in the environment, and by the nature of the use, has a good potential for getting into ground water. We certainly have anecdotal examples of where that has come to pass.

A particular concern associated with them is that a pesticide, by its very nature, is a biologically active material and it maybe that their presence in ground water, under some circumstances, may be in the abstract more of a concern than maybe other chemicals.

Mr. BROWN. You have identified, in the Agency, umpteen thousand toxic chemical dumps around the country which pose hazards. Many of these are illegal dumps put there with no regard to the possible contamination of ground water. The classic case in my own district, the Stringfellow Acid Pit, was put into a properly licensed legal repository. Geological surveys were taken that had shown that it was over an impervious granite basin and they were wrong. It's now leaking into the ground water. If that can be done with a legally licensed site in an impervious situation, then all of these thousands of illegal sites are even worse.

The question that I raised in earlier years is the quality of the monitoring being done. Now you made reference to a national and regional monitoring. The fact is there is no national and regional monitoring at the present time. Am I correct?

Mr. MOORE. You're correct, Congressman. If I could expand upon that just for a minute. We have been working with the Office of Water trying to devise a program specific for addressing pesticides in ground water. We have a variety of instances where we've identified a problem but the data doesn't readily lend itself to extrapolating to a national circumstance with some degree of confidence. We are in the final stages of trying to develop a study that would do just that. We proposed to look nationally and would take samples from several thousand sites and analyze them for somewhere around four dozen pesticides which we have reason to believe are the best candidates for possibly making it into ground water; these results would give us a construct of what circumstances are of greatest concern.

Mr. BROWN. What you have done is to identify those chemicals which pose the greatest threat because of their solubility and so on and you have probably included that information on the labels, in some cases. What happened in the case of EDB was that it was ac-

cidentally detected in the ground water with no monitoring program at all. Probably that happened with Temix, too, didn't it?

Mr. MOORE. Yes, sir.

Mr. BROWN. In most other cases, also. You can alert the users to the hazards but the fact is there isn't even, on a local basis, sound knowledge of the dynamics of ground water in the region. That needs to be corrected. Someone suggested that the Agency might come up with a scheme to address that problem. You're still working on that, aren't you?

Mr. MOORE. Yes; the scheme for this monitoring plan is going to be finished sometime in August or September.

Mr. BROWN. Could you keep the committee informed of your progress on that? I would very much like to see us emerge with some sort of a national monitoring scheme that would be reasonably adequate to address the problem it faces. It's an interstate problem. Many of our largest aquifers cover several States, particularly in the Midwest. We need a multistate approach to this problem. Thank you.

Mr. BEDELL. Thank you, Mr. Brown. Mr. Roberts.

Mr. ROBERTS. Do we have to call it a scheme?

Mr. BROWN. Call it what you will.

Mr. ROBERTS. How about a plan. Dr. Moore, on numerous occasions there has been concern expressed before this subcommittee on the fact that some foreign governments do not have access to our health and safety data. I know this is a very sticky wicket, especially in regard to the Communist bloc countries and how we can adequately protect that data once it is given to those countries. Do you have any suggestions on how we could set up some sort of mechanism for releasing data to foreign governments? What criteria.

Mr. MOORE. Congressman, you do correctly identify an area that has posed some problems in the past, and may still. As far as our ability to share data, I think FIFRA would need to be amended to allow us to do this in such a way. Several things come to mind that may well be criteria that would identify those circumstances in which we would go ahead and share data with a foreign government. For example, one might say that a bilateral agreement had to exist between the United States and that country for the sharing of such data, that EPA had gone through a process of notice and comment whereby you alert the public as well as the registrants of the possibility of entering into such an agreement and have the benefit of their comments on that as part of the decisionmaking process, and then maybe determine that the sharing of such data is in the best interest of the U.S. Government.

Conversely, if we are in a position of sending data to a foreign government for their benefit, we also should have some language in there that would allow us to explicitly state that we could provide appropriate protection for any data we might receive on the reciprocal end of such an agreement.

Mr. ROBERTS. If I could followup on that, I think Mr. Gunderson and I would agree that we also make it mandatory that those countries buy our dairy products and our wheat products, but I won't go into that.

With those criteria that you mentioned, aren't we going to bring the State Department in as a player? I always live in mortal fear with the State Department and what it does to agriculture. Is that going to cause yet another agency to look over your shoulder and slowup this process or get into more kinds of problems?

Mr. MOORE. I think that's always a theoretical possibility that anytime we enter into any kind of agreement with a foreign country that the State Department would claim it has some legitimate purview or chance to comment on the process.

Mr. ROBERTS. I don't know of anything on the whole laundry list of activities that the State Department doesn't claim some legitimate interest in, but go ahead.

Mr. MOORE. It's my understanding that our ability to interact in areas of pesticide interest with foreign governments or international organizations have not been in the main generally hindered by any advice or interaction by the State Department.

Mr. ROBERTS. So, you don't think that's a problem?

Mr. MOORE. No, and my colleagues confirm that.

Mr. ROBERTS. I see some nodding heads. In the situation where the regulator in a foreign country is also a producer of the pesticide, how would the regulatory system propose any kind of safeguards for the data?

Mr. MOORE. I assume you're referring to the—restate that again for me, Congressman.

Mr. ROBERTS. In the situation where the regulator in a foreign country is also a producer of that pesticide, how would the regulatory system you propose safeguard the data?

Mr. MOORE. As I understand it, some of the concerns people have on sharing of data with foreign governments is that they would come into receipt of data that would then allow them to go ahead and produce that pesticide. In other words, the fact that they received data allowed them to be able to go about producing it. To the degree that they are already producing that pesticide in that circumstance, I don't think that would become a major issue.

Mr. ROBERTS. I want to mention the IBT situation in regard to a question here and I'm talking about where you have a situation where some data has been submitted in support of registration and later proven to be false. If the Agency is granted authority to cancel a registration based on the submission of false and misleading data, how would you handle the situation where that person who actually did the submitting doesn't know that the data is false?

Mr. MOORE. I think you hit on a point that is important in trying to correct what may be an aberration in the current statute—that is, somehow the Agency should have to factor into its decision as to whether it was going to cancel the registration or not the culpability of the registrant. Indeed, in the IBT circumstance that you alluded to, in addition to the Agency maybe being duped with falsified data, the registrant, in most instances, also was unaware that the contract lab that was doing the work was just flat falsifying data.

Mr. ROBERTS. If I might be permitted one more question, Mr. Chairman. I would like for you to submit for the record to the subcommittee a complete update on the IBT chemicals. We went into

that in great length during the last session and it is still a point of real concern for the subcommittee and to this member. If you could submit that for the record, I would appreciate it.

Mr. MOORE. I would be glad to.

[The information follows:]

Status of IBT Studies

EPA has reviewed all the IBT studies which deal with health effects critical to regulatory decisions, such as cancer and other long-term or reproductive effects. There are 724 studies in this category. As of April 1985:

- 107 replacement studies have been reviewed and accepted as valid by EPA.
- 460 others do not require replacement for a variety of reasons. Either the IBT studies were found to be valid, or the pesticide involved is not registered in the U. S., has been cancelled, or the type of study is not required for registration.
- 50 replacement studies have been received and are under review.
- 97 replacement studies are underway with specific due dates for submission to EPA.
- 10 studies have been requested via data call-in or registration standards.

Attached is a list of the specific studies which have not yet been finally accounted for through either final acceptance of a replacement study or determination that replacement is not necessary.

As of April 9, 1985

IBT MATRIX*
REPLACEMENT STATUS CODES

C	REPLACEMENT STUDY IN PROGRESS AT COMPANY
I	REPLACEMENT STUDY RECEIVED AND UNDER REVIEW
O	REPLACEMENT STUDY REQUESTED VIA DATA CALL-IN PROGRAM
R	REPLACEMENT STUDY REQUESTED VIA REGISTRATION STANDARDS

*This matrix is being updated on a continuous basis as new information becomes available.

OBS	IBT NUM	SEQ	CHEMICAL	COMPANY	TYPE	SPECIES	VALIDATE	AVAILABLE	REPLACE	EXPECTED	RECEIVED
56	J-9029	1	DISYSTON	MOBAY	TERATOLOGY	RABBIT	I	NA	C	12/31/87	
57	663-6352	2	DISYSTON	MOBAY	SUBACUTE	RAT	V	CI	C	12/31/85	
58	621-6138	1	DOWCO 233	DOW	CHRONIC	RAT	S	S	C	04/29/88	.
59	623-3859	1	DOWCO 290	DOW	REPRODUCTION	RAT	I	NA	I	.	09/30/83
60	621-03115	1	ENDOTHALL	3M/PENWALT	CHRONIC	RAT	I	NA	C	04/29/88	.
61	A 9040	1	ETHION	FMC	SUBACUTE	RABBIT	I	NA	C	12/31/85	.
62	B-8706	1	ETHION	FMC	CHRONIC	RAT	I	NA	C	06/28/85	.
63	C-8705	2	ETHION	FMC	CHRONIC	DOG	V	P	C	12/31/85	.
64	C 975	1	ETHION	FMC	CHOLINESTERASE	DOG	I	NA	C	12/31/85	.
65	E-1057A	1	ETHION	FMC	MUTAGENICITY	MOUSE	V	NA	C	06/28/85	.
66	F-8948	1	ETHION	FMC	CHOLINESTERASE	HUMAN	V	CS	C	12/31/85	.
67	J-1059	1	ETHION	FMC	NEUROTOXICITY	HEN	I	NA	C	12/31/85	.
68	2705	3	ETHION	FMC	REPRODUCTION	RAT	I	NA	C	06/28/85	.
69	621-01058	1	ETHION	FMC	CARCINOGENICITY	MOUSE	I	NA	C	06/28/85	.
70	J-9995	1	FENITROTHION	SUMITOMO	TERATOLOGY	RABBIT	I	NA	D	.	.
71	651-9998	1	FENITROTHION	SUMITOMO	CHRONIC	DOG	V	CI	I	.	09/30/84
72	A-3681	1	FOLPET	CHEVRON	TERATOLOGY	RABBIT	I	NA	I	.	05/01/84
73	B-3566	1	FOLPET	CHEVRON	REPRODUCTION	RAT	I	NA	C	10/30/87	.
74	C-7111	1	FOLPET	CHEVRON	CHRONIC	DOG	I	NA	C	10/31/85	.
75	J-152	2	FOLPET	CHEVRON	REPRODUCTION	RABBIT	I	NA	C	09/27/85	.
76	710	1	FOLPET	CHEVRON	CHRONIC	RAT	I	NA	C	10/31/85	.
77	B-5345	1	FORMETANATE HCL	NORAM	CHRONIC	RAT	I	NA	C	09/30/87	.
78	C-5346	1	FORMETANATE HCL	NORAM	CHRONIC	DOG	I	NA	C	11/28/86	.
79	J-9141	1	FORMETANATE HCL	NORAM	TERATOLOGY	RABBIT	I	NA	C	06/28/85	.
80	F-5347	1	FORMETANATE HCL	NORAM	REPRODUCTION	RAT	I	NA	C	06/27/86	.
81	P-9140	1	FORMETANATE HCL	NORAM	MUTAGENICITY	MOUSE	I	NA	C	09/30/86	.
82	B-569	1	GLYPHOSATE	MONSANTO	CARCINOGENICITY	MOUSE	I	NA	I	.	09/13/83
83	J-565	1	GLYPHOSATE	MONSANTO	CHRONIC	DOG	V	I	I	.	07/12/74
84	8580-8921	1	GLYPHOSATE	MONSANTO	TERATOLOGY	RABBIT	I	NA	I	.	05/13/80
85	J-4915	1	IRGASAN	CIBA-GEIGY	CARCINOGENICITY	MOUSE	I	NA	C	10/31/87	.
86	P-7113	1	IRGASAN	CIBA GEIGY	REPRODUCTION	RAT	I	NA	C	10/31/85	.
87	622-06047	1	IRGASAN	CIBA GEIGY	CHRONIC	RAT	I	NA	C	05/31/85	.
88	C-1181	1	LASSO	MONSANTO	CHRONIC	DOG	I	NA	I		12/14/84
89	B-8965	1	META SYSTOX-R	MOBAY	CHRONIC	RAT	I	NA	C	09/30/87	.
90	C-8966	1	META SYSTOX-R	MOBAY	CHRONIC	DOG	V	CI	C	09/30/87	.
91	J-9025	1	META SYSTOX-R	MOBAY	TERATOLOGY	RABBIT	I	NA	I		04/19/84
92	B-7369	1	METHAZOLE	VELSICOL	SUBCHRONIC	RAT	I	NA	C	10/31/85	.
93	C-7370	1	METHAZOLE	VELSICOL	SUBCHRONIC	DOG	I	NA	C	11/29/85	.
94	E-2097A	1	METHAZOLE	VELSICOL	MUTAGENICITY	MOUSE	I	NA	C	08/30/85	.
95	8532-8239	1	METHAZOLE	VELSICOL	CHRONIC	DOG	S	NA	C	06/30/87	.
96	8580-8238	1	METHAZOLE	VELSICOL	CHRONIC	MOUSE	I	NA	C	02/29/88	.
97	B-5485	1	MONITOR	CHEVRON	CHRONIC	RAT	I	NA	C	09/30/85	.
98	C-5468	1	MONITOR	CHEVRON	CHRONIC	DOG	I	NA	C	09/30/85	.
99	E-9517	1	MONITOR	CHEVRON	MUTAGENICITY	MOUSE	I	NA	C	09/30/85	.
100	J-9515	1	MONITOR	CHEVRON	TERATOLOGY	RABBIT	I	NA	C	09/30/85	.
101	P 6255	1	MONITOR	CHEVRON	REPRODUCTION	RAT	I	NA	C	09/30/85	.
102	B-2804	3	NALED	CHEVRON	REPRODUCTION	RAT	I	NA	C	04/30/85	.
103	B-2948	1	NALED	CHEVRON	CHRONIC	RAT	I	NA	C	04/30/85	.
104	8580-8991	1	NALED	CHEVRON	TERATOLOGY	RABBIT	I	NA	C	06/30/86	.
105	C-1772	1	NOREA	BFC	CHRONIC	DOG	I	NA	C	10/30/87	.
106	1771	1	NOREA	BFC	CHRONIC	RAT	I	NA	C	10/30/87	.
107	2476	2	NOREA	BFC	REPRODUCTION	RAT	I	NA	C	10/30/87	.
108	B-1242	1	OMADINE	OLIN	TERATOLOGY	RAT	I	NA	R	.	.
109	B-9269	1	ORTHENE	CHEVRON	CARCINOGENICITY	MICE	I	NA	I	.	06/07/82
110	B-1350	1	PARAQUAT	CHEVRON	CHRONIC	RAT	I	NA	I	.	02/09/84

Mr. ROBERTS. Thank you.

Mr. BEDELL. Thank you, Mr. Roberts. Mr. Gunderson.

Mr. GUNDERSON. Thank you, Mr. Chairman. Dr. Moore, in the last session I was the ranking member on the subcommittee with jurisdiction over OSHA and I notice in your testimony that you indicate that there ought to be better cooperation and interaction between OSHA and EPA as it regards the various uses and disclosure of regulations, et cetera. Can you elaborate on exactly what you are suggesting?

Mr. MOORE. Congressman, as you may be aware, the current circumstance is that any action that EPA may take to control workplace exposure under FIFRA preempts OSHA from taking any action in that same area. This has led to concern that FIFRA labeling sometimes minimizes worker exposure levels and may prevent OSHA from setting a maximum permissible exposure level, for example, even though there may be no inconsistency between the two actions. There are examples where we had proposals of things to put on the label which we were led to believe would probably preempt OSHA's ability to finally promulgate and enforce a permissible exposure limit. I think they could do a better job than we could in this area so far as the objective is to achieve worker protection. In that circumstance, their mechanism would have been better than ours. A simple solution is to maybe amend the statute so that EPA actions do not preempt OSHA, provided that OSHA's actions are not inconsistent or unnecessarily duplicative of what EPA may have done on a label.

Mr. GUNDERSON. If we do something like that, whether it be legislatively or through regulation, I have to plead with you as I have done with OSHA. The working man and woman in this country could care less what formula you put on labels because they don't understand them anyway. If we are going to do labeling, for gosh sakes do it in a way where the average person can get some benefit out of that label. If we aren't cognizant and concerned about that, the whole effort is going to be futile.

Since we're talking labeling, you mention on page 16 that the Agency is now considering the possibility of using labeling to identify inert ingredients which may pose significant risks to human health and environment. If I read section 2(1) of FIFRA, you already have the authority to regulate inerts, is that correct?

Mr. MOORE. The Agency does maintain that it has authority now to require the listing of inerts.

Mr. GUNDERSON. Does that include labeling, in your opinion?

Mr. MOORE. Yes. One thing that would help is that some people may not agree with our interpretation and may well contest it. I might suggest that an amendment could clarify our authority in the area and clearly demonstrate EPA's commitment to the process.

Mr. GUNDERSON. If you would indicate to us at some point in time what kind of clarification you feel is necessary, I think that would be helpful.

Could you clarify just what is the Agency's cross media enforcement bill and what that has, or does not have, to do with FIFRA?

Mr. MOORE. I believe it was last year the Agency concluded an effort where we tried to look at what the compliance and enforce-

ment activities were in each of our statutes with the intent of achieving better consistency of the penalties and the requirements across them. In essence, it identified that there is great variance in certain circumstances between various statutes.

For example, the TSCA statute, which I have responsibility for, is very aggressive in its penalty requirements compared to FIFRA. What we would suggest that one could do is to take a look at the penalties, make some adjustment in FIFRA penalties to bring them up to date, still keeping the dichotomy between agriculture and commercial firms, and also look at recordkeeping requirements for some degree of consistency in this area, as well as inspection authorities. As I mentioned, we do not have authority to inspect a laboratory to see if they're in compliance with good laboratory practices.

Mr. GUNDERSON. You would like that authority?

Mr. MOORE. Yes, sir.

Mr. GUNDERSON. Concerning the special review process—and I think everyone from the industry to the environmental community is always interested in that issue and the procedures that are used—you've talked about streamlining the special review process. Could you elaborate exactly on what you are anticipating?

Mr. MOORE. As I mentioned in my testimony, we do have some proposed changes in regulations which will allow us to maybe streamline the current system. I maintain that the current system needs to be looked at. You can only go so far in making a silk purse out of a sow's ear, if you will.

The problem with the system is that a tremendous amount of effort goes into getting all the information on the record. When we've issued the final decision as the outcome of this process, if somebody disagrees with it, they have the right, under the current statute, of asking for a judicatory hearing process. In that adjudicatory hearing process, we basically start all over again because everything that we have built during this PD1,2,3,4 system is almost nonexistent. We get into cross examination. We have to start building the case. I just think it is one of the reasons why the Agency may not be as efficient as it could be in addressing some of these concerns. Certainly I think it's one of the main reasons that I think erodes the public's credibility in the process. By the very nature of saying this is a special review, we announce to the world that here is something that is a particular concern to us and we're going to look at it with great scrutiny. Then years later, we still have a process that, after we've come out and the Agency has decided to do something, we start all over again and the public says well I guess the Agency decided but nothing seems to happen because it's now going to go on for a couple of more years. Then we can appeal that and make the Administrator review it, and if we don't like his decision, they can go to the courts.

I just submit that this may be a bit overbearing. We might be in a better position of getting rid of that process and go to a process that is more akin to what is done in most of our other statutes which is the informal notice and comment rulemaking. At the end of that if somebody is still upset with the outcome of that rulemaking, they can take the additional course of going to the courts.

Mr. GUNDERSON. Thank you. Thank you, Mr. Chairman.

Mr. BEDELL. Thank you, Mr. Gunderson. Mr. Penny, Mr. Roberts has requested that he go next, without objection. Mr. Roberts is going to go over and see that we get adequate police protection, as I understand it, and we all feel that is very important.

Mr. ROBERTS. Lord knows, any Member of Congress, with the statements we make around here, needs a certain amount of security. That's to be understood.

I would like to followup in regard to Mr. Gunderson's question and I appreciate my colleagues letting me go out of order. This is on the informal rulemaking process. I don't see anybody in the audience with brown overcoats and Sam Brown belts taking notes but I am a little concerned about OMB scrutiny and opening up the special review process to OMB scrutiny—I am pausing there—that's everybody's favorite four-letter word in this town. At any rate, could this tie up your agency even more? Welcome to the hot seat.

Mr. MOORE. By going from the current process we're in to informal rulemaking, one clearly would be in the circumstance where the appropriate Executive orders would have us submit the rules for OMB comment to a much greater degree than in the current process.

Mr. ROBERTS. It's not the comment that I worry about from OMB, it's the proposals. They not only saddle the horse, they tell us which way to ride or even if we're going to get him out of the chute. I have some real problems with that, but that's another matter.

Since the subcommittee last held hearings on FIFRA, the Agency has begun a negotiated rulemaking process in regards to section 18 emergency use provisions. Are there any other areas that this type of process could be used to address some of the contentious issues in FIFRA?

Mr. MOORE. That section 18 negotiated rulemaking was a first for the Agency, particularly in the area of pesticides. As it related to the outcome of section 18, we were basically pleased with the outcome of that process. That's not to say it wasn't contentious and everything else to get such a diverse group with very strong opinions to agree on what that rule should be. Hopefully it will allow us to have anticipated what some of these comments may be and as the end result be able to get the final rule out faster. I don't think negotiated rulemaking will work in every circumstance. Given the success that we've had under section 18, we're certainly eager to stay attuned to those circumstances in which it looks like it would have success.

Mr. ROBERTS. Your Agency has undertaken a rather ambitious program on Data Call-In. How will your Agency handle the projected workload that I would predict will happen?

Mr. MOORE. Basically, we have been putting together what we call our flaging criteria that we will be requiring the registrants to employ. The short of the flaging criteria is that we will have identified to all registrants, in advance, certain types of data that should be brought to our attention. Indeed, the obligation will then be on them that when those circumstances are net, they flag for us that here is a data set that fits your criteria that you say you want us to alert you to.

The hopeful outcome will be that we minimize the possibility that we miss a very significant data piece and only get to it as we wade through the stack. Indeed the data of greatest concern will be flaged to us so that we can address it in a priority manner.

Mr. ROBERTS. There is one question that Mr. Combest of Texas wanted to ask, but his schedule does not permit him to be here. If the FIFRA requirements on data compensation are amended to allow for full judicial review, what impact will this have on the Agency?

Mr. MOORE. Our feeling is it would have little or none to our circumstances. Where we are right now is that, because people are frustrated with the current system, they go into court and try to get restraining orders, et cetera. Then, we are held up in being able to register some products because of the claims that you can't use my data or things of that sort.

Mr. ROBERTS. Mr. Chairman, I, again, want to thank the subcommittee members for allowing me to ask these questions out of turn. I appreciate very much your patience and your answers, Dr. Moore. Thank you.

Mr. BEDELL. Thank you, Mr. Roberts. Mr. Penny.

Mr. PENNY. Thank you, Mr. Chairman. Dr. Moore, would you describe the considerations or the criteria that you use in placing these chemicals on your priority list for reregistration.

Mr. MOORE. Several years ago, the Agency developed a scheme whereby the chemicals that would come up for review first are those chemicals that are food use pesticides, and, as a result, are likely to pose a circumstance of large use and great potential for exposure should something adverse be found with those chemicals. Those are coming first.

The practical outcome of that is that we're in the current process of reviewing the existing chemicals that represent some of the chemicals that are in very heavy use in agriculture right now.

Mr. PENNY. That does represent heavy use in agriculture.

Mr. MOORE. Yes, sir. Things that would fall behind the food use category would be chemicals that are nonfood use. We have just made a conscious decision that they would be of a secondary priority.

Mr. PENNY. When you indicate that you have reregistered 98 chemicals, what exactly does that mean?

Mr. MOORE. The 40,000-odd registrations that we have of pesticides basically represent some 600 active ingredients or combinations of active ingredients. When we talk about registration standards, we talk about those 600 chemicals. We have completed 90-odd of those standards. Some of the early standards that were put together several years ago, in some respects, reflect a collation of what was missing as well as a review of what data were there.

Now, at the time we are reviewing a chemical, we will have what we consider to be some of the key data in hand, rather than say it's going to be coming in another year or whatever the case may be. It has been a shifting circumstance leading up to the stage whereby we will soon be basically reviewing a data set that is equivalent for chronic data to that required to get a new pesticide on the market.

Mr. PENNY. How are you handling inert ingredients?

Mr. MOORE. With difficulty. We have come up with a set of criteria for the 1,200 inerts that exist, whereby we have looked at those inerts to try to identify those that are of particular concern. We have submitted our process on how we are going to review these to the Science Advisory Panel which is a part of the FIFRA mandate that we have a scientific review board. In addition, they have agreed with the process. Just this week, at their meeting 2 days ago, we showed them those 40-odd chemicals that are of greatest concern to us. Our intent is to identify those chemicals and to also possibly consider the requirement that those chemicals be listed on formulations that contain them.

Part of our hope is that in the process of identifying these inerts of particular concern, many registrants will voluntarily quit using those inerts to the degree that's possible.

Mr. PENNY. I have one other question in regard to inspections. Do you set the standards on chemicals or the amount of residue of chemicals that will be allowed on imports and, if so, who actually conducts the inspection?

Mr. MOORE. Residues are set under the Federal Food, Drug and Cosmetic Act. EPA has the responsibility of identifying the level of residue that would be allowed for a particular pesticide. In essence, we do that and then it's FDA's responsibility to enforce or to monitor and enforce.

Mr. PENNY. Are you satisfied that there is a close enough working relationship there that we are catching things that we ought to catch?

Mr. MOORE. I'm very comfortable with the relationship that we have with FDA in this area. One thing that we are very active in right now is going through the list of old pesticides that have been cancelled for a variety of reasons over the past number of years and either eliminating those residues or lowering those residues to the degree that is possible so that American agriculture is not at a disadvantage. Otherwise it could still be used in a foreign country and we import it because our residues will allow it. We are in the process of dropping those residues or eliminating them to prevent this from happening. Aside from the disadvantage to agriculture, it also makes no sense to allow it to be coming in on imports, from a public health view.

Mr. PENNY. Yes, I tend to agree with that. Do you have any examples of where we've actually shut down imports based on either a chemical pesticide that we don't allow used here that was in evidence on imported commodity, or where the residue standards were in excess of what we allow?

Mr. MOORE. There are examples. One that comes to mind occurred last fall whereby we were in the process of importing something in the nature of a fresh fruit in which there was no tolerance set in this country. As a result, we held up those shipments. FDA seized the shipments. I could provide for the record examples of where this occurs.

Mr. PENNY. I think that might be helpful. Thank you, Mr. Chairman.

[The information follows:]

- Imports in Violation of Tolerance Requirements

The subcommittee has asked for examples where the U.S. has "shut down" imports, either because a pesticide use not allowed in this country was in evidence, or because residues exceeded tolerance levels. The vast majority of imports analyzed by the Food and Drug Administration (FDA) comply with tolerances. Each year, however, there are numerous instances where the Food and Drug Administration (FDA) detects violative residues in foreign commodities and prevents the commodities from entering the country, either because residues exceed tolerances, or residues are detected where there are no tolerances. The majority of violations involve particular pesticide/commodity combinations for which no U.S. tolerance has been established, although the pesticide is registered for some uses and has tolerances for other commodities. Violations and detentions involving pesticides not registered for any use in this country, or pesticides that we have cancelled, are less frequent, but they do occur.

FDA, rather than EPA, compiles records of these actions on imports, but the following recent actions are noteworthy. Within the last year, FDA detected residues of BHC and DDT in Mexican cabbage shipments that were above existing U.S. tolerance levels. After two shipments were found in violation, no further Mexican cabbage was allowed to enter the U.S. unless the shipper could produce a valid certificate of analysis showing that a shipment did not contain illegal residues of BHC or DDT. In recent months, FDA has also stopped shipments of mangoes from Mexico and from Haiti because EDB was detected at levels above our interim tolerance of 30 parts per billion for EDB on mangoes. Pineapples from Mexico have also been detained because shipments were found to contain residues of carbaryl, which until recently had no U.S. tolerance on pineapples.

EPA has sent copies of its policy statement on Revocation of Tolerances for Cancelled Pesticides, published in the Federal Register September 29, 1982, to all Codex member nations, including Mexico. The Agency has also circulated its proposals for specific tolerance revocation actions to Codex members for comment. As you may know, EPA has recently proposed revocations of tolerances for several cancelled pesticides, including DDT and BHC. This exchange of information with other countries is intended to help ensure the compliance of imports with U.S. tolerances.

Mr. BEDELL. Thank you, Mr. Penny. Mr. Volkmer.

Mr. VOLKMER. No questions.

Mr. BEDELL. Mr. Moore, in regard to the foreign use of pesticides and chemicals, I'm not sure I understood your answer because on those chemicals that are prohibited from use here in the United States, my understanding is that they can be used in foreign countries on products that are imported here into the country if there's not a residue found. Some of us feel that is quite unfair to our producers in that our producers are not simply required to say there isn't any residue. They are told they can't use it. Is there any inclination toward any changes in this policy or would you have any recommendations in legislation we pass in regard to those policies?

Mr. MOORE. I don't know how we could enforce——

Mr. BEDELL. It would be pretty easy to enforce it. All we would have to do is say that we would prohibit the importation of any products into these United States from a country which permits the use of any chemicals that are prohibited in our country.

Mr. MOORE. I think that would imply the necessity for some agent of this country to be in that country to see if there was no residue.

Mr. BEDELL. Not at all. It would simply depend upon somebody checking the laws of that country to see whether that country permitted the use of that chemical, or whether they didn't.

Mr. MOORE. You'd make the assumption if it was registered for that use you would presume it was being used for that purpose.

Mr. BEDELL. Sure. We prohibit it here; therefore, if they wanted to import into our country, they would have to prohibit it there. We would operate on equal terms. Would you be supportive of that or opposed to that or have an opinion as to such a proposal?

Mr. MOORE. I think the Agency would not have any strong opinion on that one way or the other if that is what the law would require. We certainly would enforce it. I think the issues that might be raised in that regard wouldn't come out of EPA; they would be coming out of other parts of the administration that were concerned about trade barriers. That's an area that EPA doesn't want to get in the middle of.

Mr. BEDELL. OK, I think you've got a few problems already. You gave an answer to Mr. Roberts in regard to culpability where false data had been used and you were going to determine whether it was intentional or not. Would there be any type of appeal or recourse if anybody felt that your ruling had been unjust in their case?

Mr. MOORE. I think we'd always think that it's appropriate that due process be available as appropriate in any circumstance, this one included.

Mr. BEDELL. This is a recommendation that you had. If you were to furnish such a recommendation, you'd also recommend that there be come type of appeal process. Is that correct?

Mr. MOORE. Yes, sir.

Mr. BEDELL. That gets into the next question. Your testimony has been very helpful and very specific and we are very pleased. I want to commend you for your statements, as well. The people on this subcommittee know that's not too common for me as chairman, frankly.

Mr. MOORE. Thank you.

Mr. BEDELL. Can we get cooperation and help from your staff if we attempt to draft legislation? You've got a lot of knowledge over there of things that could help you to work better. Can we have your assurance of the cooperation and help from your staff if we try to draft our own legislation in these areas?

Mr. MOORE. Yes, Mr. Chairman. We certainly are willing to provide technical assistance as appropriate and as requested.

Mr. BEDELL. Mr. Gunderson talked to you about changes in the system and you had some recommendations which sounded to me to be very reasonable and most helpful. Then when Mr. Roberts asked you if FIFRA requirements on data compensation were amended to allow full judicial review, and what effect you would see on your Agency, you implied that you didn't think it would have any effect because you already have all this judicial review. If we were to change the legislation as you recommended to Mr. Gunderson, then I assume that this would have a substantial effect, am I correct? I thought your recommendation to Mr. Gunderson would get away from all of the requirements that you duplicate your efforts for judicial review on these matters.

Mr. MOORE. As it relates to special review, if we were to change and go into informal notice and comment rulemaking, it would then eliminate the adjudicatory part of the process and basically take it through the normal rulemaking process and then into the court of appeals if somebody was concerned about the equity of that.

Mr. BEDELL. In your answer to Mr. Roberts where he asked if the FIFRA requirements on data compensation were amended to allow for full judicial review you said you felt it would not be any great deterrent to your ability to move more quickly.

Mr. MOORE. I understood Mr. Roberts question to deal with the *Union Carbide* case that's currently before the Supreme Court. That dealt only with the arbitration decision. The current statute requires binding arbitration to which there is no appeal. The case is basically arguing that you've taken away from me the due process of appeal. The current system is causing us problems because of the registrants disliking the systems and saying it's unconstitutional. This situation holds up our ability to register somebody who is willing to compensate somebody else who developed data as is appropriately set by an arbitrator. To the degree that's in the courts and there are restraining orders associated with it, we can't do business.

Mr. BEDELL. I think there was a misunderstanding on Mr. Roberts' question. Can I read you his question as he had it and from which he read it?

I fully appreciate that the Agency from time to time has been tied up by numerous court decisions. If the FIFRA requirements on data compensation are amended to allow for full judicial review, what import would this have on the Agency? I think that is the question he meant to ask.

Mr. MOORE. On a day in, day out basis as far as our involvement in any dispute, it would have no effect. A practical consequence may well be if it was changed to allow judicial review after this arbitrator had set a judgment, I would presume that registrants

that were unhappy with the arbitration results would not necessarily tie up the whole process while they're seeking relief if they had some mechanism to insure that they would get compensated in the end.

Indirectly, if we made this change, it would help us. We are not direct participants to any of this.

Mr. BEDELL. Thank you. Mr. Brown.

Mr. BROWN. Let me just take another crack at a couple of items here, Dr. Moore. You indicated in connection with the amount of resources available to you that it had been approximately level and that you expected to cope with that problem. I have the figures from your budget submission and they're somewhat less optimistic than that. I'll read these and if you have any problems with them, I wish you would correct me. This is the section on pesticides, special registration, and tolerances and it shows that for registration the total goes from $15.9 million to $13.7 million in 1986, a decrease of $2.2 million and that's around 7 or 8 percent in dollars. For special registration, the figures are $2.2 million in 1985, and $1.9 million for 1986, again a decrease of about 10 percent. For tolerances, $3.2 million in 1985 and $2.87 million in 1986, a decrease of a little over 10 percent in dollars.

The figures for permanent work years are equally bleak. The total work years in each of the three categories go down by amounts which range from about 3 percent for registration, about 5 percent for special registration, and about 7 percent for total work years on tolerance. This indicates to me that both your dollars and your permanent total staff are dropping at a time when you're making good progress and doing an admirable job. You're still faced with backlogs that run up to possibly 20 years.

I haven't misstated these figures, have I?

Mr. MOORE. You have a more detailed breakout of my budget than I brought with me this morning. I have no reason to quarrel with your figures. What I can refer to is that if we set aside the R&D component of the pesticide 1986 budget request, what we have for the regular operations—I'm not disputing the decrease in numbers that you are talking about, but what has happened is that we are basically reorienting some of those numbers. For example, the generic chemical review part of the budget in fiscal year 1986 has gone from 250 FTE's in 1985 to 260. There are internal shiftings.

Mr. BROWN. The categories that I was reading were the ones I indicated.

Mr. MOORE. I don't dispute your figures.

Mr. BROWN. Back to the monitoring, you have enforcement powers under both FIFRA and the Clean Water Act and the Clean Air Act. The monitoring problem is the same for all of those. We have stories of pesticides being blown by the atmosphere from Texas to the Great Lakes and contaminating the fish in the Great Lakes and producing cancers in people eating fish. A monitoring problem has to cross all media or all of the different programs, at least. The question I have for you is in looking at the monitoring situation, if you're looking at it broadly or just on the ground water situation. If so, how do you justify this in view of the intermedia impact?

Mr. MOORE. We're clearly looking at it from a water standpoint with particular interest on ground water as opposed to surface water and we're doing that in conjunction with the Office of Water within the Agency.

With regard to air programs, they are starting a new monitoring program and they have asked us to participate in putting together a process. I would say based on that that we are behind.

I do get a sense in the Agency that there is much greater interest and willingness of the various fiefdoms to realize that these are cross-media issues.

Mr. BROWN. I think we have always known that but there are problems just because of the way it's organized and authorized. You have too many laws over there.

May I ask you to provide the subcommittee a little progress report on how you're doing in the monitoring field. You anticipate a report in the fall, but I would be interested to know just how broad a scope your plans include and what you're contemplating doing.

Mr. MOORE. Yes, sir.

[The information follows:]

National Monitoring Plan for Pesticides

The Office of Pesticide Programs (OPP) has prepared a report entitled the National Pesticide Monitoring Plan, which discusses on-going and planned pesticide monitoring projects and related activities in the context of regulatory decision-making. The plan reflects OPP awareness that monitoring data on the occurrence and effects of pesticides in all environmental media provide vital supporting information to measure the effectiveness of past decisions and to plan future regulatory actions. The scope of monitoring activities described is very broad, and includes monitoring for pesticides in ground and surface water, air, food and feed commodities, animal and human tissues, as well as projects to assess exposure for applicators and other workers, and to monitor the occurrence of poisonings and other adverse effects incidents involving pesticides. The Plan emphasizes the importance of cooperative efforts with other EPA programs and other federal and state agencies and private organizations with shared interests in monitoring activities.

The Plan is now in the final stages of Agency review, and should be forwarded to Congress in the next few weeks.

Mr. BROWN. Thank you.

Mr. BEDELL. Mr. Volkmer.

Mr. VOLKMER. I do have a couple of questions. You have touched on funding on enforcement not being adequate, is that correct?

Mr. MOORE. Our funding for enforcement is basically level.

Mr. VOLKMER. Is that sufficient?

Mr. MOORE. Some people have questioned that if we become more aggressive in a restricted use category and in testing for proficiency and knowledge for becoming a certified applicator, that would put a greater burden on the States which they would be very hard pressed to realize with the current level of funding.

Mr. VOLKMER. The question I have is about a review of the operation of some of the independent labs and your being able to monitor their work and approve or disapprove. What about the funding for being able to do that?

Mr. MOORE. I'm fairly comfortable that we have a critical mass in that area. As you know, we did promulgate good laboratory practices a year and a half ago. I also integrated the good laboratory practice data audit functions of the Office of Toxic Substances and the Office of Pesticide Programs. So often they are going to the same laboratories. Their approach at looking at data is the same.

I also have been much more aggressive in interacting with FDA as well as the National Toxicology Program who also conduct GLP's and data audits, so that we get broader coverage by knowing what each other is going to be doing. I'm reasonably comfortable with the critical mass in that area.

Mr. VOLKMER. In reviewing the testimony, I note that you say you are trying to administratively find ways to speed up the special review process. I was wondering if you or your staff have reviewed the present legislation in effect as to whether there's any impediment in the law that delay any of the registrations that could possibly be changed without impinging on the scientific level and making sure that everything is sound.

Mr. MOORE. We've looked at some of those things and have proposed or instituted a few changes. We are now proposing in the changes to the existing regulation that we will not enter something into special review until we have some exposure information to tie in with what is usually first available which is some hazard data that suggest some type of toxicity. Those two pieces are critical in risk assessment. You can't do risk assessment with just one piece; you need both pieces.

We're trying to have those pieces available so that when we do move forward, we can possibly do it in a move expedited fashion.

Mr. VOLKMER. Are you telling me that you see no need for any change in legislation in regard to this?

Mr. MOORE. I think the change that possibly is needed is to get us out of the process whereby we go through this special review and then are subject to going to adjudicatory review and then subject, theoretically, into further review by the Administrator, and then remedies into the courts. We would suggest that there's got to be a faster way of doing that. One way that has some appeal to us might be to change the whole process that we currently have and conduct this through informal notice and comment rulemaking, with the outcome being that, if anybody is still upset, they can go directly into the court of appeals and will eliminate this adjudicatory segment of the process.

We probably would also identify that we don't want to throw away the option of using the other mechanism. There may be benefit once you've done a rulemaking on an active ingredient, as you treat the dozens or several hundreds of registered products that contain that ingredient, one might best go through those, possibly using the adjudicatory hearing process.

Mr. BEDELL. Will the gentleman yield?

Mr. VOLKMER. Yes.

Mr. BEDELL. I think Dr. Moore indicated in questions by Mr. Gunderson that they do believe there needs to be some changes in legislation and that they would work with us in regard to such changes to streamline that process and make it more rapid for them.

Mr. VOLKMER. Thank you, Mr. Chairman.

Mr. BEDELL. Dr. Moore, you mentioned that you have 25 standards a year now. Will you explain what standards are.

Mr. MOORE. In the process of reregistration of existing chemicals, we basically go through a process whereby we review all of the data that's in the file pertaining to the registration. We review it for accuracy and value by today's standards even though it might have been submitted 15 or 20 years ago. Is it still acceptable in 1985? Also, what's missing. Using our pesticide registration requirements, we look at what's missing? It's common that we may have a study that assesses a chemical's possibility for causing birth defects in one species. Our current requirement is that you have to do that in two species. We would then identify that we still needed a second study by 1985 standards.

The outcome of it is that it's a twofold process as we're currently realizing it. One, we're still identifying what data pieces may yet be missing and it also is a full review of what data we have as to its adequacy. If the data are adequate, if we find no particular concern, we then move on. To the degree that we find something that is inadequate or something that is of concern which we would like to explore further, we might require additional data through the process. If the nature of the data suggests some adverse effect of some priority, we will then put it into special review.

An example of the special review criteria may well be when we've got studies that assess ability to cause cancer that are positive. Something that may be acutely toxic is another criteria. Those criteria have been outlined in a regulation as to what those criteria are. The composite of all of this effort basically is a registration standard which is the Agency's way of announcing to itself as well as to the rest of the world, this is what we know about that active ingredient; this is what we're comfortable with; this is what we're asking for more information on.

Mr. BEDELL. I was afraid that would be your answer. So, the reality is that by having those standards does not mean that you have necessarily completely tested and satisfied yourself that that chemical is something that can be registered and used. Is that correct?

Mr. MOORE. Correct.

Mr. BEDELL. You've got 600 potentially subject to registration and right now you're doing 25 standards a year. I'm not as knowledgeable about all this as I wish I was, but if that was my business, I would say at my age you're not going to get done with what you have right now if you don't get another one for the rest of my life. That's a pretty terrible problem, Dr. Moore. I realize the restrictions, but I don't understand how you keep from tearing your hair out.

Mr. MOORE. You have hit on what I think is the Achilles heel of the Pesticide Program as it currently operates today or as it is perceived to operate as far as credibility with the public. That is the

inability of the Agency to have completed a review of all of these old pesticides that were registered decades ago. That review must be done under new criteria.

Mr. BEDELL. Do you think the criteria are too restrictive then?

Mr. MOORE. No.

Mr. BEDELL. What the devil are we going to do? We've got a terrible mess on our hands.

Mr. MOORE. I think the best answer I can give you is that given the resource that we have available for doing this, we have tried to prioritize the approach to it by picking those pesticides that are the most important and doing them first. Also, to make sure that nobody is theoretically getting a free ride by thinking that they are not going to come up for review for another 10 years—and as a result they do nothing toward getting the data that we are going to require—we're aggressively trying to issue all of the Data Call-In requirements for these products so that the company up front must commit to the investment of that data.

If we then put flaging criteria on the data, it then will allow us, as these materials come up, to have the registrant flag for us those data sets that are of particular concern to us so that we can get to them on a priority basis.

Mr. BEDELL. You have had some legislative proposals that you have worked on. I presume this is one of the major things that you would look at is how the devil you get out of the problem you're in with the limited resources you have. Will you submit to us whatever suggestions you have? I don't think you ought to be bashful about whatever those suggestions are to help solve what would appear to me to be a terribly difficult problem.

Mr. MOORE. Yes, sir.

Mr. BEDELL. You say the large influx of data is expected this year,

> To insure that the Agency receives all the data it needs and to insure that we can keep abreast of the most significant of the new data, we will be issuing a final interpretative rule this spring.

That's just additional work, is it not, Dr. Moore?

Mr. MOORE. Yes, sir.

Mr. BEDELL. With no additional help. You say here that the Agency has remained alert to current FIFRA language that may limit our efficiency in implementing our statutory mandate. Will you give us recommendations as to what this implies?

Mr. MOORE. Some of those I have articulated this morning as a response to a number of the questions that have been asked, but, yes, I would be glad to provide that.

Mr. BEDELL. The special review process, I guess we reviewed that quite completely. You recommend some major changes in that, as I understand it.

Mr. MOORE. Yes, sir.

Mr. BEDELL. Will you give us language as to what you think you need for better enforcement?

Mr. MOORE. We would be willing to provide you with technical assistance as well as a general outline of where we think penalties may warrant consideration for maybe updating to current day's standards.

Mr. BEDELL. As I said, at least for me, this session has been most informative. I appreciate your candor and straightforwardness. I appreciate the help you've promised us in terms of staff assistance as we try to move forward.

In spite of the great disappointment that we had over the fact that we thought we were going to have a bill from you and now do not have one. I hope we can forget what has happened and move forward now with legislation. It appears to me that there are great deficiencies in our current legislation that need to be corrected if you're going to operate as efficiently as you possibly could. I think it would be our desire to make the necessity changes.

Mr. MOORE. I look forward to working with you.

Mr. BEDELL. Thank you very much. The subcommittee will adjourn.

[Whereupon, at 11:35 a.m., the subcommittee recessed to reconvene at the call of the Chair.]

[Material submitted for inclusion in the record follows:]

STATEMENT OF JOHN A. MOORE
ASSISTANT ADMINISTRATOR FOR PESTICIDES
AND TOXIC SUBSTANCES
U.S. ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE SUBCOMMITTEE ON
DEPARTMENT OPERATIONS, RESEARCH AND FOREIGN AGRICULTURE
COMMITTEE ON AGRICULTURE
U.S HOUSE OF REPRESENTATIVES
WASHINGTON D.C.

APRIL 18, 1985

Good morning Mr. Chairman and members of the Subcommittee. Eighteen months ago, in November 1983, EPA's then Administrator, William D. Ruckelshaus, testified before this Subcommittee. Though pesticide regulation has always presented difficult social policy issues, the program at that time was embroiled in controversy. Numerous parties felt that only major legislative changes could set the pesticide program on the right course. However, Mr. Ruckelshaus argued that many of the problems with the pesticide program could be addressed administratively, and pledged that EPA would vigorously pursue improvements without waiting for changes in the law.

I can unequivocably report to you that it has made good on that promise. I have implemented Mr. Ruckelshaus' commitment to improve the program; clear policy guidance has been given which has led to significant progress in addressing long-standing problems facing pesticide regulation. Lee Thomas and I will continue to provide the firm direction needed to protect public health and the environment and at the same time assure that society may enjoy the social and economic benefits these products can offer.

When I became Assistant Administrator for Pesticides and Toxic Substances shortly after Mr. Ruckelshaus testified, the pesticide program needed to restore credibility to the regulatory process, by improving the timeliness and scientific quality of its regulatory decisions, and by ensuring that the decision process itself was conducted in an open and impartial manner. The last 18 months have been very active ones and the program has made great strides in accomplishing these goals of timeliness, scientific soundness, and openness of decision making.

Even with these great strides, I believe there are areas where FIFRA could be improved to assist EPA in implementing its statutory mandate. After briefly discussing the principal administrative initiatives that have been implemented, I would like to outline for you the areas where I believe significant improvements could be made in the management of FIFRA.

° ASSURE TIMELY REVIEW AND DECISIONS ON EXISTING PESTICIDES

Reregistration of all previously registered pesticides is the most complex task assigned to EPA under FIFRA. For a number of reasons, the data bases for many of these pesticides are woefully inadequate and the existing data have not been evaluated by current standards. Thus, I placed the highest priority on getting reregistration moving. The Agency now has an aggressive reregistration program underway.

Of the 600 pesticide chemicals potentially subject to reregistration, the Agency has reviewed and issued registration standards for 98; 47 of these standards have been completed in the last two years. We are now doing 25 standards a year and will continue at that pace, giving priority to high volume and food use chemicals and those which may pose special problems such as ground water contamination.

To ensure that the key data are available when we reevaluate a pesticide, we have accelerated the pace of the existing Data Call-In program for chronic health effects data on food use chemicals. These key health data include chronic toxicity studies, two year cancer studies, studies to assess the potential to cause birth defects, and fertility and reproductive studies that span two generations. By the end of this fiscal year, we will complete issuing this data requirement for all food use chemicals. This represents a total of 403 chemicals, 226 of which have been issued in the last two years. In addition, a special data call-in was issued in 1984 to require environmental fate data on over 100 pesticides preliminarily identified as potential groundwater contaminants. A third major call-in program is now being developed to ensure that the Agency has precise information on the chemical composition of each registered pesticide (over 49,000 products).

The Agency takes its reregistration responsibility quite seriously and expects pesticide registrants to be equally committed to carrying our their responsibilities. We have initiated a new data call-in project in which registrants of 31 non-food use pesticides are themselves identifying and then filling any significant data gaps. I hope this approach will work so that it may be expanded in the future.

We have begun to closely monitor each registrant's progress in meeting their commitments to develop data. Basically, when a registrant makes a commitment to develop needed data by a certain time, we expect the commitment to be kept; extensions will be granted only when the schedule has been delayed for reasons beyond the registrant's control. When a registrant fails to keep these commitments, we are exercising our authority to suspend their product registrations until the data are submitted.

The composite effect of these various efforts will result in the submission of a large amount of new data on these older pesticides. The first large influx of data is expected this year. To ensure that the Agency receives all the data it needs and to ensure that we can keep abreast of the most significant of the new data, we will be issuing a final interpretive rule this spring. This rule will emphasize

and clarify every registrant's responsibilities for submitting adverse effects data to the Agency promptly. We will also propose a new rule that requires registrants to highlight those portions of these data which meet certain specified risk criteria.

While reregistration is the overall process of reevaluating existing pesticides, Special Reviews (or RPARs) single out for intensive risk/benefit evaluation those registered pesticides which may be posing unreasonable risks. This part of our program is quite active again after a period of virtual dormancy. For example, in Fiscal 1983, no new Special Reviews were initiated, and only 6 decisions issued, including 2 decisions returning chemicals to regular registration and one voluntary cancellation. In the last 18 months, 25 decisions have been issued, including 10 new Special Reviews (PD 1's), 4 proposed regulatory positions issued for review and comment (PD 2/3's) and 8 final decisions published (PD 4's); 2 decisions returned pesticides to the regular registration process, and there was one voluntary cancellation. We expect that about 6 to 8 new Special Reviews per year are likely.

The Special Review process is now more fully integrated with the Registration Standards program. The reviews and call-ins of data for Standards development are the primary

means for identifying chemicals for Special Review. However, a Special Review can be, and has been issued before a Standard is developed, when the evidence of potential hazard warrants.

The Agency has just published proposed rules to revise the procedures and criteria for Special Reviews. Among other things, the revised procedures include provisions for expediting Special Reviews. We are committed to improving the timeliness of Special Review decisions by determining up-front whether an intensive risk/benefit review is appropriate and vigorously pursuing the data needed to resolve any outstanding questions.

Revoking the tolerances for pesticides which have been cancelled for use in this country is another area that is being aggressively addressed. When tolerances or legal residue levels for cancelled pesticides remain in effect, these pesticides can be used on food commodities grown abroad and imported into this country. Because of this, dietary exposure continues, undermining what is often the principal purpose of cancellation. This is the so-called "circle-of-poison" issue. Another adverse result is that this often clearly works to the detriment of American agriculture. For example, foreign producers of food commodities imported into the United States may benefit in terms of increased yields from the use of a particular pesticide, possibly of low cost, that can't be used by American producers because its use has been cancelled here.

We are now in the process of revoking tolerances for 14 pesticides which were cancelled in the 1970's. Most represent the very long-lasting chlorinated hydrocarbons such as DDT, BHC, aldrin/dieldrin and chlordane/heptachlor. Tolerance revocations have been proposed for 8 pesticides so far and proposed revocations for the other 6 will be issued in May of this year. In most cases, it is our intention to replace the existing tolerances with lower, discretionary residue levels which can be adjusted downward over time as the background levels of these pesticides in the environment decline. It is EPA policy now to consider the need for revoking the tolerances for a pesticide during the decision process for determining whether registrations will be cancelled. These actions will help to ensure that imported food commodities are held to the same standards for pesticide residues as domestic products.

° ASSURE SOUND SCIENTIFIC BASIS FOR DECISIONS

I have placed great emphasis on the importance of ensuring the scientific soundness of pesticide regulatory decisions. There are two aspects to this goal. First, we must ensure that data submitted to EPA in support of registrations are valid and meet today's scientific standards. Second, we need to ensure that Agency decisions which authorize the use of a pesticide are based on sufficient valid data to assess the effects of the pesticide. A number of important steps have been taken to realize these goals.

The Agency has issued Good Laboratory Practices (GLP) regulations, and Pesticide Assessment Guidelines: these inform pesticide registrants and the laboratories which conduct pesticide testing of the acceptable procedures for developing data.

To assure the quality of the actual studies submitted to the Agency, EPA needs an effective laboratory and data audit program. The audit program has been reorganized to include audits for toxic substances testing as well as pesticides, and to broaden the types of testing subject to the audit process, i.e., ecological effects as well as health effects. The number of pesticide data audits has been increased from about a dozen in 1982 to a target of 76 for Fiscal Year 1985.

We are now coordinating our audit program with the Food and Drug Administration and the National Toxicology Program. Our goal is to use federal resources effectively to avoid duplication, to implement consistent approaches to inspection and audit procedures, and to ensure that laboratories conducting health and environmental effects testing are regularly inspected and audited.

Comprehensive Standard Evaluation Procedures for use by EPA staff are being developed; various measures to improve internal quality control of data reviews have been implemented.

Data Submission Guidelines to inform registrants of the EPA-preferred format and content of their submissions are also being developed. These standardizing measures should improve Agency efficiency in handling submissions and facilitate any future reviews of submitted data.

Our concern for adequate data to support decisions is also reflected in our policy of not granting emergency exemptions under section 18 of FIFRA to allow the use of new or old chemicals for unregistered uses when the supporting data base is inadequate. This policy has been in effect since last year and has resulted in a significant drop-off in the number of section 18 applications received (from 638 in FY 1983 to 444 in FY 1984) and approved by EPA (from 590 to 320.) This more stringent approach to data available to support section 18 exemptions is also incorporated into the proposed rules just published on April 8, which would formally revise the procedures and criteria governing these exemptions. The proposed criteria call for evidence of progress toward regular registration for repeated exemption requests.

An adequate basis for regulatory action is also addressed in the recently proposed rule to revise procedures and criteria for conducting Special Reviews. One of the most important lessons EPA has learned in conducting the Special Review process is the importance of having both toxicity and exposure

data. It takes valid evidence of potential effects, which is generally laboratory generated toxicology data, as well as information on the likelihood of actual human and environmental exposure in order to assess the risks posed by pesticide use. Congress, in amending the FIFRA in 1978, also affirmed the need to consider both types of evidence by specifying (section 3(c)(8)) that Special Reviews be initiated only on the basis of validated tests or other significant evidence of unreasonable risks to public health or the environment.

The proposed rule incorporates exposure considerations into the risk criteria which trigger Special Reviews. This will improve both the credibility and efficiency of the Special Review process by ensuring that resource-intensive reviews undertaken address potential real-world risk situations, for which at least preliminary exposure estimates are available.

• OPENING UP THE REGULATORY PROCESS

This Administration recognizes that EPA's regulatory processes must provide for participation by all interested parties, including the general public, in order to justify confidence in the complex and far reaching decisions we are called on to make. We have taken steps to encourage equitable participation by interested parties in Agency decisions and also to make information on pesticides more widely available.

In 1984, the Agency published a comprehensive description of the data required to register pesticide products. This information is primarily to inform registrants of their obligations, but it is also the first publicly available detailed listing of the studies required to register products.

Making information available about specific pesticide chemicals is an important aspect of facilitating participation in the regulatory process. Thus, the Agency is now making available to any requestor pesticide information fact sheets summarizing the available data and regulatory status of specific pesticide chemicals. These fact sheets are prepared for each Registration Standard issued, and also for the registration of new pesticide chemicals. EPA is also publishing notices of applications for new chemical registrations and significant emergency exemption requests.

The commitment to public participation opportunities is also reflected in 3 recent Agency rule-making activities. EPA published proposed rules (March 27, 1985) to provide additional opportunities for public participation in the development of Registration Standards. These procedures include establishing a docket, or publicly available record of relevant documents, including correspondence and records of meetings between EPA and any party interested in the particular Standard. Similar public access provisions are also included in the recently proposed rules concerning Special Reviews and Section 18 emergency exemptions.

The section 18 rule proposed on April 8 is a particularly significant effort at opening up the decision process. This rule was negotiated, in the sense that EPA invited representatives of interested parties in government, industry, labor and environmental organizations to sit down with the Agency and work out a rule acceptable to all. This has been a very successful exercise in opening up the decision process. Since the resulting rule already incorporates principles agreed upon by the various interests directly involved, we can expect effective implementation of these changes.

In summary, the foundation has been laid for a pesticide registration and reregistration program in which the public can have trust. Our decisions are based on sound science, made in the open, on a timely basis. However, it would be less than candid to suggest that there are no problems to be dealt with or that our job is basically done. Increasingly, concerns are being raised about pesticides in the nation's ground water. We are developing a ground water strategy for pesticides, as part of the Agency's overall ground water protection strategy, that includes national and regional monitoring, identification of pesticides which are potential ground water leachers, and the development of a nationwide survey of drinking water from groundwater sources. These are but the first steps of a long march. We are just now beginning to take a look at inert ingredients of pesticide products, some of which are just as biologically active as pesticide active ingredients and most of which

have never been evaluated. In short, we have accomplished much, but have much more to do.

One of our biggest assets in meeting these challenges is the FIFRA itself. Having now carried out its legislative mandate for a year and a half, I know that it is a fundamentally sound environmental law. The FIFRA risk/benefit balancing standard gives the Agency the critical flexibility necessary to make decisions which can both protect public health and the environment and assure us the benefits of pesticide use. FIFRA provides the authority to require data needed to make sound decisions, the authority to take stringent action when necessary to prevent unreasonable risks, the authority to make new pesticides and new pesticide uses available when they're needed, and the authority to effectively regulate whole new types of pesticides when they are developed.

As you know the Administration has sent to Congress a bill which would reauthorize FIFRA in its present form for two more years. While the Agency has spent the last two years implementing a number of administrative changes in the pesticide program, the Agency has remained alert to current FIFRA language that may limit our efficiency in implementing our statutory mandate. No statute is perfect, and carrying out a statute as complex as FIFRA is a difficult task. That is why the Agency has sought the advice of various groups on ways that EPA's administration of FIFRA can be changed to permit it to carry out its responsibilities to provide the greatest degree of public and environmental protection possible.

In 1984, the Administrator established a Pesticide Advisory Committee (APAC) which advises the Agency on major policy issues of pesticide regulation. The Committee includes representatives of industry, academia, labor, and environmental organizations, and has provided a valuable forum for dialog to explore pesticide issues from all points of view. This group has brought to the surface several potential problems with the way certain issues are being addressed under FIFRA. EPA is continuing to examine the various suggestions of APAC members, exploring their desirability, and assessing the potential for addressing them through the administrative process.

One of the issues raised by APAC was the need to improve the timeliness of the Special Review Process. There was general agreement that the current process should be speeded up. We must find a way to improve the process and make it less cumbersome. As mentioned earlier, we recently published a proposed rule to make the process more efficient. We also solicited comments on the overall effectiveness of the Special Review process.

A second issue which was discussed by the pesticide advisory committee and on which that group reached general consensus, was that of sharing data with other government entities, particularly state governments. The group agreed that providing EPA the ability to share data with states who have protection for CBI equivalent to that provided under FIFRA would be a desirable thing.

Another data issue that was discussed by the Administrator's Pesticide Advisory Committee is the need to ensure the data the Agency relies on is of the highest quality. As I stated

earlier, EPA has issued GLP regulations and Pesticidal Assessment Guidelines that clearly spell out how to conduct valid pesticide testing. Registrants should have no doubt about how to produce the reliable, scientifically sound data needed for regulatory decision-making. For new studies, subject to the GLP regulations, registrants must, in fact, either certify that these studies were conducted in accordance with the regulations or identify precisely how the studies deviate from them.

While we have made a start in this area, issues have arisen that we have not yet addressed. Among these is EPA's inability to inspect pesticide testing facilities to ensure they are following Good Laboratory Practices. In addition, the violation of GLP regulations is not an unlawful act. Another issue has arisen over what actions the Agency should take where the data base for an already registered pesticide is found to be of unacceptable scientific quality.

While on the topic of data, I would like to mention briefly one other issue. As you know, the Supreme Court has before it a case concerning judicial review of data compensation awards. While the issues involved do not directly pertain to the health and safety evaluations EPA performs, the final decision of the court could have a significant impact on the Agency's ability to run its registration programs. If the Court were to rule against the Government, your prompt attention to this matter might prevent confusing and costly disruption.

A fourth area which EPA is looking at concerns restricted use pesticides. This is an area the Administrator's Pesticide Advisory Committee considered in depth and is of particular

interest to me. One of my key goals in the regulation of pesticides is to develop a flexible regulatory program in which potential problems are attacked with a scalpel, not a sledge hammer. Classifying a pesticide for restricted use is an essential tool in achieving this goal. The Agency is looking to see if anything further can be done to ensure that restricted use pesticides are properly used by persons whose knowledge and qualifications are commensurate with the degree of risk posed by the pesticide.

A key element in any regulatory program is the ability to enforce statutory and regulatory requirements. The Agency is looking hard at this area and, in fact, has established a cross-media task force to specify ways to improve the enforcement provisions of all environmental statutes. I also believe the EPA needs to find ways of integrating its actions under FIFRA with those of the Occupational Safety and Health Administration.

Another issue the Admisistrator's Pesticide Advisory Committee has discussed in depth is inerts. After a long period of neglect, the Agency has begun to focus on inert ingredients used in pesticides, particularly those where we already have evidence of concern. There are a number of scientific, legal and economic complexities involving inerts which will take significant time and the best efforts of us all to resolve. The Agency is now considering the possibility of using labeling to identify inert ingredients which may pose significant risks to human health and the environment.

Finally, I would like to mention two funding issues. First, the current scheme of indemnification and disposal may be flawed. No other environmental or health law provides this form of federal "bail out" for the manufacturers of chemicals or drugs that are shown to be unsafe. EPA is studying the need to eliminate this provision.

The second funding concern deals with the issue of registration fees. There appears to be considerable sentiment both within and without the Administration that registrants should be responsible for paying the costs involved in the federal pesticide registration program. While the Executive Branch has authority under the Independent Offices Appropriation Act to collect user fees, it is unclear whether that authority is broad enough to collect fees for all pesticide activities, such as Special Review. While the Administration believes it does have authority to recover all costs, we are currently exploring methods to assess and collect fees in the most efficient effective manner possible.

Mr. Chairman and members of the Subcommittee, in concluding my testimony this morning, let me assure you that the Agency remains ready to serve you so that the FIFRA reauthorization process can be constructive, taking into account the concerns of all those affected by the regulation of pesticides.

57-556 O—86——3

May 21, 1985

The Honorable Beckley Bedell
Chairman, Subcommittee on Department Operations,
Research and Foreign Agriculture
House Agriculture Committee
1301 Longworth House Office Building
Washington, DC 20515

Dear Congressman Bedell:

I would like to take a moment of your time to present the National Association of Conservation District's views on the Federal Insecticide, Fungicide, and Rodenticide Act now before your subcommittee. Let me say right at the beginning, NACD favors reauthorization of this legislation. Agriculture chemicals are an integral part of present farm management. FIFRA is needed to ensure that the chemicals are both available for use and safe for both the farmer and the nonfarm public.

My primary concern at this time is make sure that all of the interested parties give their full attention to any substantive changes in the statutes. I fear that the 1985 Farm Bill and the FY86 Budget are going to consume much of the energies and time of congressional staff, the Congressmen, and the public. Perhaps, it would be more prudent to extend the present legislation for a year and then formulate any necessary substantive revisions to the statutes in 1986 when those involved can give the subject the attention it deserves.

Thank you for allowing me to present NACD's views on this issue. I would be happy to discuss this further with you or your staff.

Sincerely,

Charles L. Boothby

Charles L. Boothby
Executive Vice President

National Association of Conservation Districts
Rm. 730, 1025 Vermont Ave., N.W., Washington, DC 20005
Phone (202) 347-5995

PESTICIDE PUBLIC POLICY FOUNDATION

ADMINISTRATIVE ADDRESS
1511 K Street NW, Suite 623
Washington, D.C. 20005

ISSUES ADDRESS
1270 Chemeketa Street NE
Salem, OR 97301
1-800-GET-PPPF

April 29, 1985

Hon. Berkley Bedell
Chairman,
Subcommittee on Department Operations,
Research and Foreign Agriculture
House of Representatives Agriculture Committee
2440 Rayburn, HOB
Washington, D.C.

Dear Chairman Bedell:

The Pesticide Public Policy Foundation (3PF) is a coalition of urban/suburban pesticide user interests. The coalition includes "green industry" representatives (Arborists, lawn care, turf, landscape, golf course, etc.) as well as pest control operators. 3PF supporters number more than 2,500 individuals, businesses and associations located throughout the United States.

3PF appreciates your committee's desire to comprehensively review FIFRA during the reauthorization process. FIFRA itself is a dynamic instrument and program. The need to assess both the instrument and the success of the program is self-evident.

While our members recognize this need, we are concerned that the review process may take on a "life of it's own." In other words, the review process may set a perception that changing FIFRA is the only measure of a successful review. We do not believe that such a standard of measurement is necessary or desireable.

That is not to say that we oppose any amending of FIFRA. In fact, we would strongly support language within the statute that clearly restates the Congressional Legislative history of 1972 regarding a state's political subdivisions' regulatory authority. A plain reading of that history shows that Congress reserved to the Federal Government, the states and territorial administrations the authority to regulate pesticides. Even the grant of authority to the states and territories was limited.

In spite of this plain reading, a growing number of cities, towns, counties and other local governments are or are attempting to enter the pesticide regulatory field. If very many of this nation's nearly 80,000 local governments similarly involved themselves in this regulatory area, chaos would result.

Thus, an amendment clearly preempting any state's political subdivisions from entering this regulatory field is absolutely essential in our minds.

Other issues, where policy trends or common sense plainly show the need for change, may also be identified in the review process. And, like you, we are committed to viewing such issues in an objective manner.

We are also committed to the proposition that such issues must be addressed in terms of what is practically possible or necessary.

A good example of this attitude is the current regulatory requirement for use of restricted use pesticides under the direct supervision of a certified applicator. "Direct" is defined to mean that supervision may be off-site under certain circumstances. This recognizes that pesticide use conditions vary markedly and demand regulatory flexibility.

There has been some suggestion that this flexibility be eliminated; that application of restricted use pesticides be limited to certified applicators only. This approach, in our minds, fails to recognize what is practically necessary.

Obviously, it is highly desireable to assure the safest possible use of restricted use pesticides. But, just as obviously, current use patterns do not support the idea that significant abuse of the existing regulatory mandates is occuring.

To cure occasional abuses of the "under direct supervision" requirements may not necessitate amendment of FIFRA at all. The cure might better be prescribed through more adequate funding to the states for training, certification and inspection.

Such an approach, in our minds, better addresses what is practically necessary in the improvement of pesticide use safety.

We hope, during the FIFRA review process, to bring to bear similar attitudes of what is possible or necessary as various issues arise. Our viewpoint will be somewhat unique in this regard as our 3PF members deal with people's health and environment protection needs in, largely, urban and suburban situations. Our members are thus acutely aware of the need to manage risk and maintain the highest of professional standards.

Mr. Chairman, its difficult for us to be more precise at the moment. Until your committee has had further opportunity to define the scope of your review, we simply wanted to indicate what we hope are areas of mutual interest and pledge our willingness to provide assistance as you may need.

We would make one final observation.

The pesticide controversy usually focuses on risk and risk alone. Statutory and/or regulatory initiatives also usually focus on the issue of risk. We live in a world of risk and we hope that practical risk management will become the cornerstone of your deliberations. Further, we urge that the many benefits from needed use of pesticides are recognized during your deliberations and that these benefits (health protection, environmental enhancement, food and fiber production) be maintained through reasoned risk management practices.

Those risk management practices are occuring today, are improving with time and can continue to be encouraged if FIFRA maintains it's flexible and comprehensive nature.

3PF thanks you for your consideration and attention.

Sincerely,

David H. Dietz

David H. Dietz
Program Director
3PF

DHD:kew

April 26, 1985

MAY 0 6 1985

Rep. Berkley Bedell, Chairman Subcommittee
House Agricultural Committee
House of Representatives
Washington, D.C. 20515

Dear Representative Bedell:

This letter is in response to your hearings regarding the FIFRA and its necessary revisions. I feel some changes are necessary because as a farmer and a Pharmacist, I am well aware of the dangers and abuses involved. Some of the suggestions I would have for changes in the act are as follows:

Distribution controlled by Veterinarians and Pharmacists who would be required to have extensive continuing education which could be obtained from all State University Extension Departments.

All farmer operators and commercial applicators would also be required, to a lessor degree, to have continuing education.

I feel the mechanisms are all in place and inconvenience to all would be insignificant. The major objection would come from the chemical companies but they are also responsible for the problems we are having because of their highly promotional marketing techniques.

They would be tempered by controlled distribution. The Prescription Legend Drug System does a very magnanomous job in controlling abuses and protects the public in their health matters. I feel the same safety could be obtained in the FIFRA controlled distribution.

As a concerned citizen, farmer and Pharmacist, I am offering these ideas to be considered in the legislative changes necessary to protect the American Public in the production of our foods.

Thank you for your time in listening to this proposal. The American Public would be the benefactor. I would appreciate a response at your earliest convenience.

Sincerely yours,

Tony Dvorak

Tony Dvorak

TD/s

CC: Senator Harkin
Senator Grassley
Charles M. West, Exec. Vice President, NARD
Darwyn J. Williams, Exec. Committee, NARD
Tom Temple, Exec. Director, IPA
Rep. Lightfoot

ROBERT M. LUSTBERG
*JOAN M. FERRETTI**
Attorneys at Law
11 Hillcrest Avenue
Larchmont, N.Y. 10538

(914) 833-0078

*Member D.C. Bar

May 30, 1985

Mr. Tim Galvin
Subcommittee on Department Operations
Research and Foreign Agriculture
U.S. House of Representatives
1301 Longworth Office Building
Washington, D. C. 20515

Re: Proposed Amendments to FIFRA, 7 U.S.C. 136

Dear Mr. Galvin:

On behalf of People Against Chlordane, a non-profit citizens' group based in New York State, I submit the following proposed amendments to the Federal Insecticide, Fungicide and Rodenticide Act ("FIRFA") for your consideration.

1. The maximum civil penalties assessable for violations of FIFRA provisions should be increased, to make them equivalent, at a minimum, to those assessable under the Clean Water Act and Clean Air Act. The continuance or assumption of State FIFRA programs should be made contingent on the adoption of state laws providing for equivalent civil penalties.

2. Sections 26 and 27 of FIFRA (7 U.S.C. §136 w1-2) should be amended to provide that EPA has enforcement authority which is co-extensive with the various states, and to eliminate all pre-conditions for EPA enforcement except notification to the affected state.

3. Provision should be made to decrease practical restrictions on public access to records submitted in support of registration and in support of policy decisions; in particular, to increase the free flow of materials as is already provided at FIFRA, §10 (7 U.S.C. 136h(d)).

Mr. Tim Galvin May 30, 1985

4. To amend FIFRA §3(c)(5), (7 U.S.C. §136(a)) by: (a) expressly providing that the burden of proof as to all pre-requisites for registration lies on the applicant; (b) deleting the word "shall" and inserting the word "may", such that the first sentence will read: "The Administrator may register a pesticide ...." Compare 33 U.S.C.§§ 1342 and 1344; and (c) add new subsection (E): "that when used for the purpose for which it is intended or in which it is commonly used, it will not cause unreasonable risks to human health or property."

Thank you for your consideration.

Sincerely yours,

Joan Ferretti

JMF:rt Joan M. Ferretti

cc: Patrick Menichino, Co-Chairman
People Against Chlordane

TAlmadge 3-8300

the 707 company
1530 STILLWELL AVENUE • BRONX, N. Y. 10461

April 4 1985

Repr. Berkley Bedell,
Chairman, Dept. Operations, (DORFA)
House Agricultural Committee
Washington, D. C.

Dear Repr. Bedell -

In considering reuathorization of the Federal Insecticide Act (FIFRA), please take following into account:

All household insecticides in America have to be registered with EPA. Their standards are strict and protective. There is no need for duplicated registrations by each of the several states.

I ask that in reauthorizing FIFRA, it be specified that federal registrations preempt state registrations.

As it now stands, we are compelled to pay fees and useful time-consuming procedures, to each State, and the fees are UNFAIR, BECAUSE the exact same amount is charged to a small firm like ours, which sometimes sells a dozen cases of an item, as is charged to a national firm like Raid, who sell tens or hundreds of thousands of cases in a State.

Often, we have to decline orders where the registration fees charged by a State is more than our profit on less popular items, like bedbug spray, which has some demand but is not made by larger firms.

Do you care to help out small firms like ours?

Let federal registrations pre-empt State registrations. It's constitutional, and considerate.

Cordially,
Edward H. Hannes
Edward H. Hannes, Pres.
707 COMPANY.

FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

MONDAY, MAY 20, 1985

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON DEPARTMENT OPERATIONS,
RESEARCH, AND FOREIGN AGRICULTURE,
COMMITTEE ON AGRICULTURE,
Washington, DC.

The subcommittee met, pursuant to call, at 9:40 a.m., in room 1302, Longworth House Office Building, Hon. Berkley Bedell (chairman of the subcommittee) presiding.

Present: Representatives Brown, Penny, Volkmer, Morrison, Gunderson, Evans of Iowa, and Combest.

Also present: Representatives Ray, Seiberling, and DeLay.

Staff present: Phillip L. Fraas, counsel; John E. Hogan, minority counsel; Mark Dungan, minority associate counsel; Peggy L. Pecore, clerk; Bernard Brenner, Timothy J. Galvin, and Gary R. Mitchell.

OPENING STATEMENT OF HON. BERKLEY BEDELL, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF IOWA

Mr. BEDELL. The Subcommittee on Department Operations, Research, and Foreign Agriculture meets this morning to begin 2 days of hearings on legislation to amend the Federal Insecticide, Fungicide, and Rodenticide Act. The subcommittee has pending before it three bills which propose to make changes in FIFRA: H.R. 1416 by Mr. Heftel; H.R. 1910 by Mr. Seiberling; and H.R. 2482 by Mr. Roberts and myself.

Additional legislation is expected in the near future. Although we expect to receive a good deal of testimony directly on these proposals, the witnesses are free of course to comment on other issues arising under FIFRA.

I am hopeful in the course of these hearings that we can identify those areas which need to be addressed and fashion legislation which, on balance, will find acceptance among those concerned with the availability and safe use of pesticides. It is my intention to keep process on track so that we can report a bill to the House this summer.

All witnesses have been advised to keep their oral presentations to 5 minutes or less. I ask for your complete cooperation in adhering to this request so that we can maximize the time available for questions and still hear from the many witnesses we have scheduled for these 2 days. Unless there is objection within the subcom-

mittee, I will ask the clerk to keep time for the witnesses and we will advise the witnesses if their time has expired.

I don't know of a better way to start out this beautiful week than with 2 full days of hearings on FIFRA. I want to welcome all of you to the subcommittee here this week. I suppose we would be out fishing or something if we didn't have the opportunity to discuss FIFRA here.

[The bills, H.R. 1416, H.R. 1910, report from U.S. Department of Agriculture, and H.R. 2482, appear at the conclusion of the hearing.]

Mr. Brown.

Mr. BROWN. No.

Mr. BEDELL. Mr. Evans.

Mr. EVANS of Iowa. No statement.

Mr. BEDELL. Mr. Combest.

If not, we are privileged to hear from our colleague Richard Ray, first. We are glad to have you here, Richard.

STATEMENT OF HON. RICHARD RAY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF GEORGIA

Mr. RAY. Mr. Chairman, thank you for allowing me to testify before your subcommittee here, and I want to compliment you on your nomination and support and election to this committee. I have worked with you on the Small Business Committee through the last term, and I know the committee will be served well by your chairmanship here.

Mr. Chairman, distinguished members of the committee, and others who will offer testimony here this morning, I want to thank you for allowing me to appear before you today, and I want to commend you for holding these hearings.

I know that we all share a common goal of wanting to make sure that the public receives all the benefits from the miracle of chemical technology, which helps to produce our food and fiber and which helps to make our environment safer.

Mr. Chairman, we are also genuinely concerned that we have in place a system of regulations and safeguards necessary to enjoy and take full advantage of chemical science without endangering our society.

I come before you today as a small businessman who, for the first few years of my adult life, made my living as a farmer who depended on fertilizer and chemicals to produce crops. I am one of those broke farmers in the fifties. I have taken my lumps and I sympathize with the farmer of today and the problems that they are incurring.

In addition, Mr. Chairman, for 23 years after I left farming, I was in the business of providing protective pest control service for homes, industry, and agriculture.

In this Congress, the 99th, we have two people from this profession, the gentleman from Texas and myself, and that compares with only one medical doctor that we have in the House of Representatives. So I think we are gaining.

This service included sanitation inspections and consultations for food manufacturing plants to assist them in preparing for Federal

inspections and to help them put in place programs of good sanitation practices and chemical safety.

For 9 years, I served on the Structural Pest Control Commission of the State of Georgia, and for 2 years served as its chairman. I mention this background, Mr. Chairman, only to emphasize that I testify this morning with some knowledge of the pest control industry and my involvement in it.

Through the years, as a staff person for a U.S. Senator and now as a Member of the House of Representatives, I have worked with EPA and the various chemical companies and industries to shepherd FIFRA legislation into law. I believe that this legislation has ably accomplished its objectives and has focused on the safe manufacture, distribution, and use of pesticides.

In the pest control industry, we must have chemicals that will control insects and other noxious pests, but they must be used carefully and without endangering the safety of the technicians applying the chemicals as well as the general public.

The FIFRA legislation, in order to ensure the utmost safety, has created a certified applicator's system for private and commercial distributors, applicators, and farmers. These certified applicators must be properly qualified by State law before they can use or supervise the use of restricted use pesticides. Restricted use pesticides are those pesticides which have been classified by EPA as potentially hazardous.

The EPA carefully considers the benefit-risk equation before deciding whether or not to place a pesticide in a restricted use category, and it is my observation that this system works very well.

FIFRA was wisely designed, recognizing that the characteristics of pesticides and their effects on the public and the environment require that they be regulated and properly controlled and that those people handling these pesticides must be highly competent. Therefore, it is necessary that workmen and technicians be thoroughly trained and supervised.

Mr. Chairman, I believe that the FIFRA legislation, which has been so carefully crafted by Congress and the Agency, along with strong input from industry and concerned citizens, has worked well.

The committee certainly should review and evaluate the workability of our pesticide application laws, and we must always be ready to reevaluate, rework, update, and improve the industry's ways of handling the application of these chemicals. I also agree that EPA must carefully and scientifically examine each pesticide for its benefits as compared to the risk it might pose to the public.

As this committee evaluates FIFRA to determine if there is a need for change, I feel confident that it will do so with the most commonsense judgment and fairness.

It is my own judgment that the current Federal and State systems are functioning with a minimum of problems, and I sincerely hope that, if the committee decides there needs to be some fine tuning, such change will be accomplished with minimum disturbance and expense to our Government and to our citizens.

Again, I appreciate the opportunity to testify before your subcommittee and look forward to working with you in any way that I can in the future.

And, if you would permit me to do so, as we go down through the panel, your No. 4 category, a gentleman who I have an extreme amount of respect for, Mr. Robert M. Russell, vice president for Government Relations for Orkin Pest Control Co., in Atlanta, a man who I worked with for many years, is very expert in this particular field and will bring some expert testimony to you.

I thank you for letting me appear before you today.

Mr. BEDELL. Thank you very much, Mr. Ray.

Mr. Brown.

Mr. BROWN. Let me just ask you one question, Mr. Ray.

We are fortunate in having a Member of Congress who has long professional experience in this field. In your experience, have you encountered any serious health problems resulting from the use of pesticides on the part of those members of your profession who are engaged in providing this service?

Here, I am not asking for scientific studies or anything, but merely your general impression from working in the industry as to whether or not it has been conducted in a safe manner without hazards to the individuals involved.

Mr. RAY. Mr. Brown, I was actively involved for more than 23 years. In the beginning years—being forced out of the agriculture and farming business into a business that I really didn't know much about, and having to take short courses and all kinds of general courses to learn the knowledge and to become certified. I have worked for 23 years, and during that period of time had as many as up to two dozen, in the early years, and finally 300 people working directly under my supervision, and I never had any particular individual that I know of that suffered from hazards from the applications of chemicals that were used—chlorinated—hydrocarbons, and other types of chemicals.

We, however, did make sure that periodically people took blood tests and examinations to be sure that tolerances weren't building up in their systems. While I know there have probably been adverse situations—I, in my lifetime, have not had any personal experience in dealing with any of them.

Mr. BROWN. Thank you very much.

Mr. BEDELL. Mr. Evans.

Mr. EVANS of Iowa. Thank you, Mr. Chairman.

Mr. Ray, we are certainly pleased to have you here this morning.

You were a certified applicator?

Mr. RAY. Yes, I was. I went into the system when the State of Georgia enacted a law in 1955. Actually, my certification was No. 1, all the time that I was in the industry. And later on I became the chairman of that commission and served two times over a period of 9 years, and helped to activate that law, write that law, to enforce that law; then was an active participant in it.

Mr. EVANS of Iowa. You had a number of technicians working under you who did apply the chemicals who were not certified applicators; is that correct?

Mr. RAY. That is true. Eventually, you would have one or two that would be certified. But certification fell back on the responsibility of the certified. It is the enforcement of the law.

Mr. EVANS of Iowa. You were not involved in the application of agricultural chemicals when you were in the business?

Mr. RAY. Yes, I was. I also worked in the agriculture area distributing, treating stored grains, applying herbicides to control weeds in crops. I never got into the air application, but I did work very much in agriculture chemicals.

Mr. EVANS of Iowa. One of the problems that comes up from time to time in my part of the country is a technician who is not certified in application of chemicals to crops, and will from time to time do something that is rather stupid.

Mr. RAY. That is right.

Mr. EVANS of Iowa. How do you suggest that the committee approach that kind of a problem? Should we certify everybody?

Mr. RAY. I think, Mr. Evans, it would probably be almost impossible to do that. In all facets of life, you have got to have a capable supervisor in charge. I think we have to control everything that we do, including the application of chemicals, through an appropriate certified individual who tightly supervises and controls the people who work for him in whatever endeavor they are in.

I think you will stall down most any industry if every technician had to be totally certified by the State or Federal Government.

Mr. EVANS of Iowa. Do you think that a certified supervisor, then, should have some responsibilities in the sense that he is liable, to some extent, for the actions of those that work for him?

Mr. RAY. I think the certified—the one who is certified must be accountable, yes, sir. Of course, most industries that I am involved in have to be certified with various types of insurance and bonds to protect that individual in case he gets off track.

Mr. EVANS of Iowa. Thank you very much.

Mr. RAY. Yes, sir.

Mr. BEDELL. Mr. Combest.

Mr. COMBEST. Thank you.

Mr. Ray, you make an excellent witness because of your understanding of the industry, having come from it.

Did you deal also in the application of pest control in homes?

Mr. RAY. Yes, sir, I did very much. That was the major part of my business.

Mr. COMBEST. We are finding in Texas that there are under consideration a lot of new regulations on pesticides and this type of thing that are just now coming under State jurisdiction that previously have been pretty well directed by the Federal Government.

Did you find in your business in the State of Georgia, a discrepancy between the control of pesticide use or chemicals by the State versus that of the Federal Government's control?

Mr. RAY. Not really. The State of Georgia tried to not only pattern its regulations along the lines recommended by the Federal Government, but to actually exceed those regulations. And I found that in EPA it is—I think the Environmental Protection Agency in Georgia has probably stricter and stiffer regulations than the national regulations. And in the State, in my experience with it, we had no serious conflict with the Federal Government.

From time to time, of course, we had meetings and arguments of varying kinds, trying to prevent unreasonable regulations from being enacted that would make it just an unworkable situation; in fact, would not be commonsense regulations.

Mr. COMBEST. From the State level?

Mr. RAY. Yes, sir.

Mr. COMBEST. But in most instances where there was discrepancy in exactly the handling of the chemicals, regulation was more strict by the State of Georgia than it was from the Federal Government?

Mr. RAY. That was my experience.

Mr. COMBEST. Thank you very much.

Mr. BEDELL. Mr. Gunderson, do you have any questions?

Mr. GUNDERSON. No.

Mr. BEDELL. We are certainly delighted, Mr. Ray, that you have this knowledge, and I would hope that we will be able to draw upon it as we go forth with our legislation.

You mentioned there is another Member from Texas. Is that public knowledge?

Mr. RAY. Tom DeLay. He has just been elected in the 99th Congress.

Mr. BEDELL. He has had similar experience?

Mr. RAY. He has had extensive experience.

Mr. BEDELL. My understanding is that at this time the Enrironmental Protection Agency says that it depends upon the chemical whether you will have to be a certified applicator to apply it, or whether you can assign that to other people.

Is that the way it was when you were there; do you know?

Mr. RAY. No, sir, the certified operator—you have to understand I have been out of this business 9 years, over on the Senate side as a staff person and over here my second term in Congress, so there is a little lapse of time. I am not quite up to date on what is happening right now.

Back in the time that I was very active, the certified operator had the jurisdiction to apply federally approved and State-approved chemicals.

Mr. BEDELL. Now there are some chemicals that you can have your subordinates apply, and some chemicals that, as I understand it, you are required to have a certified applicator apply.

Do you feel comfortable having EPA making that decision as to what chemicals could be applied by others?

Mr. RAY. I do know that toxics, some fumigants—10-80, which is very deadly; a rodenticide chemical that is used—I think that ought not to be totally dispersed to people who don't have——

Mr. BEDELL. You feel the present proposal is probably a reasonable one?

Mr. RAY. Not knowing the exact particulars, I would lean in that direction.

Mr. BEDELL. We are certainly delighted to know of your knowledge in this area. And, as you indicated, I worked with you on the Small Business Committee and I felt you were a very, very helpful member of the Small Business subcommittee that I chaired; and we will certainly be looking for your help as we proceed and be checking with you informally, if not formally.

Mr. RAY. Thank you, Mr. Chairman.

Mr. BEDELL. If there are no further questions, our next witness will be Ms. Karen Darling, Deputy Assistant Secretary for Marketing and Inspection Services, USDA, Washington, DC.

We understand that she is accompanied by Charles Smith, Departmental Coordinator for Pesticides and Pesticide Assessment. And I guess there is someone else?

STATEMENT OF KAREN DARLING, ACTING ASSISTANT SECRETARY, MARKETING AND INSPECTION SERVICES, U.S. DEPARTMENT OF AGRICULTURE, ACCOMPANIED BY CHARLES SMITH, DEPARTMENTAL COORDINATOR, PESTICIDES AND PESTICIDE ASSESSMENT, AND WILLIAM HELMS, ASSOCIATE DEPUTY ADMINISTRATOR, PLANT PROTECTION AND QUARANTINE

Ms. DARLING. This is Bill Helms from the Animal and Plant Inspection Service.

Mr. BEDELL. We would ask you to hold your testimony to 5 minutes, if you possibly can. We have an awful lot of witnesses today, and it would be most helpful if you could do so.

Ms. DARLING. Thank you. I won't even take 5 minutes this morning, but I do have two experts with me in case the questions are technical in nature.

The one thing that I would like to say, on our coordination with the Environmental Protection Agency lately, is that we seem to be cooperating, coordinating in a better degree that I have memory of before. The Environmental Protection Agency has been quick to cooperate when we do have an emergency need for an exemption on a pesticide, say like during the Mediterranean fruitfly episode in California in 1981. EPA did cooperate by giving us an exemption on ethylene dibromide. That exemption helped on the quarantine for export purposes, even though it will disappear in September.

I am also glad to see that EPA is looking at their rulemaking and so forth from an administrative point to try to streamline as well as make more timely both the registration and cancellation thereof. The Agriculture Department seems to be a constant intervenor in most cancellation proceedings, and perhaps with the streamlined system we will find that we won't find ourselves constantly before an Administrative Law Judge or in court.

I do compliment Mr. Ruckelshaus and his successor, Mr. Thomas, in going ahead to try to streamline some of the clumsy procedures under FIFRA. They have asked us on numerous occasions about the loss of certain chemicals and agriculture production business. As you all know, we are quite dependent on pesticides these days, and we find that if it gets down to harvest time and EPA might be about ready to cancel a pesticide on us, it causes nothing but havoc in the agricultural realm.

They have been much better in the last couple of years, letting us know one of those cancellation proceedings might ensue so the affected industry working with the manufacturer of that chemical might be able to meet any data drop requirement.

The only one concern that I might address is in the specially used chemicals. We find numerous problems because of the new exemptions that we might encourage here, and maybe there could be a category formed for the small specialty use. The chemical companies seem somewhat loath at having to comply with the great extent of data submission to EPA when the usage of a particular pesticide might be very small, and I think that might be one thing,

Mr. Chairman, as your hearings proceed, that we might want to look at a little more closely.

We haven't specifically addressed the three bills in question. With your bill just being introduced, it seems to cover a very vast array of different sections under the FIFRA. We do look forward to working closely with the committee as you develop the bill and remain available and open to anything that we, from Agriculture, might be able to provide.

That is all I really have to say this morning, except thank you for including us in your witness list.

[The prepared statement of Ms. Darling appears at the conclusion of the hearing.]

Mr. BEDELL. Thank you.

Mr. Brown.

Mr. BROWN. I have no questions.

Mr. BEDELL. Mr. Evans.

Mr. EVANS of Iowa. Thank you, Mr. Chairman; yes, I do.

You mentioned the small usage chemicals in the new category. Could you give me some examples or an example of the type of use and type of chemicals?

Ms. DARLING. Like, as you well know, many other countries demand certain chemicals applied to our products before export; and, as one example, celery. Most importing countries of our celery ask that it be treated with a chemical called triguard, a somewhat of a fly controller. And each year we are back over to EPA asking for an exemption on triguard small use celery.

I don't know what it might be used on. It always seems to come up in the case of celery. Perhaps those specialty small use could be somehow viewed in the same kind of light.

We are encouraged with the risk management approach that EPA seems to be taking rather than just the hazard approach, because of—certainly for our export purposes and looking at all the studies with time and dissipation of a chemical.

Mr. EVANS of Iowa. Thank you.

Mr. BEDELL. Mr. Combest.

Mr. COMBEST. Ms. Darling, you mentioned relative to the emergency exemption remaining available—I agree with you completely that they would need to, in certain instances. The question I would have, for example where you had used the nonlabeled pesticide for the Mediterranean fruitfly eradication, when those situations appear and there is an emergency exemption declared, is the actual use of that chemical to curb that emergency. Can these cases be used in testing or in the process of labeling? Or can they be used—research data coming from the actual application rather than strictly from research? If you are going to go in and actually use them, can that information be used for specific data for the permit process, the labeling process that particular chemical might be undergoing?

Ms. DARLING. Mr. Combest, that would depend upon what the Environmental Protection Agency would demand of such cause.

Mr. COMBEST. I didn't hear what you said.

Ms. DARLING. For an exemption like EDA during Medfly, or maybe like Larva Dex. During that we used—during the flu eradication program in Pennsylvania and Virginia last year where there

was—it was a product that had been on the market, EPA had targeted it for a chemical that might come out of society because of the emergency nature of the Eradication Program—we were permitted to use Larva Dex in the chicken houses, in the chicken coops, during the Eradication Program. And I am sure that any data, any resultant data from people using it or being around it were taken into account by EPA, because I know that they did not cancel Larva Dex.

Mr. COMBEST. Thank you.

Mr. BEDELL. Mr. Gunderson.

Mr. GUNDERSON. Thank you, Mr. Chairman.

Do you expect participation by the Department of Agriculture will be taking a separate and specific position on one of the bills in front of us in the future? Is it your intent to allow EPA to, quote, "channel the administration"?

Ms. DARLING. It is hard to tell. I certainly think that the focus from some of the rest of our colleagues in the administration will be to focus upon EPA; and yet, if there are things like in Mr. Bedell's bill or so, we in Agriculture feel that we absolutely could not live with, I have a sense that we will probably be up here arguing about that.

Mr. GUNDERSON. Would any of you be willing at this point in time to tell us what you think, from the Department of Agriculture perspective, some of the basic most essential changes required in the reauthorization?

Ms. DARLING. Well, without a good analysis of the new legislative——

Mr. GUNDERSON. I am not asking you to comment on any bills that are introduced. I am saying, if you were to sit down today and determine what are the most basic changes, revisions, modifications needed from an Agriculture perspective to better serve the needs of American agriculture, regulation of chemicals, what would they be?

For example, you mentioned in your second paragraph the timeliness of actions to pesticide applications for approval, the decision-making process. Is that the most essential need we have from an agricultural perspective, or is there something else?

Ms. DARLING. It certainly is an important one. My view would be a lot different today than it would have been 6 months ago, by seeing the administrative thrust to try to clarify and streamline the procedures. We have the same thing as regulators in Agriculture that we became a little bogged down by our own rulemaking, or our own proceedings. And I think that we have come such a long way in the chemical business that perhaps—not necessarily looking on a case-by-case basis in some of these pesticides, but perhaps more in a generic sense—I think that EPA is trying to make an effort to see that our specialty crop efforts, as well as the large crop efforts, are met.

We have become so dependent upon being regulated as regulators, being regulated by other regulators, that no matter what EPA decides on anything, it does affect the agricultural community. And I would hate to see anything happen to the section that permits us to intervene, and I think it is important that we hold that.

I think also that the section 8 for the exemptions—or 18—I think if we were to lose our exemption ability, that agriculture would be in real trouble.

Mr. GUNDERSON. Thank you.

Thank you, Mr. Chairman.

Mr. BEDELL. Thank you.

Ms. Darling, do I interpret your testimony correctly in that you are indicating that the cooperation with EPA and their work with you is improving, and that you are working quite well together now? Is that what you are telling us?

Ms. DARLING. Yes; I am.

Mr. BEDELL. I didn't understand something about one concern you had. You think sometimes they are more concerned about management or hazard or something.

What do you mean specifically by that?

Ms. DARLING. To view a chemical from a risk management viewpoint rather than just from a hazard that that particular chemical might have.

Mr. BEDELL. What do you mean specifically, though. I don't understand what you mean.

Ms. DARLING. To manage the chemical, or to look toward managing the chemical, rather than hazard or risk benefit; but the overall on the potential use of that chemical, be it a pesticide—the potential use of that and the management of that pesticide.

Mr. BEDELL. Management of the application; is that what you mean, how you apply it?

Ms. DARLING. That, as well as not just looking for the hazard that that pesticide might threaten the society with.

Mr. BEDELL. Do you think they do too much of one or the other—I didn't understand your comment.

Ms. DARLING. Well, I think their law is pretty specific. They will look for hazard. We look for the benefit, or more from the management standpoint on, if this pesticide is used, what might be the benefit of using that pesticide; not just the hazard of using that pesticide.

Mr. BEDELL. You think there should be more concern over the management and less over the hazard? I didn't understand what your point is. What is it you think should be different? I didn't understand.

Ms. DARLING. I am sorry, Mr. Chairman. My point being that in not just looking on the risk side but also taking into consideration some of the societal benefits of using a particular pesticide.

Mr. BEDELL. Oh, that was your point.

Ms. DARLING. Yes, sir; that is my point.

Mr. BEDELL. I am sorry that I didn't understand.

Any further questions?

Mr. BROWN. Ms. Darling, there is one area that I would appreciate getting your views on. In some of the proposals that will be before the committee, there is proposed to put additional restrictions on agricultural chemicals which have been canceled in this country, but can be exported to other countries where there is no similar cancellation or regulation of the chemicals.

Now, sometimes these banned chemicals, banned in this country, there is a good market for them in other countries; they are used

in those countries. And on some occasion at least they come back in as ingredients on some of what we import, some of the agricultural products.

Does the Department of Agriculture have any particular point of view with regard to the need to modifying the restrictions on the export of chemicals which have been canceled for use in this country?

Ms. DARLING. Mr. Brown, what usually happens is that we in Agriculture end up looking at products for any residue of a chemical that has been banned in this country.

Mr. BROWN. You have to inspect the imported material?

Ms. DARLING. That is correct. And we implement what, say, EPA has set forward, be it by tolerance—or if FDA can keep its action levels from an action level. We spend a lot of time looking for residue in products, and yet we find—what seems to happen after this country has banned a particular chemical—that it doesn't take too terribly long before the rest of the world has. With international communities setting standards and looking at chemicals, I think we will see more worldwide decisions on what chemicals should be in society and what should not.

I think that there is a responsibility among countries back and forth that perhaps if there is something of an eminent and extreme hazard, that we wouln't necessarily want to see it out there, either.

Mr. BROWN. Thank you.

Mr. BEDELL. Are there further questions?

If not, we appreciate very much your being here. We look forward to working with you as we move forward with our particular legislation.

Ms. DARLING. Thank you, Mr. Chairman.

Mr. BEDELL. Our next witness will consist of a panel: Liza Roos Prior, Patrick T. Menichino, and Marjorie J. Smigel.

Again, I will ask you to try to hold your testimony to 5 minutes. We will first hear from Ms. Prior.

STATEMENT OF LIZA ROOS PRIOR, LANGHORN, PA

Mrs. PRIOR. My purpose for being here today is twofold. First, I want to refute the notion that pesticides and lawn care chemicals present little or no danger to the public health. Second, I hope to impress upon this committee the importance of registration for chemicals already in use, as well as for new chemicals. I am not here to testify as an authority on law or toxicology. I am here to relate the protracted and agonizing death of my husband, and why I believe his death was the direct result of exposure to a pesticide.

During the summer of 1982, my husband, Lieutenant George Prior, frequently played at the Army-Navy Country Club in Arlington, VA. Just before Labor Day weekend, he took time off from work to polish up his game. Within 20 days, he died from Toxic Epidermal Necrolysis, a disorder which burned the flesh off his body from the inside out and caused each of his internal organs to fail. After an unusually thorough autopsy and extensive research by the Armed Forces Institute of Pathology and the Naval Research Laboratories, it was concluded that my husband died from

exposure to chlorothalonil, a fungicide which is used to prevent brown spots on lawns.

George was a perfectly healthy, athletic 30-year-old Naval Flight Officer. He had flight physicals regularly and was in top physical condition when he became ill. The illness began with a headache that started while he was still playing golf. By evening, he had developed flu-like symptoms, including a fever and nausea. Within 2 days, a sunburn-like rash began to appear on his abdomen and arms.

We became sufficiently alarmed that I took him to Bethesda Naval Hospital. After several hours of examination, he was admitted with a 105-degree fever. Within 24 hours, the rash grew to cover most of his body and then turned to baseball-sized blisters that hung, filled with fluid, from his arms and back. When these blisters burst, the skin came off in large sheets leaving raw skin exposed. This layer of skin was so tender that the weave of the hospital bedsheets felt razor sharp so that he was unable to lie on them.

Four days after playing golf, his kidneys started to fail. His whole body began retaining fluid causing severe bloating. This buildup of body fluids caused George to develop asperation pneumonia. At this point, the Navy doctors told me that the pneumonia would probably kill my husband within a couple of hours. However, George was so physically fit that his lungs survived.

Now, in addition to causing physical suffering, the illness began to isolate my husband from those around him. He couldn't speak during his last days because a respirator was in his throat. He could not write because his arms were so swollen. He couldn't see because his eyes had begun to blister. He also was receiving a drug which was probably causing deafness.

Although George was becoming increasingly cut off from his surroundings, he was still very much aware and alert, and in great pain. Finally, after 14 days, George went into a coma and, mercifully, died on September 16, 1982. The course of this illness turned the bright, normal, handsome person I loved into a hideously disfigured, swollen shell. We buried him at Arlington with full military honors soon after.

Since Toxic Epidermal Necrolysis is often caused by exposure to chemicals, we started to look for the culprit while George was still alive. I was hoping that finding the cause would be helpful in the treatment of the illness. I called the golf club first because that is where he became ill. The groundskeeper at Army-Navy told me that they had sprayed twice during the week George had played there with a fungicide called Daconil, or Chlorothalonil, produced by the Diamond Shamrock Co. Unfortunately, knowing that this was a possible cause could not alter the progression and outcome of the disease.

After George died, a Navy pathologist, Dr. Jonathan Lord, was assigned to try to solve the mystery of George's dramatic deterioration and death. Dr. Lord received assistance from scientists at the Navy Research Lab. Together, they did a thorough autopsy and investigation which far exceeded what would normally be done. Dr. Lord and his associates examined George's workplace, home, and

car, in addition to the golf course, in a search for potentially toxic agents.

Weeks of research led them to conclude that the chemical agent responsible for George's death was, in fact, Daconil—the golf course fungicide. The evidence for this conclusion included aerial, infrared photography of the fairways, which showed Daconil to be present in large quantities. Daconil was also found on my husband's golf clothes, his equipment and on his shoes. In all, Dr. Lord determined that George's body had reacted violently to inhalation of and dermal exposure to chlorothalonil.

Pesticide poisoning is an insidious and usually anonymous killer. Symptoms of pesticide poisoning can be as diffuse and seemingly innocent as headaches, rashes, irritability, coughing, fatigue, anxiety and other mild complaints. Since my husband's death, I have become aware of many other cases of acute chemical sensitivity. Many are seriously injured, and many others are dead. The difference between these victims and my husband is that they don't have the Armed Forces Institute of Pathology researching their case. It is my belief that George's death is unique only in that the cause was so thoroughly investigated.

Several months after receiving the pathologist's report, I sued the Army-Navy Country Club and Diamond Shamrock for the wrongful death of my husband, for his pain and suffering, and for my loss. The suit is almost 2 years old right now, and we are still in only the discovery phase. My attorneys have formally requested specific information from the EPA several times. They have yet to receive any response whatsoever. They are now forced to file suit under the Freedom of Information Act so that the EPA will be required to acknowledge their requests.

I have in my possession several documents obtained for me by concerned persons in the environmental movement. One of these documents is the new registration standard for chlorothalonil. This chemical has been on the market for almost 20 years without a formal registration standard. The new label requirements are more severe than when George was killed. Perhaps others may not meet George's fate if they are adequately warned of the dangers of chlorothalonil.

If this committee concludes that we need stricter, faster and more thorough registration of pesticides, and that the public has a right to Government information about these chemicals, then I will feel that George's death will have had some meaning.

Thank you.

Mr. BEDELL. Thank you very much for that very moving testimony, Mrs. Prior.

We will hear from all of the witnesses before we ask questions. Next we will hear from Mr. Patrick Menichino.

STATEMENT OF PATRICK T. MENICHINO, EXECUTIVE DIRECTOR, PEOPLE AGAINST CHLORDANE, ACCOMPANIED BY ROBERT FORTE

Mr. MENICHINO. Members of the subcommittee, ladies and gentlemen, my name is Patrick T. Menichino. I am executive director of People Against Chlordane. I live on Long Island in New York.

In 1980, my home was treated by a licensed pesticide applicator to prevent termite problems. That application resulted in the contamination of my home and transformed my wife and myself into chlordane victims.

For a number of years following the application, my family was unknowingly being exposed to an invisible toxic time bomb in the air we breathed. We experienced the following adverse health effects: headaches, dizziness, blurred vision, nausea and vomiting. Due to the lack of public awareness concerning chemical hazards, our adverse health effects were undiagnosed.

It was not until some time after we had received surface and air test results that we began to realize that our trust and faith in agencies designed to help the public was unwarranted. In fact, after obtaining those results we could not get a representative of either the New York health department or New York department of environmental conservation [DEC], to indicate officially whether or not our home was safe. The reason for this dilemma was the lack of any indoor pesticide exposure standards.

Needing to learn as much as I possibly could about the chemical which poisoned my home, I attended a meeting comprised of other families who also had become victims of chlordane contamination. This group of families became known as People Against Chlordane. Our main goals are, and have been, to: obtain aid for chlordane victims, obtain accurate information, and to actively endorse the banning of all chlordane uses.

The termiticide chlordane attacks the central nervous system, is hepatotoxic, is absorbed and stored in human tissues, is passed on to human infants in breast milk, and chlordane causes cancer.

Chlordane is persistent, lasting 30 years in the environment. Its effects can presently be seen in New York's environment—killing wildlife, contaminating lakes and rivers. Both fresh and saltwater fish have chlordane levels above the U.S. Food and Drug Administration guidelines. Chlordane has been detected in Long Island ground water.

In the 1970's, the Environmental Protection Agency, [EPA], cancelled most uses of chlordane on the findings of imminent hazard but continued to permit its use as a subsurface termiticide on the belief that the potential for human exposure was very low. We now know this is not the case.

In New York, following the establishment of a Pesticide Hotline telephone number by the DEC, approximately 11,000 telephone calls were received. DEC arbitrarily determined that it could only investigate 900. As of March 1985, of those 900 investigations, 600 have been documented misapplications involving commercial application businesses.

Each misapplication has the potential to result in indoor air levels that exceed the National Academy of Sciences recommendation for indoor ambient air levels.

The New York State department of health has recently given testimony that, as of January 31, 1985, of 1,000 air samples taken in private homes and analyzed for chlordane, 39.8 percent of all samples were found to exceed the NAS Interim Guideline for airborne chlordane of 5ug/m^3. Further, 75 percent of all living areas, and 90

percent of all nonliving areas had detectable levels of chlordane. So much for EPA's beliefs in the 1970's.

The New York State department of health further states, "The NAS did not suggest [5ug/m^3] as a standard or guarantee of absolute safety."

Dr. Nancy Kim, director of the bureau of toxic substance assessment in the New York State department of health, and member of the Environmental Health Committee of EPA's Scientific Advisory Board, has testified that the "excess cancer risk associated with a lifetime of exposure, 24 hours a day, to [NAS guideline of 5ug/m^3] . . . range from 500 to 6,600 per million." These risk levels are clearly in excess of the 1 in 1 million, or 1 in 100,000 risk levels which are usually suggested for regulatory purposes.

People Against Chlordane submitted thousands of pages of information during the New York State rulemaking process on termiticides. Based upon the record before it, DEC banned all uses of chlordane in New York.

Our experience in New York demonstrates several points: No. 1, persistent pesticides like these termiticides must be reevaluated for registration in a review which requires the manufacturer to prove that use of the substance will not cause adverse health effects; No. 2, EPA must be given broad authority to enforce FIFRA violations and the civil penalties under FIFRA must be substantially increased; No. 3, throughout all of the experiences described above, EPA has failed to take any action to protect citizens of the United States from the effects of termite pesticides. In fact, EPA denied the citizens access to a draft policy document which it had already provided to industry for review.

We request permission to submit proposals for FIFRA amendments for your consideration and will be happy to provide any documentation you may require.

Thank you for this opportunity to have our comments included in the record.

Mr. BEDELL. I thank you very much.

Ms. Smigel.

STATEMENT OF MARJORIE J. SMIGEL, CHAIRPERSON, ECOLOGY COMMITTEE, SPRINGFIELD GARDEN CLUB OF MONTGOMERY COUNTY, MD

Ms. SMIGEL. Thank you, Mr. Chairman and members of the subcommittee. I am Marjorie J. Smigel, Ecology Committee chairperson, Springfield Garden Club of Montgomery County, MD. I have been a resident of Montgomery County for more than 30 years; however, I come from a family of pioneers in the Western Reserve Territory of Ohio and am familiar with rural farm life.

I appreciate the opportunity to bring to your attention our effort to address the problems concerning the application of pesticides by commercial lawn care and landscape firms in urban/suburban areas.

Over the past years, our members have become increasingly concerned about mistakes, accidents, and excessive or unnecessary application of pesticides by contract lawn maintenance and similar establishments. Harmful incidents involving the use of pesticides

have been frequently reported in the press, and many of our own members have experienced or witnessed examples of careless or irresponsible application.

We became aware that many pesticide applicators were poorly trained and ignorant of the toxic nature of the materials they handled. For example, we discovered an applicator spraying trees in our backyard. He was at the wrong address and was unable to tell us the name of the substance he was spraying. He was using no protective equipment. Although Maryland law—Title 15.05.01—requires that commercial pesticide applicators be provided with necessary safety equipment for their protection, they are rarely observed wearing such clothing.

Adjoining neighbors are often adversely affected without consent by drifting sprays and runoff of contaminated ground water. An incident of contamination of a children's sandbox and toys by such spray drift is described in the attachments to this testimony.

We learned that pets can have severe toxic reactions from walking across a lawn after it is sprayed. A veterinarian who handled calls to the National Animal Poison Control Center at the University of Illinois states that only a fraction of the actual occurrences are ever reported. He described the difficulty in obtaining needed information from lawn treatment firms to enable veterinarians to diagnose and prescribe specific treatment.

Our research revealed that pesticide poisoning often goes unrecognized. The symptoms of allergy, asthma, headache, dizziness, nausea, irregular heartbeat, diarrhea, fatigue, et cetera, can easily be attributed to other causes. Certain individuals, such as those who suffer from Myasthenia Gravis, can be severely affected by relatively small amounts of pesticides. Hyperallergic reactions can be life threatening.

We researched Federal and State laws covering commercial application of pesticides by commercial lawn care firms and found them to be inadequately and poorly enforced. In addition, homeowners are not aware that pesticides are registered with the Environmental Protection Agency on a risk/benefit formula. They believe that the Federal Government approves or guarantees the safety of pesticides, thus they have a false sense of security.

The 1980 report of the National Academy of Sciences' Committee on Urban Pest Management [1] substantiated our own findings and became the cornerstone of our effort. It confirmed our own findings and urged that nonagricultural use of pesticides be monitored more carefully to address increasing health risks, since there is presently no Federal agency specifically responsible for policy decisions in urban pest management. The study found:

One, pesticides are used in larger quantities on urban/suburban land than on agricultural areas—unnecessarily and carelessly.

Two, children and pesticide applicators themselves are at special risk.

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[1] "Urban Pest Management," Environmental Studies Board, Commission on Natural Resources, National Reseacher Council, Washington, DC., National Academy Press, 1980.
"Toxicity Testing: Strategies to Determine Needs and Priorities," Board on Toxicology and Environmental Health, National Research Council, Washington, DC: National Academy Pres, 1984.

Three, incidental exposure of the general population is subtle but widespread; the variety of chemicals in use means that exposure is multiple. Long-term health hazards are just beginning to be documented and little is known of the cumulative effect of relatively small doses of pesticides. With our concerns about cancer and birth defects, which can result from subtle exposure to chemicals, chronic exposure has become as significant as acute exposure.

Four, there is need for education and an effort by local jurisdictions to work with citizens at the community level to address these problems. That is what we went about doing.

In May 1983, our membership unanimously adopted a resolution requesting Montgomery County officials to take appropriate action to address the grave health and environmental problems associated with the use of pesticides on our lawns and gardens. Our request was supported by a broad base of citizen groups, as well as the National Capital Area Federation of Garden Clubs—141 clubs—and our own district IV—37 clubs.

We were invited by Montgomery County officials to participate in a Pesticide Management Working Group which included representatives from the lawn care industry and environmental groups, as well as State and county officials. In the spring of 1984, a draft statute was prepared by the county under which residents would receive notice of pesticide application to their lawns. However, industry representatives were first offered the opportunity to comply voluntarily with the objectives of the draft legislation. The industry was unwilling to cooperate and rejected the suggested voluntary agreement.

In March of this year, therefore, County Executive Charles W. Gilchrist proposed that the county council pass legislation that would require landscape and lawn care firms to provide customers with the names of pesticides to be applied and the precautions necessary to safeguard health and protect the environment. It would also provide neighbors and chemically sensitive people with notice of pesticide application through the use of signs posted on lawns.

In addition, the county announced its own program of public notification when pesticides have been sprayed on county property. They will have this little flag out to alert citizens. Such action will enable individuals to take necessary precautions to protect those at high risk: children, pregnant women, the chemically sensitive, elderly, household pets, and last but not least, pesticide applicators themselves.

Continuing research reveals mounting evidence that pesticide hazards are becoming a national concern. Massachusetts officials convened a State pesticide board this past summer to examine the extent to which lawn care service contributes to the total exposure of the population to toxic agents. The National Research Council's Board on Toxicology and Environmental Health Standards in 1984 found that complete health hazard assessment is possible for only 10 percent of registered pesticides.

The right to know legislation in Montgomery County has received national coverage by radio and television, as well as in major publications. We are encouraged to hear from gardeners and local legislators across the Nation who share our concerns. They

join us in calling for restoration of health and harmony in our environment through prudent and responsible use of pesticides.

Our twofold effort to educate individuals to make informed choices concerning pesticides and to secure right to know legislation has received the National Council of State Garden Clubs' Frances Hickey Award. The NCSGC represents 10,852 clubs in 50 States and the District of Columbia, with headquarters in St. Louis, MO. We have also received the National Capital Area Federation of Garden Clubs' Beatrice M. Coiner Environmental Conservation Award, in addition to a special award from our own district IV.

I am submitting several documents to substantiate the testimony I have presented, and I would appreciate their inclusion in the record if possible.

Thank you.

[The information follows:]

January 24, 1985

Last spring, ChemLawn was spraying chemicals on the trees of our neighbor, Mary Elizabeth Hotchkiss. The chemicals were being sprayed indiscriminately into the air, over our fence, and into my son's sandbox. Luckily, my son had gone into the house for a moment and therefore was not subjected to this spray. It was necessary to clean a layer of sand out of the box and scrub all his toys.

As a result of the above incident, Ms. Hotchkiss wrote a letter to ChemLawn informing them not to spray her trees without first providing us with notice. Her letter will be found in their files.

Shortly thereafter ChemLawn was again spraying our neighbors' trees. No notice to us was given, as had been promised. As a result, chemicals were indiscriminately sprayed into the air and onto our porch, contaminating my daughter's highchair and covering the toys of both my children.

ChemLawn's representative named "Jeff" told me that he was new and that no one told him about notifying us. I informed him why I was upset, he told me that he was a "nice guy" to come over to explain the situation.

This incident is not the first occasion when we have had problems with ChemLawn. It has been our observation that these dangerous chemicals are usually dispersed by extremely young employees with no apparent regard for their danger. While we enjoy having an attractive lawn, we will not continue to do so at the expense of the health of our children.

Marjorie J. Mitzner

Marjorie J. Mitzner
5509 Pollard Road
Bethesda, Maryland 20816

January 30, 1985

Neil Fitzpatrick
Audubon Naturalist Society
8940 Jones Mill Road
Chevy Chase, MD 20815

Dear Mr. Fitzpatrick:

I have reviewed the news release from the Springfield Garden Club dated November 29, 1984. As both a private citizen concerned with my own families health and as a veterinarian with a veterinary clinical toxicology background, I feel that the four proposed measures outlined in the news release would be very usefull in helping to prevent problems associated with the use of lawn care chemicals.

As one of the veterinarians handling calls to the National Animal Poison Control Center at the University of Illinois for two years I received numerous calls concerning toxicities related to exposure to the pesticides used in commercial lawn care products. The majority of these related to exposures of dogs to 2-4-D used as a weed control agent. Dogs are particularily sensitive to 2-4-D and instances have been recorded of severe toxic reactions from dogs simply walking across a lawn after it was sprayed. Specifics on the number of calls could be obtained from the NAPCC. It is likely, however, that only a fraction of the actual occurances are ever reported in such a manner.

The major factor in most problems related to these products is not that the products are too toxic to be used safely, but rather that sufficient information is not being disseminated to allow their safe use. If customers were informed to keep children and pets off of treated areas for an appropriate period of time most of the problems could be avoided. One would think that such precautions would be the natural course of action, but sadly it is not. Many people consider these products to be of little concern due to their widespread use and without appropriate education by the applicator tend to not appreciate the potent nature of many of the pesticides used to control weeds and insects.

A further difficulty we encountered at the Poison Control Center was with identification of the specific products used. If we suspected a toxicity to be related to the lawn treatment the callers seldom if ever had information available on what chemicals were actually used. Often these calls were after normal business hours and the company office could not be contacted until the following day. This lack of informaton hampered both diagnosis and the recommendation of specific treatment. Even in the case of national companies with 24-hour phone numbers, changes in formulations to meet regional and seasonal needs did not allow company personnel to provide more than a list of possible chemicals that might be present.

I feel that the proposals made would not be overly burdenson on the lawn care companies and in fact would seem to consitute the minimum that one would expect from a business which by necessity must handle

and spread a wide variety of potent pesticides under situations in which the general, and usually highly uninformed, public may come in contact with them. I certainly understand the companies reluctance to overly alarm their customers, but feel that this reluctance, based on business considerations, should be tempered by considerations for the health and safety of these same customers and their families and pets.

If I can supply any further information or be of additional assistance please feel free to contact me at any time.

Sincerely,

Richard F. Cullison DVM

11621 Gail Place
Silver Spring, MD 20902
Home: 946-5002
Work: 443-5362

SPRINGFIELD GARDEN CLUB
of
Montgomery County, Maryland

NEWS RELEASE
Ecology Committee
November 29, 1984

Telephone: 320-4493
229-7062 or 229-1861

For over a year the Springfield Garden Club of Montgomery County has participated in meetings of a Pesticide Management Working Group under the aegis of the Montgomery County Department of Environmental Protection, along with members of the lawn-care industry, County and State officials, and representatives of environmental organizations. "Right to know" legislation was drafted early this year. However, County Executive Charles Gilchrist proposed first seeking a negotiated settlement with the lawn-care industry.

We deplore the decision by FARE (Federation Against Regulatory Excess), a recently-formed group of a few lawn-care firms, to reject the initiative of Mr. Gilchrist for a voluntary agreement. Mr. Gilchrist's proposal would have provided citizens at risk with information needed to protect themselves from unknown and unconsented exposure to pesticides. We regret this situation all the more, as we feel that the lawn-care industry has missed a golden opportunity to affirm its concern for the health and safety of the public and the environment.

Recent studies by the National Research Council of the National Academy of Sciences have found that suburban lawns and gardens receive heavier pesticide application than most other land areas in the United States. The Council stresses the need for citizens and their locally elected representatives to develop sound pest-management procedures.

The Springfield Garden Club of Montgomery County, with the support of the National Capital Area Federation of Garden Clubs (141 clubs), the Audubon Naturalist Society, and a broad base of civic and environmental organizations, will continue its efforts to secure:

1) Disclosure, before application, of the generic names of pesticides to be used
2) Notification of precautions to be taken by the customer to safeguard health and to protect the environment
3) Placement of marker on lawn to indicate pesticides have been applied
4) Posting of a decal or logo to identify property under contract and thus prevent wrong entry and chemical trespass

Our objectives are aimed at enabling individuals to make prudent decisions and to take necessary precautions to protect those at high risk: children, pregnant women, the chemically sensitive, the elderly, household pets and, last but not least, pesticide applicators themselves.

Stanley H. Way
5204 Drake Terr.
Rockville, Md. 20853

March 26, 1985

Stewart McKenzie
Montgomery County Council
Council Office Bldg.
Rockville, Md. 20850

Dear Mr. McKenzie,

As per our recent phone conversation, I have included documentation pertaining to the relationship of Myasthenia Gravis (a neuromuscular disease) and commonly used Insecticides. I hope it will provide you with additional information that can be used in your presentation of the bill for sign posting of areas being treated with pesticides or other chemicals.

Since Myasthenia Gravis is a disease of the neuromuscular junction and many common pesticides directly affect the neuromuscular junction (e.g. Malathion and Parathion) it is not surprising that patients like myself are adversly affected. Myasthenia Gravis (MG) is a disease that affects patients in many varying ways. Each patient has to adapt to his conditions and the things that affect his daily life style. Many factors in the environment can alter the MG patients disease. As you can see from the enclosed literature, Organophosphates (Malathion and Parathion) and carbamate pesticides (Sevin) are two such catagories that have adverse affects.

While the number of MG patients is not large (est. 1 in 10,000), it is a fact that some of these patients are constantly on the verge of life threatening medical crisis and could be severly affected by relatively small amounts of pesticides. Many MG patients have fairly will controlled symptoms and would probably suffer only transient muscular weakness as a result of exposure to these pesticides.

It is certainly important for all MG patients to be aware of the presense of pesticides. Therefore, I strongly support the bill that will require the posting of signs warning of pesticides or other chemicals.

Please keep me informed of public hearings and let me know if the information I have included is insufficient.

Enclosures:

Sincerely,

Stanley H. Way

344-8818 (O)
460-8117 (H)

cc: Shirley Briggs
Rachel Carson Council

M. Schmiegle
Springfield Garden Club

Susan Meggs
Human Ecology Action League

57-556 O—86——4

testine, bronchi, heart, blood vessels, bladder—as well as the eyes and sweat glands. It therefore controls all sorts of functions, from breathing to sexual activity, from sweating to digestion. It consists of two divisions, sympathetic and parasympathetic. These divisions oppose each other, but a careful balance is maintained by special centers in the brain.

Impulses from the brain and spinal cord join the autonomic network of nerves along nerve fibers which run into ganglia (rather like electrical switch boxes). The impulses are transmitted at these junctions by chemical transmitters. The nerve fibers running *to* the junctions are called *pre*ganglionic nerve fibers, and they all use the same chemical transmitter—acetylcholine. This transmitter works for only a very short time, because once it is liberated at nerve junctions to act as a chemical transmitter another chemical starts to break it down. The latter chemical is an enzyme called cholinesterase. Nerve fibers running *from* the nerve junctions (ganglia) are called *post*ganglionic nerves.

Parasympathetic postganglionic nerves also use acetylcholine as a chemical transmitter; they are therefore known as cholinergic nerves. The sympathetic postganglionic nerve fibers, which use epinephrine and norepinephrine as chemical transmitters, are known as adrenergic nerves.

Drugs Which Act on the Parasympathetic Nervous System

Drugs which act like acetylcholine are called cholinergic drugs; they may also be called parasympathomimetic because they mimic the actions of the parasympathetic nervous system.

Stimulation of the parasympathetic division produces stimulation of secretory glands—salivary, tear, bronchial, and sweat. It slows the heart rate, constricts the bronchi, produces increased movement of the gut, contracts the bladder, and constricts the pupil. It stimulates nerve endings in voluntary muscles, stimulates and then depresses the brain, and dilates blood vessels.

CHOLINERGIC DRUGS

There are three groups of cholinergic drugs:

CHOLINE ESTERS: carbachol, methacholine, bethanechol. These act at all sites like acetylcholine.

ALKALOIDS: pilocarpine, muscarine. These act selectively on those nerve endings which respond to acetylcholine.

CHOLINESTERASE INHIBITORS OR ANTICHOLINESTERASE DRUGS: physostigmine and neostigmine. These inactivate the enzyme (cholinesterase) which is responsible for breaking down acetylcholine, allowing acetylcholine to go on working.

Not all effects occur with each cholinergic drug. Also, the intensity of effect varies. Methacholine may be used to slow down fast heart rates, and carbachol may be used to stimulate bowel and bladder function after surgical operations. They both have to be given by injection under the skin. Bethanechol is related and may be given by mouth. Pilocarpine is used to constrict the pupil and decrease the pressure inside the eye in patients with glaucoma. The anticholinesterase drug physostigmine is used to stimulate the bowel and bladder after surgery, in the treatment of myasthenia gravis (a disease caused by defective transmission of impulses by acetylcholine, and characterized by severe muscle weakness and fatigue), and as an antidote to neuromuscular blocking drugs. Many related drugs are also "used" as nerve gases, and some are pesticides.

Drugs Which Oppose Parasympathetic Activity

These may be called acetylcholine antagonists or parasympatholytics. They prevent acetylcholine from acting as a transmitter. There are three groups: anticholinergic drugs, which act principally at parasympathetic nerve endings; ganglionic blocking drugs, which act on ganglia; neuromuscular blocking drugs, which act on nerve endings in voluntary muscles.

ANTICHOLINERGIC DRUGS

Typical of these drugs is atropine, and they are therefore often referred to as atropinelike drugs. Atropine is an alkaloid from the plant *Atropa belladonna*. It competes for the same chemical receptors as acetylcholine, thus blocking its effects. It produces dry mouth and a reduction in all secretions except milk, effects opposite to that of stimulation of the parasympathetic division. In the stomach it reduces the amount of acid produced. Sweating is inhibited, and bronchial secretions are reduced. It causes a relaxation of muscles in the bowel, bronchi, and bladder and is used to relieve muscle spasm in these organs (e.g., intestinal colic, bronchospasm). It dilates the pupils and increases the pressure inside the eyes. It increases heart rate, stimulates the brain, reduces motion sickness, and decreases the tremor and rigidity of Parkinsonism. Higher doses of atropine produce a rapid heart rate, dry mouth, blurred vision, dilated pupils, and restlessness. In overdose, atropine produces excitement, hallucinations, delirium, mania, and coma.

Other atropinelike drugs are: scopolamine, which depresses the brain and is used preoperatively and in motion sickness; homatropine, used to dilate the pupils; scopolamine butylbromide, which relaxes involuntary muscles and is used to relieve colic; cyclopentolate, used as eye drops to dilate the pupils; and propantheline, one of many

CONTRAINDICATED DRUGS

Curare and its derivatives
Morphine and other narcotic analgesics, tranquilizers, barbiturates
Ether, Methoxyflurane, Halothane
Quinidine, Pronestyl
Quinine, tonic water, muscle relaxants
Procainamide, Propanolol, Lidocaine and related drugs
Potassium depleting diuretics
Common cold preparations
Enemas and strong cathartics should be evaluated on an individual basis

*Streptomycin	Polymyxin A and B
Kanamycin	Colistin
Gentamicin	Geomycin
Viomycin	Tobramycin
*Neomycin	Amikacin
Sulfanomides	Tetracycline

Insecticides: Organophosphates-Parathion and Malathion
The fluorocarbon propellants in spray cans may be poorly tolerated.
Flu shots should be taken at the discretion of your physician.

I AM ILL

I have a disease, called
MYASTHENIA GRAVIS,
which makes me so weak that I cannot stand up or speak. I am not intoxicated. Please call my physician or hospital right away.

MYASTHENIA GRAVIS FOUNDATION, INC.
P.O. Box 24607
Philadelphia, PA 19111
HOTLINE - 342-7650

Gregory May
14609 Pine Forest Drive, #102
North Royalton, OH 44133
(216) 582-3713

AKRON, OHIO
1 PM
30 MAR
1985

Greg May
14609 Pine Forest Dr.
N. Royalton, OH 44133
216/582-3713

Marjorie Smigel
5807 Ridgefield Rd
Bethesda, MD 20816

Dear Marjorie,

I'm writing you upon request from Kim Hill to tell you of my experience with Tru Green lawn care in Pontiac, Michigan.

I was hired as an employee at Tru Green in 1981. after I had been spraying lawns for about three weeks, I started experiencing terrible headaches and [redacted] nausea. One day, I was disabled from the intense headache pain, not being able to lift the heavy bags of fertilizer to fill my trucks. Upon calling the poison control center, I found I had organo-phosphate poisoning, from absorbing the Lescosan thru my skin. I was fired from my job within a month for being unable to do my work.

I attribute my poisoning to the following factors:

1) no gloves or boots were supplied to the sprayers
2) we were forced to continue spraying even in high winds
3) Leaks were not repaired in the trucks
4) Spilled chemicals were not cleaned up for days

I believe that overall, the lawn spraying companies are bad for our health and our environment.

Sincerely,
Greg May

STATEMENT IN SUPPORT OF
PESTICIDE RIGHT-TO-KNOW LEGISLATION IN MONTGOMERY COUNTY

I. BACKGROUND

Since 1983, a broad based coalition of citizens groups[1] in Montgomery County, initiated by the Springfield Garden Club with the support of the Rachel Carson Council and the Audubon Naturalist Society, has sought to address the grave health and environmental problems associated with the use of pesticides on residential lawns. The coalition was concerned about mistakes, accidents and excessive or unnecessary application of pesticides by lawn maintenance companies, as well as inadequate consumer awareness of the potential hazards of pesticides.[2]

In September 1983, members of the Springfield Garden Club Ecology Committee and representatives of the Rachel Carson Council

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1. The coalition includes the League of Women Voters, National Audubon Society, American Association of University Women, Friends of the Earth, Springfield Civic Association, Men's Garden Club of Montgomery County, Maryland Wildlife Federation, National Coalition Against the Misuse of Pesticides, Clean Water Action Project, Concern, the Human Ecology Action League, the National Capital Area Federation of Garden Clubs (representing 141 garden clubs), and District 4 of the National Capital Area Federation of Garden Clubs (representing 37 garden clubs).

2. The lawn care industry has erroneously claimed that the coalition's efforts were motivated solely by customer complaints over billing and the storage of nerve gas near a public school. In addition to being patently false, these assertions belittle the important role which County officials have played in trying to address the very real health effects associated with the application of pesticides to residential lawns.

and Audubon Naturalist Society were invited by County officials to participate in the Pesticide Management Working Group, which included representatives from the pesticide industry, as well as state and County officials. The industry's reluctance to support any meaningful proposals hindered the Working Group's effectiveness. In the spring of 1984, in response to a draft statute prepared by County officials, under which residents would receive notice of pesticide applications and information about the pesticides applied to their lawns. the County Executive announced his support for a voluntary compliance scheme that would achieve the same objectives. The coalition supported the voluntary compliance scheme. Several months later. the industry, through the trade association FARE (Federation Against Regulatory Excess),[3] rejected it.

The coalition, having worked cooperatively -- and patiently -- with all parties for a voluntary compliance scheme without result, is now asking the County to adopt legislation that would: 1) provide for full notification to the customer of the names of the pesticides being applied to the customer's lawn, and the potential health effects of those pesticides; 2) provide notification of pesticide applications to neighbors through the use of small markers posted on lawns; and 3) provide for a small

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3. FARE's response to the voluntary compliance scheme was unsigned, and FARE has never disclosed which companies comprise the organization.

decal to mark clearly homes to be treated over the duration of the contract, so as to prevent the wrongful application of pesticides.

II. WHY A "RIGHT-TO-KNOW" ORDINANCE IS NECESSARY

The ordinance prepared by the coalition of citizen groups is a response to the increased awareness, both nationally and in Montgomery County, of the hazards associated with the widespread[4] use of pesticides on residential lawns in suburban areas. Coalition members have received numerous complaints about pesticide misapplications and poisonings in the County. The exact number of such incidents is unknown, since there is no central repository for complaints in Montgomery County, nor any requirement that doctors who are alert to the symptoms report incidents.[5]

There are many known health effects which result from various pesticide poisonings. Repeated, low-dose exposure may cause immediate effects, including partial paralysis, irregular heartbeat, dizziness, headaches, nausea, diarrhea, muscular pain, fatigue, allergies and asthma. Long-term effects, whether from

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4. By FARE's own estimate, 54,000 households in Montgomery County alone are served by lawn care contractors.

5. The coalition is compiling Environmental Protection Agency data on complaints received with respect to those pesticides which are used by lawn maintenance companies in Montgomery County. When complete, that compilation will be presented to the County government and other interested parties as a supplement to this document.

one or repeated exposures, include sterility, birth defects, toxicity to fetuses, miscarriage, mutations, neurologic, kidney, heart, liver and blood damage, behavioral disorders and cancer. Individual reactions and susceptibilities may differ. Some people who have developed super sensitivity to toxins must avoid any exposure. The National Research Council's report, Urban Pest Management,[6] states that the medical significance of long-term exposure has become as great as that of immediate exposure. There is little general public awareness of the risk of exposure to pesticides. Moreover, according to the report, children and the elderly are at special risk of pesticide exposure and pets are frequent victims of unwise domestic use of pesticides.

Even more alarming is the fact that many of the health risks of pesticides are unknown. In its report entitled Toxicity Testing: Strategies to Determine Needs and Priorities,[7] the National Research Council reports that data sufficient for complete health hazard assessments are available for only 10% of the pesticides currently in use in the United States and that an additional 24% can only be partially assessed. This means that little -- or nothing -- is known about the health hazards of two-thirds of the pesticides in use today. Many of these were registered by the U.S. government for use before adequate testing

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6. National Academy of Sciences Press.

7. Ibid.

was required in the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA") revision of 1972, and most have still not been brought into compliance.

It was also discovered a few years ago that one of the primary laboratories used for toxicity testing of pesticides, Industrial Bio-Test Laboratories, falsified the results of many tests on over 200 pesticides. Other commercial laboratories have also been found at fault. These tests are being repeated at the behest of the United States and Canadian governments, but the process is still not complete. Moreover, the registration process of the Environmental Protection Agency is no guarantee that the newer pesticides on the market have been adequately tested. The EPA approves hundreds of "emergency exemption" requests each year that permit unregistered pesticides to be used and also allows such products to be used under "conditional registration" and "special local need" exemptions. In 1982, EPA approved 1,656 special local need registrations alone. Recent rulings of federal district courts in Oregon establish the principle that EPA registration of a pesticide is not adequate justification for its use, and that a "worst case analysis" must be drawn up by any government agency using a pesticide widely.

Given the known health risks from pesticide exposure and the scarcity of adequate data about pesticides, it is imperative that Montgomery County take the initiative and provide its residents with the information they need to make informed choices about

pesticides. That is what the proposed ordinance seeks to do. It will promote the health and safety of County residents, and increase their awareness of the potentially hazardous pesticides being applied to their lawns. The coalition, which supports this ordinance, recognizes that pesticides are a fact of life; it does not seek to end pesticide use in the County. What the coalition does want is a better informed and safer citizenry.

III. ENACTMENT OF THE PROPOSED RIGHT-TO-KNOW LEGISLATION IS WITHIN THE COUNTY'S LAWFUL AUTHORITY

Montgomery County is not preempted by state or federal law from enacting legislation directed towards disseminating information and protecting the health, safety and general welfare of County residents.[8] The Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA") regulates pesticide registration,

8. In its response to the voluntary compliance scheme, FARE cites a number of cases to support its sweeping assertion that localities are preempted from enacting pesticide ordinances. These cases are examples of ordinances which directly conflict with either a state or federal law: Long Island Pest Control v. Town of Huntington, 341 N.Y.S.2d 93 (Sup. Ct. Suffolk County 1973, aff'd on appeal without opinion, 351 S.2d 945) (local ordinance required pesticide registration and regulated transportation of pesticides); Town of Wendell v. Bellotti, Civil Action No. 15119 (Mass. Superior Ct. 1984) (local ordinance required pesticide registration and approval of pesticide use by local board); Town of Salisbury v. New England Power Co., 121 N.H. 983 (Sup. Ct. 1981) (local ordinance restricted use of chemical defoliants). The proposed ordinance contains no such conflicts with either state or federal laws. Where there is no conflict, as in People v. County of Mendocino, 204 Cal Rptr 897 (Cal. Sup. Ct. 1984) (aerial spraying of pesticides not covered by state or federal law), a local law will not be preempted.

certification, use, sale and labeling. It contains no express preemption of state or local legislation. In fact, §24 of FIFRA authorizes additional state regulation of the sale or use of pesticides as long as there is no conflict with the federal law, essentially leaving the states to determine for themselves in what manner additional legislation could be enacted by localities. Under the Maryland Constitution, chartered counties -- such as Montgomery County -- are granted broad legislative powers to protect the health and safety of their residents. Those powers are nearly as extensive as those of the state. Thus, the state of Maryland, by its Constitution, has made the choice to allow chartered counties to determine the best mechanisms to protect the health, safety and general welfare of their residents.

Moreover, FIFRA does not impliedly preempt the proposed ordinance. First, the ordinance does not conflict with FIFRA. FIFRA regulates only the registration, use, sale and labeling of pesticides. It does not address the dissemination of information about pesticides to consumers. Second, FIFRA's express authorization of state legislation indicates that Congress did not wish to occupy the field of pesticide law.

FARE places great weight on the legislative history of FIFRA. FARE points out that a House and a Senate committee rejected a proposal which would have expressly authorized legislation by political subdivisions. However, FARE neglected to mention a proposal by the Senate Committee on Commerce which sought to

permit such local legislation.[9] These differing positions led to a compromise in the House-Senate conference under which neither position was adopted. One cannot infer any Congressional intent from such inconclusive legislative history.

The proposed ordinance is also not preempted by Maryland law. The pesticide sections of Title 5 of the Maryland Agriculture Code contain no express preemption provisions. Moreover, the ordinance falls clearly within the powers of a chartered county to protect the health and general welfare of its residents. Thus. nothing in Maryland law expressly preempts legislation of this type.

Nor is the ordinance impliedly preempted. Such preemption might occur if the ordinance conflicted with state law, or if there was some evidence that pesticides were an exclusive state concern. First, there is no conflict with state law. Like the FIFRA regulations, Maryland regulations pertain to the manufacture, registration, distribution, and labeling of pesticides. They do not concern the dissemination of information to consumers. The ordinance will neither interfere with nor pose an obstacle to compliance with state law by pesticide applicators. Second, pesticides are not an exclusive state concern. The state pesticide regulations are not the type of detailed and comprehensive regulatory scheme -- such as the state's education and election laws -- that Maryland courts look for in determining

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9. S. Rep. No. 970, 92d Cong., 2d Sess. 27-28 (1972).

whether an area is of exclusive state concern.[10]

FARE also asserts that the proposed ordinance violates the Equal Protection Clause of the United States Constitution because the ordinance discriminates against a particular class of persons (lawn maintenance companies) without establishing a rational basis for such "discrimination." FARE's interpretation of the Equal Protection clause is erroneous. First, while the 14th Amendment does protect "suspect classes" that have experienced discrimination, this protection has only been applied to classifications based on race, sex or national origin. Second, it is not true that statutes which govern commerce cannot differentiate between commercial establishments and private individuals. Many statutes do so. The most pertinent example is the Maryland pesticide law, which exclusively pertains to businesses that manufacture, sell or apply pesticides. It does not regulate private individuals who use pesticides. While it might be desirable to require private individuals to comply with certain provisions of a right-to-know ordinance, there is nothing

10. FARE cites §5-102 and §5-104 of the Maryland Agriculture Code as support for its argument that the proposed ordinance would contravene the legislature's desire for uniformity in pesticide regulation. However a careful look at those sections reveals that the uniformity referred to was directed towards other state agencies, other states and the federal government, and towards regulations governing pesticide labeling, coloring, manufacturing and selling. Those sections do not pertain to localities, and they do not refer to laws which are designed to provide information to consumers.

in the U.S. Constitution that mandates it. Of course, since such a requirement is not precluded under the Constitution, the coalition would feel free to so expand its ordinance at a later date.

_____
Springfield Garden Club

_____
Rachel Carson Council

_____
Audubon Naturalist Society

Reducing Pesticide Use

Rachel Carson's "Silent Spring" was an account of the immense environmental harm pesticides were doing in 1962 when it was published. DDT, the worst offender, was banned in 1972, and others have been banned since. But the chemical pesticide issue is not dead. While today's pesticides are less persistent, and often less toxic, serious safety questions still remain.

Substances which kill insects, weeds or fungi by their very nature usually also kill "non-target" species and disturb nature's balance (often destroying natural enemies of the target species). Even some of today's safer pesticides can cause serious harm to humans, including birth defects and cancer. And while the multitude of influences which degrade waterways such as Chesapeake Bay are difficult to pinpoint, pesticides no doubt are significant.

The feeling grows that the federal Environmental Protection Agency, which is charged with monitoring safety and health effects of pesticides, is doing a poor job. That feeling is so strong that California passed a law requiring state agencies to review the safety of pesticides on their own, independent of the EPA. A federal circuit court has upheld the right of state and local governments to impose stiffer regulation than EPA. A bill requiring a California-style review of pesticides in Maryland by the state Health Department didn't get out of committee this year, perhaps appropriately so in view of how new the issue is here. Needed is a detailed study of the issue by a legislative committee during the summer.

In other Maryland action, the Montgomery County Council is expected to consider a "right-to-know" ordinance under which lawn-care contractors would have to inform customers of the hazards of pesticides they use, and erect signs on treated lawns to warn neighbors. The National Academy of Sciences says there is more pesticide use in urban and suburban areas than on farms. An estimated 54,000 households in Montgomery county use lawn-care services. Requiring the companies to tell customers what is being used on their lawns, and how harmful it may be, is a modest regulation that ought to be approved — in Montgomery county and elsewhere.

Lawns can be made beautiful without pesticides — through aeration, fertilizers and proper mowing. Crops can be protected with integrated pest management plans that minimize pesticide use. Pesticides should be used as sparingly as powerful drugs are used, for many of the same reasons. Fortunately, that idea is catching on.

The Baltimore Sun 3/13/85

Opinion

A10 THE MONTGOMERY JOURNAL WEDNESDAY, MAY 15, 1985

We'll soon see signs warning of poisons

The Montgomery County government soon will place bright orange signs on county property that has been sprayed with pesticides. The signs will explain which agency did the spraying, a date when the chemical no longer is likely to be a danger and a phone number for more information.

That is such a sensible idea that it's surprising it took two years for it to develop from the time the Springfield Garden Club in Bethesda raised the issue.

The lawn care industry, asked to post similar signs when it sprays poisons on lawns in the county, doesn't exactly love the idea. The industry's desire to avoid petty nuisance laws is understandable, but some of the industry's claims are a little hard to swallow.

For example, an industry spokeswoman says that scientific studies "clearly contradict claims" that the application of lawn care sprays are a danger to public health. She also says that "all professional applicators are carefully trained" and that professional lawn care companies "meet all EPA and state regulations and standards." There's more PR than substance in those claims.

A few jurisdictions in various parts of the country require commercial lawn care companies to post signs every time they spray for insects or weed control, and the companies have turned this law to their advantage by making the signs another form of advertising. Typically, they say something like "Another lawn getting weed control by XYZ Co."

It's hard to understand why the industry resists a law that forces their customers to become advertising vehicles.

There aren't many scientists who deny that modern pesticides and weed killers are poison. The signs telling the public which specific areas have been sprayed should be particularly useful to the parents of small children, who crawl through the grass and like to put things in their mouths. The signs also should be of considerable interest to people who are allergic to certain kinds of chemicals.

But, as County Council member Esther Gelman says, "For most people the public's right to know is reason enough for the signs."

The decision to use these signs on all government projects is welcome. The industry would be wise to follow suit voluntarily, so that we don't need a law requiring commercial concerns to notify people that poison has been sprayed in their neighborhoods.

THE NEW YORK TIMES, SATURDAY, DECEMBER 1, 1984

National Pesticide Policy Is Dangerous to Your Health

By Samuel S. Epstein

CHICAGO — The village Board of Trustees of Wauconda, Ill., (pop. 8,758) last February unanimously adopted a "right-to-know" ordinance requiring pesticide-applicating firms to post signs on lawns and in yards, barring other places, identifying the pesticides used and warning the public to stay off treated areas for 72 hours. This modest ordinance, which has become the target of a lawsuit filed by the pesticide industry, may well become a bellwether for the entire nation.

First prompted by a resident whose 4-year-old daughter is hypersensitive to certain pesticides, Wauconda's ordinance is one of no more than a dozen grass-roots attempts to protect people from involuntary exposure to unknown pesticides, and to establish minimal local control over a tiny portion of the 1.4 billion pounds of pesticides produced in the nation annually, of which some 75 percent is accounted for by 10 large manufacturers. Wauconda is not asking for local regulation of the sale and use of pesticides, nor for informed consent prior to use, nor for safety and monitoring data, but only for disclosure of the identity of pesticides after their application.

"Pesticides" is a generic term for some 40,000 products — herbicides, insecticides, miticides, fumigants, fungicides and rodenticides — of which some 50 percent have nonagricultural uses that include not only applications to building materials, food containers, school yards, roadsides, golf courses and parks but also routine fumigation of public buildings and treatment of private lawns and trees. A recent survey of suburban Chicago by an environmental organization showed that lawn applications averaged 10 pounds per acre annually compared with the 3 pounds per acre used nationally by soybean farmers.

Pesticides are classified as "unreasonably hazardous" substances under strict liability laws of many states. Reflecting concerns about the hazards, a Supreme Court decision in July, in Environmental Protection Agency v. Monsanto Company, favored public access to safety data on which pesticide registration is based. However, such laws are toothless and such data are useless if the public is denied the right to know when and in what pesticides it may have been exposed.

Public confidence in assurances of safety by the industry and in the Government's ability — or intent — to protect citizens from hazardous exposure has dwindled. This follows growing realization of gaping loopholes in pesticide laws, evidence that most pesticide ingredients have never been adequately tested for long-term health risks, disclosures of collusion between Government and industry officials, bungled and suppressed research and commonplace falsification and manipulation of safety tests by industry. Still more alarming is knowledge of the continuing large-scale national use of numerous pesticides such as hexachlorobenzene and chlordane, known to induce chronic toxic effects including cancer, and phenoxy herbicides, known to induce birth defects.

Predictably, the pesticide industry is anxious to retain regulation under the centralized authority of Federal and state governments. Most states simply rubber-stamp Federal regulatory decisions.

Wauconda is not alone in acting to protect citizens from involuntary exposure, and already three small investment firms are having little difficulty in complying with the ordinance. And in Eugene, Ore., Montgomery County, Md., and Lyndhurst, Ohio, local governments contemplating right-to-know ordinances are watching Wauconda.

On Sept. 18, the Pesticide Public Policy Foundation, a national organization of major pesticide manufacturers and application firms, filed a lawsuit against Wauconda in Federal district court in Chicago. The suit charges that the right-to-know ordinance is illegal on several grounds. Federal and state laws pre-empt local control, the village lacks authority to enforce such an ordinance; the ordinance unfairly applies only to commercial operations; it constitutes an illegal restraint on commerce. A study group in the E.P.A.'s Middle West region is currently reviewing the impact of local ordinances on Federal and state pesticide regulations.

The outcome of the legal battle is crucial to the nation's health. The controversy is no longer about the safety of pesticide chemicals but over more fundamental issues of public policy. E.P.A. regulations are based not just on safety considerations but on decisions, largely reflecting data that the industry considers trade secrets, that balance economic benefits against hazards.

Is the public to be totally excluded from participating in balancing, say, the risks of cancer or birth defects against the profits of dandelion extermination, even to the extent of being denied knowledge of the pesticides used in public places and in their homes? While testifying to industry's concern about the safety of its employees, the common sight of lawns being treated by commercial operators protected by "space suits" does not dispel concern about hazards to children playing on treated lawns.

We should keep Wauconda in mind when we read Thomas Jefferson's words written in 1816: "I hope we shall crush in its birth the aristocracy of our monied corporations which dare already to challenge our country to a trial of strength and bid defiance to the laws of our country."

Samuel S. Epstein, M.D., is professor of occupational and environmental medicine at the University of Illinois Medical Center. (This article was written with the assistance of Carol Van Strum and Mary H. O'Brien of the Northwest Coalition for Alternatives to Pesticides, in Eugene, Ore.)

THE NEW YORK TIMES, SUNDAY, DECEMBER 2, 1984

Lawn-Care Concerns Fight Pesticide Sign Rule in Illinois City

WAUCONDA, Ill., Dec. 1 (AP) — Residents here who take pride in neatly manicured, pesticide-treated lawns are being forced to post signs warning of toxic chemicals, and commercial pesticide applicators are so upset they have gone to court.

"When I moved down here, I was absolutely horrified because it was like leaving into the frying pan," said Jane Larson, 40 years old, who fought for approval of the new requirement. "Everybody was using DDT."

Mrs. Larson said her daughter was allergic to such chemicals.

David Dietz, program director of the Pesticide Public Foundation, a coalition of pesticide applicators, said the signs were "a badge of shame" to embarrass people into not having their lawns chemically treated.

Commercial pesticide applicators sent out the signs for 72 hours after [illegible]

Illinois city of about 3,800 people. The signs must read: "This lawn chemically treated. Keep children and pets off for 72 hours."

"I don't know of a pet that can read," Mr. Dietz said. "And then, too, children simply are not going to be in a position to comprehend what that sign will say."

'Lawndi' Filed in Chicago

Signs need not be posted if residents themselves apply chemicals to their lawns.

In a lawsuit filed Sept. 18, Pesticide Public Foundation, based in Washington, D.C., and Salem, Ore., asked a Federal district judge in Chicago to overturn the ordinance. Among other things, the lawsuit argues, the ordinance discriminates against commercial pesticide users.

"Why is it that a lawn-care firm, for example, [illegible] under the Wauconda ordinance," Mr. Dietz asked.

Similar ordinances have been passed in several Northern and Eastern states, but Wauconda's ordinance is the first the foundation has challenged, Mr. Dietz said.

Mrs. Larson said she began researching pesticides 25 years ago, two years after her daughter Kathy, then 6 years old, was exposed to a toxic chemical and hospitalized for an allergic reaction.

The sign ordinance, she said, "is meant only to protect the children." She said the pesticide companies "want to keep the people ignorant" of chemical hazards.

Mr. Dietz said lawn-care companies were reluctant to enter Wauconda because of concern about industrial liability. He said it could a company could be sure vandals or the wea[illegible] would not [illegible]

quires them to pay a $25 yearly licensing fee and to report the pesticides they plan to use, Mr. Dietz said.

Some residents disagree with Mrs. Larson's fight to get the ordinance.

One of them, Herbert Dost, said he wasn't sure it was Mrs. Larson's business what people did with their own property.

CHILDREN'S HOSPITAL OF PITTSBURGH
125 DESOTO STREET
PITTSBURGH, PA. 15213

November 30, 1984

Mrs. Gertrude C. Goeke
5315 Briley Place
Bethesda, MD 20816

Dear Mrs. Goeke:

Since the Pittsburgh Poison Center is one of my areas of responsibility, our Administrator has referred your letter of November 26, 1984 to me.

Your proposal to use the MR. YUK sticker on the lawn markers to alert neighbors, with children, to avoid areas which have been sprayed with harmful chemicals is a very good one. We certainly would be willing to grant permission for you to use the MR. YUK sticker. We would only ask that you work through the local Poison Center located at Georgetown University. I have alerted Dr. Toby Litovitz, Director of the Poison Center at Georgetown, of your request and she will be anticipating a call from you (202-625-6073).

The Georgetown University center is licensed to use the MR. YUK stickers and they should be your source of supply. We wish you every success in your good work and we will be supportive through the National Capital Poison Center at Georgetown.

Bethesda is a very special place to me and my wife because that is where we started out together 35 years ago.

Sincerely yours,

Glenn D. Lanier
Associate Administrator

cc: Toby Litovitz, M.D.
Richard Garber

OFFICE OF THE MAYOR

JAKE M. GODBOLD
MAYOR

JACKSONVILLE, FLORIDA
32202

October 26, 1984

Mrs. Gertrude C. Goeke
Ecology Committee Member
Springfield Garden Club of Montgomery County
5315 Briley Place
Bethesda, Maryland 20816

Dear Mrs. Goeke:

Thank you for your letter of inquiry dated September 27, 1984. The Consolidated City of Jacksonville has no local ordinances governing pesticides. Commercial pesticide operators in Florida are licensed by the State Department of Agriculture and Consumer Affairs and certified by the State Department of Health and Rehabilitative Services, Entomology Division. They are licensed to use only EPA-approved pesticides and are monitored by the licensing agency. Several of the pesticide companies voluntarily place temporary signs on lawns treated with pesticides to warn the public to keep children and dogs away, particularly while the lawns are still wet. Companies admit, quite candidly, that the placement of such signs is good advertising.

I hope the above information will be of help to you.

Sincerely yours,

Jake M. Godbold
Mayor

JMG/srl

GREEN BUT TOXIC

Use of lawn pesticides concerns state officials

Boston Globe 4/28/84

By Chris Chinlund
Globe Staff

An estimated 700,000 Massachusetts homeowners, mostly middle-class suburbanites in search of lush, weed-free lawns, invest more than $120 million each year in the booming lawn care industry. Their investments buy several applications of chemical pesticides. All are toxic.

The chemicals are legal, commercially available and, according to the industry, applied safely. Yet some are controversial because they are suspected of causing cancer, nerve damage or birth defects. State officials say it is time to take a closer look at the rapidly growing industry.

Most standard pesticides can be easily absorbed through the skin, so avoiding a just-treated lawn is critical, says Lewis Wells, director of the regulatory services division of the Food and Agriculture Department. "It's taking the baby and rolling him down the lawn that I am concerned about," he says.

Some pesticides are sprayed; others are spread in granular form. All are used in diluted form. They are applied with fertilizers, and for $175 or $200 homeowners can get four or more applications over the season. The problem, say some officials, is that homeowners often have no idea what is applied to their lawns, and take no precautions.

"I think we need to look at to what extent this kind of service is contributing in any way to the total exposure of the population to toxic agents," says Health Comr. Bailus Walker.

Jeff Carlson, state Pesticide Bureau chief, plans to convene a state Pesticide Board meeting this summer to determine further action. "What we would like to look at in the lawn care business is whether labeling on products is adequate, ... whether the industry standards are adequate, and whether regulatory actions are needed," says Carlson. There is no crisis, he said, but there is need for a thorough review.

2,4-D controversial

One of the most controversial pesticides is 2,4-D, a mainstay of the industry. It is one of two components of the Vietnam defoliant Agent Orange. Environmentalists have protested its use, and 2,4-D is among the pesticides restricted, although not banned, by the National Park Service. Others of the eight pesticides routinely used have what one state official called "toxicological shadows."

In 1981, a state advisory committee of the Environmental Quality Engineering and Public Health departments said of 2,4-D: "The scientific data are sufficiently suggestive of a carcinogenic effect . . . that 2,4-D use should be restricted to areas in which human exposure can be kept to a minimum." The panel also said, "Broadcast methods of application that potentially expose the general population should be stopped." A ban was not recommended, and the pesticide is still widely used.

Meanwhile, the lawn care business, which didn't exist 20 years ago, is growing 25 percent a year in Massachusetts and nationally. Industry officials estimate. One in four middle-class Massachussets homeowners now contracts with a lawn care company.

"I am more concerned about use [of herbicides] on lawns, around houses, than I am about use on power lines and rights of way, which have caused environmental groups to complain," says Wells of the Food and Agriculture Department. A study shows herbicides are used on at least 160,000 acres of Massachusetts lawns, compared with less than 15,000 acres of rights of way.

John Kenney says there is no reason for worry. He is president of the Professional Lawn Care Assn. of America, representing 500 companies as well as president of Turf Doctor, the second largest lawn chemical company in Massachusetts behind the industry giant, Chemlawn. "All things are hazardous materials, the wood in my desk is hazardous material. If I eat too much, I am bound to get ill," says Kenney. "I don't feel good about dealing with materials that are hazardous, but I don't know any other way to live."

James Brooks, association executive director, concurs: "Chemicals on the lawn are probably less toxic than those kept in your kitchen cabinet." Industry spokesmen say the chemicals they use are designed to be toxic on pests, not people, and that only a few cases of illness have been reported from exposures.

Carlson of the state Pesticide Bureau identifies seven pesticides as "industry standards," used widely by lawn care companies. All are approved by the Environmental Protection Agency and registered for use in Massachusetts. Among them:

- Dursban, an insecticide that can affect the nervous system. Overexposure results in sweating, fatigue, nausea and tightness in the chest. Tests to determine long-term damage caused by this and other organophosphates are inconclusive, according to Dr. Judith Marquis of the Boston University School of Medicine.
- Diazinon, also an insecticide and organophosphate that can affect the nervous system. An EPA spokesman said the agency has received complaints that birds have died after feeding on diazinon-treated lawns. Dr. Ellen Silbergeld, a toxicologist with the Environmental Defense Fund, said the chemical also may cause liver and kidney damage.
- Benomyl, a fungicide that was put under special review by EPA because laboratory tests indicated it causes birth defects and genetic mutations. In 1982 the agency announced new precautions for users of benomyl. The fungicide has toxic effects on the liver, and may accumulate in the body, according to Silbergeld.
- 2,4-D, a herbicide that kills plants by causing them to grow too quickly. Although this chemical, which made up 50 percent of Agent Orange, contains none of the dangerous dioxin that was part of the Vietnam defoliant, controversy over its use continues. There is conflicting evidence on whether 2,4-D causes cancer, and an EPA study is under way. It is also suspected of causing nerve damage.

Three other widely used chemical herbicides – Dicamba, MCPP, and Bensulide – have been less controversial. Still, they are toxic, and Dicamba's use has been criticized while EPA testing for cancer, reproductive problems and mutations remains incomplete.

Although pesticide applicators must pass a state test, Carlson of the state Pesticide Bureau suspects the quality of work varies widely among lawn-care companies.

The industry's Kenney shuns suggestions that homeowners should be told to stay off freshly treated lawns. "We would, if we had ever had any concern about safety," Kenney said of his company. "We have never had a health problem with employees or customers." Although some companies issue warnings, Kenney said he believes most share his view that it is unnecessary.

But Dr. Ruth Shearer, a genetic toxicologist who has worked for EPA and the National Cancer Institute, says none of the pesticides widely used for lawn care have been retested under the stricter guidelines set by Congress in 1972.

Dr. David Ozonoff of the Boston University School of Public Health is also a skeptic. He said the effect of certain pesticides on children remains unknown, and noted that children's nervous systems are still developing. And he worries about the environment.

"Herbicides are chemicals specially engineered to have biological effects to kill things, and they are one of the few chemicals we purposefully put into the environment in high volume," he said. "It's not a matter of barrels leaking somewhere. We spray the stuff, which is a very unusual situation that we don't think much about."

Rising use of lawn chemicals concerns state officials

Mr. BEDELL. Thank you very much, Ms. Smigel.

Mr. Brown.

Mr. BROWN. Thank you, Mr. Chairman.

I would like to say I think this panel has touched on several areas of very deep concern to the committee, and it is my hope that we can improve the administration of the law to cover some of the situations that have been discussed here.

Mrs. Prior, I am deeply disturbed by the story that you have given us this morning with regard to your husband. I assume that your husband had an initial sensitivity to this chemical; that is what the evidence seems to indicate.

Mrs. PRIOR. He was certainly not sensitive that we were aware of beforehand. He was perfectly healthy; had no allergies that we were aware of.

I don't believe he is unique. I believe that only the research is unique.

Mr. BROWN. I am sure he wasn't unique. The question is, even if one person suffers these kinds of difficulties, that is sufficient to be deeply concerned. But we also need to be concerned about how many others might experience the same or even some lesser degree of difficulties as a result of this.

I was wondering if the research with regard to your husband's case had indicated the degree to which others might be sensitive, also.

Mrs. PRIOR. That wasn't addressed in the autopsy. I am aware of at least four to five other cases of the same illness that are documented, caused by a similar pesticide. Unfortunately, without an adequate autopsy and research, it will be impossible to come to the bottom of other deaths that are similar.

Mr. BROWN. Do these other similar cases—did any of them arise out of the situation at the Army-Navy Country Club?

Mrs. PRIOR. No, not there. There were cases of fumigation of homes.

Mr. BROWN. Can you repeat again the experience you had with EPA on this? As far as you know, they have been nonresponsive to your requests for information; and do you know if they have taken any corrective action at all with regard to the use of this particular fungicide?

Mrs. PRIOR. In the last year, my lawyers have written to EPA several times. I cannot give you dates or accurate numbers of letters. I can tell you they have never even had the courtesy of a response saying, "We received your letters." Nothing has been received.

Mr. BROWN. You know of no action that they have taken to prevent the recurrence of something of this sort?

Mrs. PRIOR. I know of no action.

Mr. BROWN. Mr. Chairman, I would like to request that the subcommittee request of EPA an analysis of this situation and a statement of their own views with regard to the reasons for their failure to take any action on the case.

Mr. BEDELL. Is there any objection?

If not, it is so ordered.

[The material follows:]

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUL 15 1985

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Honorable Berkley Bedell
Chairman
Subcommittee on Department
Operations, Research and
Foreign Agriculture
Committee on Agriculture
House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

During the May 20 hearing before your Subcommittee concerning reauthorization of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), Mrs. Liza Prior, a citizen testifying about the death of her husband, indicated that she has experienced difficulty in getting information from the Environmental Protection Agency (EPA). Mrs. Prior believes the death of her husband was the result of exposure to chlorothalonil, a fungicide, used on a course where he played golf. Mrs. Prior is seeking information from EPA in connection with a pending lawsuit against the registrant of the fungicide and the golf course.

We have been in contact with both Mrs. Prior and her attorney, Mr. Edwin C. Brown, Jr. Consequently, we have determined that we did receive a general request from Mr. Brown. This request did not identify either Mrs. Prior or chlorothalonil but concerned criminal investigations involving Industrial Bio-Test (IBT). We had no other record of any contact by Mrs. Prior or her attorney. Mr. Brown's request was referred to our Office of General Counsel by the Office of Pesticide Programs (OPP). The request was apparently not properly tracked and a response was not made. The Office of General Counsel will be responding to Mr. Brown. Basically, Mr. Brown requested information indicating that chemical companies sponsoring studies carried out by IBT had prior knowledge of the problems with studies and the fraudulent test reporting by IBT. Let me assure you that EPA has no evidence that any manufacturer or registrant of chlorothalonil had any knowledge of such problems.

As a result of our discussions with Mrs. Prior and Mr. Brown, information beyond that originally requested has been identified. Specifically, we will be providing to Mrs. Prior the studies supporting the Registration Standard for chlorothalonil, including the requested toxicological data. In addition, we have provided Mr. Brown with information concerning labeling requirements and Mrs. Prior with the the Pesticide Incident Monitoring System report on chlorothalonil.

As you know, section 10 of FIFRA permits the Agency to release pesticide health and safety data to the public. It also requires EPA to protect data which are determined to be trade secrets or commercial or financial information, commonly referred to as Confidential Business Information (CBI). In order to ensure that the Agency does not release CBI, we ask the owner of the data to review the studies and make its CBI claims prior to release. This process is specified in our regulations (40 CFR 2). The owner of the data then has 15 days after receipt of the request to respond to EPA.

We have completed preparation of all studies and have forwarded the studies, in two separate submissions, to the owner with a request for an expedited CBI review. Barring any unforeseen problems, we hope to be able to forward the first group of studies to Mrs. Prior by July 24 and the remaining studies to her by July 31.

We sincerely regret the difficulty encountered with the original request submitted by Mr. Brown. I believe that we have now provided the necessary assistance to Mrs. Prior and are responding to her requests as expeditiously as possible. Please be assured that my staff will continue to follow up on Mrs. Prior's request to ensure that she receives all the information she has requested. If, in the meantime, she should have further questions, she may call Mr. Lou True, Director of the Program Management and Support Division, who oversees OPP's Freedom of Information requests.

Finally, to ensure that problems of this nature do not occur in the future, we have recently examined our FOI procedures and have instituted appropriate changes. The Deputy Director of OPP, Ms. Susan Sherman, is personally monitoring this program and will make any additional changes that may be necessary to remedy future problems of the kind experienced by Mrs. Prior.

If I may be further service, please let me know.

Sincerely yours,

John A. Moore
Assistant Administrator
for Pesticides
and Toxic Substances

Mrs. PRIOR. Thank you.
Mr. BROWN. I have no further questions.
Mr. BEDELL. Mr. Evans.
Mr. EVANS of Iowa. No questions.
Mr. BEDELL. Mr. Combest.
Mr. COMBEST. No questions.
Mr. BEDELL. Mr. Gunderson.
Mr. GUNDERSON. Thank you, Mr. Chairman.

This may be a followup to Mr. Brown's question. I would be interested—Mrs. Prior or Mr. Menichino can respond. In your statement, Mr. Menichino, you indicated that there was the reaction of EPA in the 1970's. To your knowledge, has there been some change in the regulation of Chlordane? I am trying to find out, is the situation today identical, in terms of the regulations, as it was in the 1970's, to which you refer; or are you simply referring to something that happened back then, recognizing but not suggesting in your testimony there has been a change?

Mr. MENICHINO. What the situation was was that chlordane had many uses before EPA acted in the 1970's. It could be used on agricultural crops, also. EPA eliminated its use to subsurface injection for termite treatments and for dipping of nonfood plants with the belief that human exposure would be low. That was the purpose of EPA's action in the 1970's, was to eliminate the possibility of human exposure to this compound.

We now know that human exposure is taking place in the homes, and we need to protect the public from that exposure.

Mr. GUNDERSON. You are saying that regulation is not adequate; what we need to do is ban?

Mr. MENICHINO. I think what the New York situation has proved is regulation that is inadequate; it cannot prevent misapplications. And the United States nor New York has enough funds to police every licensed applicator in this country.

Mr. GUNDERSON. I recognize that. One of the questions which may be difficult to answer today—I would be interested, if either of you are considering sharing with the subcommittee a written response—would be exactly how the process seems to be changed to better deal with this particular chemical? I think that is what we are interested in. In reauthorization, I don't think anyone in this room would want us to begin the process of, by legislation, legalized, or making illegal a particular chemical—I am not qualified to do that. I don't want to suggest to you I am—I don't think this coverage of the United States in the political environment is qualified to do that, what in the process needs to be changed. It would be very helpful to us.

I found it very interesting, on page 3 of your testimony, you said—confirmed our own findings and urge that nonagriculture use of pesticides be monitored more carefully. It kind of jumped out to me because I think this committee so often looks at what can be the proper regulation and use of chemicals from an agriculture perspective. You touched on a new issue.

Are you suggesting we really ought to have different standards for regulation?

Ms. SMIGEL. I believe there should be some coordination that would bring in agencies such as the Consumer Product Protection

Agency and the health department and something like that. I am not suggesting setting up another bureaucracy, but I think there could be some kind of method to look at this with a coordination of other groups who are interested in public health.

I also think that local legislators should not be closed off from taking action, as has been done, which has been called reasonable. And I think a mild sort of thing that they are doing in Montgomery County, which of course is not enthusiastically greeted by the industry, putting out a simple marker and the right to know, the right to information, I think should be a right that is that of every citizen of the United States.

Mr. GUNDERSON. That puts us on a very difficult and controversial question for this subcommittee, and I guess this Congress has been unable to resolve for the 5 years I have been here, and that is: How do we deal with the local rights to be involved and their right to know, and at the same time trying to prevent a situation where we have 50 different regulations of chemicals used in the country from the State perspective, saying nothing of local justifications.

Above and beyond that, I am sure you can assume if that happened there would probably be little or no enforcement, there would be no consistency of law, and everyone would simply ignore it in their general commercial and trade.

You have got some ideas for us?

Ms. SMIGEL. There are two problems, of course—the fact that most homeowners, as I said, are unaware there is any need they should look into these things, we need to awaken their questions.

The other thing is, people have a right, for instance, in something so simple as smoking and nonsmoking, to be protected against that kind of thing, especially in their own homes. That right should be able to be delegated as they have done on community levels; community levels have enacted such legislation like that.

Mr. GUNDERSON. There might be a compromise here whereby we can look at States, or the Federal Government would be the legal—but to allow local jurisdictions the authority in terms of notification, right to know those. There may be some kind of balance there.

Thank you.

Mr. BEDELL. Mr. Penny.

Mr. PENNY. No questions.

Mr. BEDELL. Mr. Morrison.

Mr. MORRISON. No questions.

Mr. BEDELL. Mr. Gunderson, if you desire more time, the chairman will be glad to yield.

Mr. COMBEST. From your own personal situations, having been involved with use of pesticides, would you say that in your experience the biggest problem would have come from the chemical itself or the misapplication of that chemical?

Mr. MENICHINO. I would have to say that it is from the chemical itself. In the case of Chlordane, the manufacturer of the chemical has been well aware for many years even when the product is properly used according to the EPA directions and labeled instructions, that levels can occur in the home which approach the NAS guideline. So what we are saying is that even if they follow the label,

people are going to be exposed to the chemical. The manufacturer is aware of that. There have been studies done that show it.

Further, once the chemical is in the air, once a surface is treated with the chemical, there is no way to decontaminate that surface. Decontamination involves ripping houses apart, to the tune of in excess of $50,000 or $100,000. One case in New York, the house was demolished, knocked down.

Mrs. PRIOR. I don't know which was greater at fault. I believe both.

Mr. COMBEST. In your specific instance, did there seem to be—or do you have any facts or knowledge of the fact there actually had been—a misapplication when that was treated?

Mrs. PRIOR. I have no knowledge of that whatsoever. I have read the label myself. I am not certain what is known about applying it and what directions were followed.

Ms. SMIGEL. Our position is that chemicals are selectively useful, but they should also be used with prudence and common sense and people need the proper and appropriate information as to how these chemicals are registered, that they are not approved, the risk and benefit, so they can evaluate and make responsible choices.

Mr. COMBEST. I guess it was your testimony which seemed to include a broader range of chemicals than the other two witnesses were specifically talking about. I would understand that, being from the garden clubs, I seem to read into yours, or seem to understand what you were saying, at least you are directing more in terms of misapplication, or it was not being applied correctly, or it was not proper notification, rather than specifically a problem about the chemical itself.

Is that incorrect?

Ms. SMIGEL. I think you have said it fairly correctly. The main point is that the public needs information of the risk and the benefit, and they need to know what the chemicals are so that they can evaluate. That is what we want the applicators—to let them know, so they can make a decision whether they want this on their lawn at all. If they do have it, what precautions should they take, if they decide. It may be a problem that doesn't need to be treated.

That is one of the areas that we found things are often just given a shotgun approach when there is a preventive application, when there is no need of course that is damaging to the environment—they be used selectively, carefully, such as integrated pest management—great caution.

Mr. COMBEST. Thank you, Mr. Chairman.

Mr. BEDELL. Mr. Morrison.

Mr. MORRISON. Just one question, Mr. Chairman.

Mr. Menichino, I think in response to Congressman Combest's question you said the chemical itself was the problem. Yet, I think your example was strictly in the use of chlordane in the application in homes for termite control.

Is that accurate?

Mr. MENICHINO. What I meant to say is that there can be misapplications of the product by applicators, but there is also evidence to show when the product is properly applied, according to labeled instructions, that levels can still occur in the home subjecting the humans in the home to exposure.

Mr. MORRISON. You did not mean to imply other uses of chlordane have been more successful through the years in those uses that don't involve homes?

Mr. MENICHINO. I don't think I understand your question.

Mr. MORRISON. Chlordane is used in a variety of ways. When you said that the chemical was useful, it was part of our efforts here to decide what to do about this.

Mr. MENICHINO. The only varieties of ways the chemical can be used according to the EPA is subsurface, being nonplant foods.

Mr. MORRISON. You don't question those procedures. Your questioning is about the use in homes?

Mr. MENICHINO. No. I don't question the dipping of nonfood plants; just in the home use.

Mr. MORRISON. Thank you, Mr. Chairman.

Mr. BEDELL. Are there any further questions?

If not, we certainly appreciate your testimony. It has been very helpful, certainly very moving to many of us, and we appreciate the fact that you have come and that you have testified, and we want to thank you all very, very much.

Next we have a panel: Robert M. Russell, Robert Dold, and Ed Duskin.

Congressman DeLay, who is from Texas, is here, and he will introduce each one of the witnesses.

Are we correct that you have been in the industry?

STATEMENT OF HON. THOMAS D. DeLAY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. DELAY. I am in the industry, and I still have a pest control company. But I did fall under the guidelines of outside income.

Mr. BEDELL. Apparently, you and Congressman Ray have personal knowledge of this issue and had experience in it. We are going to lean upon you, if we might, for some of your expertise.

Mr. DELAY. I would be glad to, Mr. Chairman.

With your permission, I would like to give you a little of my background.

I have a degree in biology and a minor in biochemistry from the University of Houston. My first job out of college was with a pesticide formulation and supply company, Redwood Chemical in Houston. After about 4 years of running that company, I went into business for myself and built a rather nice, little company in Houston, TX, called Albo Pest Control, which I still have. I have crawled under houses, I have been drenched in the so-called bad chlordane, and I have had accidents with this and other products.

I know that we are not here this morning to talk about registering chemicals; we are here to discuss the use of these chemicals. It has been my experience that homeowners, are very concerned about the benefits and risks of pesticide use and usually ask what we are using and how we plan to use it. Let's face it, we are not talking about a $20 job, we are talking about a $500 up to $1,200 job. Homeowners are not going to spend that kind of money unless they know what is involved. Pesticide applicators explain to the homeowners that pesticides can be dangerous if they are misused and proceed only with the consent of the homeowner.

I don't think any law requiring the applicator to tell the homeowner what he is using will change anything because 90 percent of the time the applicator informs the homeowner anyway.

I would like to respond to a previous panelist's reply to Congressman Combest's question, Is the chemical the bad guy or is the misuse the bad guy? The panelist said the chemical is the bad guy. That makes about as much sense as blaming the gun for a murder and punishing the gun rather than the murderer. Because the gun was misused by a person, you go after the person that has misused it. It's common sense: treat the cause not the symptom.

I have been in this business since 1970 and have lived under FIFRA since it was passed. I think there are some problems with FIFRA that tie a pest control operator's hands. To make FIFRA more restrictive, even more than it is now, would be very detrimental to this business, a business that protects the health and property of the citizens of the United States.

Pest control operators will tell you that the problems we are encountering right now in trying to get insurance stem from all the media hype and scare tactics currently employed against this business and against FIFRA. Unfortunately, these same tactics can affect the purpose of chemical testing.

I remember when the EPA was trying to ban chlordane. For the purpose of experimentation, mice were raised to contract cancer with and without chlordane. In the first test they were using as background to ban chlordane, the control mice not impregnated with chlordane contracted more cancer than those mice that were impregnated with chlordane.

The lawyer for Velsicol who went before the administrative judge concluded that it was obvious that chlordane cured cancer because the chlordane mice contracted less cancer than the control mice. It makes as much sense to conclude the opposite, that chlordane causes cancer because a mouse contracted some cancer by being impregnated with chlordane. Chlordane is not the problem.

I will be glad to answer any questions you may have of me after the following testimonies. Now I would like to introduce Mr. Dold, the past president of the National Pest Control Association, who will share his experience for the benefit of this subcommittee.

Mr. DOLD. Thank you.

Mr. BEDELL. Why don't we hear from you first, Mr. Dold.

STATEMENT OF ROBERT J. DOLD, IMMEDIATE PAST PRESIDENT, NATIONAL PEST CONTROL ASSOCIATION, ACCOMPANIED BY GEORGE RAMBO, TECHNICAL DIRECTOR, AND DIRECTOR OF EDUCATION AND TRAINING, AND JACK RYAN, DIRECTOR, LEGISLATIVE AREA

Mr. DOLD. Thank you, Mr. Chairman.

I also would like at this time to introduce Dr. George Rambo, our technical director of the National Pest Control Association, and director of education and training, who is with us here today; and also Mr. Jack Ryan, who is director of our legislative area.

Mr. Chairman, I am pleased to be here and testify before this subcommittee. My name is Robert Dold. I am the immediate past president now of the National Pest Control Association, which is a

national trade association of pest control, structural pest control operators from around the United States, and includes a number of foreign countries. I am also president of the Rose Exterminator Co. in Chicago and Hammond Pest Control in Hammond, IN.

On behalf of the National Pest Control Association and its 2,600 members, I thank the committee for this opportunity to present our experience in working with pesticides under the provisions of the current FIFRA.

The members of NPCA are those service companies in the Nation's business that work to protect the public health, our food supply and our building structures from pest infestations and disease vectors carried by these pests. Hospitals and doctors' offices are kept germ free with pesticides. They also keep restaurant and school kitchens free of insects and rodents. Our job is to protect the health and the property of this country, and I am proud that our industry does this.

You need also to know that our members are small independent businessmen. They are hard working. They are concerned. They want to learn. They want to do a good job. They are what I call middle America. Truthfully, they are your neighbors. We are a family owned industry and many firms are passed from father to son as in the family farm.

I am one of those. My father was in the business for 40 years before me. Members of our association do over 70 percent of the structural pest control services that are done throughout our country.

The structural pest control industry has used integrated pest management since its inception for effective pest management. It has not and does not now depend exclusively on pesticides in its work.

Pesticides are an important resource, however, for eliminating and controlling many pest 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 depend exclusively upon pesticides that are classified by EPA for restricted use. We estimate that currently over 95 percent of pesticides used in our industry are the same ones that are approved by EPA for purchase and use by the general public.

In the early 1970's, NPCA supported the legislation which gave the Environmental Protection Agency the 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 its membership, to use only those pesticides that are registered by the responsible authorities of State and Federal Governments in a manner described in the manufacturer's registered label and as recommended by professional authorities in our field.

The NPCA technical guidance is referenced by both Federal and State regulatory agencies on how to safely and effectively control pests—from cockroaches and termites to vertebrates, such as rats and birds.

In general, our experience confirms that the existing law is working to accomplish its purpose of providing for safe pesticide use; it does not need any changes to improve its effectiveness. My belief is that unless it is broken, don't fix it.

The NPCA proposal to the committee at this time is: Congress reauthorize the existing FIFRA for 3 years with no changes in the provisions for pesticide classification and applicator qualifications for pesticide use. Our reasons for this recommendation are based on the following experience.

The EPA records of pesticide poisonings throughout the United States indicate that the annual number of such instances remain stable and are probably decreasing despite increases in the population and the volume of pesticides used.

In 1971 through 1976, the EPA Pesticide Incidents Monitoring Service recorded 900 to 1,000 pesticide poisonings per year of all types nationwide.

For 1978 and 1979, the National Clearinghouse for Poison Control Centers has reported that less than 360 individuals were poisoned and hospitalized by pesticides. This accounted for less than 5 percent of all poisonings of all types for each of those 2 years.

Extensive studies by scientists of this data have found that almost all pesticide poisoning deaths in the USA are resulting from self-inflicted or homicidal incidents. Deaths from pesticide poisonings for subsequent years are estimated by knowledgeable sources to be following the pattern reported by Drs. Hayes and Vaughn.

For January through April 1983, the Poison Control Center of Los Angeles, CA received 24,000 telephone inquiries, and of those inquiries 1,182 were pesticide related. Of this number, 97 percent were consumer-oriented use or misuse pesticide incidents. The remaining 3 percent—35—of the inquiries resulted from pesticide applications by commercial or private—farm—applicators.

My reason for citing these trends is to point out to you that FIFRA in its current form is an excellent piece of legislation that is accomplishing its purpose in making sure that the commercial applicators of pesticides are not creating the problems of pesticide poisoning to the citizens of the Nation. They are trained to apply hazardous materials appropriately and safely under the existing State and Federal laws.

It is our conclusion from this information that if any changes or expanded Government action is needed to further reduce pesticide risks, it is to use the existing FIFRA authority to focus on educating the population that is currently experiencing the pesticide misuse or poisoning: the general use of pesticides—not the commercial and private applicators.

At this point, I would like to compliment Mr. Lee Thomas, the new Administrator of EPA, for his recognition of the need for redirecting EPA's use of resources for focusing on where the problems are occurring. In his comment to the public on April 3, 1985, he outlined his proposals for "The Next Four Years—An Agenda For Environmental Results." In that presentation, he indicated that EPA must, and I quote, "* * * plan controlled solutions with a multimedia prospective. We have to reduce risk and not merely transfer it." He concluded his comments on this subject by stating

that "We, EPA, must focus our resources on the most important problems, and fix them so that they stay fixed."

The National Pest Control Association and its members would like to feel that this means looking at where the problems are occurring and focusing on reducing those risks rather than continuing to focus increased regulatory burdens on the small business community that has an excellent record of safety—and that is continually improving.

On our environmental concerns, the environmental risk from pesticides is an area that EPA has in the past and continues to address with increased intensity, and we think appropriately. We believe that the current FIFRA provides EPA the essential authority and the necessary methods to quickly identify new scientifically confirmed data on environmental or health risks, and to take action to quickly restrict or remove from the marketplace the materials that pose the unacceptable risks.

As far as the appropriate actions, recommendations, we really feel that there are three. They need to assign the responsibilities for training to the employers, would be one recommendation that we would make. They need to strengthen that.

The second recommendation we would make is that we require State enforcement personnel to meet the certification requirement in the areas where they are assigned pesticide enforcement responsibilities.

The third area, we recommend the committee authorize a funding level of at least $5 million per year for the certification of training programs under FIFRA section 23. These funds are needed to provide additional financial and consultative guidance to the States to strengthen the pesticide applicator training and certification programs. Such funds provided for training and certification reduce the need for enforcement action; training does not eliminate the need for a basic enforcement responsibility.

Mr. BEDELL. Are you about through, Mr. Dold? We are trying to hold people to 5 minutes.

Mr. DOLD. Let me conclude by saying this, Mr. Chairman: If there is an area that needs to be looked at at all, the legislative area that probably needs clarification has to do with the State authority. Let me say, in this area, clarification, I come from Chicago, and I feel that the States should be the lowest level of authority in regulating pesticides.

There are some 200 to 250 communities around Chicago. If each community is allowed to regulate pesticides, there is no way that my firm or other firms can possibly keep up with all those regulations of those communities. It is just simply an impossible task for us.

In conclusion, Mr. Chairman, let me say that I am a user of pesticides and I am concerned about my health. I am concerned about the health of my family, about the health of our employees, and about the health of our customers; that I am proud that our industry does protect the health and property of our country.

Thank you.

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

Mr. BEDELL. Mr. Russell.

STATEMENT OF ROBERT M. RUSSELL, ORKIN PEST CONTROL

Mr. RUSSELL. Mr. Chairman, members of the subcommittee, I am Robert M. Russell of Orkin Pest Control. Our company is the world's largest in structural pest control. We operate in 43 States in this country; we employ 5,000 people; we serve over a million customers. We offer these comments for our company, for all other conscientious users of pesticides, and on behalf of our employees and customers.

We are glad that this subcommittee, this congressional body, is examining the issue of safe pesticide use in the context of FIFRA. Pesticides, when used according to the label, protect the food, fiber, structure, health and peace of mind of our Nation—and have done so with an outstanding safety record. If the benefit-risk relationship under the existing FIFRA is satisfactory, then I am sure all of us wish to save the expense which would follow from unneeded Federal law changes and the ripple effect upon the States, industry, and the ultimate payee—our children.

We would like to indicate to this subcommittee the high efficiency and safety of our structural pest control industry.

The latest national report from the Council of Better Business Bureaus, Inc., published for 1983, shows the quality and safety of our industry. Of 409,156 complaints received from all types of companies nationwide, only 1,701 concerned structural pest control companies. The fact that the pest control industry ranked only 46 in the number of complaints, with a percent of the total of 0.42 percent, is an outstanding achievement. Furthermore, this figure represents a significant improvement from the 0.53 percent level of total complaints in 1982.

And if you remember, 1983 was the year when the nationally prominent television program, "60 Minutes," dramatized the risks of a termiticide while hardly acknowledging the benefits. Also, there was additional publicity concerning the Massachusetts hearing and the Long Island House bulldozing.

Fortunately, in that year, EPA, with its "Analysis of the Risks and Benefits of Seven Chemicals Used for Subterranean Termite Control," stated on pages VI—1 and 2:

> At this time, in assessing the risks and benefits associated with the total national use of the termiticides based on available data, and considering the lack of data outlined above, the agency finds that the benefits from the use of the currently registered termiticide products outweigh the potential risks.

Accordingly, these pesticides are still registered by EPA. Moreover, most of the pesticides we use are categorized as general use rather than restricted use pesticides.

There is also some very encouraging data being published relative to the safety of the pesticides used by the structural pest control industry. A recent study by the California department of food and agriculture, worker health and safety unit, showed that only 3 percent of pesticide accidents were caused by the structural pest control industry. This study covered the year 1982.

In another California study, the Poison Control Center of Los Angeles, during the period January through April 1983, received 24,000 telephone inquiries. Of the 1,182 pesticide related calls, 97 percent concerned pesticides purchased by all consumers. Only 38,

or 3 percent, related to pesticides applied by pest control operators, and none of these could be classified as poisonings.

These studies strongly indicate that accidents resulting from trained applicator misuse are infrequent and a small percent of the total.

We next would like to comment on the general good health in this country and the steady improvement in life expectancy. In my statement, there are figures from the "National Center for Health Statistics, Life Expectancy Data for 1981, section 6, Life Tables." And to show the relative safety of pesticides as compared with other substances and practices in this country, we are presenting a chart from an article published by Scientific American in February 1982, the "Biological Effects of Low-Level Ionizing Radiation."

Please note from this study that pesticides are ranked only 28 out of 30 factors, and deaths per year do not constitute any significant threat to life or health as compared to many other substances or practices.

I also wish to address the issue of the application of restricted use pesticides by or under the direct supervision of a certified applicator. This is now required by Federal law and rightly so for those supervisors of a work unit such as a structural pest control branch office. The existing law acknowledges the structure of our industry by defining "under the direct supervision" of a certified applicator to mean that the certified applicator must be available but not physically present.

There are some who now advocate testing or certification for service technicians at the supervisory level of the certified applicator. This suggestion is, one, unnecessary in light of the safety record of the pest control industry, and two, completely incompatible with the structure of that industry.

First, service technician and certified applicator represent two separate and distinct positions. To show the difference in required knowledge and skill at these two levels, our company position descriptions for the two positions are attached. We believe all or most other pest control companies would show an equivalent difference in duties and responsibilities.

To require each position to be tested equally would result in one of only two probabilities. Either the standards for the certified applicator would be reduced—and this is counterproductive—or these standards would remain above the normal ability of the technician. This, too, would be counterproductive. The latter situation would result in manpower shortages, increased costs to customers, and no effective increase in safety.

We earlier documented that the majority of pesticide accidents result from consumer use. What advantage is there to certifying technicians while about 97 percent of the problems originate with consumers? Are we looking in the right direction? With public access to the same pesticides we use, why focus on technician certification?

The FIFRA Coalition, a responsible body representing millions of concerned people, has made constructive comments in this area and as a participating member of the National Pest Control Association, we support its position. The FIFRA Coalition has proposed

to resolve this matter by focusing on the training provided to service technicians.

In this respect, we would note that the regulations issued under section 4 of FIFRA—40 CFR 171.6(a)—offer broad possibilities for training. We definitely support initial and continuous training of technicians as a superior alternative to testing.

In conclusion, I would repeat that if proof of need for change in the scope of certification is presented, our company and our industry would support a review of this issue. The expense alone of unnecessarily broadening a successful system would create an extreme burden upon the States, the industry, and eventually our customers. Training, not universal certification, offers the best avenue for continued improvement.

By law, establish only those requirements that are absolutely necessary for safety. And let us go forward with our successful system, using the established progress and good record of our industry as a base.

I thank you for this opportunity to present this testimony, and I would be happy to answer any questions which you might have.

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

Mr. BEDELL. Mr. Duskin.

STATEMENT OF EDGAR W. DUSKIN, EXECUTIVE VICE PRESIDENT, SOUTHERN AGRICULTURAL CHEMICALS ASSOCIATION

Mr. DUSKIN. Good morning, Mr. Chairman and members of the subcommittee. I am Edgar Duskin, executive vice president of the Southern Agricultural Chemicals Association.

To place our association in proper perspective, I would like to tell you a little about SACA, as we call it. We are an independent regional association representing the interests of the agricultural pesticides, formulators, distributors and manufacturers who sell their products in 13 southern States. We are based in Dawson, GA. The association was formed in 1954 in North Carolina, originally representing only the interests of formulators and distributors in Virginia and the Carolinas.

Over the years, the industry's interests have caused SACA to expand throughout the South. While we have some overlapping members and much commonality of interest with other trade associations testifying here before you, we speak primarily for those firms in the agricultural chemicals business who are independent regional or intrastate formulators, distributors, and dealers whose interests and viability also are critically affected by the actions you will take as a result of these and other hearings.

On April 18 we heard with interest the testimony of Dr. Moore and responses to questions posed by the subcommittee. Till now, we have not seen draft legislation from EPA or the subcommittee. We therefore can offer comment only on the general statements made and certain specific items.

On balance, we would just as soon see a simple 2-year reauthorization of the existing FIFRA. At this time, it does not require major restructuring. There are perhaps a few fine-tuning amendments which might facilitate its operation. Adequate resources ap-

plied in the right places in EPA would do more than fiddling with the law, in our opinion.

In the event it is decided to amend the law, our segment of the industry also would support stronger penalties against willful violators and falsifiers of data to include cancellation, fines, and jail. Nondisruptive lab and other inspections should cause no problem. We are confident that in light of recent unfortunate happenings all labs and data are justifiably subject to much closer scrutiny and supervision both by ourselves as well as regulators. Sometimes some seem to forget that we too are very much embarrassed when we learn of accidents or misdeeds. Public confidence in our product's effectiveness and safety are just as important to us as to those outside our industry.

Of major concern to us is the slowness of the registration process for me, too and new uses, as well as for new products. We hope that resources allocated in EPA's budget to product registration, both internally and by the Congress, will be generously looked at.

At the same time, while on that subject we continue to strongly oppose the imposition of substantial fees for registration of products. The burden of such invariably falls disproportionately on the formulator-distributor, who may have many end-use labels for different formulations and mixtures of the same active ingredients.

A potential problem of unrestrained and uncoordinated regulation continues to evolve as more and more localities attempt to severely restrict or ban use of certain pesticides. Except in extremely rare cases, these actions are based on emotional reaction to fears generated by various sources. Localities lack expertise to critically and scientifically evaluate the problem.

We believe regulatory actions should, at the lowest, be controlled at the State level where expertise is available. Preferably, this authority should not be delegated; however, a system of State approval of local actions, as in California, could work in some States. Though a State now may take action to set the lowest level of regulatory authority, we believe it preferable to clarify the authority of States and intent of Congress in its choice of language in sections 24(a) and 24(c).

We believe it would improve efficiency and reduce State requests for duplicate testing if EPA-held test data could be shared with States when its laws concerning protection of data are equally as stringent as Federal requirements.

We strongly oppose removal of requirements for EPA to indemnify owners and requirements to assume responsibility for disposal of pesticides when they are summarily suspended. This provision was placed in the law to protect small businessmen who, through no fault of their own, could be caught with a large portion of their assets in unsalable or unusable inventory with no recourse. We sympathize with EPA's problem of unbudgeted expenses, but do not believe this responsibility should be passed on to distributors and users. It would seem that a budgeted fund could be established in EPA to take care of such problems.

The right to judicial review of arbitration decisions under section 3(c) should be afforded.

We believe that authorization for EPA to establish separate simplified standards for low toxicity or low exposure products of the

home and garden, horticultural, and sanitizer variety would greatly facilitate speeding up the registration process since it would allow such products to be rapidly processed through the system, thus allowing more time and resources to be allocated to those posing greater risk.

Automatic cancellation of Federal registrations for section 24(c) State registrations, when such are cancelled by the issuing State, should be authorized.

We understand the desire to improve safety in pesticide application through proposals to modify the provision which now authorizes restricted use pesticides to be applied under the supervision of a certified applicator. However, allowing restricted use pesticides only to be applied by certified applicators could place impossible burdens on farmers and end users. We believe that improved training of all applicators is the real key to improving safety in application. Our efforts should be directed toward this instead of simply attempting to tighten rules on who may apply pesticides.

Thank you for your attention and this opportunity to express our views. I shall be happy to attempt to respond to any questions you may have.

Mr. BEDELL. Thank you very much, Mr. Duskin.

Mr. Brown.

Mr. BROWN. Mr. Duskin, you seem to concur with the other witnesses that there aren't any substantial changes required in FIFRA and that the nature of the changes that you discuss are in the nature of a fine-tuning. Is that an appropriate way to describe it? Most of the proposals, the suggestions that you make seem to coincide with those that EPA has suggested with the exception of that compensation for cancelled products. We have to look at that from the standpoint of the taxpayer. It is a rather severe burden over all.

I think the figure that we were given was something like $5 million, some recent year, maybe it was last year. Do you think there is any possibility that this situation could be handled in a mutually satisfactory way without increasing the Federal budget? Is there a possibility that it could be handled through the way in which you write your contracts with your suppliers or through some form of insurance, or some other system of that sort, that would spread the burden?

Mr. DUSKIN. It is entirely possible there are many ways to work it out. Right now we have in the law the indemnification without funding.

Mr. BROWN. We have the indemnification and we don't have a budget item for it, so it comes out of the hide of other programs. And you have indicated that we are already shorting some of these other programs. We need additional funds for training and for some other things. We have to find some satisfactory way of handling this.

It doesn't look too promising that we are going to get a large increase in EPA's budget, and so we have to explore other possibilities, even the medical profession, which has been faced with serious problems of malpractice suits and so on, and has had to invent some ingenious ways of covering this with insurance rather than having the taxpayers take up the cost of it.

Mr. DELAY. On the compensation issue, let me give you an example of how when the government, particulary the Federal Government, gets involved in taking a product off the market by using, in my opinion, somewhat suspect testing methods. Right now in Texas and thoughout much of the South, there is a tremendous problem with the imported fire ant that is migrating north. The fire ant gets into fields and tears up machinery and kills calves that are born on the mounds in yards. My own daughter was in a fire ant mound and was completely covered with fire ants in just seconds. If you have ever been bitten by fire ants you know the pain and the blisters that they cause.

The only material that was effective against the fire ant was a chemical that had been banned. Later it was found that the chemical should not have been banned after all. In the meantime, the Mississippi manufacturer that had been producing it went out of business. Even after Mirex was reregistered nobody would produce it. You can see how damaging this mistake was. Not only did the manufacturer lose a tremedous amount of money, not only did Mississippi suffer from a loss of jobs, but fire ants are still spreading through Texas and many other States.

So the question of compensation is indeed a thorny one. I am not sure that I can support the Federal Government compensation except in this type of situation where Government action erroneously put a company out of business.

Mr. BROWN. I appreciate that suggestion. That would certainly limit the taxpayer's liability if it could be limited to indemnification only in those cases where the Government made a mistake in cancelling the chemical. There aren't too many cases of that sort. My recollection may be one of them. There are a lot of cases where chemicals have been cancelled and the holders of those chemicals have been indemnified for it.

Thank you, Mr. Chairman.

Mr. BEDELL. Mr. Combest.

Mr. COMBEST. Thank you, Mr. Chairman.

Gentlemen—it might be directed to any of you—in the case where we are talking about a restricted use of pesticides being applied under the supervision of the certified applicator rather than specifically by a certified applicator, how do you adequately oversee or monitor the activities of the service technician who might be many miles away from a certified applicator?

Mr. RUSSELL. The present law in section 4 addressed this point I think fairly adequately. First, they stated that there must be verbal training, instruction, between the certified applicator and the technician.

Second, they state that he must be available, if not necessarily directly on the job site, with the technician.

Third, they define that that technician must be competent. That is in the law. I think this assures if there is a level of training and supervision that the end result of the technician use is satisfactory.

Mr. DELAY. I might go further than that to answer your question, how do you supervise when the technician is miles away. In my own company, my supervisors are certified and don't start a termite job unless the supervisor is at the site that morning. He may not stay on the site throughout the job, but he comes back

that afternoon to make sure that the job was done properly and closed properly. So, in the case of my company—of course I can do that a little bit easier than the big boy like Orkin—we have hands-on supervision of our technicians.

Mr. RUSSELL. What can I say now?

Mr. COMBEST. Thank you, Mr. Chairman.

Mr. BEDELL. Mr. Morrison.

Mr. MORRISON. Thank you, Mr. Chairman.

Mr. Duskin, perhaps your are the best one to answer this question. Are the States in the South, where your chemical association is active, making progress or have fairly uniform programs of training of farm applicators of pesticides?

Mr. DUSKIN. The training is primarily through the Extension Service and it is toward certification of those that require certification. The training of an individual applicator per se, the guy who drives the equipment, could be trained, is probably trained by either the, if he is working for a professional applicator of course he is trained by him or trained by the certified farmer on how to run and operate the equipment and how to apply it safely. There are no State programs that I am aware of that train all applicators per se, certified or uncertified.

Mr. MORRISON. Have you seen movement in the direction of better and better State programs in recent years as far as the training and certification process?

Mr. DUSKIN. I think we have only had one major program but there are efforts in all the states and EPA to rework the core manual, so to speak, and improve the quality of the training. I think you will see it ongoing through all the States in the South. People are becoming more and more interested in being certain that the products work right and are put on right and that we don't have these risks from misapplication that could be caused by lack of knowledge.

Mr. MORRISON. Do you belive that the certification programs that are in place are partially responsible for the improved safety record that we have seen?

Mr. DUSKIN. I think it is absolutely a great major factor and I would like to see it continued and funded to even a greater degree.

Mr. DELAY. If I may respond. Frankly, I fought the FIFRA and the certification in Texas. In fact, the certification in Texas is what got me into politics; the next year I ran for the State legislature. But I must admit that I felt the licensing was anticompetitive, and I have even fought my own industry to stop the anticompetitive regulations. But I also must point out its benefits on the training and educational levels and on structural pesticide controls. In the agricultural areas in Texas, our Extension Service holds pesticide seminars on a regular basis through our county agents.

On the structural side of pest control I have seen gentlemen and ladies that barely got out of high school running their own companies. At the beginning of the certification process, many of them withdrew because it scared them half to death. But the ones who stayed in and studied hard to be certified became better biologists and entomologists and certainly better professionals because of it.

I can give you all kinds of horror stories. I won't take up your time but maybe privately we could talk about some of these people

to whom, before certification, I would not even sell chemicals because I feared they would kill themselves. Because of the certification process I have seen a vast improvement in the professionalism in our industry. However, if you go too far out of harassment, regulation becomes counterproductive to what we are trying to achieve.

Mr. MORRISON. We appreciate whatever got you started in politics you shifted from one kind of pest to another.

Mr. DELAY. Thank you.

Mr. MORRISON. Thank you, Mr. Chairman.

Mr. BEDELL. Thank you.

Mr. Menichino indicated that in 1980, his home was treated by a licensed pesticide applicator to prevent termite problems, and he claims that this caused a serious health hazard for his family. Do you believe that he is incorrect in that testimony.

Mr. DELAY. No.

Mr. BEDELL. What is your reaction to the testimony?

Mr. DELAY. I understand your problem, Mr. Chairman, but let me say that I have no doubt that he is telling you the truth. There are exceptions to every rule. A license doesn't make you good, and no amount of further regulation is going to make you any better. In any industry in America you have the good guys and bad guys. Fortunately, in our industry the bad guys are fewer than in most industries.

If more and more regulations and more certification restrictions are placed on an industry, you could follow that with restrictions on lawyers, doctors, and real estate agents. Every industry has people that many would not like to have in its industry. But, by and large, if you look at the safety records of the pest control industry and the intense commitment of my State and other States to continuing education in the area, you will probably find that our industry is safer than most unlicensed industries.

Everybody makes mistakes and I have made my share of mistakes, but I have never been brought before a board. When I make a mistake, I go back to take care of that mistake. But one or two isolated houses in New York do not mandate shutting down an entire industry that protects the health and fiber of our citizens.

Mr. BEDELL. I don't think the issue is whether you are going to shut down an industry. The issue is what could be done, if anything, to address the problem, if a problem exists, and I guess the question would be, if Mr. Menichino is correct that that did happen, what can be done? Can a house be decontaminated somehow? What could be done?

Mr. DELAY. I know the case that he was talking about, and I agree with him that those houses probably will have to be replaced. But there are millions of houses and only a couple of incidents of contamination. I disagree with his testimony because we could show you as many studies to dispute him as he has studies to support his claims about chlordane.

He made a statement earlier that when you put something on the surface of a baseboard it cannot be decontaminated. Most of the chemicals other than most of the pesticides that we use—chlordane, heptaclor, or chlorinated hydrocarbons—are organo phosphates that naturally break down under pressures of sunlight, humidity and water. As they age, they decomtaminate themselves. So

his claim that that pesticides cannot be decontaminated is totally false and makes me suspect the rest of his testimony.

Mr. BEDELL. If his testimony is correct, and if you are correct, then you have to tear the house down. If that is correct, what recourse does he have under current law?

Mr. DELAY. He has recourse of normal law where he could seek relief through the courts and go after the pest control operator that misused that pesticide.

Mr. BEDELL. Should there be anything in legislation that would make it easier for a person to seek damages if that indeed happened?

Mr. DELAY. If that happens, I don't know many lawyers who would turn down the case because the return for the lawyer would be tremendous. You are not talking about a thousand-dollar law suit, you are talking about hundreds of thousands of dollars. I think we have recourse now—we have it certainly in Texas. If we pest control agents misuse pesticide or if we commit fraud, the citizen has resources available to him. Additional laws will not change that.

Mr. BEDELL. Any further questions?

If not, we thank you for your testimony very, very much. We appreciate your being here also.

Mr. DELAY. Thank you, Mr. Chairman.

Mr. BEDELL. Our next panel is Mr. Malcolm Moore, Auburn, KS; and Mr. Norman Freestone, Ecology Sound Farms, Orosi, CA. We will hear from you, Mr. Moore. We will ask you to hold your testimony to 5 mintues.

STATEMENT OF MALCOLM MOORE, FARMER, AUBURN, KS

Mr. MOORE. Thank you, Chairman Bedell. My name is Malcolm Moore and I am a farmer from near Topeka, KS. My wife and I farm over 1,000 acres of wheat, soybeans, corn, and milo. We also run a cow herd which usually includes around 100 head of cattle. With the farm ground, pasture, and hay meadows we lease over 3,000 acres. This is a medium to large operation of our area.

This past fall I was hired by the Kansas Chapter of the Sierra Club in Topeka to lobby for them during the legislative session. Until this time our only income was from the farm. Since 1980 the weather and farm prices have forced us to look for other options for some off-the-farm income. I was asked by the Sierra Club to testify today on behalf of the many farmers who use chemicals.

My main use of farm chemicals involves herbicides for corn and soybeans and spraying of 2-4-D in pastures. We stopped using 2-4-D approximately 5 years ago because of drift problems. We live close to Topeka and we have a lot of 5-acre plots with houses on them next to the ground that we farm and rent, and we were having too much of a problem with the drift.

Although most of the farmers in our area greatly benefit from the use of herbicides, we are not totally dependent on them. The benefits are noticeable with most fields being reasonably free of weeds. But talking to some of your neighbors you soon realize that farmers pay the price for the weedless fields, not only through the actual cost of the chemicals but through the mental anguish of not

knowing whether the chemicals cause health hazards to the farmer and his family.

The family farm may be still alive, I am not sure. When you have your children, and members of your family working in the field with you, it concerns you. When you handle these chemicals you are not sure what they do.

Health risks are encountered through exposure when mixing or spraying, or by inhaling dust while incorporating the chemicals into the soil, or by ingesting residues through foodstuffs. This is in the back of every farmer's mind in the United States.

Another problem is flooding in the area when the top 8 inches of soil are washed into the rivers. All these chemicals are then in the water supply of the cities downstream.

Farmers are concerned that the chemicals they are using haven't been fully tested for long-term health effects. We sometimes feel like guinea pigs or the canary that sits in the coal mine. The farmer, the extension agent, and the general public need to have these questions answered fully and truthfully.

We know that a lot of the chemicals are unsafe when after using them for 5 or 6 years, suddenly they are taken off the market. Herbicides my father used 30 years ago are now outlawed, and I am sure 30 years from now most of the chemicals I use will be off the market.

The cancer rate for farmers is considerably higher than the national average, and I am sure the exposure to farm chemicals causes most of the increase.

Most of a farmer's information on pesticides comes from the chemical companies themselves. The only information we get through the local salesman is the chemical salesman that comes around to the local co-ops or feed stores and this is where we get most of the information. We have a great need for unbiased testing of these chemicals before they reach the market.

A farmer has enough stress from all the variables of weather and prices. We shouldn't have to worry about using unsafe products. We have learned in our operation that it is possible to get by with less herbicides and little or no insecticides by utilizing crop rotation and growing varieties adapted to our region.

If some pesticides are taken off the market, because of more restrictive laws, it won't jeopardize the production of American agriculture. Agriculture must change the course it is on now to avoid further contamination of ground water and streams. Thank you.

Mr. BEDELL. Thank you, Mr. Moore.

Mr. Freestone.

STATEMENT OF NORMAN W. FREESTONE, JR., ECOLOGY SOUND FARMS, OROSI, CA

Mr. FREESTONE. Thank you, Mr. Chairman, subcommittee members. My name is Norman Freestone. I am a farmer. I am also a college graduate. I served in the U.S. Marine Corps as an officer for 3½ years, and I served on our local school board for 10 years. I am currently president of the California Certified Organic Farmers' chapter for Tulare and Fresno Counties.

I have farmed for 22 years, the first 15 years with chemicals and the last 7 years without chemicals—organically. I farm 90 acres of a variety of specialty crops, kiwifruit, Asian pears, persimmons, oranges, and plums.

The change in farming practices occurred because of two factors: escalating pest control costs, and, more importantly, because I became ill due to pesticide exposure. As a teenager I worked on a cotton farm during the summer months. A major highlight was our 5 a.m. early rise to watch—not a sunrise—but the skill of a crop duster as he sprayed a fine mist of poisons—parathion—over the cotton fields. These early exposures did not augur well for becoming a chemical farmer like myself, one who would be a very efficient user of pesticides.

My health problem started slowly, occasionally with headaches, fatigue, insomnia, indigestion, soon to spread to frequent headaches, insomnia, indigestion, et cetera., to include numbness, chest pains, fuzzy thinking, personality changes, and a myriad of other physical symptons. In fact, ecological illnesses can mimic many known diseases.

Finally, I sought help: many doctors, a psychiatrist, two clinics, and a clinical ecologist, who diagnosed the cause as toxic chemical buildup within the body precipitated by pesticide exposures. The doctor suggested I might move to a clean environment, but there were no guarantees I would get well. A pesticide blood test was taken. Poisons were found in my blood that I had never knowingly came in contact with or consumed. Even now, two members of my family cannot eat oranges sprayed with insecticides without acquiring headaches, yet both can eat organic, unsprayed oranges without a reaction.

At one point I was a total reactor. I would develop physical and mental symptoms from such items as most foods, the telephone receiver, newsprint, wet wood and dog hair. During this period, I wore a mask constantly whenever I left the house.

I contribute my recovery to consuming clean—organic—foods, maintaining a clear awareness of the mind-body connectiveness, and a strong family support system.

As a chemical farmer for 15 years, I am a personal witness to the slow, subtle contamination of our land, our water and of the food we consume as a result of our continued reliance on pesticides. A vivid example can be illustrated when we realize that we, as orange growers in the San Joaquin Valley, spent about $16 million last year to spray insecticides to control one insect, red scale.

The continual application of these pesticides have contributed significantly to the pollution of our air, water, soil, and food supply. This has resulted in reduction of soil fertility, destruction of natural pest enemies, developing minor pests into major pests and creating human health risks through exposures of these toxic residues into our food and water supply systems. Even with all these environmental costs, growers still loose about a quarter of a million dollars worth of fruit each year to red scale.

Pest resistance has become a problem in California. A University of California entomologist that we have worked closely in regards to biological control of red scale estimates that insect resistance to insecticides has doubled in the last 10 years. About 75 percent of

our State's most damaging crop insects and mites are genetically resistant to at least one or more insecticides.

I have witnessed the unwarranted, inappropriate misuse of pesticides ever since I began farming. Aerial applications are the worse offenders. Open fields have been sprayed because of faulty equipment or human error. Adjacent to sprayed fields, farm workers have been sprayed by aerial applicators numerous time because of pilot error, faulty equipment, or just drift of the poisoned air. Our home, tucked against a hillside, has been sprayed twice because of faulty equipment.

Also the instructions on the pesticide labels make no correlation to the risk of low, cumulative exposures over a lifetime, risks that include nervous system injury, immune system deficiencies, cancer, et cetera. What are the synergetic effects of long-term cumulative exposures from many different pesticides and chemicals?

These facts and experiences are disconcerting results of the use of pesticides. But there are alternatives, and they work. We do not have to live with the burdens of these poisons; we do not have to continue to contaminate our food and ground water supply. We can reduce and eliminate the use of pesticides.

Farming for the last 7 years without chemicals—organically—has been a challenge. Mistakes have been many, but all have been recoverable. I have learned that farming organically is more efficient and less expensive than chemical farming. Eight years ago we sprayed nine times to control six different pests to protect two crops. Today, farming five different crops without chemicals—organically—we do not spray, and we have only two or sometimes three pests per growing season. The other pests are no longer pests, they are now being controlled by natural enemies.

We use parasites, summer oil, botanical insecticides and natural vegetation. This is our means of pest control. It is a safe and healthy program for us and for our future generations. Interestingly, as a chemical farmer, I had more fruit damage from pests while using pesticides than I now have using insects plus nature.

Organic, biological farming is the trend of the future because it is energy efficient, labor intensive, and safe for our future generations. When we look at a farmers' budget, the most rapidly expanding items are pesticides, chemical fertilizers and electrical costs. Pesticides and chemical fertilizers are increasing at the rate of 25 to 30 percent a year.

Energy costs are forecast to increase 250 percent in the next few decades. Labor costs are rising only about 5 percent a year. Organic farmers do not use pesticides or chemical fertilizers, and they use less energy. Energy costs are less as water and pump usage is reduced now that the soil has increased its life, structure and porosity.

To farm efficiently we must farm differently. We are substituting chemicals—high cost items—for labor and insects—low-cost items. Eighty-eight percent of all insects are our friends. We feel fortunate when friends are able to help lower our costs and improve the environment. When pesticides are used to kill insects we inherit nature's work. And in today's world that can be costly and unsafe.

Organic farming can be a major solution to our environmental problems. Organic farming is an inexpensive and realistic way of

cleaning up our lands and our water supply. It can be a profitable alternative to the chemical farming treadmill. More importantly, it is a major commitment to restoring our lands and our life-sustaining resources for future generations.

Thank you again for your time in listening to me today.

[The attachment follows:]

William H. Philpott, M.D., Director
820 N E 63rd Street
Oklahoma City, Oklahoma 73105
(405) 840 - 4357

March 4, 1981

RE: Norman Freestone
41681 Road 126
Orosi, CA. 93647

Norman Freestone was under my professional care for four weeks, November and December, 1980. As per my diagnostic recommendation it was necessary for him to stay in a relatively ecologically pure environment, specifically an all electric apartment.

He was diagnosed to have adverse reactions to pesticides, hydrocarbons, and multiple food allergies.

He will need to return in six months for re-evaluation so that his current condition can be monitored and treatment adjusted accordingly.

Sincerely,

WILLIAM H. PHILPOTT, M.D.

CPST-CHLORINATED PESTICIDE SCREENING TEST RESULTS

PATIENT NAME Norman Freestone SAMPLE NUMBER 0118

PHYSICIAN Pathology Institute DATE COLLECTED 12/20/82

by [signature]

date 12/29/82

(--) Frequency per 100 specimens to date

Environmental Affairs, Inc.
3660 Gentilly Blvd.
New Orleans, Louisiana 70122
504-943-4427

1201 25-3

IMMUNODIAGNOSTIC LABORATORIES
400 29TH STREET • SUITE 114
OAKLAND, CALIFORNIA 94609
EDWARD E. WINGER M.D.
PATHOLOGIST • DIRECTOR
TELEPHONE • (415) 839-6477

DECEMBER 3, 1982

Re: NORMAN FREESTONE
To: Phyllis Saifer, M.D.
3031 Telegraph Ave. Ste 213
Berkeley, CA 94705

Cellular Immune System Consultation

Mononuclear cells were isolated from approximately 20cc. of whole blood collected in EDTA solution employing Ficoll-Hypaque after the technique of Boyum et al. (Boyum A, Isolation of mononuclear cells and granulocytes from human blood, Scand J of Clin and Lab Invest. Suppl. 97, 77-78, 1968.). Cells were washed in phosphate buffered saline in preparation for incubation with monospecific antibody. T cell subsets were identified using monoclonal antibodies capable of recognizing unique antigenic determinents found on the various T cell subsets. These antibodies were produced using hybridoma technology which has allowed the development of well-characterized monospecific antisera. Cells labelled by specific antisera following a period of incubation with test cells, were detected by a secondary fluorescein-isothiocynate-conjugated antibody specific for the primary monoclonal antibody. B cells were identified using a goat anti-human gamma globulin conjugated to fluorescein isothiocyanate. Non-specific, surface-bound gamma globulin was removed by incubation of test cells in multiple changes of wash solutions. Percent labelled cells detected by each antibody label were determined by fluorescent microscopy using an epifluorescent illumination system.

	FINDING	EXPECTED
WBC	4850/cc	4000-10,000
Lymphocyte	38%	25-40%
OKT11+ cells	54%	55-80%
OKT4+ cells	39%	32-50%
OKT8+ cells	16%	22-34%
Surface Ig+	3%	4-16%
Null cells	43%	
Absolute lymphocyte count	1843/cc	1500-4000
Total T cells (OKT11+)	995/cc ↓	1000-2500
Total B cells (surface Ig+)	55/cc	250-500
Total null cells	792/cc	
Total helper cells (OKT4+)	719/cc	
Total suppressor cells (OKT8+)	295/cc	
Helper/Suppressor ratio	2.4/1 ↑	1.8/1

IMPRESSION: B cells are very low. Helper/suppressor ratio is borderline but probably not significantly deviated.

Edward E. Winger, M.D.
Pathologist

Mr. BEDELL. Thank you very much. Mr. Morrison.

Mr. MORRISON. Thank you, Mr. Chairman.

Mr. Freestone, I really enjoyed your comments. I have been a farmer for the last 30 years, growing tree fruits in Washington State, and have seen the gradual increase in use of pesticides. We have made a significant change up in our country to very selective materials, and I trust that was part of the shift that you have described as well, as you went all the way to no chemical forms at all other than your summer oil, which we have always considered in chemical application.

Mr. FREESTONE. That is true, under the California State organic food law it's accepted material to qualify for organic applicators, organic farmers. I agree, however, it does ecological damage within a given geographical area and it is used as a transition to get over the chemical requirements necessary to control pests.

Mr. MORRISON. Are you located in an area that your neighbors are also following the same practices you are using, or are you isolated so that you don't suffer when they goof up in some way and end up sending you an infestation of insects you have to use chemicals to control?

Mr. FREESTONE. No, that is not true, I am not isolated, I am surrounded on three sides by farmers that use chemicals. I do have a hill. The drift in either situation is not conducive to clean environments, so that insects are totally protected. But we have found with other crops, particularly avocados, it is not necessary to have ecological area totally free from the use of either chemicals or integrated pest management to be able to function without the use of chemicals.

Mr. MORRISON. I notice that nowhere in your testimony did you really say that the use of these materials or your neighbors shouldn't be using them, you just in essence said there is some alternatives that we should investigate.

Perhaps Mr. Chairman, I should mention that this committee, or at least the full Agriculture Committee, has passed our organic farming measure which will attempt to steer some of the research programs in the direction that you have already chosen to utilize, so we are certainly not opposed to it. Do you propose any changes that we should consider in looking at the Federal regulations as they relate to pesticides, or do you feel that your way of life will gradually take over because it is less expensive and you feel that it's better for everyone?

Mr. FREESTONE. I do believe that organic farming, biological farming, whatever we want to call it, is a trend of the future, as previously expressed, but I think that for example the reentry data is inadequate and think it could be addressed more effectively. I think there should be restrictions on reentry in regard to pesticide use.

Aerial applications, I think, should be restricted, particularly around urban areas and schools, and boundaries should be set up with half-mile restrictions around dwellings or homes. In regard to reentry data, that is an area where farmworkers as well as farmers are being compromised because of drift and exposures. It is not practical to have a reentry period of 14, 17, 30 days, on farms particularly, and orchards. As you are aware, you cannot farm an iso-

lated piece of ground, or an enclosed piece of ground for that matter, without constantly monitoring that operation.

And who is going to go in there and monitor it? And are you going to wear a mask constantly? And if the home and dwellings, where the farmworker lives or the farm is within that reentry boundary or in or within the boundaries of that reentry area, are they going to be evacuated for 7 days? Of course not, It hasn't been practical, it hasn't worked out, it is not effective. So there should be some insights, some knowledge, some adjustments, some restrictions made in the reentry data.

One idea, one suggestion of course, from a biological farmer of course, would be to restrict the use of pesticides so that pesticides that would be used would have a limited reentry data, 48 hours for example, 24 hours. That would help eliminate the potential exposure that one might come in contact with.

Mr. MORRISON. My experience indicates that that actually is happening, that some of the more specific materials now that are being used have better options for access to the orchards and fields. I appreciate your testimony and the information both of you have provided to the subcommittee. Thank you.

Mr. BEDELL. Thank you.

Mr. Moore, you have quite a farming operation, as I understand it, a sizable operation. Do you still use chemicals to the extent you previously did? Have you seen any change in your operation?

Mr. MOORE. We have gotten away from it over the last 3 or 4 years. We still use chemicals. We don't use any insecticide at all and we are able to do that through crop rotation, in the valleys where corn is raised every year, there is quite a bit of insecticide that goes down. We rotate beans, wheat, and corn, and we get away from a lot of dependency upon the insecticides. In our area, I have a lot of 5-acre fields, 6 acres. They are small patches, and then I have large fields also. It's impossible for one person or one family operation to get over that much area to cultivate.

I still use herbicides on the corn and on the soybeans.

I am still dependent upon chemicals to that extent, but we have found through crop rotation even the herbicide in the corn and soybeans, we can get by with lesser rates than we could when we were going continuous.

Mr. BEDELL. My understanding is you have some material you would like to have entered in the record. Without objection, that will be done.

[The material follows:]

For Submission

KANSANS FOR SAFE PEST CONTROL
639 Mississippi Street
Lawrence, Kansas 66044

STATEMENT ON THE FEDERAL PESTICIDE REFORM ACT OF 1985

There is a need for comprehensive reform of FIFRA. I will concentrate these comments on Section 24(c) because we have worked on the special local needs issue in Kansas more than in any other state. However, I hope to provide some reasons for seeing some connections between problems with various sections of FIFRA. In particular, much of the abuse of Section 24(c) arises from problems with Section 3 registration, but there problems in the registration process in general are also related to the lack of environmental and health monitoring and regulation of pesticide use.

Special Local Needs

Section 24(c) of FIFRA allows states to register additional uses of federally registered pesticides or unregistered products that contain a combination of registered ingredients to meet special local needs. Federal regulations define a special local need to be "an existing or imminent pest problem within a state for which the State lead agency, based upon satisfactory supporting information, has determined that an appropriate federally-registered pesticide product is not sufficiently available."

As defined by regulations (40 CFR 162.151(i) and 162.153(b)), a special local need is a special need--there is no pesticide sufficiently available for that use. This means that it is not sufficient to say that pesticide A is better than those available. However, the existence of an effective non-chemical control is not sufficient reason under FIFRA for denying a SLN application.

A special local need is also a local need--SLN registrations are not appropriate, for example, if the pest problem is not local. The regulations explicitly state that situations a state may consider an not involving a special local need "may include, but are not limited to, applications for registrations to control a pest problem present on a nationwide basis, or for use of a pesticide product registered by other States on an interregional or nationwide basis."

Another important requirement of federal regulations (40 CFR 162.153(c)) is that in certain cases the state must determine that the registration will not cause unreasonable adverse effects on man or the environment. These cases are:
(1) For a product with a composition different from any federally registered product.
(2) For a new use pattern, i.e., one requiring a change in precautionary labeling.
(3) For uses of a product for which other uses of the same or a

similar product have had a registration denied, disapproved, suspended, or cancelled by EPA.

The legislative intent in writing Section 24(c) was to provide for cases where local conditions might call for different application rates or where specialty crops might not provide a large enough market to stimulate industry to do the research necessary for a regular (Section 3) registration. However, prior to 1972, states were allowed to issue their own registrations for pesticides not registered by USDA--the rationale was similar, but there were not such extensive testing requirements for federal registrations.

Implementation of Section 24(c), however, has largely ignored both the legislative intent and Federal regulations. As an example, Kansas issued a SLN registration for aerial application of Tordon 22K to Kansas rangeland to control musk thistle. The active ingredient in Tordon 22K herbicide is picloram, a highly persistent, water-soluble, non-selective herbicide that is translocated both down from the leaves and up from the roots of plants. It will kill almost any actively growing plant except established perennial grasses and is sometimes used as a soil sterilant. Objections were raised because of the possible effects of this proposed use--Kansas pastures are often hilly, with trees in low-lying areas, so off-target effects from aerial application of this persistent and mobile herbicide are certainly possible. It was objected that before such a registration was issued, it should be determined that it would not have unintended effects on the trees or water supplies. In spite of objections, however, the registration was issued without addressing the issues raised in objections or in the regulations.

In some respects, this registration appears typical of all SLN's in Kansas and, indeed, the country. The Board of Agriculture had made no attempt to verify the points required by federal regulations, and no one even signed his name to the claim that a special local need exists. There was no data in the file to support the existence of a special local need. In fact, musk thistle is a weed at least from Montana to Virginia. Kansas State University research comparing Tordon with other herbicides registered for that use found that in no trial was Tordon the most effective herbicide. So not only was there not a special local need, there wasn't even a need.

According to the scheme, EPA should have taken action to see that Kansas issued SLN's in accordance with Federal regulations. However, the opinion of John A. Todhunter, then Assistant Administrator for Pesticides and Toxic Substances, was that EPA was powerless unless a state grants a SLN for a use previously suspended or cancelled, a use without the necessary tolerances, a use of a totally new chemical, or a use posing an imminent hazard (Staff, 1982). This opinion has been recently reaffirmed under present Assistant Administrator John Moore (D. Campt, personal communication).

This situation was not peculiar to Kansas. Three studies, one by Allen Spalt of the Rural Advancement Fund (Spalt, 1983), one by the staff of the Department Operations, Research, and Foreign Agriculture Subcommittee of the House Agriculture Committee (cited herein as Staff, 1982), and one by EPA (OPP, 1983), looked at SLN registrations nationally. They found several patterns:

--An increase in the number of SLN's issued from 440 in FY 1976 to 656 in FY 1982.

The registrations are, in 91% of the cases, sought by manufacturers rather than growers or states.

--Although 15% of federal registrations are supported by questionable IBT data, 43% of the SLN's granted in 1981-1982 depended on IBT tests. For example, safety testing for the 3 most widely-used SLN pesticides (Furadan, Sencor, and Paraquat) was conducted by IBT. Among them, they received 361 SLN's in the 25 states in Spalt's study in 1981-82.

--Most of the SLN's were not for specialty uses--the top 5 use sites are soybeans, livestock, small grains, cotton, and fruit.

--There was a general pattern of many SLN's for certain uses of certain products. For example, in the 25 states that Spalt looked at, there were 182 SLN's issued for permethrin to control flies on livestock--more than 7 per state! On the other hand, the House Subcommittee staff report mentions that one SLN authorizes the use of the pesticide for control of 23 pests on 122 sites.

There are some obvious reasons that Section 24(c) registrations have been so widely used and abused:

(1) The pesticide does not need to be shown effective for the use unless the use involves a public health need(40 CFR 162.153(d)).

(2) Special local needs registrations can extend the use pattern in spite of a faulty safety data base.

(3) It is easier and cheaper than a regular Section 3 registration--in most states, only a 1-page application (and no fee) is required (C.E. Poindexter, personal communication).

(4) EPA has disapproved only 14 applications since 1976 (0.8%) (OPP, 1983).

Recommendations for SLN Policy

What is the framework for considering a reasonable special local needs policy? I suggest that the following questions are central, keeping in mind the context of the current legislative and administrative policy on registration of pesticides in general:

(1) Are there local pest problems that require treatment with pesticides that could not be made readily available through the Section 3 process?

(2) Is it possible to simplify the registration process for special local needs without losing safeguards for human health and the environment provided by the Section 3 process?

(3) What safeguards can we build into the system to prevent abuse?

A reasonable conclusion upon perusing the three studies of the SLN process is that the answer to (1) is: Yes, there are local pest problems for which no pesticide is available through the Section 3 process, but the number of those truly local, special needs is quite small.

Because the number of true special local needs is so small, it is possible that a simplified process might be devised to handle those needs without losing the safeguards provided by Section 3 of FIFRA. Certainly, a prerequisite for meeting this criterion must be that pesticides with "data gaps"--those which continue to be registered in spite of reliance on invalid data or in spite of a lack of data on health and safety questions--not be allowed to expand their uses through the SLN process. In fact, John Moore, Assistant Administrator for Pesticides and Toxic Substances has said recently that EPA would not allow registrations of such pesticides to be expanded. However, EPA has just refused to disapprove a SLN for paraquat, a pesticide with many data gaps (Campt, personal communication).

Similarly, the provision that allows non-registered products to receive SLN registrations should be removed. This provision allows the registration of products with a high potential for unknown effects to non-target organisms (including crops) because of possible chemical reactions between ingredients, as well as the potential for neutralization of effectiveness or synergistic environmental effects. The most important point about this provision is that we have no idea of what the effects of an untested mixture of registered ingredients might be.

I believe that the current system, with modifications providing safeguards against abuse, could be revised to allow for SLN registrations for documented special local needs without a loss of Section 3 safeguards. The requirements for such a revised special local needs process are the following:
--Section 24(c) registrations should be allowed only for pesticides with full Section 3 registrations and with no data gaps.
--All registrations under Section 24(c) should document the absence of unreasonable adverse effects on man and the environment.
--Safeguards against abuse must be built into the system.

The first two requirements can be met by changes in regulations and do not require legislative action. The third, as we will see, requires both regulatory and legislative action.

We can get a clearer understanding of where abuse occurs and how it can be prevented by looking at recent procedural changes in Kansas, and contrasting the SLN process with the process in Region VII for approving emergency exemptions (Section 18).

The Kansas State Board of Agriculture recently changed its procedures for considering special local needs registrations. It now publishes notice of applications and issues formal decisions.

One result of the adoption of the new procedures appears to be a 75% reduction in the number of applications received by the agency. In addition, the rejection rate has risen to 40% (2 out of 5) from about 5%.

However, merely requiring documentation is not sufficient, for the agency continues to approve SLN registrations for pests that are not local. The three SLN registrations issued this year under the new procedures are for stored grain pests, weeds in alfalfa, and broad-leaved weeds in winter wheat. None of these can be called local pests, but the decision by the Board of Agriculture (Garwood, 1984) in approving a SLN for paraquat to control weeds in alfalfa between cuttings in alfalfa reads in part:

"It is determined from historical survey data in Board of Agriculture files that a special local need for the control of weeds in alfalfa between cuttings does exist. Although alfalfa is grown nationwide and weeds infest alfalfa wherever it is grown, the need for control of weeds in alfalfa is determined by local factors which tend to limit the need for control at any specific time to localized areas."

No state agriculture department wants to take the lead in denying their state's farmers a potential "weapon in the war against pests." Thus, some motivation to prevent abuse must come from outside the state agriculture department.

As an example of safeguards against abuse of the system might work, contrast special local needs registrations with emergency exemptions (issued under Section 18 of FIFRA), as administered by Region VII of EPA. There have been very few emergency exemptions issued in Region VII states (for example, Kansas averages 2.6, with a maximum of 3), while use of emergency exemptions has grown exponentially in some other states.

The reason is that until recently (when staff cuts forced Region VII to relinquish control over Section 18 to Washington), the Registration Division of Region VII required states to document, point by point, the statutory requirements for emergency exemptions. These requirements are somewhat similar to those for special local needs registrations. The same state officials who have had empty support files for their special local needs registrations have provided detailed documentation about pest distribution, environmental effects, and pesticide availability and efficacy for emergency exemptions.

With the aid of this example, we can suggest some specific changes to prevent abuse of the special local needs registration system:

--EPA should require the states to provide documentation of the special and local nature of the need and the nature of effects on man and the environment.

--There should be a rebuttable presumption that any need for which there are registrations under Section 24(c) in 5 or more states is not local.

--Criteria for EPA's disapproval of SLN registrations should be broadened to include lack of essentiality.
--State registrations should not become effective until after EPA has reviewed the application.
--EPA should be required, rather than permitted, to disapprove or dec are nvalid SLN registrations that do not meet the requ rements of FIFRA and federal regulations.
--EPA should be required, rather than perm tted, to suspend the authority of individual states to issue SLN registrations if they do not comply with FIFRA and federal regulations.

The first two of these changes could be made by EPA through regulations. The other changes would require changes in FIFRA, and are, in fact, included in the FIFRA Reform Bill S1774/HR3818, which failed to pass Congress this session.

Present regulations and procedures make it difficult to challenge a registration through the courts. The above suggestions, while they do not deviate from the central legislative intent, would make resolution of differences easier.

A somewhat more radical suggestion would be to include the requirement that there be no other control of any sort sufficiently available before a special local needs registration could be approved.

What would be the impact of the proposed changes on pest control?

They should reduce the number of special local needs registrations drast cally. Some of those denied registrations would go through the Section 3 process and be approved. In fact, the data necessary to get a SLN registration would probably be suffic ent for expansion of Section 3 registration. Others would not have sufficient data to support a Section 3 registration and would die.

Since special local needs registrations do not need to be shown effective, one result of reducing reliance on SLN registrations would be that users of pesticides would not be offered the choice of (legally) wasting their money on those ineffective or less effective products.

Implications for the Registration Process in General

Perhaps we can use the special local needs process to tell us something about the Section 3 registration process. Clearly, since the abuse of SLN's arises largely from alternative paths being sought for chemicals with data gaps, the Section 24(c) process is being abused at least in part because decisions are not being made in the course of the Section 3 process to determine the suitability or unsuitability of pesticides for these proposed uses. It is also clear from the reregistration backlog and data gaps that there are tremendous problems in the

registration process that prolong the process and leave us with no confidence in the protection that it provides. It also appears that different EPA Administrators with different approaches have not made a significant difference in either efficiency or inspiring public trust (Senate Staff, 1976; Staff, 1982).

Ideally, we should have a nationwide pesticide registration system that determines efficacy and levels of risk for each proposed use of a pesticide. It should not register any use if the pesticide is shown to be ineffective or if the use poses unreasonable adverse effects.

I believe that the information we have about the use of the SLN, Section 18, and other loopholes in FIFRA tells us that it is not the registration of new products that holds up the process and creates problems. The problem is that the system cannot correct mistakes.

Most of the pesticides involved in the abuse of the system are old chemicals--pesticides which lack some of the required data and would therefore have difficulty expanding their Section 3 registration to new uses (Spalt, 1983; Staff, 1982). We see greater problems in reregistration decisions than new registrations--once a product gets a share of the market for a given use, it is practically impossible to suspend or even restrict the use. The process for registering new pesticides apears to be working smoothly. Manufacturers have much to lose from a suspension or cancellation, and they are able to draw support from user groups who rely on their products. (The process of restricting the use of 2,4,5-T took 5 years.) Because pesticides are poisons and do pose hazards, showing substantial benefit (usually economic) is a necessity in any risk-benefit analysis.

The reason special local need registrations pose such a serious threat is that they gain this de facto support with no scientific support. It is a fallacy to claim that farmers will not use it unless it works. A good example is field bindweed. Field test data by Kansas State University and Extension Field Stations show that bindweed cannot be eradicated with herbicides--herbicides are at best a substitute for tillage--but Noxious Weed Departments still recommend, and farmers still use, 2,4-D regularly in attempts to eradicate bindweed (Nilson, 1982).

Therefore, we need a tight, restrictive system for registering new pesticides because it is so difficult to correct mistakes. However, at the same time, we also need to be better able to correct mistakes when we make them.

How can we improve our ability to correct our mistakes? Three strategies are:
(1) Take use decisions out of the hands of farmers (and other users)--that is, institute a prescription system.
(2) Increase citizen participation in reregistration decisions.
(3) Actively pursue feedback from users about efficacy, health problems, and other non-target effects.

It has often been argued that pesticide misuse would be greatly decreased if the decision to apply pesticices were made by certified independent crop consultants rather than farmers themselves. (See, for example, van den Bosch, 1978; Perkins, 1982; Rowland, in press.) It may not have been fully appreciated that the prescription system might also, by creating a more educated and informed group of decision-makers, prevent manufacturers from calling upon a frightened group of users for support. (Rowland (in press) combines this suggestion with a Federal crop insurance program.) Thus the prescription system might increase chances for a satisfactory, prompt reregistration decision.

Environmental organizations and other interested citizens currently have no right under FIFRA to demand a hearing when a reregistration decision does not place adequate restrictions on the chemical to ensure reasonable levels of risk. Allowing <u>any</u> "persons adversely affected by the notice" (of intent to rereg ster cancel, etc.) standing, including members of the publ c without econom c interests, would decrease the inertia in the system (McGar ty et al, 1983). This inertia, which makes it so difficult to correct our registration mistakes, can only be overcome by decreasing the registrants' control over the system.

The only <u>system</u> we have had nationwide for generating feedback about the effects of pesticides as they are actually used is the Pesticide Incident Monitoring System (PIMS). PIMS collected reports of "incidents"--generally acute effects of single events of m suse--and stored them without evaluation (Jon Flint, personal communication). Of more use to the reregistration decision process, however, would be research directed at discovering patterns of use, resistance, and health effects. For example, there should be a reporting system for all poisonings related to pesticides, like California's system (Ca. Dept. of Food and Agriculture, 1978.) Patterns of miscarriages, birth defects, and cancers might provide valuable epidemiological evidence if we had reliable data for their incidence and pesticide use. Historical surveys of pesticide use, in combination with entomological survey data (currently collected by state agriculture departments and the USDA) could yield evidence of pesticide resistance. Most importantly, all of these things give information about pesticides when used "in accordance with widespread and commonly recognized practice," which, according to FIFRA, is the prescribed basis of making decisions that are usually made on the basis of laboratory data and theoretical models.

<u>Conclusion</u>

In conclusion, documented abuses of the special local needs registration system have led us to some recommendations for improving SLN pol cy. They have also suggested some more fundamental changes in pesticide registration-- application by prescription, public involvement in making reregistration decisions, and an emphasis on research into the effects of pesticide use--as well as the possibility that Section 24(c) may not be necessary for meeting our pest control needs.

Terry Shafer

Terry Shafer
Coordinator, Kansans for Safe Pest Control
Conservation Chair, Kansas Sierra Club
Pesticide Coordinator, Sierra Club Hazardous Materials Committee
10 May 1985

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Mr. BEDELL. Mr. Freestone, you say you raise five crops. What are those five crops?

Mr. FREESTONE. Yes, sir; I raise oranges, plums, persimmons, kiwifruit, and Asian pears.

Mr. BEDELL. That is an orchard operation?

Mr. FREESTONE. Yes, sir.

Mr. BEDELL. What are the insects that affect those crops and what do you do about them?

Mr. FREESTONE. Yes; we have two insects that we still have to control with means other than nature helping us. One is red scale, as mentioned before. Orange growers in California would have a very difficult time making the transition without using some means of insecticide to control red scale. We use summer oil, as I mentioned before, as well as parasites. Hopefully, we will be able to eliminate the summer oil as the predators begin to feed on it, their food source, red scale.

We have just had the opportunity to bring in one of the more vociferous of red scale just released out of quarantine from the University of Riverside. We were able to place that in our orchard. It's an inside fighter of red scale, which means it works on the inside part of the tree where we have the greatest difficulty in controlling red scale. So we are optimistic about eliminating oil, which is a very expensive operation. If we can eliminate it, the cost of oil, our costs will be less than half of what a chemical farmer pays.

Right now we are just about—we are even in terms of pest control costs. Our costs are basically even though a summer oil and release of parasites are very similar to the chemical farmer in that respect.

In regard to the other pests, we have what we call omnivorous leaf roller that works on kiwifruit that feeds on fruit and we release a parasite called Triktagami at a certain period of time when we know it will work, with etomologists we can set out traps. We know when to release these insects. And these insects lay their eggs on the larvae, lay their eggs on the egg of it and then feed on that egg that hatches out of it. So consequently we have better control of insects than we did when we were using chemicals to control LOR.

Mr. BEDELL. What do you do about fertilizers?

Mr. FREESTONE. Fertilizer is not a problem for us. As a matter of fact, that was one of the concerns that we had when we were making the transition, was how would we fertilize, where would we get enough natural fertilizers to compensate for the lack of chemical fertilizers. As a matter of fact, in our situation, we have overfertilized and we have an overfertilization problem, so we have had to supplement that, to correct the problem, with limestone.

The reason for that is because I did get concerned about that, applying too much natural fertilizer, and with the fertilizer that the nitrogen particularly that we are pumping from the underground water, via overfertilization from years past, not just in our operation but in the majority of operation, we have a high nitrate in our well water. So consequently we really do not have to apply any natural fertilizers for the next few years.

We also, of course, mow our vegetation. We used to have weeds, now we no longer have weeds, we just have vegetation. We mow

that. That breaks down into organic matter which adds nutrients to the soil. We also have earthworm activity, 2,000, 4,000, 10,000 earthworms in a given area. That is a lot of fertilizer, when they deficate 1 pound a year, deficate the weed, wait 1 year, so fertilizer is not a problem for us.

Mr. BEDELL. Are you saying that your water is sufficiently polluted, is the only word I know, with nitrate so that you get fertilizer from the polluted water? Is that the same water that they are using for drinking purposes?

Mr. FREESTONE. There are many wells in our area that are unsafe to drink, according to the department of health. Somewhere roughly around 45 parts per million of nitrate level, that is considered unhealthy as drinking water source, and our well is not in that category. We are looking at about 25 to 35 parts per million. But with 12 to 14 irrigations a year, we can add approximately 7,500 or almost 1 pound of actual nitrogen via the water. That is a sufficient amount of nitrogen. Of course nitrogen is only one element that we are looking at in terms of our fertility program.

Mr. BEDELL. Any more questions?

Well, we thank you very much for your testimony. We want to thank all the witnesses for their testimony this morning and the subcommittee will recess to convene at 2 o'clock this afternoon.

[Whereupon, at 11:55 a.m., the subcommittee recessed to 2 p.m. of the same day.]

AFTERNOON SESSION

Mr. BEDELL. I think we go ahead. We hope that more members will join us as the times goes on, but we always run out of time at these sessions.

Our first panel will be Ms. Kay Pinkus, association attorney for International Sanitary Supply Association, Inc., of Chicago, IL; Mr. Robert Miller, who is on the board of directors, Professional Lawn Care Association of America, Marietta, GA; and Dr. David F. Hamilton, director of technical services, American Association of Nurserymen, Inc.—they are not here.

I understand Mr. Hamilton and his assistant were unable to make it. We will start with you, Ms. Pinkus.

STATEMENT OF KAY S. PINKUS, COUNSEL, INTERNATIONAL SANITARY SUPPLY ASSOCIATION, INC.

Ms. PINKUS. Thank you, Mr. Chairman.

The International Sanitary Supply Association is a trade association comprised of approximately 3,000 companies in this country which are in the cleaning and maintenance industry. The members of ISSA manufacture and distribute a wide variety of products and chemicals which are used for cleaning and maintenance. Some of these products are registered as pesticides under FIFRA.

My testimony will not deal with many issues which are going to be discussed concerning the various aspects of FIFRA. We only have one narrow concern with this legislation. It is narrow in terms of the wide array of issues that will be discussed in these 2 days. However, for the cleaning and maintenance industry, this particular issue is of paramount importance.

The problem that arose for the cleaning and maintenance industry results from the nonspecific definition of "pesticide" in the Federal Insecticide, Fungicide, and Rodenticide Act.

Many cleaning products are regulated by EPA as pesticides, although when most people consider the term "pesticides" they don't think of these type of products. I am talking about pesticides such as Lysol, Comet, sanitizing dishwashing rinses, air fresheners, and even toilet bowl disinfectants. These products are classified as pesticides because they destroy or mitigate bacteria, germs, and other similar pests. These types of pesticides can be referred to generally as antimicrobials.

The problem for ISSA is not that these antimicrobial products are regulated as pesticides. The problem is that many people are not aware that this is the case. The cleaning and maintenance industry has dealt with many problems which arose because neither the regulators nor the regulated public were aware that these cleaning products fall under the definition of pesticide.

The reason for this confusion is clear: antimicrobials do not fall within the commonly understood definition of pesticide. In the Federal Insecticide, Fungicide, and Rodenticide Act the definition of pesticides is any substance which destroys or mitigates a pest, and further defines a pest as any insect, rodent, fungus, weed, virus, bacteria, or other microorganism.

In many cases, people reading this definition assume that it refers to agricultural pesticides and indoor-use insecticides and rodenticides, and do not have the slightest idea that products used in the cleaning and maintenance industry are covered.

Let me give you two brief examples of the sort of problems that are rampant in the cleaning and maintenance industry as a result of this confusion. The State of Illinois enacted a law in 1982 which requires certification in order to use any pesticide. In this situation, no one was aware and even the sponsor of that bill wasn't aware that they were regulating antimicrobial products. If they were, they wouldn't require the examination and certification for the use of products such as Lysol.

The reason this was a problem is—and this is the basic scenario that has happened at the State and local level—is their law references the definition of pesticide in FIFRA. In that Federal definition, there is no indication that it includes our industry. What happened was we had to go and get an amendment to that law. This is something that we have had to do over and over again. We can't do it in every case. It is expensive and time consuming.

Not only that, it is wasteful because in the State of Illinois, as in many other States, our industry was never intended to be regulated at all.

Another area where this is a problem is for the public that is being regulated. Many of the members of ISSA are small family-owned businesses. They simply buy and resell the pesticide products that are used in the cleaning and maintenance industry.

There are requirements for the use of these pesticides. They have to be registered sometimes and these small companies aren't even aware that they are pesticides. Oftentimes they will have a corporate counsel who isn't aware that these products are pesticides and

if this attorney would look over all the environmental laws, there still wouldn't be any indication in FIFRA itself.

I can basically close with that and just to say that ISSA would like to see the word "antimicrobial" and the specification of what that includes in the law. That is all we would like to see. We don't want any change in the substantive regulations, simply an indication that our industry is covered under the law so that we aren't accidentally regulated.

[The prepared statement of Ms. Pinkus appears at the conclusion of the hearing.]

Mr. BEDELL. Thank you, Ms. Pinkus. I appreciate your limiting your time to the 5-minute period.

Mr. Miller, I would appreciate you holding your time to 5 minutes also.

STATEMENT OF ROBERT W. MILLER, MEMBER, BOARD OF DIRECTORS, PROFESSIONAL LAWN CARE ASSOCIATION OF AMERICA

Mr. MILLER. Thank you, Mr. Chairman.

As introduced, I am a member of the board of directors of the Professional Lawn Care Association of America located at 1225 Johnson Ferry Road, Northeast, Marietta, GA. I am also vice president in charge of technical services for ChemLawn Services Corp., a professional lawn service company headquartered in Columbus, OH. Prior to my association with ChemLawn, I was a professor of agronomy with the Ohio State University College of Agriculture.

There are three subjects I want to discuss: background information on PLCAA and the lawn care industry; second, the problems that we have with local regulation of pesticides; and the third is our belief that existing FIFRA language preempts local regulation of pesticides should be strengthened.

PLCAA, is a trade association with a membership of 650 lawn service companies. It is the only trade association for that industry. The lawn service industry has experienced significant growth during the past 15 years. The members now operate in 50 States and the District of Columbia.

The lawn care industry services more than 7 million customers and employs more than 160,000 people. Much of the industry is comprised of small businesses. While lawn care companies offer only mechanical services, many provide chemical-based services as well.

Liquid or dry fertilizers are applied and pesticide products are added at appropriate times during the season. The service typically consists of four to five applications per year. Lawn care companies do not manufacture or formulate fertilizers and pesticides. They purchase materials from manufacturers based on efficacy, cost and safety to employees and customers. These products contain the same active ingredients and require the same application rates as lawn care products purchased by do-it-yourself users at retail outlets.

During the past 10 years, 60 local governments in 17 States have considered regulating pesticides. Much of the regulatory initiatives have taken place recently. Ironically, local ordinances do not apply to the larger do-it-yourself market segment where, because of the

lack of training in the use of pesticides, the possibility of mishap is greatest.

Local registration of pesticides is disruptive and counterproductive for the following reasons: One, lack of uniformity. Most professional lawn services operate in more than one municipality. If numerous local governments adopt differing pesticide ordinances, lawn service companies face a difficult and time-consuming task.

With 65,000 political subdivisions below the State government level and the United States, it is not unforeseeable that lawn services will become overwhelmed by varying local laws.

The second reason is absence of scientific expertise. A thorough knowledge of chemical and toxicology are fundamental to assess the risk to humans or the environment from the use of pesticides. Expertise in these areas exist at Federal and State levels, but rarely at local levels.

Third, lack of enforcement and loss of public confidence. Federal and State governments have established a comprehensive system to regulate pesticides, the primary function of which is the protection of the public health and the environment. Local officials who promote local pesticides regulation frequently justify their efforts by criticizing Federal and State regulatory efforts.

Ironically, local governments that may choose to regulate pesticides rarely possess the resources and technical expertise to provide even minimal enforcement of local pesticide laws.

There is an incentive to do-it-yourself users. By regulating only commercial applicators, local pesticide regulations foster a belief by the public that the materials applied by the lawn services are more toxic than those found in over-the-counter do-it-yourself products.

The fifth reason is a burden on commerce. Local pesticide ordinances clearly impose restraints on the free flow of commerce. Law services that fail to comply with a local ordinance may be prohibited from doing business in a community even though they have met all Federal and State requirements.

It is our belief that if left to local forces, inconsistent and ineffective regulation of pesticides will proliferate.

The Professional Lawn Care Association therefore requests that this subcommittee consider amending section 24(a) of FIFRA to expressly confine the regulation of pesticides to the Federal and State Governments. Be assured that our members will actively support regulatory efforts at the Federal or State level that promote applicator competency, increase customer and employee safety, and provide consistent and equal treatment for all segments of the lawn care industry.

Thank you for your attention.

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

Mr. BEDELL. Thank you very much.

We appreciate particularly you summarizing your statement and your entire statement will be made part of the record.

Mr. MILLER. Thank you.

Mr. BEDELL. Mr. Combest.

Mr. COMBEST. No questions.

Mr. BEDELL. Mr. Volkmer.

Mr. VOLKMER. No questions.

Mr. BEDELL. Ms. Pinkus, I think your testimony has been most helpful. I think probably what we need to do is have the staff check with the EPA and see if they have any particular objections to your suggestions, but it certainly is helpful to have them.

Ms. PINKUS. Thank you.

I spoke with them myself and as far as I am aware, they don't have any objections, but I don't want to speak for them definitively.

Mr. BEDELL. Thank you.

Mr. Miller, were you here this morning for testimony?

Mr. MILLER. Yes; I was here for part of the testimony.

Mr. BEDELL. You folks in the lawn care business use the same chemical that Mrs. Prior's husband apparently was affected by——

Mr. MILLER. You mean the pesticide Daconil that she spoke about?

Mr. BEDELL. Yes.

Mr. MILLER. Most of the lawn care industry, Mr. Chairman, does very little in the control of diseases. There is a very limited amount of that pesticide used by lawn care companies.

Mr. BEDELL. Have you used it?

Mr. MILLER. Only a limited amount of it only on a problem basis.

Mr. BEDELL. Have you had any problems where you have used it?

Mr. MILLER. None whatsoever. Our company, I can speak for our company itself, our company at this point in time has more than 3,500 applicators applying pesticides, and over the past several years have had many more than that, and we have yet to experience the first known health effect from application of pesticides.

Mr. BEDELL. That was quite a moving statement, I thought, that she made this morning.

Are there further questions? If not, we appreciate your testimony very, very much.

Our next panel is Mr. Jim Walesby, cochair, and Mr. Peter Nygaard, cochair of the Farm Chemicals Committee of the National Association of Wheat Growers; Mr. Mark Maslyn, assistant director, National Affairs Division, American Farm Bureau Federation; and Mr. Dale Stansbury, National Association of State Universities and Land Grant Colleges.

First, we will hear from Mr. Seiberling since he was scheduled to be on the witness schedule at this time.

John, we are asking everybody to hold testimony to 5 minutes.

STATEMENT OF HON. JOHN SEIBERLING, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OHIO

Mr. SEIBERLING. Thank you, Mr. Chairman.

I appreciate this opportunity. I introduced a bill recently, H.R. 1910, to prohibit the sale of pesticides and herbicides for agricultural production unless tests prove that such substances are not likely to endanger human beings. I have been concerned for some time that the use of dangerous pesticides and herbicides could pose serious health threats to consumers and agricultural workers. Once the pesticides and herbicides enter the food chain and our groundwater, the long-term effects of these substances are largely unknown.

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Because of these concerns, it seemed to me that agricultural pesticides should not be used unless appropriate tests indicate they are unlikely to cause harm in human beings.

The story about EDB is too well known to go into the details, but this EDB crisis demonstrated the serious inadequacies of our system of regulating pesticides and herbicides. And there are many other dangerous pesticides and herbicides that need to be focused on as well. For example, the most widely used agricultural herbicide in my State of Ohio, alachlor, has been found to cause cancer in rats.

It is estimated that 30 percent of Ohio's 7.7 million acres of croplands are treated with alachlor. I submit to you that where traces have been found in the rivers that serve as drinking water for many Ohio cities, and where it is possible that alachlor could get into the food supply, it is high time that we took a closer look at this situation, particularly when you consider that most municipal water treatment systems do not filter out alachlor.

There are also problems with the aerial spraying of the chemical. EPA has banned aerial spraying and has banned the use of the chemical on potatoes because it may leave a residue on them, but EPA has refused to suspend all uses of this herbicide until more test information is available. There again we have a need for a tightening up of the current system.

The general public shouldn't have to worry that their drinking water contains dangerous pesticides and herbicides, and certainly the problems and dangers for farm labor are already well known to your subcommittee.

Serious problems with the current system of pesticide regulation are obvious. Under the current system when tests are inconclusive about the dangers of the particular pesticide, the use of the pesticide or herbicide is approved. I think we should not approve a chemical unless appropriate tests indicate that it is unlikely that it will endanger human beings.

I notice that the bill that is about to be introduced by Congressman George Brown, certainly an excellent piece of proposed legislation, focuses on the effect on birth defects. But I suggest that while anything likely to cause birth defects may well also cause cancer, for example, we need to broaden the proposal and cover cancer as well as other possible serious adverse effects.

It has been argued that reducing the availability of herbicides will hurt farmers by curtailing farm production. But to the extent that farmers are not forced by competition to buy pesticides and herbicides, their costs will be lower. And to the extent that agricultural production is reduced, crop surpluses will be reduced or eliminated, thereby saving crop price support costs presently borne by the American taxpayers.

H.R. 1910 would change the current regulatory structure to ensure that pesticides and herbicides used in agricultural production are truly safe.

Before EPA could register any currently used agricultural pesticide or herbicide or approve any new one, the agency would be required to conduct the tests to determine if it could endanger humans, and if it did, it could not be approved. To encourage EPA to move quickly to conduct the proper tests, after 3 years the bill

would revoke the registration of any agricultural pesticide or herbicide already in use unless EPA tests were complete.

I want to thank the subcommittee for hearing me on what I consider to be an extremely important issue, and I would be happy to answer any questions.

Let me say one other thing. As my colleagues may know, in January I found out that I had cancer of the prostate. For 3 months I didn't know, until I had an operation in April, whether I had metastasized cancer or not. In the interim, I did a lot of thinking and reading, particularly reading as to what are the causes of cancer in human beings. Having cancer certainly sharpens your powers of concentration on this kind of a subject. As a result, I became even more convinced that the time had come to try to do something about this particular issue of pesticide regulation, and that is why I am here.

Thank you, Mr. Chairman.

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

Mr. BEDELL. Thank you very much, Mr. Seiberling.

Mr. Combest.

Mr. COMBEST. No questions.

Mr. BEDELL. Mr. Volkmer.

Mr. VOLKMER. No questions.

Mr. BEDELL. Mr. Gunderson.

Mr. GUNDERSON. Thank you, Mr. Chairman.

Thank you, John, from your statement and your interest in this issue. I can't help but comment initially as I read your paragraph on page 3 about the cycle if we ban the chemicals we will reduce production and if we reduce production, it will increase price, I wish it were that easy.

Mr. SEIBERLING. I was attempting to answer the argument that if you enact my bill agricultural production will go down. Yes, but costs will go down, too.

Mr. GUNDERSON. Could you elaborate on what you mean by banning chemicals that are likely to produce endangering human beings—I don't want to sound simple but I didn't know that EPA was legalizing chemicals likely to endanger human beings now?

Mr. SEIBERLING. It seems to me that some generalized standard in legislation is needed, to be followed by regulations. You remember the Delaney amendment which says that any food additive that produces cancer in laboratory animals in any quantities cannot be used. It seems to me that that is the kind of approach that I would hope that EPA would be required to undertake when evaluating the chemicals that could get into the food chain or could affect agricultural workers who are working out in the fields.

Whether that is the best approach is something I think you would have to leave up to EPA, but certainly I would hope that the legislative history of any legislation, whether it be the Brown bill, my bill, or some other, would make it clear that if the chemical produces cancer or birth defects in laboratory animals in any quantity, then it should not be used in the production of food for human beings.

Mr. GUNDERSON. Is your bill that exact that if——

Mr. SEIBERLING. No. My bill does not spell it out that exactly.

Mr. GUNDERSON. Thank you.

Mr. SEIBERLING. Thank you.

Mr. BEDELL. In regard to the Delaney clause, there have been those who have argued that we now have such sophisticated analytical equipment that we now can detect a very, very minute amount of anything in a food stuff or in the water, and to say that there can't be any of it probably is somewhat questionable.

I take it you don't agree with that.

Mr. SEIBERLING. The test that I have put in the bill is "if it is likely to endanger the health of human beings," which gives some latitude. I think we have to look at the cumulative effects over a long period of time. The virtue of using laboratory animals is that you can have many generations in a very short period of time. It seems to me that if the pesticide or herbicide produced cancer or birth defects in quantities that are comparable if you scale them up to consumption by human beings over a period of a life time, and you take into account the fact that there are probably other chemicals that we are taking in at the same time, the test should be a fairly tight one in my opinion. The long-term effects of the use of these pesticides are subtle and difficult to pinpoint in human beings.

If a person at the age of 65 gets some kind of cancer of the liver, let's say, who can say what caused it? Yet if we could show that he has eaten various chemicals that cause cancer in laboratory animals, I think we would begin to see some basis for making a correlation. The exact amounts, I think, should have to be left to the experts.

Mr. BEDELL. Mr. Brown, do you have any questions?

Mr. BROWN. No, Mr. Chairman.

Mr. BEDELL. Mr. Evans.

Mr. EVANS of Iowa. No, thank you.

Mr. VOLKMER. Mr. Chairman, I do have one pertaining to the last part of the statement, John.

Mr. BEDELL. Mr. Volkmer.

Mr. VOLKMER. The thing that we have had this proposal before on reregistering and pesticides in use that have to be tested in the 3-year limitation. There is no question in my mind that it is completely impossible for EPA to run the tests or have the test results analyzed on all of them within that 3-year period. The quandry in my mind is how do they make the decision of which ones they are going to reevaluate, in other words, which ones after three years are going to fall through the crack and not be able to be used even though they may not be harmful to humans and even though they may be very effective in their use.

Mr. SEIBERLING. You subcommittee members are experts, and I am not, on this subject. Perhaps 3 years is too short a period. Maybe it ought to be twice that long. I would leave it up to this subcommittee, but I would suggest that there ought to be a deadline at which point pesticides and herbicides would have to be recertified, whether it is 3 years, 5 years, or some other period of time.

Mr. VOLKMER. Thank you.

Thank you, Mr. Chairman.

Mr. BEDELL. We appreciate very much your being here, John, and we appreciate your work in this area.

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

Mr. BEDELL. My understanding is that we really have only Mr. Walesby and Mr. Maslyn here, so we will hear from you first, Mr. Walesby.

We would appreciate if you would try to hold your testimony to 5 minutes.

STATEMENT OF JIM WALESBY, CHAIRMAN, FARM CHEMICALS COMMITTEE, NATIONAL ASSOCIATION OF WHEAT GROWERS, ACCOMPANIED BY PETER NYGAARD, COCHAIRMAN

Mr. WALESBY. Thank you, Mr. Chairman and members of the subcommittee, the National Association of Wheat Growers appreciates this opportunity to present its views on the reauthorization of FIFRA, and the particular concerns of farmers relating to pesticide regulation.

I am Jim Walesby, chairman of NAWG's Farm Chemicals Committee, and a wheat producer from Almira, WA. Appearing with me today is my cochairman, Peter Nygaard, also a wheat producer, from Williston, ND.

Maximizing agricultural productivity must always be a basic goal of sound economic policy. Efficient agricultural techniques necessarily include the use of a broad range of pesticides. But public misperceptions related to the use of these chemicals seem to be growing, in large part because of our technical ability to measure chemical residues at infinitely small levels. The existence of any such residues is often perceived by the public to be in itself harmful, and this misperception makes the balancing of risks associated with chemical residues against the benefits of using agrichemicals increasingly difficult for the EPA.

Ironclad rules to fit the circumstances of any risk benefit analysis are not possible to create. EPA's regulatory decisions must protect the public health, while at the same time encourage research and development of beneficial agrichemicals. Because of these dual requirements, some discretion in applying regulatory guidelines will be necessary in determining where the true public interest lies.

The farmer has a great deal at stake, from both perspectives. He depends on the availability of efficient pesticides to control weeds and insects, and he must, at the same time, be concerned about the health implications of handling such chemicals.

The handling of chemicals poses several issues for the EPA, including certification of restricted use applicators, and supervision of noncertified applicators. Requiring certification for anyone who handles restricted use chemicals, even if supervised by certified applicators, is beyond what is necessary and practical.

Supervisors should be required to properly train and oversee applicators under their responsibility, so that the worker understands the importance of careful and safe handling of restricted use chemicals. But often farm workers are hired on a temporary basis for specific tasks, and making arrangements for certification train-

ing programs would prove impractical from the point of view of both the worker and the farm operator.

Such a requirement would essentially force farm operators to hire professional contractors to perform their chemical applications, which is an expensive alternative for the farm operator, and an equally undesirable alternative for farm workers.

In regard to certification training programs for which the Extension Service is responsible, most farmers agree that the quality of these programs should be significantly improved in order to achieve the educational objectives for which they have been authorized by Congress. Label information is useful only to the extent that the user is adequately informed on how to use the information, and on his legal responsibility to do so.

It is unfair to hold a user liable for misuse when the system designed to educate the user regarding proper application is not recognized as the most fundamental means to ensure safe use of pesticides. We do not believe that rules and regulations specifying the type of clothing which must be worn by applicators, reentry periods following pesticide applications and the like should replace educational programs as the primary means of strengthening safety standards on the farm.

As an organization representing users of chemical materials, the NAWG has recognized the importance of applicator training, and has sponsored a series of applicator clinics across the country as a means of improving equipment calibration and other applicator techniques. But the fundamental responsibility for certified applicator training lies with the Extension Service, and these programs must be improved for the protection of the farmer and the community.

The EPA has clearly, and correctly, recognized that an essential regulatory priority is completion of reregistration, so that harmful chemicals can be identified and discontinued, and that safe and beneficial chemicals can be recognized as such. Quicker resolution of special reviews is also under evaluation, as well as more direct procedures for cancellation of registered chemicals. These initiatives must not prevent full opportunity for disclosure and discussion of data which favor continued registration, and for economic benefits arguments to be completely heard.

The role of the USDA in presenting benefits data must be strengthened, in the interests of establishing a fair analysis of chemicals under special review at EPA. The EPA maintains that benefits analyses are disadvantaged by the poor quality information it receives from USDA. But the ability of the USDA to collect benefits data depends upon the commitment of research personnel to this task, and the pesticide assessment program has not been given the proper support within the Department.

We urge the committee to help correct this situation.

Expedient registration of new compounds is of utmost importance to wheat growers. As older products are removed from the market, effective substitutes are often not available, and new products must be registered to fill the gap. Often new pest problems develop in response to weather conditions and changing cultural practices, and new methods of control must be found, and, as more

effective compounds are discovered, growers are anxious to be able to utilize these tools to improve their production.

State and local initiatives to restrict and control pesticide use continues to disrupt the marketing and use of beneficial chemicals by farmers, pest control businesses, homeowners, and others. Unreasonable requirements to post notices of intent to spray and other means of impeding timely use of pesticides are examples of local regulations which are becoming serious problems for farmers.

Although the FIFRA law makes provision for States to regulate the sale and use of pesticides, apart from Federal authorities contained in the statute, it has not been the intent of this law for political jurisdictions below the State level to preempt Federal and State authorities with additional restrictions. This should be clarified in any FIFRA reauthorization with a specific prohibition of use restriction by local jurisdictions. In addition, States should be encouraged to adhere to Federal guidelines in the regulation of pesticide use and required to conform to Federal tolerances for pesticide residues in food.

Thank you very much for your consideration of our views, and Peter and I will be pleased to answer questions at the appropriate time.

Mr. BEDELL. Thank you.

We will next hear from Mr. Maslyn and then we will question you both.

STATEMENT OF MARK A. MASLYN, ASSISTANT DIRECTOR, NATIONAL AFFAIRS DIVISION, AMERICAN FARM BUREAU FEDERATION

Mr. MASLYN. Thank you, Mr. Chairman, and members of the subcommittee.

The American Farm Bureau Federation is a general farm organization in 48 States and Puerto Rico. Farm Bureau membership produces nearly every crop grown and marketed in commercial quantities in the United States. Today the American farmer produces enough food to feed himself and approximately 80 other people.

Critical to agriculture's ability to sustain this unprecendented level of production is the scientifically sound regulation of agricultural chemicals. We appreciate the opportunity to present our concerns on this important issue.

Section 3(a) of H.R. 2482 proposed to eliminate the language "under direct supervision" thereby limiting the use of restricted use chemicals to only the certified applicator.

No justification for this proposed change has been given nor has any evidence of a problem been provided. To the contrary, the agricultural community has demonstrated a commitment to professionalism and environmental concern in the handling of agricultural pesticides since the inception of the Training and Certification Program in 1975.

In the 10 years since this program was established, over 1.5 million farmers have been through the Training and Certification Program. Furthermore, tens of thousands annually upgrade their training through the recertification process. At this time no evi-

dence of need nor claim of a benefit that would justify this proposed change has been provided.

Sections 11 and 13 would strike current FIFRA provisions which provide for indemnity payments to owners of pesticide products for which registrations are suspended and canceled. Under the proposed change, the Environmental Protection Agency would no longer be responsible for the disposal of any suspended or cancelled pesticide, nor incur any costs through the indemnification of owners of existing stocks of these chemicals.

From strictly an agricultural standpoint, we believe this change would be unwise. To date, the Indemnity and Disposal Program has only been implemented for two suspended chemicals. We believe the program, as currently provided, is necessary to assure the safe and adequate disposal of stocks of suspended and cancelled pesticide products.

Mr. Chairman, I would also like to comment briefly on H.R. 1416, by Mr. Heftel.

We believe that this bill is good for agriculture since it eliminates one of the unfair advantages that foreign agricultural producers have over U.S. producers. This bill seeks to ensure that pesticides banned for use in the United States are not used by foreign agricultural produers to grow products which are ultimately shipped to U.S. markets.

Not only will this bill reduce the competitive disadvantage faced by American farmers, but it will also restore confidence and trust in the American people about the food products they purchase.

Before concluding, I would like to briefly address two provisions of a widely circulated draft reauthorization measure prepared by a coalition of environmental groups.

Farm Bureau is unalterably opposed to including in FIFRA any citizen suit provision. Such a provision would in the very least result in the harassment of farmers through nuisance suits alleging violations of FIFRA in the course of normal farming practices. We believe strongly that farmers who follow federally approved label instructions should be absolved from liability claims of environmental pollution.

Second, we are concerned over attempts to include ground water protection provisions within the jurisdictions of FIFRA. No one is more entitled to speak on this issue than farmers whose water needs are overwhelmingly served by ground water sources.

The issue of ground water protection is a rapidly emerging issue which will be in the forefront of discussion for years to come. We believe the magnitude of this issue is such that a uniform and comprehensive approach should be taken rather than reacting with a scattered patchwork of ground water provisions in every environmental statute under the sun.

Farmers consider themselves environmentalists by nature and necessity. We have an inherent interest in the reauthorization of FIFRA, not only from an economic and business standpoint but from a personal health and safety aspect as well.

We look forward to working with the members of this committee to ensure that the final product is not only effective and workable but reasonable in its impact.

Thank you.

Mr. BEDELL. Thank you, Mr. Maslyn.
Mr. Combest. Mr. Volkmer.
Mr. VOLKMER. No questions.
Mr. BEDELL. Mr. Gunderson.
Mr. GUNDERSON. No questions, Mr. Chairman.
Mr. BEDELL. Mr. Brown.
Mr. BROWN. Mr. Maslyn, I am quite sympathetic to most of the points you raised in your statement, but I am wondering if you are not a little inflexible on the situation involving ground water. I think the question is one of how is the best way to address this problem more than anything else.

You may recall that the situation that developed with EDB stemmed out of, amongst other things, the fact that it was discovered that it was occurring in ground water to a much greater extent than had ever been anticipated, and I am not quite sure what the proper way to address that is, but one of the things we have been hassling EPA on for many, many years is the inadequacy of their monitoring in certain media, and that includes the underground water resources.

I am wondering just how adamant the Farm Bureau would be about legislation which made a little bit more effective EPA's role in at least the monitoring of ground water supplies so that we don't get caught short in some of these additional situations like EDB that may crop up again in the future.

Mr. MASLYN. I don't think we would have any trouble with that. We are very concerned. Obviously the farmers in this country served by ground water sources in rural areas have a very inherent need to be concerned about what is in that ground water and they would support that I am sure.

Mr. BROWN. The EDB ban hit us harder in California than almost any other place I think because it is widely used as a preventative for nematodes in the citrus industry there and the problem was that we had no information as to how prevalent it was or what the pathway was by which it went from the soil in a citrus orchard to the adjoining wells, and I think EPA does have some responsibility to improve their capability of making judgments in that area.

One other thing, you don't like the language in the bill which deals with indemnification or the ending of indemnification for canceled pesticides.

Do you have any bright ideas about how we can handle that situation? You know the problem that faces us is EPA doesn't have a budget for that. They are underfunded for some of the things you are very interested in, better training in certification for example and other things, and whenever they are stuck with a heavy indemnification award they have to take it out of some of these other items and we don't quite see how they are going to be able to continue to do that.

On the other hand, it isn't fair to those holding large stocks of these chemicals. In many cases they are not the same people who even manufactured them, that they should be stuck with the burden of paying for it. It is a situation where there is no real good solution but we would like to get the best one we can.

Mr. MASLYN. I wish I had a specific recommendation for you. It is my understanding that most of the people who are indemnified are somewhere in the retail chain, not the manufacturer, but the bulk of the payments go to either the retailer or the applicator and I have been unable to get the specific information to distinguish even whether it is the private applicator or the commercial applicator.

I don't have a specific recommendation. I certainly understand EPA's dilemma and we do support increased funding overall for the Pesticide Program.

Mr. BROWN. Well, it may be that we will have to do sort of like we have in the savings and loan crisis, require some form of Federal insurance to pay for it or some form of insurance, the cost of which would be borne by people who are in this business.

It is a little unfair to ask the public as a whole to bear the cost of this when they get no observable and direct benefit. They get an indirect benefit obviously, but that is about all.

Mr. BEDELL. Mr. Evans.

Mr. EVANS of Iowa. Thank you, Mr. Chairman.

I would like to explore with the representative of the Farm Bureau and the wheatgrowers how they would react and how they would prevent from happening again a situation that occurred in my district last year.

A corn producer contracted with the local cooperative elevator applying chemicals to his field of corn. The person that came out was a technician, not a certified applicator. He put on the chemical and when he had finished there was a significant amount remaining in the tank. He stopped along the road at a small dry water course and dumped the remainder off the edge of the road from the tanks into that water course.

It went down into a small pasture that was a holding pasture for a dairyman, a pasture that is frequented every day. Within a matter of a day, most of the cows in the herd were obviously very, very ill. It is not apparent at this time however the effect of the chemicals, because as you well know it sometimes takes several days for chemicals to show their effects on vegetation.

The dairyman ultimately lost virtually all the herd as well as milk production for a period of time. By the time it was recognized what the problem was there was no way of proving from tissue in the cattle that this was the problem. Too much time had passed.

There are many elements to the problem including the applicator who is not certified and who is a technician. From your point of view as producers, how would you approach preventing incidents like that from happening?

Mr. MASLYN. Well, I don't know how far you can go to prevent situations like that. It seems to me that it is a matter of common sense, first of all, and you can't require that.

I would have little sympathy for an individual who drained a tank like that into a water supply.

Mr. EVANS of Iowa. Should there be penalties against that person?

Mr. MASLYN. I would think that there currently are penalties.

Mr. EVANS of Iowa. But they have not been imposed. So that there is room for better enforcement?

Mr. MASLYN. I would certainly think there is room for better enforcement.

Mr. EVANS of Iowa. How do we get better training of that person? I understand the objection is to certifying every technician or every person that is hired only for a short term to go out and apply these pesticides, but I think that is where a considerable amount of problem is. I recognize the great disadvantages of putting a certification process on every person that is supposedly working under supervision, but clearly it is not universally successful the way it is right now.

I am just hoping that someone have some practical successes for an acceptable way of at least dramatically reducing the number of these instances and still doing it in a way that makes it manageable.

Mr. WALESBY. Possibly I could respond. If I understand the scenario right that you are describing here, and unfortunately we do hear of things like that happening from time to time. It sounds like it was a commercial application made on a contract basis by the farmers co-op or elevator to him.

Many States govern this by State law whereas no commercial application of any type can be made on a contract basis unless that applicator is licensed and bonded.

The second part of your question, what would I do as a farmer, I would be hopping mad, because obviously the fellow didn't put all the chemical on the crop and had to dump it somewhere.

So obviously the individual made a stupid mistake. Unfortunately those things do happen.

Mr. EVANS of Iowa. Thank you, Mr. Chairman.

Mr. BEDELL. Thank you, Mr. Evans.

I have a couple of questions.

In your testimony, Mr. Maslyn, you say you are unalterably opposed to including any citizen suit provision. Do you believe that that farmer in Mr. Evans' case should not be permitted to sue the elevator, the co-op that was responsible for doing this?

Mr. MASLYN. Not at all. In fact, I would recommend—I would be surprised if he hasn't sued him already. I guess what we are concerned about is currently under FIFRA there is no private right of action.

From our information, virtually every State has pesticide regulations and laws and statutes that govern a situation as Mr. Evans described, and in that particular case we feel that the State statutes, common law, would be the place to begin.

I guess from a farmer's standpoint the concept of citizen suit brings to mind the professional litigant that would be hovering over the average farmer just in wait of a mistake.

We don't think that is the proper thing to do. If there is a problem with enforcement, then it should be dealt with directly through EPA or the State statutes. We don't feel that the making available the citizen suit to enforce FIFRA is the best alternative.

Mr. BEDELL. You also, say "we are concerned over attempts to include ground water protection provisions within the jurisdiction of FIFRA." I should think that is where you would want it to be.

Would you rather have it in Henry Waxman's committee?

Mr. MASLYN. Probably not, Mr. Chairman. I think it is a very unique issue. It is something that has surfaced relatively recently, and we don't know all that we need to know about it.

Maybe in the long run FIFRA is where it should be, but I guess what concerns us is having to fight this battle not only in the Safe Drinking Water Act and Clean Water Act but FIFRA as well.

We all know the relationship between groundwater contamination and the use of agricultural chemicals. It is something that concerns farmers very much. On the one hand we are using chemicals that are federally approved and registered and the label is approved by the Environmental Protection Agency.

The chemical is then recommended for use by the Extension Service, and 20 years later this chemical shows up in the ground water, not only in the public water supply, but in the farmer's own well. It is something that concerns us a great deal.

We just don't know exactly where this ought to be addressed but it is a very serious problem and we feel that it should be addressed in a comprehensive manner.

Mr. BEDELL. Are there any other questions?

Mr. BROWN. Would the gentleman allow me one more question?

Mr. BEDELL. Certainly.

Mr. BROWN. The issue of the private right to sue is going to give us a big headache. It has come up before and we recognize the issues that are involved here. If I understand correctly, what this really means is that the person desiring to sue must have recourse to the State courts under the general tort laws or whatever rather than having it written into the Federal law that they would have a Federal court recourse. Is that correct?

Mr. MASLYN. Yes.

Mr. BROWN. What bothers me a little bit here is that your position may be one of temporary expediency. It seems to me fairly conceivable that under some circumstances you might get a situation where a widespread public concern about some of these issues might create a climate in the State court level which would be the reverse of what it is now, where currently I think the State courts tend to be somewhat more sympathetic to the problems of the local citizens and the local farmers and so on, but that situation might be overcome, and I can envision the possibility of your coming back here and saying, why can't we have a Federal provision that preempts the State provision as we are saying now with regard to some other parts of the bill, where you don't want chaotic State and local regulations and saying that you would rather have this handled on a uniform basis at the Federal level.

Has that thought occurred to the Farm Bureau and have they considered the merits of that possibility?

Mr. MASLYN. Obviously it has. I think it is a very valid point. Even more so, I think farmers generally feel that they would like some provision in Federal statute that said if they follow the label that is approved by the Federal Government in more than one agency, then they should be absolved from any liability, barring gross negligence.

We don't want to be in a position of defending an applicator who has no regard for the law. That is not in anyone's best interest. But what we want to do is protect the family farmer, the mom and pop

farmer who has very little reresources to fight a nuisance suit, let alone any suit for significant damages.

Mr. BROWN. Well, what you are really saying is you want fair equitable an uniform legal standards that the farmers and others using the chemicals can live with.

Mr. MASLYN. That is correct.

Mr. BROWN. And not be subject to the chaos that you might otherwise get, which is a very reasonable position. The question is whether you get it better from leaving the exising situation, which very frankly, gives you different results in different places, and I think you are probably aware of examples of that.

But you still prefer that situation and for the time being to rewriting the statute to give a private right to sue in Federal court.

Mr. MASLYN. This was a policy that was surfaced at the grassroots level and was approved and voted on all the way through the county, State, and national annual meeting by the farmers that make up this organization, and that at the present time is their feeling.

Mr. BROWN. I think that may be reflecting the fact that your members may feel that they have more influence at the State level than they do at the Federal level. I may be guessing wrong.

Thank you.

Mr. BEDELL. Any further questions? If not, we appreciate your testimony very much. If there are no further questions, the committee will be adjourned until 9:30 a.m. tomorrow morning.

The subcommittee will be adjourned.

[Whereupon, at 3:12 p.m., the subcommittee adjourned, to reconvene at 9:30 a.m., Tuesday, May 21, 1985.]

[Material submitted for inclusion in the record follows:]

UNITED STATES DEPARTMENT OF AGRICULTURE
STATEMENT OF
KAREN DARLING, ACTING ASSISTANT SECRETARY
MARKETING AND INSPECTION SERVICES
BEFORE THE
SUBCOMMITTEE ON DEPARTMENT OPERATIONS, RESEARCH
AND FOREIGN AGRICULTURE
OF THE
HOUSE COMMITTEE ON AGRICULTURE
MAY 20, 1985

MR. CHAIRMAN AND MEMBERS OF THE SUBCOMMITTEE, IT IS A PLEASURE TO APPEAR BEFORE YOU TODAY TO PRESENT THE U.S. DEPARTMENT OF AGRICULTURE'S (USDA) VIEWS ON CHANGES TO THE FEDERAL INSECTICIDE, FUNGICIDE AND RODENTICIDE ACT (FIFRA).

WE ARE PLEASED WITH RECENT ADMINISTRATIVE ACTIONS TAKEN BY THE ENVIRONMENTAL PROTECTION AGENCY (EPA) TO ENHANCE THE TIMELINESS OF REGULATORY DECISIONMAKING WHILE ENSURING SCIENTIFIC SOUNDNESS OF THOSE DECISIONS AND THE OPENNESS OF THE DECISIONMAKING PROCESS. SINCE THE AGRICULTURAL COMMUNITY DEPENDS ON THE SAFE USE OF EFFICACIOUS PESTICIDES TO HELP PROTECT OUR PRODUCTIVITY AND OUR ACCESS TO FOREIGN MARKETS, INITIATIVES TO IMPROVE THE EPA REGULATORY PROCESS ARE CLEARLY IN THE INTERESTS OF AGRICULTURE.

IN TESTIMONY BEFORE THIS SUBCOMMITTEE, DR. JOHN A. MOORE, EPA'S ASSISTANT ADMINISTRATOR FOR PESTICIDES AND TOXIC SUBSTANCES CHARACTERIZED FIFRA AS A FUNDAMENTALLY SOUND LAW AND USDA CONCURS WITH THIS APPRAISAL. DR. MOORE ALSO

ADDRESSED AREAS OF CONCERN, IDENTIFIED BY A SPECIAL EPA SPONSORED TASK FORCE, IN ALLOWING EPA TO CONTINUE TO ACHIEVE ITS GOALS OF PROTECTING PUBLIC HEALTH AND THE ENVIRONMENT WHILE MAKING SURE THAT SOCIETY MAY ENJOY THE ECONOMIC AND SOCIAL BENEFITS THESE REGULATED PRODUCTS CAN OFFER.

MR. CHAIRMAN, WE UNDERSTAND THAT YOU HAVE INTRODUCED H.R. 2482, A BILL TO AMEND FIFRA. WHILE WE HAVE NOT HAD AN OPPORTUNITY TO REVIEW THIS BILL, SOME OF THE CONCERNS EXPRESSED BY DR. MOORE HAVE SPECIAL SIGNIFICANCE FOR AMERICAN AGRICULTURE. WE CERTAINLY SUPPORT EPA'S EFFORTS TO IMPROVE THE TIMELINESS OF THE REVIEW PROCESS. PROLONGING THE PROCESS UNNECESSARILY CAN CREATE COSTLY UNCERTAINTY AMONG PRODUCERS WHO NEED TO BE ABLE TO MAKE PLANS BASED ON FULL KNOWLEDGE OF WHAT PRODUCTS WILL BE AVAILABLE TO THEM. OF COURSE, WE ARE ESPECIALLY CONCERNED THAT ANY CHANGES ENSURE CONTINUED CONSIDERATION OF THE FULL RANGE OF CONSEQUENCES OF PESTICIDE REGISTRATION OR LOSS OF REGISTRATION.

ANOTHER AREA OF SPECIAL CONCERN TO US IS POSSIBLE CHANGES AFFECTING RESTRICTED-USE PESTICIDES. IMPLEMENTATION OF DECISIONS REGARDING RESTRICTED-USE PESTICIDES REQUIRES EARLY COMMUNICATION WITH THE DEPARTMENT SO THAT TRAINING NEEDS FOR APPLICATORS CAN BE CONSIDERED. WE RECOGNIZE THE DESIRABILITY OF ASSURING THAT RESTRICTED-USE PESTICIDES ARE USED BY OR UNDER THE SUPERVISION OF THOSE WHOSE QUALIFICATIONS ARE COMMENSURATE WITH THE RISKS POSED BY THE PESTICIDE. WE ALSO APPRECIATE THE EPA'S WILLINGNESS TO WORK WITH US IN MAKING SURE THAT AGRICULTURAL APPLICATIONS ARE FULLY CONSIDERED AND THAT ACTIONS THAT WOULD UNNECESSARILY INCREASE THE COST OF AGRICULTURAL PRODUCTION ARE AVOIDED.

WE ALSO WANT TO EXPRESS OUR GENERAL CONCERN THAT ANY CHANGES TO FIFRA ENSURE THAT THE EPA ADMINISTRATOR RETAINS THE FLEXIBILITY NEEDED TO ADDRESS CONCERNS FULLY. SPECIFICALLY, WE WANT TO ENSURE THAT EMERGENCY EXEMPTIONS REMAIN AVAILABLE. CURRENTLY UNDER FIFRA THE DEPARTMENT HAS AUTHORITY TO DECLARE A CRISIS EXEMPTION WHEN NO LABELED PESTICIDE IS AVAILABLE TO TREAT THE SPECIFIC PEST OR DISEASE AND WHEN THE NEED FOR TIMELY TREATMENT IS SO CRITICAL THAT A SPECIFIC EXEMPTION CANNOT BE OBTAINED. EPA JUST PUBLISHED A PROPOSED RULE THAT ENSURES THAT EXEMPTIONS ARE PROTECTIVE OF PUBLIC HEALTH AND ARE USED ONLY WHEN NECESSARY. AS AN EXAMPLE, THIS EXEMPTION WAS USED FOR THE MEDITERRANEAN FRUIT FLY ERADICATION IN CALIFORNIA IN 1981 AND OUR CURRENT PROGRAM IN FLORIDA. THIS PORTION OF THE ACT IS ESSENTIAL TO ENSURING THAT WE HAVE THE TOOLS AVAILABLE TO RESPOND TO DISEASE AND PEST EMERGENCIES THAT COULD QUICKLY DEVASTATE OUR AGRICULTURAL PRODUCTION SYSTEM. WE ARE CONCERNED THAT ABILITY TO RESPOND EFFECTIVELY TO THESE SITUATIONS IS RETAINED.

AS LEGISLATION IS DEVELOPED AND INTRODUCED, WE WELCOME THE OPPORTUNITY TO WORK TOGETHER WITH THE EPA AND WITH THE CONGRESS TO ENSURE THAT OUR COMMON GOAL OF PROTECTING THE ENVIRONMENT IS ACCOMPLISHED AND THAT THE VIEWS OF AGRICULTURE ARE FULLY CONSIDERED AS PROPOSED CHANGES TO FIFRA ARE EXAMINED. WE BELIEVE THAT A CLIMATE HAS BEEN ESTABLISHED THAT WILL ENSURE THAT WE CAN WORK TOGETHER EFFECTIVELY. IN CONCLUSION WE WOULD LIKE TO REITERATE THAT WE BELIEVE FIFRA IS A SOUND LAW THAT FULFILLS ITS PURPOSE. THE RECENT ADMINISTRATIVE CHANGES IMPLEMENTED BY EPA ARE FURTHER EVIDENCE OF FIFRA'S FLEXIBILITY AND OF THE EFFECTIVENESS OF THE CURRENT REGULATORY SYSTEM. THIS CONCLUDES MY STATEMENT, AND I WILL BE HAPPY TO ANSWER ANY QUESTIONS.

Presented by:
Robert J. Dold
Immediate Past President
National Pest Control Association

Mr. Chairman and members of the Committee:

INTRODUCTION

My name is Robert J. Dold. I am the Immediate Past President of the National Pest Control Association, the national membership association of owner/operators of structural, general household, industrial and institutional pest control companies in the United States. Besides my office as Immediate Past President of the National Pest Control Association, I own and operate Rose Exterminator Company, Chicago, Illinois.

On behalf of the National Pest Control Association and its 2,600 members, I thank the Committee for this opportunity to present our experience in working with pesticides under the provisions of the current FIFRA.[1]

The members of NPCA are those service companies in the nation's business that work to protect the public health, our food supply and our building structures from pest infestations and disease vectors carried by these pests. Hospitals and doctor's offices are kept germ free with pesticides. They also keep restaurant and school kitchens free of insects and rodents.

The structural pest control industry has used integrated pest management since its inception for effective pest management. It has not and does not now depend exclusively on pesticides in its work.

Pesticides are an important resource, however, for eliminating and controlling many pest 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 depend exclusively upon pesticides that are classified by EPA for restricted use. We estimate that currently

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[1]The Federal Insecticide, Fungicide, and Rodenticide Act (as Amended 1978).

over 95% of pesticides used in our industry are the same ones that are approved by EPA for purchase and use by the general public.

NPCA SUPPORTS FIFRA

Before submitting my recommendations for your action on FIFRA this congressional session, I would like to provide some background on the industry's position on FIFRA for the record.

In the early 1970's, NPCA supported the legislation which gave the Environmental Protection Agency the 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 its membership, to use only those pesticides that are registered by the responsible authorities of state and federal governments in a manner described in the manufacturer's registered label and as recommended by professional authorities in our field. The NPCA technical guidance is referenced by both federal and state regulatory agencies on how to safely and effectively control pests -- from cockroaches and termites to vertebrates, such as rats and birds.

For your purpose today in receiving comments for reauthorization of FIFRA, I will present our industry members' experience in operating under the current FIFRA. In general our experience confirms that the existing law is working to accomplish its purpose of providing for safe pesticide use; it does not need any changes to improve its effectiveness. My belief is that unless its broken, don't fix it.

OUR RECOMMENDATION

The NPCA proposal to the Committee at this time is:

> CONGRESS REAUTHORIZE THE EXISTING FIFRA FOR THREE YEARS WITH NO CHANGES IN THE PROVISIONS FOR PESTICIDE CLASSIFICATION AND APPLICATOR QUALIFICATIONS FOR PESTICIDE USE.

THE REASONS WHY

Our reasons for this recommendation are based on the following experience:

- The EPA records of pesticide poisonings throughout the United States indicate that the annual number of such instances remain stable and are probably decreasing despite increases in the population and the volume of pesticides used.

- In 1971 through 1976 the EPA Pesticide Incidents Monitoring Service recorded 900 to 1000 pesticide poisonings per year of all types nationwide.

- For 1978 and 1979 the National Clearing House for Poison Control Centers has reported that less than 360 individuals were poisoned and hospitalized by pesticides. This accounted for less than 5% of all poisonings of all types for each of those two years.

- Extensive studies by scientists of this data have found that almost all pesticide poisoning deaths in the U.S.A. are resulting from self-inflicted or homicidal incidents.[2] Deaths from pesticide poisonings for subsequent years are estimated by knowledgeable sources to be following the pattern reported by Drs. Hayes and Vaughn.

- For January - April, 1983 the Poison Control Center of Los Angeles, California received 24,000 telephone inquiries and of those inquiries, 1,182 were pesticide related. Of this number 97% were consumer oriented use or misuse pesticide incidents. The remaining 3% (35) of the inquiries resulted from pesticide applications by commercial or private (farm) applicators.

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[2] W. J. Hayes and W. K. Vaughn, "Mortality from Pesticides in the United States in 1973-74, Toxicology and Applied Formicology, Vol. 2, Academic Press, Inc., 1977.

My reason for citing these trends is to point out to you that FIFRA in its current form is an excellent piece of legislation that is accomplishing its purpose in making sure that the commercial applicators of pesticides are not creating the problems of pesticide poisoning to the citizens of the nation. They are trained to apply hazardous materials appropriately and safely under the existing state and federal laws.

It is our conclusion from this information that if any changes or expanded government action is needed to further reduce pesticide risks, it is to use the existing FIFRA authority to focus on educating the population that is currently experiencing the pesticide misuse or poisoning: the general public use of pesticides -- not the commercial and private applicators.

At this point I would like to compliment Mr. Lee Thomas, the new Administrator of EPA, for his recognition of the need for redirecting EPA's use of resources for focusing on where the problems are occurring. In his comment to the public on April 3, 1985, he outlined his proposals for "The Next Four Years - An Agenda for Environmental Results." In that presentation he indicated that EPA must --

> "... plan controlled solutions with a multimedia prospective. We have to reduce risk and not merely transfer it." He concluded his comments on this subject by stating that "We (EPA) must focus our resources on the most important problems, and fix them so that they stay fixed."

NPCA and its members would like to feel that this means looking at where the problems are occurring and focusing on reducing those risks rather than continuing to focus increased regulatory burdens on the small business community that has an excellent record of safety -- and that is continually improving!

ENVIRONMENTAL CONCERNS

Environmental risks from pesticides is an area that EPA has in the past and continues to address with increased intensity, and we think

apropriately. Increased knowledge of sometimes damaging effects of pesticides on the environment, and the growing technological competence to detect these problems, should not be used to indict prior decisions made based on the science available at that time. We believe that the current FIFRA provides EPA the essential authority and the necessary methods to quickly identify new scientifically confirmed data on environmental or health risks, and to take action to quickly restrict or remove from the market place the materials that pose the unacceptable risks.

ADMINISTRATIVE ACTION RECOMMENDED

Furthermore, we believe the existing FIFRA language also provides EPA and the states with legal authority to further reduce the already low frequency of pesticide misuse by both commercial and private applicators. FIFRA does not need to be amended, but the EPA Administrator should:

(1) Revise the regulations for Part 4a(1) that provides that all persons working under certified applicator supervision be trained in the safe use of restricted use pesticides and provided with the latest EPA and state revisions in registration and use directions for the Restricted Use Pesticides before such individuals are legally allowed to apply pesticides under supervision.

We believe this can be accomplished by mandating in the regulations that the responsibility for training and supervision of the service technician resides with his employer. His employer should ensure that the state or EPA required training in safe use of Restricted Use Pesticides is provided by some credentialed source. The National Pest Control Association has developed and presented to EPA proposals for carrying out this recommendation for the structural pest control industry. We believe that it is also applicable to the other special categories of pesticide applicators.

The EPA action needed is merely to designate the responsibility for carrying out specific prescribed training for those people who are working under supervision in applying Restricted Use Pesticides.

(2) Revise the regulations for FIFRA Part 4a(2) to require the EPA state cooperative plans to have enforcement personnel meet the certification requirements in the area where they are assigned pesticide enforcement responsibility.

Such is not always the case today in many of the states. The authority for this action contained in Section 4a(2)(B) states "The Administrator shall approve the plan submitted by any state or any modification thereof if such plan, in his judgment, contains satisfactory assurances that such agency has or will have the legal authority and qualified personnel necessary to carry out the plan;".

(3) The Committee authorize a funding level of at least $5,000,000.00 per year for the certification and training programs under FIFRA 23. These funds are needed to provide additional financial and consultative guidance to the states to strengthen the pesticide applicator training and certification programs. Such funds provided for training and certification reduce the need for enforcement action; training does not eliminate the need for a basic enforcement responsibility. Both activities are essential, but more attention and resources need to be invested in reducing the likelihood of pesticide misuse.

FIFRA AMENDMENT TO CLARIFY INTENT OF STATE PRIMACY

If any legislative action by Congress is needed at this time, it would be primarily to clarify what may not now be clear enough to implement the original intent of the 1972 Act and the 1978 Amendments

to FIFRA relating to federal and state authority to regulate pesticides and their use. The problem is local ordinances that are creating unnecessary confusion and increasing the complexity of different rules in various communities for pesticide use.

If every suburban community adopts its own differing rules for pesticide use, you can imagine it will be near impossible for the pesticide service personnel to keep those rules straight. It is a threat to the sound foundation for safe pesticide application in the practical world. It is costly not only to the business community but also to the safety of the public because it impairs our ability to provide professional pest control.

This clarification would not pose a threat to the sharing of primary regulatory authority between the states and local levels of government where appropriate.

If this FIFRA amendment is deemed feasible this session it can be done in the definition of a state in Section 2(z)(aa). This clarification will provide clear authority for state primacy in pesticide use rules but will not restrict the state from sharing appropriate enforcement authority with localities. It will require the state approval of any local pesticide regulatory action. Examples of such cooperative state action exists in California and New Jersey. Agreements are reached in these states with localities to provide enforcement authority for flexible use, depending upon the needs of the locality to prevent drift or notify sensitive individuals of future pesticide applications on a community-wide basis.

In conclusion, Mr. Chairman, I would like to thank you for this opportunity to present our experience on use of pesticides under the existing FIFRA. We share the Committee's goals of ensuring the continued effective and safe application of pesticides.

I will be pleased to respond to any questions you may have on our recommendation to simply reauthorize the existing FIFRA for another 2 to 3 years without changes, and our proposals for increasing the effective administration of that Act by EPA.

Thank you.

TESTIMONY

OF

ROBERT M. RUSSELL

ORKIN PEST CONTROL

ATLANTA, GEORGIA

I am Robert M. Russell of Orkin Pest Control. Our company is the world's largest in structural pest control. We operate in 43 states in this country; we employ 5,000 people; we serve over a million customers. We offer these comments for our company, for all other conscientious users of pesticides, and on behalf of our employees and customers.

We are glad that this Subcommittee, this congressional body, is examining the issue of safe pesticide use in the context of FIFRA. Pesticides, when used according to the label, protect the food, fiber, structure, health, and peace of mind of our nation -- and have done so with an outstanding safety record. If the benefit-risk relationship under the existing FIFRA is satisfactory, then I am sure all of us wish to save the expense which would follow from unneeded federal law changes and the ripple-effect upon the states, industry, and the ultimate payee, our citizens.

We would like to indicate to this Subcommittee the high efficiency and safety of our structural pest control industry.

The latest national report from The Council of Better Business Bureaus, Inc., published for 1983 shows the quality and safety of our industry. Of 409,156 complaints received from all types of companies nationwide, only 1, 701 concerned structural pest control companies. The fact that the pest control industry ranked only 46th in the number of complaints, with a percent of the total of 0.42%, is an outstanding achievement. Furthermore, this figure represents a significant improvement from the 0.53% level of total complaints in 1982.

And if you remember, 1983 was the year when the nationally prominent television program, "60 Minutes," dramatized the risks of a termiticide while hardly acknowledging the benefits. Also, there was additional publicity concerning the Massachusetts hearing and the Long Island House bulldozing. Fortunately in that year, EPA, with its "Analysis of the Risks and Benefits of Seven Chemicals Used for Subterranean Termite Control" stated on Pages VI - 1 and 2: "At this time in assessing the risks and benefits associated with the total national use of the

termiticides based on available data, and considering the lack of data outlined above, the Agency finds that the benefits from the use of the currently registered termiticide products outweigh the potential risks." Accordingly, these pesticides are still registered by EPA. Moreover, most of the pesticides we use are categorized as general-use rather than restricted-use pesticides.

There is also some very encouraging data being published relative to the safety of the pesticides used by the structural pest control industry:

1. A recent study by the California Department of Food and Agriculture, Worker Health and Safety Unit, showed that only 3% of pesticide accidents were caused by the structural pest control industry. This study covered the year 1982.

2. In another California study, the Poison Control Center of Los Angeles, during the period January through April, 1983, received 24,000 telephone inquiries. Of the 1,182 pesticide related calls, 97% concerned pesticides purchased by all consumers. Only 38, or 3%, related to pesticides applied by pest control operators and none of these could be classified as poisonings.

These studies strongly indicate that accidents resulting from trained applicator misuse are infrequent and a small percent of the total.

We next would like to comment on the general good health in this country and the steady improvement in life expectancy. From the "National Center for Health Statistics, Life Expectancy Data for 1981, Section 6, Life Tables," we quote:

LIFE EXPECTANCY FOR ALL RACES, BOTH SEXES, ESTIMATE AVERAGES

1950	68.2 Years of Age
1960	69.7 Years of Age
1970	70.8 Years of Age
1981	74.2 Years of Age

During this time, use of pesticides was also increasing. Based on figures published in 1978 by the U.S. International Trade Commission, the amount of pesticides applied during the period 1965 through 1975 increased significantly:

1965	750,000,000 Pounds of Pesticide
1970	825,000,000 Pounds of Pesticide
1975	1,225,000,000 Pounds of Pesticide

Thus, though more people were exposed to more pesticides, it in no way seemed to affect the health of our nation, for life expectancy continued to increase.

To show the relative safety of pesticides as compared with other substances and practices in this country, we are presenting a chart from an article published by Scientific American in February, 1982, "The Biological Effects of Low-Level Ionizing Radiation."

	SUBSTANCES/PRACTICE - ESTIMATED NUMBER DEATHS PER YEAR	
1.	Smoking	150,000
2.	Alcoholic Beverages	100,000
3.	Motor Vehicles	50,000
4.	Handguns	17,000
5.	Electric Power	14,000
6.	Motorcycles	3,000
7.	Swimming	3,000
8.	Surgery	2,800
9.	X-Rays	2,300
10.	Railroads	1,950
11.	General Aviation	1,300
12.	Large Construction	1,000
13.	Bicycles	1,000
14.	Hunting	800
15.	Home Appliances	195
16.	Fire Fighting	195
17.	Police Work	160
18.	Contraceptives	150
19.	Commercial Aviation	130
20.	Nuclear Power	100
21.	Mountain Climbing	30
22.	Power Mowers	24
23.	Scholastic Football	23

24.	Skiing	18
25.	Vaccinations	10
26.	Food Coloring	Less than 10
27.	Food Preservatives	Less than 10
28.	PESTICIDES	Less than 10
29.	Prescription Antibiotics	Less than 10
30.	Spray Cans	Less than 10

Please note, from this study, that pesticides are ranked only 28th out of 30 factors and deaths per year do not constitute any significant threat to life or health as compared to many other substances or practices.

So before this Subcommittee decides to recommend any changes in the laws and programs affecting the application of pesticides, it should be sure that there is significant evidence of the need for change -- not just a clamor or a demand that change for the sake of change be initiated. If there is evidence of need for changes, we will be your strongest supporter. If there is no evidence, let us continue our good record and steady improvement under the laws as they are.

In this respect, we would like to quote one President, Woodrow Wilson, who said in 1912, "The history of liberty is a history of limitations of government power, not the increase of it." So please, no more law unless necessary.

I also wish to address the issue of the application of restricted use pesticides by or under the direct supervision of a certified applicator. This is now required by federal law and rightly so for those supervisors of a work unit such as a structural pest control branch office. The existing law acknowledges the structure of our industry by defining "under the direct supervision" of a certified applicator to mean that the certified applicator must be available but not physically present (Sec. 2(e)(4) of FIFRA)

There are some who now advocate testing or certification for service technicians at the supervisory level of the certified applicator. This suggestion is (1) unnecessary in light of the safety record of the pest control industry and (2) completely incompatible with the structure of that industry.

First, service technician and certified applicator represent two separate and distinct positions. To show the difference in required knowledge and skill at these two levels,

our company position descriptions for the two positions are attached. We believe all or most other pest control companies would show an equivalent difference in duties and responsibilities.

To require each position to be tested equally would result in one of only two probabilities. Either the standards for the certified applicator would be reduced -- and this is counterproductive -- or these standards would remain above the normal ability of the technician. This, too, would be counterproductive. The latter situation would result in manpower shortages, increased costs to customers, and no effective increase in safety.

So, to request certification for all pesticide users regardless of job description is no solution at all. The utopian theory about technician certification does not reflect the reality of the different levels of required skill and knowledge. Further, it is of particular concern to us that consideration is being given to eliminating the supervision of restricted-use pesticide application by certified applicators. If this be done, supervision will be lessened rather than strengthened.

This major change strikes at the foundation of our structural pest control industry. We are a relatively small industry in size, applying approximately 5% of the pesticides used in this country. Our industry is built, as are most all service industries, upon a competent and trained individual working on his own. This technician needs certain knowledge and physical skills. If this technician becomes certif ed, this person will gain a title to his work position through the state certification process. To replace such an individual for cause, we would have to have available a replacement with certification credentials or our customers would suffer. Thus, our ability to supervise is lessened by the necessity of meeting an external requirement. Actual job performance would be reduced accordingly.

Second, we earlier documented that the majority of pesticide accidents result from consumer use. What advantage is there to certifying technicians while about 97% of the problems originate with consumers? Are we looking in the right direction? With public access to the same pesticides we use, why focus on technician certification?

The FIFRA Coalition, a responsible body representing millions of concerned people, has made constructive comments in this area and as a participating member of the National Pest

Control Association, we support its position. The FIFRA Coalition has proposed to resolve this matter by focusing on the training provided to service technicians.

In this respect, we would note that the regulations issued under Section 4 of FIFRA (40 C.F.R. 171.6(a)) offer broad possibilities for training. We definitely support initial and continuous training of technicians as a superior alternative to testing.

As this Subcommittee is aware, our industry is becoming increasingly concerned about the difficulties which would be created by permitting local governments to establish multiple and varying levels of regulation of pesticide use within their jurisdiction. In 1978, after considerable work by this Subcommittee, the Congress developed an effective clarification of the relative enforcement powers of the States and the Federal Government under FIFRA. Now this system is threatened by many new entrants into the regulation business. We would hope that this Subcommittee would courageously address this issue and bring forth a logical solution. Here again we support our own National Pest Control Association and the other responsible members of the FIFRA Coalition.

In conclusion, I would repeat that if proof of need for change in the scope of certification is presented, our company and our industry would support a review of this issue. However, if there is only a request and no supporting factual data, we would question the wisdom of taking any action. The expense alone of unnecessarily broadening a successful system would create an extreme burden upon the states, the industry, and eventually, our customers. Training, not universal certification, offers the best avenue for continued improvement. We are equipped to supervise training through our industry, our association, and our state officials. The use of training is already authorized in the existing regulations. Let us move accordingly within the safety and efficiency of our free enterprize system. Another President, Herbert Hoover, expressed this most eloquently when in 1932 he said "We have . . . a system of individual sm peculiarly our own which must not be forgotten in any governmental acts, for from it has grown greater accomplishments than those of any nation."

We have no proof from state or federal officials that present certification procedures are <u>not</u> working. If minor adjustments are needed, we will work with EPA and the states to see that it is done. By law, establish only those requirements that are absolutely necessary for safety. And let us go forward with our successful system, using the established progress and good record of our industry as a base.

I thank you for this opportunity to present this testimony and I would be happy to answer any questions which you might have.

(Attachment follows:)

BRANCH MANAGER

POSITION DESCRIPTION

BASIC FUNCTION:

This position is responsible for the integrity, ongoing profitability, safety and morale of branch operations through the selection, training, and supervision of branch personnel.

PRINCIPAL ACCOUNTABILITIES:

A. Produce revenue and profit.

B. Understand, administer and enforce all Company policy.

C. Improve the Company's image.

D. Upgrade quality of personnel.

E. Develop all Company employees through training.

F. Insure that employees are fairly compensated and prepared for promotional opportunities.

G. See that quality service is delivered.

H. Collect all funds due the Company.

I. Responsible for the security of all Company property.

J. Maintain buildings, grounds, vehicles, and equipment.

TERMITE TECHNICIAN

POSITION DESCRIPTION

BASIC FUNCTION:

This position is responsible for destroying and preventing the return of termites in homes and businesses.

PRINCIPAL ACCOUNTABILITIES:

A. Provide superior termite control service according to established procedures and specifications.

B. Establish and maintain good customer relations.

C. Maintain all equipment in good operating condition.

D. Respond to and resolve customer complaints as they occur.

E. Maintain a neat and professional appearnce and manner at all times.

F. Operate a motor vehicle in a safe and efficient manner.

G. Complete and turn in required documentation and paperwork.

TESTIMONY OF KAY E. PINKUS, COUNSEL, INTERNATIONAL SANITARY SUPPLY ASSOCIATION, INC.

ISSA is a trade association comprised of nearly 3,000 companies in the cleaning and maintenance industry. ISSA members manufacture and distribute a wide variety of products and chemicals used for cleaning and maintenance. Some of these cleaning chemicals are regulated as "pesticides" under FIFRA. My testimony will not deal with the many complex issues presented by the reauthorization of FIFRA. It will instead describe one enormous problem faced by the cleaning and maintenance industry. This problem is a result of the non-specific definition of the term "pesticide" in FIFRA.

Many cleaning products are regulated by EPA as "pesticides", although they would not seem to be likely candidates for this classification. These are pesticides such as Lysol, Comet, sanitizing dishwashing rinses, air-fresheners, and even toilet bowl disinfectants. These products are classified as pesticides because they destroy or mitigate bacteria, germs, and other similar pests. These types of pesticides can be referred to generally as "antimicrobials".

The problem is not that these antimicrobials are regulated as pesticides. The problem is that many people are not aware that this is the case. The cleaning and maintenance industry has dealt with many problems which arose because neither the regulators nor the regulated public were aware that these cleaning products fall under the definition of "pesticide". The reason for this confusion is clear--antimicrobials do not fall within the commonly understood definition of "pesticide" and nowhere in FIFRA is there any mention of this category of pesticide.

FIFRA simply defines a pesticide as any substance which destroys or mitigates a pest, and further defines a pest as any insect, rodent, fungus, weed, virus, bacteria or other micro-organism. In many cases, people reading this definition

assume that it refers to agricultural pesticides and indoor-use insecticides and rodenticides, and do not have the slightest idea that products used in the cleaning and maintenance industry are covered.

Let me give you two brief examples of the sort of problems that are rampant in the cleaning and maintenance industry as a result of this confusion. In 1982, Illinois enacted a law which required certification for the use of any pesticide in the state. Even the sponsor of this legislation did not realize or intend to require certification for the use of antimicrobials. Nevertheless, the cleaning and maintenance industry was forced to go through the time- consuming and costly process of obtaining an amendment to this law. This unfortunate situation has occurred many times, not only at the state level, but at the local level as well.

The lack of specificity in the definition of pesticide has also caused problems of compliance for those people who are regulated. Many members of ISSA are small family-owned businesses who distribute a wide variety of cleaning and maintenance products. Most companies distribute mops, buckets, soap dispensers and many other items, in addition to a few lines of disinfectants and other antimicrobials.

These small companies will hire a general corporate attorney to take care of their business' legal matters and provide counsel for compliance with any relevant product label and product safety issues. Many of these attorneys do not have previous knowledge of FIFRA. Even after reviewing this law, they do not have a clue that their client's products such as Lysol need to be registered in the state of sale as pesticides. This vague definition in FIFRA has led to enforcement actions against companies which were not put on adequate notice of the subject matter of FIFRA.

There are those who say that people should know that FIFRA covers antimicrobials. But the fact of the matter is, people do not. Legislators, regulators, and the regulated public are not sufficiently apprised of the subject matter of this statute. This is particularly inappropriate in a law such as FIFRA, which envisions a scheme of state regulation and enforcement.

In conclusion, it is one thing to argue over the merits of substantive regulation of pesticides; it is another to include an entire industry under a statuatory definition which does not provide sufficient notice that this industry is covered. We are asking you today to make the simple clarification in FIFRA which would put an end to this waste and confusion. This problem could be corrected by specifically stating in FIFRA that antimicrobials are pesticides. This would not change the substantive regulation of antimicrobials in any way. I have enclosed a definition in the appendix to this testimony and will submit it for the record. Thank you for listening to our concerns.

(Attachment follows:)

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PROPOSED DEFINITION OF 'ANTIMICROBIAL'

Section 2(u) of FIFRA is amended by striking out "and" immediately before clause (2) and adding the word "and" at the end of clause (2), and by adding a new clause (3):

(3) any substance or mixture of substances intended for use as an antimicrobial.

Section 2 of FIFRA is also amended by adding a definition of "antimicrobial" (and by re-lettering the definitions which follow in sequential order).

(e) The term 'antimicrobial' means:

(1) Disinfectants intended to destroy or irreversibly inactivate bacteria, fungi, or viruses on surfaces, inanimate objects, or in water; or

(2) Sanitizers intended to reduce the number of living bacteria or viable virus particles on inanimate surfaces, in water, or in air; or

(3) Bacteriostats intended to inhibit the growth of bacteria in the presence of moisture; or

(4) Sterilizers intended to destroy viruses and all living bacteria, fungi, and their spores, on inanimate surfaces; or

(5) Fungicides and fungistats intended to inhibit the growth of, or destroy fungi (including yeasts) on inanimate surfaces; or

(6) Commodity preservatives and protectants intended to inhibit the growth of, or destroy bacteria in or on raw materials (such as adhesives and plastics) used in manufacturing, or manufactured products (such as fuel, textiles, lubricants, and paints).

STATEMENT OF ROBERT W. MILLER, Ph.D.
MEMBER OF BOARD OF DIRECTORS,
PROFESSIONAL LAWN CARE ASSOCIATION OF AMERICA
BEFORE THE SUBCOMMITTEE
ON
DEPARTMENT OPERATIONS, RESEARCH & FOREIGN AGRICULTURE
UNITED STATES HOUSE OF REPRESENTATIVES

My name is Robert W. Miller. I am a member of the Board of Directors of the Professional Lawn Care Association of America located at 1225 Johnson Ferry Road N.E., Marietta, Georgia. I am also Vice President in charge of Technical Services for ChemLawn Services Corporation, a professional lawn service company headquartered in Columbus, Ohio. Prior to my association with ChemLawn, I was a Professor of Agronomy with The Ohio State University College of Agriculture.

The Professional Lawn Care Association of America, or "PLCAA," is a trade association with a membership of 650 professional lawn service companies engaged in the care of urban and suburban landscapes. Many member companies apply pesticide products to lawns, ornamentals and trees for the control of pests and disease. As pesticide applicators, our members are subject to EPA jurisdiction pursuant to the requirements of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended.

I am here today to speak about the concerns of PLCAA regarding the rapidly increasing threat of regulation of pesticides by local governments. Such regulation is having a harmful and discriminatory impact on the ability of our members to continue to provide a safe, covenient and cost competitive alternative to the do-it-yourself use of outdoor pesticide products.

The Professional Lawn Service Industry

The professional lawn service industry has experienced significant growth during the past 15 years as more homeowners and businesses opt for the convenience and reliability of professional lawn, tree and shrub care services for urban and suburban landscapes. PLCAA members operate in the 50 states and the District of Columbia. As a whole, the professional lawn service industry provides service to more than 7 million homeowners and businesses and employs more than 160,000 people. Much of the industry is comprised of small privately-owned businesses.

While some lawn care companies offer only mechanical maintenance services (such as mowing and pruning), many provide chemically-based service to private residences and commercial establishments. Liquid or dry materials are applied to provide fertilization. Pesticide products to control weeds, destructive insects and diseases are added at appropriate times during the season. The service typically consists of four to five applications per year, dependent upon geographic location and agronomic conditions.

Professional lawn care companies are service companies--they do not manufacture or formulate the fertilizers and pesticides they use. They purchase materials from various manufacturers based on efficacy, cost, and safety to employees and customers. Most pesticides applied by professional lawn service companies are classified for "general use" under FIFRA. These products contain the same active ingredients and require the same rates of application as the lawn care products purchased by do-it-yourself users at numerous retail outlets.

The Environomental Protection Agency regulates the sale and use of pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). FIFRA authorizes states to also regulate the "sale and use" of pesticides.

Federal and State Regulation of Pesticides

Few compounds used in modern life are more extensively regulated by federal and state governments than pesticides. All pesticides must be registered with the Federal Environmental Protection Agency (EPA) before they can be sold or used. In addition, each state has its own registration program. Registration and deregistration decisions are based on EPA's review of an extensive toxicology data base for the pesticide's potential for acute, subchronic, chronic and mutagenic toxicity. Moreover, the storage, mixing, use, and disposal of pesticides by commercial users, such as professional lawn service companies, are regulated extensively under federal law.

Regulation of pesticides at the state level is equally extensive. In most states, professional lawn service applicators are authorized to apply pesticides only if licensed by the appropriate state regulatory agency. They also must post a performance bond before commencing applications. Licenses are granted after competency in the handling of pesticides has been demonstrated through a licensing examination. State agencies also are given the authority to adopt comprehensive state regulations governing the handling, storage, transportation, application, and notice or posting of an application of pesticides.

Local Regulation of Pesticides

Notwithstanding the extensive regulation of pesticides by EPA and state governments, during the past ten years 60 local governments in 17 states have considered regulating pesticides. While some local pesticide ordinances were adopted during the 1970's, most of the regulatory initiatives have taken place recently. Attachment "A" presents a list of those local governments where pesticide regulatory efforts have arisen.

Generally, local regulatory initiatives have taken one of three forms: (1) an outright ban on the use of a particular pesticide or class of pesticides; (2) a ban on the aerial application of a particular pesticide; or (3) a requirement to notify neighbors or customers of the indoor or outdoor application of pesticides.

Local legislative initiatives in the first two categories often are prompted by state-sponsored spray programs to combat highly-destructive gypsy moths, by spray programs for mosquito control in urban areas, and by isolated drift incidents resulting from the aerial application of pesticides to agricultural crops.

The third category of local regulation would require commercial applicators of pesticides to notify certain residents of an application either prior to or after the application. This form of regulation has been promoted vigorously by those individuals who believe themselves to be sensitive to synthetic chemical substances, including pesticides. Proponents contend that pesticides, when used in accordance with their labeled directions, present unacceptable health risks to them and their community and that federal and state authorities have done an inadequate

job of regulating pesticides. Ironically, ordinances promoted by these individuals typically do not apply to the larger do-it-yourself market segment, that segment of the user community, where--because of the lack of training in the use of pesticides--the possibility of mishap is greatest.

Local Case Histories

The municipalities of Lyndhurst, Ohio and Wauconda, Illinois have received extensive publicity over their local regulation of pesticides. The manner in which these local governments went about the legislative process is representative of how pesticide regulation is addressed at the local level.

During 1984, the city of Lyndhurst proposed an ordinance to require the prenotification of pesticide applications by professional applicators. The Lyndhurst ordinance would have made it a criminal act for a commercial applicator (but not a do-it-yourself user) to apply pesticides to outdoor property without first providing 24-hour advance notification to residents within a 5-house radius of the customer.

Health related testimony offered by proponents of the ordinance was entirely anecdotal. At the same time, council members rebuffed commercial applicators' attempts to present independent, expert testimony on the safety of the materials being applied. One council member (who supported the ordinance) justified her refusal to hear additional testimony by admitting that the issue of pesticide safety was too complex for comprehension by council members.

Council permitted only Lyndhurst residents to speak on the ordinance during the public comment period at the council meetings, preventing non-resident lawn care companies from presenting testimony at that time. Although the Mayor vetoed the ordinance (because he felt it was illegal and the city lacked the resources to enforce it), an attempted override of the veto fell short by only one vote.

Similar treatment of the issue occurred in Wauconda, Illinois during the fall of 1983. There, the Board of Trustees enacted prohibitions against the commercial application of pesticides unless warning signs were posted for 3 days. The 15"x24" signs must appear every 75 feet of border on the treated property.

Those professional lawn care applicators regulated by the ordinance were not given an opportunity to present testimony to the Board prior to a vote on the ordinance. Following adoption, lawn care companies met with the Board president and attempted to ask for reconsideration. However, discussions ended abruptly when, without cause, the Board president refused to continue the meeting.

The Inadequacies of Local Regulation of Pesticides

The extensive regulation of pesticides at the federal and state level has not deterred local governments from engaging in pesticide regulation. The federal and state regulatory programs are designed to balance the risks and benefits of pesticides. Local regulatory programs ignore this balance and impose additional costs and governmental restrictions on those consumers who chose to use professional rather than do-it-yourself lawn care. As discussed below, the local regulation of pesticides is unnecessarily disruptive and, in the long run, counterproductive to existing federal and state programs designed to provide for the safe use of pesticides.

1. Lack of Uniformity

Most professional lawn service companies operate in more than one municipality, particularly in major metropolitan areas. If numerous local governments were to adopt differing pesticide ordinances, lawn service companies subject to these ordinances would face a difficult and time consuming task. A multiplicity of local ordinances clearly will increase the cost to consumers of professional lawn care services. For example, should communities in one service area each ban a different pesticide, lawn service companies (and, in turn, customers) would bear the increased costs associated with additional inventory maintenance needed to provide satisfactory customer service. Extensive local pre or post notification requirements will engender increased expenses for labor, telephone access and sign printing, posting and removal. With 65,000 political subdivisions below the state government level in the United States, it is not unforeseeable that lawn service companies will become overwhelmed by varying local laws. Professional lawn service companies will be deterred from doing business by the complexity of maintaining compliance with numerous and varied local requirements. Because of the increased costs of compliance with multiple local laws, the benefits and convenience derived from the professional care of lawns and landscapes may no longer remain within the reach of medium income families.

Finally, local governments rarely consider the external impact on neighboring communities when regulating pesticides. Pests do not respect local jurisdictional boundaries. Communities that ban a particular pesticide may foster or prolong the existence of a particular pest in a metropolitan area by providing a safe harbor from effective control. Such safe harbors can serve as breeding grounds for insects, diseases and other pests that will attack people, structures and plant life well beyond a local community's borders.

2. Absence of Scientific Expertise

A thorough knowledge of chemistry and toxicology are fundamental to assess the relative risk to humans or the environment from a particular type or use of pesticides. A knowlege of weed science and entomology allows for an assessment of the benefits of a pesticide and the feasibility, safety and availability of alternative controls. Expertise in these areas exists at the federal and state levels but rarely at the local level. Because local communities lack such expertise, they may give undeserved weight to essentially anecdotal accounts of alleged injury attributed to pesticides. While such accounts often succeed in elevating public anxiety over pesticides, they rarely withstand critical scientific scrutiny.

A lack of expertise also fosters simplistic solutions to complex problems. For example, some local legislatures have enacted total bans on the use of all pesticides when a single pesticide is alleged to have caused a problem. This broad-brush approach to regulation ignores the extensive scientific evidence about the risks and benefits of various pesticides generated as part of the federal and state regulatory process. To be evaluated properly, this evidence demands a level of scientific knowledge that usually does not exist at the local level. This presents the real danger that local legislators will regulate pesticides out of a fear of the unknown, or as a result of pressure from a few vocal proponents, rather than from a reasoned evaluation of scientific data.

3. Lack of Enforcement and Loss of Public Confidence

Federal and state governments have established a comprehensive system to regulate pesticides, the primary function of which is the protection of the public health and the environment. Local officials who promote local pesticides regulation frequently justify their efforts by criticizing federal and state regulatory efforts. Ironically, local governments that may choose to regulate pesticides rarely possess the resources and technical expertise to provide even minimal enforcement of local pesticides laws. Consequently most such ordinances go unenforced. This absence of an enforcement presence undermines

public confidence in our government institutions and encourages noncompliance with regulations. A lack of enforcement also provides a competitive disadvantage to those companies who voluntarily comply and thereby incur increased costs.

4. Incentives To Do-It-Yourself

By regulating only commercial applicators, local pesticide legislation fosters a belief by the public that the materials applied by professional service companies are more "toxic" than those found in pesticide products sold over-the-counter at retail stores. This misperception by the public (and the increased cost of professional lawn care service) encourages consumers to discontinue professional service as less safe than do-it-yourself care. This, in turn, increases the risk to the public and the environment from the misapplication or mishandling of pesticide products by untrained individuals.

Unlike professional applicators, do-it-yourself users may fail to read label directions and will overapply pesticide products from a belief that "more is better." This overapplication may harm plants, increase applicator exposure, and lead to run-off of excess pesticides. In addition, do-it-yourself users may store concentrates carelessly in the home or dispose of pesticides in sanitary or storm drains or in household trash. Professional lawn service companies, on the other hand, use correct application rates, handle and store concentrates only at their facilities, and save excess quantities for later use.

Despite these sound reasons for encouraging the professional application of pesticides rather than do-it-yourself use, local governments tend to do the reverse. They regulate the professional applicator and, by doing so, provide a significant incentive towards the do-it-yourself use of pesticides.

5. A Burden on Commerce

Local pesticide ordinances clearly impose restraints on the free flow of commerce. Professional lawn service companies that fail to comply with a local ordinance may be prohibited from doing business in that community, even though they have met all federal and state regulatory requirements.

In some instances, professional applicators simply will be unable to comply with the regulatory demands proposed by proponents of local ordinances. For example, one proposal would require an applicator to notify all residents within a 300 foot radius of a customer, 72 hours prior to application. For a single customer in a suburban area, this law would require notification of about 14 homes per customer prior to application. Accomplishing such notification with any certainty of success would be impossible. Moreover, the outdoor application of pesticides is weather dependent. Because of this weather dependency, professional applicators cannot predict with any certainty the time of application 72 hours in advance.

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The Need For A Strong Federal Presence and Clear Statutory Language

PLCAA members have experienced first hand the tendency of local governments to politicize the regulation of pesticides. The refusal of local governments to regulate the do-it-yourself use of lawn care pesticides along with commercial applicators demonstrates most clearly that the local regulation of pesticides is motivated primarily by political expediency rather than by an honest concern for public safety. State governments, merely by their proximity to local jurisdictions, also are subject to and mindful of these same political forces that seek to capitalize upon the public's anxiety over pesticides.

No one at any level of government has argued that the regulation of pesticides is a simple matter. Because of the complexity of this issue, decisions to regulate pesticides must be made in an atmosphere conducive to scientific scutiny and reasoned deliberation. Such an atmosphere has yet to arise at the local level, primarily for the reasons discussed earlier.

It is our belief that if left to local political forces, inconsistent and ineffective regulation of professional lawn care will proliferate. There is an immediate need for a strong and visible federal presence in the pesticide regulatory arena. We at PLCAA favor reasoned regulation and enforcement by the federal EPA and coordinate state regulatory agencies. PLCAA therefore requests that this subcommittee consider amending present Section 24(a) of FIFRA to expressly confine the regulation of pesticides to the federal and state governments. Be assured that PLCAA members will actively support regulatory efforts at the federal or state level that promote applicator competency, increase customer and employee safety, and provide consistent and equal treatment for all segments of the lawn care industry.

Thank you for your attention.

(Attachment follows:)

ATTACHMENT A

LIST OF LOCAL POLITICAL SUBDIVISIONS

California

Mendocino County (1979)

Ordinance banned the aerial application of all phenoxy herbicides in the county.

Connecticut

Town of Manchester (1983)

Ordinance prohibits the application of chemicals to trees, shrubs or property unless beekeepers within a 2 mile radius of application site are notified 48 hours in advance.

Simsbury (1984)

Proposed to restrict the commercial use of lawn chemicals in water supply areas.

Florida

Surfside (1983)

Ordinance prohibits application of pesticides to outdoor property without prior notice to occupants of abutting properties at least 12 hours prior to application. "Danger" sign must be posted for 3 days following application.

Idaho

Boise (1983)

Proposal considered to require notification of adjoining property owners by registered mail and receipt of permission from those notified prior to pesticide application.

Illinois

Evanston (1984-85)

City Council adopted ordinance to provide for the voluntary posting of signs following the application of pesticides.

Park Forest (1985)

Considering ordinance to require prenotification of application and sign posting following the application of pesticides.

Palo Heights (1985)

Ordinance being considered to ban the application of pesticides during certain periods on weekends.

Wauconda (1984)

Ordinance prohibits commercial pesticide application unless property is posted with warning signs every 15 feet of border for 72 hours after application.

Winnetka (1985)

City considering proposal to require commercial applicators to post signs every 75 feet of border for 72 hours after application.

Maine

Lebanon (1983)

Ordinance bans all commercial spraying of herbicides for non-agricultural reasons within town boundaries, unless approved by town meeting vote. Ordinance arose after traces of 2, 4, 5-T were found near power lines right-of-way.

Maryland

Manchester (1984)

Ordinance prohibits application of any "pesticide, herbicide of fungicide [sic]" within town limits without receiving permission of Mayor and Council. Areas to be sprayed shall be posted ten days in advance with warning signs 100 feet apart.

Montgomery County (1985)

County Executive has proposed ordinance to require posting of warning sign after commercial application of pesticides to outdoor property. Posting requirement would result in 270,000 sign per year in county. Ordinance would also require retail establishments to make signs available to customers purchasing pesticides over the counter.

Massachusetts (1983)

Amherst

Board of Health proposed regulations prohibiting the use of herbicides without a permit from the Board.

Brewster (1984)

Board of Health passed rules prohibiting the use of 12 pesticides (aldicarb, DBCP, alachor, atrazine, bromaci, carbofuran, dachal, 1, 2-dichloropropane, dinoseb, EDB, simazine and dicamba) within the town.

Burlington (1983)

Board of health proposed rules prohibiting the use of pesticides without a permit from the Board.

East Middlesex (1982)

Town Council adopted ordinance prohibiting the application of pesticides that may come into contact with person or the property of another unless written permission has been obtained from such other person. Ordinance also regulated microwave transmissions.

Springfield (1982)

Ordinance considered that would prohibit pesticide applications from certain areas or under certain circumstances.

Leverett (1981)

Adopted by-law prohibiting application of pesticides to land areas greater than one acre unless permission has been obtained from the Board of Health. Board is empowered to hold public hearing within 21 days of receipt of notice to consider whether to approve proposed activity.

Wayland 1983

Town adopted by-law prohibiting application of pesticides to land areas where pesticides may come into contact with person or property of another, unless written permission is obtained from the other party in advance.

Wendell (1982)

Town adopted by-law prohibiting the use of pesticides without approval of the Board of Health. Prospective user must notify Board 90 days in advance. Board must hold hearing within 30 days of receipt of notice.

Louisiana

Plaquemines Parish (1982)

Parish passed Ordinance prohibiting the application of ester compounds of phenoxy herbicides and 18 other herbicides within the boundaries of Plaquemines Parish.

Michigan

Milford

Ordinance proposed to require license from the City Manager prior to the application of chemicals to lawns.

Missouri

Olivette (1984)

City Council considered proposal to require the posting of warning signs for 72 hours following the commercial application of pesticides to lawns, trees and shrubs.

New Hampshire

Salisbury (1976)

Ordinance adopted prohibiting the use of chemical defoliants unless vegetation destroyed is replaced by desirable and useful vegetation.

New Jersey

Bloomingdale (1981)

Ordinance adopted prohibiting the commercial spraying of pesticides on ornamentals without a permit issued by the Borough.

Denville (1984-85)

Ordinance proposed to prohibit the area-wide application of pesticides unless newspaper notice is given 60 days in advance of application, and those residents who so request and who live within the target site are notified at least 12 hours in advance of application.

Application to ornamentals is prohibited unless the customer notifies by written notice property owners within 200 feet at least 24 hours in advance of application and adjacent property owners at least 12 hours in advance of application.

East Windsor (1984)

Ordinance adopted prohibiting aerial spraying of pesticides unless newspaper notice is provided within 10 days of application, and occupants within 500 feet of the target site are notified in written not less than 3 days before application.

The groundspraying of pesticides is prohibited unless all occupants within 200 feet of the target site are notified in writing at least 3 days in advance.

Ordinance also restricts aerial spraying of pesticides to between 9 P.M. and 8 A.M., Monday through Friday.

Eversham Township (1984)

Adopted ordinance prohibiting non-agricultural aerial applications of pesticides and requiring prenotification of aerial agricultural applications of pesticides.

Ringwood (1981)

Ordinance adopted requiring commercial applicators to notify citizens prior to spraying for Gypsy Moths.

Roxbury (1982)

Ordinance adopted by Board of Health prohibiting the application of "pesticides, herbicides or defoliants" without a permit from the Board of Health.

Washington Township (1981)

Ordinance adopted prohibiting the application of pesticides by means of ground spraying without a permit from the Health Officer and without notifying adjacent property owners and occupants at least 48 hours in advance.

New York

Huntington (1971)

Adopted ordinance establishing authority of Town Pesticide Control Board to register pesticides and prohibiting the use of unregistered pesticides within town limits.

Old Westbury (1985)

Ordinance being considered to require 72 hour prior notification to all residents living within 300 feet of the border of a property where pesticides are being applied.

Roslyn Harbor (1983)

Ordinance proposed to prohibit the application of pesticides by commercial applicators without a permit from the Village.

Ohio

Lakewood (1985)

Considering ordinance to requiring the advance notification of pesticide application by commercial applicators.

Lyndhurst (1984)

Council passed but Mayor vetoed ordinance to require commercial applicators to notify residents who registered at City Hall of all pesticides applications performed within 5 houses of registrant's.

Orange Village (1984)

Proposed ordinance to license all commercial applicators of pesticides.

Shaker Heights (1984-85)

Environmental Board considering proposals for notification of residents of outdoor pesticide applications performed by commercial applicators.

Columbiana (1984)

Village Council conducted hearing to consider regulation of the commercial application of pesticides to lawns.

Oregon

Eugene (1985)

Council committee presently considering regulation of the commercial application of pesticides to trees. Applicators required to give advance notification to all properties located within 150 feet of the property being treated.

Wisconsin

Saint Claire (1981)

Adopted ordinance requiring the posting of public property sprayed with pesticides. Posting shall consist of warning signs every 100 yards to remain in place for three months. Ordinance also prohibits the use of phenoxy herbicides on public lands or forests.

Madison (1985)

City attorney has been asked to draft an ordinance to require that citizens be given warnings of pesticide application to lawns by commercial applicators.

Township of Bell

Prohibits use of herbicides on town-owned roadways and rights-of-way.

Township of Clover

Prohibit the use of herbicides on all easements, i.e., roads, power lines, pipelines, and for conifer release or improvement of wildlife habitat. (use by farmers for other agricultural purposes okay.)

Township of Union

Total prohibition of certain herbicides.

Douglas County

Requires 6 months advance notice in local papers of use of Tordon.

Dairyland Township

Prohibition of herbicides except farm use may apply for exemptions.

Township of Komensky

Prohibits any kind of spraying of herbicides to control growing plants, etc. on town rights-of-way.

Township of Bradley

Requires published notice prior to application on public lands, roadways, private lands without permission.

Township of King

No use of herbicides by Township.

Township of Tomahawk

Prohibited defoliants near utility lines.

Comstock Lake Property Owner Association

Resolution to forbid aerial application in watershed.

Steven Point

No use of 2,4,-D in city parks, school grounds, playgrounds, etc.

Township of Kennan

Prohibition of all chemicals or herbicides on town lands, including rights-of-way.

Township of Bass Lake

Phoenoxies, other than private herbicide use on private lands, are banned until proven safe.

Township of Casey

A new ordinance drafted by Wisconsin's Public Intervenor's office was adopted 7/19/84. It requires a permit before applying herbicides on lands subject to public use or any aerial application of pesticides. Town may impose "reasonable requirements" such as prior notice, ground rather than aerial application, etc. Permitting process could take as long as 180 days. Placarding required.

Township of Frog Creek

Adopted 5/14/84. Requires a hearing prior to use of "aerial sprayed herbicide" for proof and evidence of non-toxic effect. Residents may petition for election to vote on allowing aerial spray.

Township of Long Lake

Prohibits herbicides on town property where electric transmission lines are located.

Township of Madge

No chemical spraying on public property. Private property owners must give permission prior to application by electric company, etc.

statement of
CONGRESSMAN JOHN F. SEIBERLING

in support of H.R. 1910
legislation to ensure that pesticides and herbicides
used in agricultural production are safe

before the Subcommittee on Department Operations,
Research, and Foreign Agriculture
May 20, 1985

Mr. Chairman, I appreciate this opportunity to comment on H.R. 1910, legislation I introduced to prohibit the sale of pesticides and herbicides for agricultural production unless tests prove that such substances are not likely to endanger humans.

I am concerned that the use of dangerous pesticides and herbicides may pose serious health threats to consumers as well as to agricultural workers. Once these pesticides and herbicides enter the food chain, the long-term effects of these substances are largely unknown. We are also unsure to what extent these chemicals are contaminating our ground water. Because of these concerns, I think that pesticides and herbicides should not be used unless appropriate tests indicate that they are unlikely to cause harm in human beings.

The ethylene dibromide (EDB) crisis demonstrated just how little we know about the long-term effects of pesticide use for food production. As you are probably all aware, a crisis arose in 1983 when traces of the pesticide EDB were found in citrus fruit and grain products. EDB was originally approved because it was assumed that the chemical was not dangerous, but by the mid 1970's it was clear that EDB caused cancer. By 1980 improved detection technologies indicated that EDB residues might be present on grain and fruit, and that EDB was probably leaching into ground water.

In 1977, the Environmental Protection Agency (EPA) began an extensive review of the use of the chemical, but the agency did not suspend use of the pesticide during these studies. As soon as EPA learned of the cancer risks associated with EDB and that EDB residues were present in food and ground water, the pesticide should have been immediately pulled off the market. But EPA refused to ban the pesticide. By 1983, the EDB problem caught the attention of the media. In December 1983, frustrated by EPA inaction on this matter, several states began ordering food products off grocery shelves because of EDB contamination. Obviously EPA procedures were totally inadequate to handle the crisis.

The EDB crisis demonstrated the serious inadequacies of our system of regulating pesticides and herbicides. The use of similarly dangerous pesticides and herbicides may pose serious health threats to consumers as well as to agricultural workers.

For example, press reports state that the most widely used agricultural herbicide in my state of Ohio, alachlor, has been found to cause cancer in rats. It is estimated that 30 percent of Ohio's 7.7 million acres of croplands are treated with alachlor. Of extreme concern is the fact that traces of the chemical have been found in four Ohio rivers which serve as the drinking water supply for many Ohio cities. The herbicide can be removed from water supplies only by the use of expensive activated charcoal filters, equipment used in only a few Ohio communities.

Because of the possible dangers associated with this herbicide, EPA has ordered farmers to wear special protective boots, goggles and rubber gloves when using the chemical. EPA has also banned aerial spraying of the chemical, and it has banned the use of the chemical on potatoes because the chemical may leave a residue on them. But EPA has refused to suspend all uses of the herbicide until more test information is available. According to the press, EPA calculates that out of every 600,000 farmers who use the herbicide, 60 may develop cancer from the substance. But the long-term effects of ingesting alachlor through the drinking water are unknown. When alachlor was found to cause cancer in rats, EPA should have pulled it off the market immediately. The general public should not have to worry that their drinking water contains dangerous pesticides and herbicides, and farm workers should not be needlessly exposed to this danger.

The serious problems with the current system of pesticide regulation are obvious. Under the current system, when tests are inconclusive about the dangers of a particular pesticide, the use of the pesticide or herbicide is approved. I think we should reverse this assumption, and not approve the use of any agricultural pesticide or herbicide unless appropriate tests indicate that it is unlikely that it will endanger human beings.

Under our current regulatory framework, EPA has no idea whether certain pesticides or herbicides already in use are safe or if they are highly dangerous. The chemical manufacturers perform certain tests to determine the safety of their own products. EPA is supposed to oversee the tests and their results, but the amount of information available is frighteningly small. The current law requires EPA to weigh the dangers and the supposed benefits of the use of each pesticide. However, it is very difficult to make this determination

when so little is known about the long-term dangers of these chemicals.

It has been argued that reducing the availability of pesticides and herbicides will hurt farmers by curtailing farm production. However, to the extent that farmers are not forced by competition to buy pesticides and herbicides, their costs will be lower. And to the extent that agricultural production is reduced, crop surpluses will be reduced or eliminated, thereby saving crop price support costs borne by the American taxpayer.

H.R. 1910 would change the current regulatory structure to ensure that pesticides and herbicides used in agricultural production are truly safe. Before EPA could reregister any currently used agricultural pesticide or herbicide, or approve any new pesticide or herbicide, the agency would be required to conduct tests to determine if it could endanger humans. If the tests indicate that the substance is likely to endanger human beings, it could not be approved. To encourage EPA to move quickly to conduct the proper tests, after three years the bill would revoke the registration of any agricultural pesticide or herbicide already in use unless EPA tests were complete. Surely it is time we acted to protect the public against the use of dangerously toxic agricultural pesticides and herbicides.

Statement of the Honorable Frank Horton
Committee on Agriculture
Subcommittee on Department Operations, Research, and Foreign Agriculture
May 20, 1985

Mr. Chairman, I regret that my schedule prevents me from appearing before the Subcommittee today, but I do appreciate this opportunity to state my views on the need to protect our environment and the American consumer from dangerous pesticides.

As the Ranking Minority Member of the Government Operations Committee, I have long been concerned about environmental issues. In October 1984, my Committee unanimously issued a report on pesticide registration by the Environmental Protection Agency. The report detailed many problems which plague the pesticide registration process, notably the unlawful work of laboratories which submit data to the EPA and the inadequate EPA procedures for pesticide regulation and standard-setting. I am pleased to note that pesticide registration program is under the scrutiny of this Committee, as well as Government Operations, and that many problems uncovered by our investigations may be corrected by legislation.

These are certainly problems in all areas of pesticide regulation, but I wish to give special emphasis to the purity of imported foods and the effectiveness of our government's program of monitoring imported foodstuffs. As we all know, many foreign countries allow growers to use a baffling array of pesticides which are restricted or prohibited in the United States. I am worried that foods containing harmful pesticides may show up on our supermarket shelves because Federal agencies do not have the data base, technology, scientific expertise, enforcement capability, and willingness to prevent adulterated food products from entering the country. This situation is simply unacceptable. I believe the American consumer should be protected from and warned of harmful pesticides.

Legislative action is necessary to better ensure the purity of imported foodstuffs. I am hopeful that the amendments to the Federal Insecticide, Fungicide and Rodenticide Act which you and Mr. Roberts, along with Mr. Heftel, plan to propose in these hearings will begin to remedy this dangerous situation. H.R. 1416 appears to address this problem most directly. I wholeheartedly support the requirement that the Administrator of the Environmental Protection Agency cooperate and collaborate with the Secretary of State, the Secretary of Agriculture, and the Commissioner of the Food and Drug Administration in identifying overseas pesticide use patterns on food crops exported to the United States. Information on foreign pesticide use is absolutely critical to effective testing of pesticide residues. The enactment of this provision will provide the first step in the formation of an adequate data base. I am also eager to learn what practical effect the provisions of H.R. 2482 concerning the testing and registration of pesticides will have on the purity of imported food.

In closing, I would like to commend the work of the Committee and the intent of the proposed changes to the Federal Insecticide, Fungicide and Redenticide Act. As the varieties and uses of pesticides increase, so must our research and protective regulations. I am hopeful that we can work together to protect the health and safety of the American public.

STRUCTURAL PEST CONTROL BOARD
1300 East Anderson Lane
Building C Suite 250
Austin, Texas 78752
Telephone: (512) 835-4066

DAVID A. IVIE
EXECUTIVE DIRECTOR

June 11, 1985

Honorable Berkley Bedell
Chairman
Agriculture Committee
United States House of Representatives
Washington, D.C. 20515

Mr. Chairman and Members of the Committee:

Testimony
of
John P. Mercer
Commissioner
State Structural Pest Control Board of Texas

Before The
Subcommittee on Department Operations
Research & Foreign Agriculture
of the House Committee on Agriculture

Hearings on
The Federal Insecticide, Fungicide
& Rodenticide Reform Act

I am John P. Mercer, and I have been in the pest control industry for 24 years. I am a certified applicator and a Commissioner of the State Pest Control Board of Texas.

Our State Agency is charged (Vernon's Texas Civil Statutes Article 135b-6) with developing standards and criteria for licensing individuals engaged in the business of Structural Pest Control. The Texas Structural Pest Control Act as amended (Article 135b-6 Vernon's Texas Civil Statutes) is to be continued in effect as approved and required under the United States Environmental Protection Agency Public Law 92-516 (Federal Insecticide, Fungicide and Rodenticide Act of October 21, 1972, and subsequently amended).

The Texas Structural Pest Control Act is the sole licensing authority in this state for licensing persons engaged in the business of Structural Pest Control. Our responsibility includes administering tests to individuals demonstrating their competence in their particular field for a Certified Applicators license, Licensing Standards, Examinations, Rules and Regulations, Coordination of Activities, Complaints, Contracts of Licensee, and Public Information Programs.

STRUCTURAL PEST CONTROL BOARD
1300 East Anderson Lane
Building C Suite 250
Austin, Texas 78752
Telephone: (512) 835-4066

DAVID A. IVIE
EXECUTIVE DIRECTOR

Therefore be advised that the Commissioners of the Texas State Structural Pest Control Board are in full support of the Pesticide Regulator Improvement and Management Act of 1985 with the exception of Page 6 Paragraph 2 and 3.

We recommend the following changes for your consideration. Paragraph (2) in Section 3(d) (1) (c) (i) that all service technicians be a certified applicator. In Paragraph (3) in section 3(d) (1) (c) (ii) deleting the words by a Certified Applicator and placing instead of Certified Applicator the words Approved Applicator.

This industry has a large turnover of personnel, and we believe that this would create a hardship on everyone concerned. On the other hand, by testing the Service Technicians in their particular field, the industry would be upgraded.

Therefore we recommend that a licensing procedures for the title of Approved Applicator be established as follows:

A. Examination Areas

(1) Safety with Pesticides
(2) Measuring, Mixing and Disposal
(3) Proper Placement of Insecticides
(4) Classroom Training
(5) Safety on the Job
(6) Formulations
(7) Labelling and Storage

Therefore we recommend that the Environmental Protection Agency be charged with implementing these changes.

Mr. Chairman and Members of this Committee, on behalf of the State of Texas, I wish to take this opportunity to thank you for allowing the presentation of our testimony today, and accordingly, we request that this Committee give serious consideration to implementing our recommendations given here today.

Thank you for your time.

John P. Mercer
Commissioner
State Structural Pest Control Board of Texas

cc: Honorable "Kika" de la Garza

STATEMENT OF
THE NATIONAL FOREST PRODUCTS ASSOCIATION

BEFORE THE

SUBCOMMITTEE ON DEPARTMENT OPERATIONS,
RESEARCH, AND FOREIGN AGRICULTURE

OF THE

HOUSE COMMITTEE ON AGRICULTURE
UNITED STATES HOUSE OF REPRESENTATIVES

MAY 20, 1985

The National Forest Products Association supports the safe and effective use of pesticides in forest management and in the manufacture of wood products, and welcomes the opportunity to submit these comments as the Subcommittee considers possible amendments to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

The National Forest Products Association (NFPA) is a non-profit trade association founded to promote the conservation and renewal of forest resources and to improve forest practices and utilization. NFPA represents directly and indirectly more than 2,000 firms engaged in the forest products industry throughout the United States. NFPA members apply pesticides, and contract to have pesticides applied, in forests, nurseries, seed orchards, and wood products manufacturing facilities.

As a user of pesticides, the forest products industry has been interested in FIFRA (and its regulations) since it was first enacted. Our goals include: maintaining the safe use of forest and wood product pesticides; assuring the scientific integrity of EPA decisions based on risk benefit analysis; and retaining our ability to gain access to new pesticides. In furtherance of these goals, NFPA submits these views as the Subcommittee considers FIFRA amendments.

While there is considerable interest in some quarters in making some major changes in FIFRA this year, NFPA's view, from the standpoint of a user, is that FIFRA and its regulations have provided an essentially well-conceived and functioning program to assure that pesticides -- which provide important benefits to the public -- do not pose an unreasonable risk to man or the environment. Accordingly, NFPA recommends that FIFRA be reauthorized with no substantive changes.

This is not to say that there in no room for fine-tuning, however, and NFPA would have some modest changes to suggest if the Subcommittee determines that a simple reauthorization is not appropriate. In that regard, NFPA's major recommendation concerns the need for an amendment clarifying FIFRA's preemption of local pesticide regulation. In addition, NFPA would support certain other amendments and ask Congress to be sensitive to the needs of pesticide users. The comments below reflect NFPA's position on these matters and on other proposals which are being debated widely and have already come to the Subcommittee's attention.

THE REGISTRATION PROCESS

The forest products industry asks the Subcommittee to consider the user -- and in particular, the minor or small-quantity user -- as it considers changes to the registration, reregistration, and state special local need registration processes. Although the forest products industry manages a large acreage of forest lands, the number of acres treated annually, and the volume of pesticides used in forest management are quite small relative to the nation's major agricultural crops. Additionally, the trend is to register pesticides for quite specific uses, for example, a pesticide registered for use on Loblolly Pine may not initially be registered for use on Douglas Fir. In many cases, each tree species requires a different registration. Clearly, this makes the prospective market even smaller.

Because of the relatively small market for most forest pesticides, there is far less incentive for a producer to seek a registration for one of these uses than for one of the nation's major food crops. In fact, with the current cost of research and registration of a new pesticide estimated at more than $25 million, no new pesticides are likely to be developed specifically for forestry. The forest products industry must rely on getting major crop pesticides' registrations expanded to include forestry uses. Therefore, access to new pesticides for forestry will depend, to a large extent, on the difficulty registrants have in meeting requirements to add a new use to an existing label or to get a state local need registration. Those regulatory hurdles are appropriate only if they are no more stringent than necessary to assure that the use will not pose an unreasonable risk to man or the environment.

In that regard, a brief example can illustrate the impact of EPA's registration requirements on minor uses. One of our companies asked a pesticide producer to add a new use to an existing label. The registrant was anxious to be helpful, but noted that adding that use to an existing pesticide label would require testing which would cost more than 100 times the amount of potential gross sales of the pesticide for that use. Those studies were required by the registration standard even though the product had been used safely for years on other crops on surrounding property at higher application rates.

Even though the forest industry is not a major user of pesticides, where they are needed, pesticides can dramatically increase forest productivity. In some situations, one herbicide treatment can make the difference between a site becoming a valuable commercial forest and one that becomes overgrown and has no commercial value.

The forest products industry asks that the Subcommittee keep in mind the user, and particularly the user of small quantities of pesticides, in its deliberations on FIFRA amendments.

CANCELLATION HEARINGS AND SPECIAL REVIEWS

The cancellation hearing process provides needed protection for pesticide users by allowing them to challenge the health risk, exposure, and benefit assessments made by EPA staff, and present their own data before an objective tribunal. NFPA would be happy to comment on specific proposals to change and possibly speed up the process, but

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does not favor suggestions to change it from an adjudication to a rulemaking. Previous adjudicatory hearings have succeeded admirably in laying out and testing all the relevant evidence on these enormously complicated issues. These hearings have helped ensure that the Agency's ultimate decisions are based on sound scientific data rather than on unfounded allegations or faulty studies.

In addition, NFPA opposes any effort to repeal the so-called Grassley-Allen amendment, FIFRA Section 3(c)(8). It seems to be the antithesis of sound public policy to advocate the repeal of this section; the result would be having EPA initiate costly and time consuming Special Review proceedings without any evidence that there is a real problem. Specifically, the Administrator would no longer need to base a Special Review on "a validated test or other significant evidence raising prudent concerns of unreasonable adverse risk to man or to the environment." We have, of course, a selfish interest in avoiding having to participate in purposeless proceedings, but this Subcommittee should be even more concerned about the Agency devoting its limited resources to unjustified proceedings when it should be allocating them to the important work that needs to be done.

FALSE REGISTRATION DATA

EPA reacted appropriately to the discovery that some fraudulent data prepared by IBT Laboratories (a testing laboratory) had been submitted in support of pesticide registrations. EPA assessed the extent of the false data, decided that no registrations needed to be suspended, and set priorities to fill the "data gaps" created by the discovery.

EPA's approach was as it should be. Discovery of false data, or a data gap from any cause, should trigger an assessment by EPA of the importance of the missing data in the context of the rest of the data on hand. If EPA has a large volume of studies supporting a pesticide use, the discovery of a few false studies should not automatically trigger a suspension or even a cancellation hearing without regard to the strength of the remaining data.

Furthermore, it is completely inappropriate to adopt the suggestion that a suspension of a pesticide registration should be used in such a situation to "punish" the registrant. The questions of (1) whether there is a culpable party in need of punishment, and (2) whether a registration is valid, are -- and should remain -- completely separate. It is simply wrong to base any registration decision on other than sound scientific principles. Even if punitive measures are appropriate, they should not take the form of removing from the market a product which has proven valuable to users and to the public in general.

PREEMPTION OF LOCAL PESTICIDE REGULATION

In passing the 1972 amendments to FIFRA, Congress granted limited pesticide regulatory authority to the states. The legislative history indicates that in amending FIFRA, Congress intended to share its authority with the states, but not with local jurisdictions. Nonetheless, local jurisdictions have been enacting, and continue to enact, restrictions that create considerable hardships for foresters and homeowners trying to control weeds, insects, and other pests.

These local pesticide regulations are flourishing because courts, not heeding the Congressional intent behind the current law, are not invalidating them.

The last several years have seen a proliferation of pesticide restrictions promulgated by counties, townships, and boroughs in at least 14 states. These restrictions range from banning specific pesticides, to requiring permits and notification, and even attempting to ban all use of pesticides in a specific area. Restrictions such as these can reduce forest productivity, stop termiticide applications to protect buildings, or affect what homeowners may or may not do to protect their lawns.

These local restrictions are routinely based on far less scientific evidence than is used in the decisionmaking process at the state and Federal levels. As a result, local regulations are likely to place unnecessary restrictions on beneficial uses of pesticides. If a regulation is properly based on scientific grounds (i.e., a showing that there is an unreasonable risk and the regulation will reduce the risk to reasonable levels), any resulting loss in benefits from pesticide use is necessary. When regulations are based on fear, hysteria, or other emotional unscientific grounds, however, the resulting lost benefits (e.g., reduced forest productivity or increased risk of termite damage) are unwarranted.

To solve the growing problem of local pesticide regulation, an amendment is needed to Section 24(a) of FIFRA, which grants limited pesticide regulatory authority to the states. With the amendment, that section would read: "A State, but no political subdivision of a

State, may regulate the sale and use of any federally registered pesticide . . . ." This amendment would clarify and reemphasize the intent of Congress in enacting Section 24 of FIFRA in 1972.

The forest products industry appreciates this opportunity to comment on some of the issues being raised in the context of amending FIFRA.

Sincerely,

Michael C. Farrar
Vice President,
Environment and Health

For the Record

CENTER FOR RURAL AFFAIRS

Post Office Box 405
Phone (402) 848-5428

Walthill, Nebraska 68067
Population 900

May 23, 1985

Honorable Berkley Bedell
Chairman
Subcommittee on Department Operations, Research,
and Foreign Agriculture
1301 Longworth HOB
Washington, D.C. 20515

Dear Congressman Bedell:

The health risks to which farmers are exposed as a result of the widespread use of pesticides are increasingly evident in medical studies. The Center for Rural Affairs recently published a summary of studies linking farming with cancer and a critique of the health effects aspects of EPA's pesticide regulatory program. These papers were published, along with others on various chronic health effects of modern farming practices, in a volume titled: It's Not All Sunshine and Fresh Air.

Because your subcommittee is currently considering reauthorization of The Federal Environmental Pesticide Control Act, and has held hearings on the subject, I would like to include these papers in the hearing record, and ask that they be so included.

Sincerely,

Marty Strange
Co-Director

Farming and Cancer

Marty Strange and Liz Krupicka

If the notion that farmers live and work in healthy environments has suffered loss of credibility in recent years, there can be no better reason than the growing evidence that modern farming practices may lead to a significantly greater risk of dying from certain kinds of cancer.

If you farm in Iowa, for example, the chances of dying from multiple myeloma (a cancer affecting the bone and bone marrow) is about 48% greater than that of the general population (1); from lyphoma (a cancer attacking the lymphatic system) about 26% (1); and leukemia (a cancer of the blood) about 24% (2).

You're also more likely to die of lip, stomach, or prostate cancer (1,3).

If you farm in the state of Washington, chances are greater that you'll die of one of the above cancers or of those that affect the liver, kidneys, or brain than they are for other Washingtonians, depending on what kind of crops or livestock you raise (4,5).

If you live on a farm in Minnesota, you're more likely to die of brain cancer than either urban residents or people who live in rural areas but not on farms (6).

The elevated risk that farmers will die of these and other kinds of cancer is underlined by the fact that they are less likely to die of lung cancer or other respiratory cancers (3), probably because they smoke less than others (9,10).

In general, cancer has been associated with the kinds of cancers shown in Table I.

Table I Cancer and Farming

Type of Farming	Type of Cancer	Research*
General	leukemia, lip, multiple meyloma lymphoma, connective tissue, liver prostate, stomach non-Hodgkins lymphoma, brain	1,3,4,5,6,7,8
Poultry	leukemia, multiple meyloma, non-Hodgkins lymphoma	1,5,2
Dairy	stomach, leukemia brain, nervous system	3,4,12,18
Grain	leukemia, kidney	4,11,2
Livestock	leukemia, brain prostate, kidney nervous system	4,11

*See references at end of chapter.

(For an excellent summation of the medical literature associating cancer with farming, technically oriented readers should see: Blair, Baron, "Cancer Risks Associated with Agriculture: Epidemiologic Evidence,"Genetic Toxicology, edited by Raymond A. Fleck and Alexander Hollaender, Plenum Publishing Corporation, 1982.)

The Leukemia Connection

The kinds of cancer most frequently associated with farming are those that attack the circulatory system, especially the production and development of blood cells (hematopoietic cancers), and the functioning of the lymph system (lymphatic cancers). Leukemia, in its various forms, is the most common of these cancers (multiple myeloma, Hodgkins disease, and non-Hodgkins lymphoma are others).

Leukemia is one of the nation's most enigmatic cancers. It is actually many cancers, some elusive as to cure, some mystifying as to source, some deadly. It can be depressingly efficient in disposing of its victims. Untreated patients with acute leukemia die in about three months; if remission follows treatment, about half will live a year, a few as much as 16 months. With chronic leukemia, treatment is more effective. Most patients can expect to control the disease for as much as four years, then two out of three die (13). Leukemia accounts for about 9% of the cancer cases and deaths from

cancer nationally.

Leukemia is a disease of the bone marrow in which abnormal blood cells (leukocytes) proliferate. White blood cells essential to the body's defense, ac ing as "scavengers" travelling through the blood consuming bacteria or other harmful agents. When leukemic, these cells are excessive in number or do not function properly, reducing the body's ability o cope with foreign substances. They also impair the functioning of other organs especially the spleen, liver, and lymph nodes. Patients suffer fat gue, anemia, achi g bones and bleeding. Though commonly thought of as a children s disease, leukemia also attacks adults. In fact, one type of leukemia losely associated with farming (chronic lymphatic) usually affects those over age 50, men about twice as often as women (13). Overall leukemia mortality rates for people over 50 is twice that of people under 10.

Normally, about 7 people in 100,000 can expect to die of leukemia, but in some rural areas, the chances are greater. In the north central United States, the rate is about 20% higher (at 8.6 per 100,000) (2,15), and in a detailed study of six counties in the Platte River Valley in central Nebraska, a rate of 13.9/100,000 was documented (15), almost twice the expected rate.

Leukemia's relationship with farming remains an unresolved but unfolding mystery. Because farming is the principal oc upation that distinguishes rural from urban populations, researchers have been eager to investigate its possible link to the disease. First reports of elevated risk of contracting the disease among farmers came as early as 1963 (21). Since then a host of stud es have made the connection (2-5, 11,12, & 16-26), in the United States and elsewhere. There has been contradictory evidence about the nature of he connection (and therefore about implications for further research , but there has been considerable evidence that this disease strikes farmers with unusually frequency. Even in counties where the leukemia rate is higher than usual for the entire population, farmers have been found to be as much as twice as susceptible as their endangered neighbors (11).

Searching for possible causes of this elevated risk presents a real problem for researchers. Leukemia kills quickly, and information about its victims is limited. Most epidemiologic studies are based on no more information about farm victims and their farming operations than can be gleaned from a death certificate. Until recently, cancer cases have not been registered in many states, especially many rural states. Interviewing live patients is now more practical in states that have a tumor registry. Still, the latency period (the time from first exposure to an agent that causes leukemia until the disease sets in) is believed to be quite long -- perhaps 15 years. Trying to piece together a cancer patient's history over that period is d fficult because residency and life style change and memories fail, leaving the researcher with a "cold trail".

Farming operations change, both as to products produced and methods used; classifying farms by type of operation in order to distinguish poss ble causes of leukemia is itself problematic. When is a farm a dairy farm it also produces corn? When is it not a grain farm? When did it stop being one and become another? More important, agriculture has changed so rapidly in the past thirty years that many ecological patterns present in rural counties the lowest level for which most agricultural data are available) at the close of

World War II have long since faded into agricultural history, and the current characteristics of those counties no longer reflect conditions during the productive lives of many of the victims.

Faced with these and other obstacles, medical research has usually restored to crude statistical techniques to relate the incidence of cancer death among farmers and others with ypes of farming practices prevalent in the area, using death certific tes and county-level agricultural data from standard source (usually the U.S. Census of Agriculture). These measures have produced intriguing correlations, but are useful primarily as a means of generating nothing more than hypotheses about casual relationships between farming and leukemia.

The most prominent studies have produced findings that are reinforcing on some key issues, but not on others. Four of these epidemiological studies are summarized in Table 2.

Each of the studies in Table 2 is a case-control study which uses statistical methods to compare the rate of death from leukemia among farmers (cases) with that of other persons who die of that isease (controls). Agricultural factors (such as level of production of a particular commodity or amount of fertilizer used) are evaluated by ranking each county in the study state as a "high" or "low" county for that factor and comparing these classifications with the leukemia mortality among farmers.

Comparison of these studies is difficult because of differences in methodology, particularly in the variables used to describe agricultural characteristics of counties of residence of the victims. Nonetheless, some general patterns emerge, particularly in the Nebraska, Wisconsin, and Iowa studies which used nearly identical methodologies.

First, all three of the studies that considered victims age at death and birthdate as factors found either that farmers who have been born more recently or that those who die at younger ages, tend to have a greater risk of dying from leukemia. This implies that farmers whose productive years were in the modern, post World War II era are at greater risk, suggesting that "agricultural exposures of recent origin" (11) and "modern farming practices" (2) are at fault. This also suggests that estimates of farmers' elevated risk may be understated by the fact that fewer each year will have farmed in a safer era.

There is also powerful evidence in those studies linking the disease with corn production. The Nebraska study (11) first made this connection, showing a 44% increase in risk among farmers living in heavy corn producing counties, and it has since been strongly affirmed by the Iowa study (2), which showed a 63% elevated risk factor. Significantly, the Iowa study ranked counties by "corn produced-per-acre", while the Nebraska stud used "acres of corn harvested" as an indication that the county is a high corn producer. The former is a better measure of intensity of production and possibly a better measure of intensity of exposure to risk fa tors in corn production. That may explain the higher risk factor found in he owa study. The Nebraska case was convincing in and of itself. Though eukemia was associated with factors other than corn production, none was as persistently implicated as corn. When researchers separated the other implicated factors for corn production, they found that

SUMMARY OF MAJOR FINDINGS OF FOUR STUDIES ASSOCIATING FARMING WITH LEUKEMIA
ELEVATED RISK OF FARMERS DYING FROM LEUKEMIA ASSOCIATED WITH VARIOUS FACTOR
(1.00 = EQUAL ODDS, 1.50 = 50% GREATER CHANCE
All Associations Are Statistically Significant

STUDY DESCRIPTION	RISK FACTORS ASSOCIATED WITH VICTIM			RISK FACTORS ASSOCIATED WITH FIELD CROPS -Residence in County With-						RISK FACTOR ASSOCIATED WITH LIVESTOCK -Residence in County With-				
	Farm Occupation	Die At Young Age	Born Here Recently	High Corn Production	High Soy-Bean Production	High Fertilizer Use	High Herbicide Use	Low Herbicide Use	High Insecticide Use	High Dairy Production Or Number Of Milk Cows	High Dairy Production And Herds With RLS	High Poultry Production	High Pork Production	High Beef Production
Iowa. Ramsioter, et. al, 1982, Death Certificate analysis of 1671 white, male farmers over age 19 who died of leukemia between 1964 and 1978.	1.20	1.36	1.39	1.63[2,3]	1.19[2,5]	NS	1.60[2,3]	NS	NS	4.96[3]	NC	1.53[2,3]	NS	NS
Nebraska. Blair, et. al. 1979. Death Certificate analysis of 1086 male Nebraskans 20 older who died 1976.	1.25	1.83	1.66	1.66[2] 1.85[2] 2.27[10]	NC	NS	NS[6] 1.36[10] 1.75[10]	1.39[2] 2.06[7] 1.75[7]	1.29[2] 1.95[7] 1.60[7]	NS	NC	NS	2.06[2,7]	1.36[7] 1.72[7] 2.00[11] 1.57[7]
Washington-Oregon. Milham, 1971. Death certificate analysis of 157 Washington Oregon residents who died of leukemia-lymphoma or cancer of pancreas between 1950 and 1967. (1950-66 for Oregon).	.[1]	.[1]	NC	NC	NC	NC	NC	NC	NC	NC	NC	.[1,9]	NC	NC
Wisconsin. Blair, et. al., 1980. Death certificate analysis 1899 males 20 older Wisconsin who died of leukemia between 1968 and 1976.	NS	1.56	1.5	NS	NC	1.62	NS	NS	NS	1.60[8]	NC	NS	NS	NS

CODE
NC variable not considered
NS statistically significant

NOTES
1. Odds ratio not calculated, but other methodology used to conclude positive (+) association exists
2. Among those born after 1900
3. Primarily unspecified lymphatic
4. Among those born 1890-1900
5. Primarily chronic lymphatic
6. In high corn producing counties
7. But only in high corn producing counties
8. Among all farmers, but no greater risk for dairy farmers than for all farmers
9. Association is not with residence in county with high poultry production, but with occupation as poultry producer
10. Acute, unspecified leukemia
11. The odds ratio is 2.00 for lymphatic cancer

none of them was a significant factor in low corn-producing counties. Corn, in other words, was the factor that overshadowed all the others. The Wisconsin study (18) did not implicate corn production in its finding. It did find an elevated, but statistically insignificant risk factor in corn-producing counties, however, even though used the less intensive measure "acres in corn" rather than bushels per acre . Its findings are therefore not inconsistent with the other studies Moreover, the Wisconsin study did find a 40% elevated risk factor in counties with heavy fertilizer use. Fertilizer is a principal input in corn production.

Factors associated with livestock also produce certain patterns. Dairy production is implicated in two of the three studies that consider it, and the absence of a supportive finding in Nebraska may be more a reflection of the state's relatively small dairy industry than of that industry's association with leukemia. The dairy-leukemia connection has been made in a number of other studies as well (12,17,22,23,25,26) though it has not been undisputed (27).

The findings for poultry, beef, and pork are less evident. Poultry production was once common but never a predominant activity on farms in any of these states. In recent years, the industrialization of poultry production has left few producers in few ocalities within these states. It is likely that data separating counties by volume of product on of poultry either overweigh the factor compared with other agricultural factors separating the same counties, or exaggerate the exposure of people to chickens in high-producing counties.

Significantly, the one study which evaluated the possible relationship between cancer and exposure to poultry in the Southeast, a region where poultry production is more common, found no excess isk of leukemia (or lymphoma or Hodgkins disease) among people occupationa exposed to poultry, though it found some weak relationships with other cancers (28). Among the Table 2 studies, hogs were found to be associated with leukemia only in Nebraska, and only in high corn-producing counties -- corn and hogs go together. The link to beef (other than dairy cattle) is also questionable. The Nebraska study showed a significant correlation with beef production only in high corn-producing counties.

The Search for Causes

The evidence that modern farming practices, especially those associated with corn production and dairy farming, have led to increased risk of leukemia among farmers has prompted a number of studies to determine the real cause of this relationship. Mostly, these studies have focused on the possible effects of pesticides and the possibility that a virus transmits the disease from animals to human. The pesticides are used extensively in grain farming, including corn production and their health implications are summarized in another section of this report. The suspected virus is one which infects cattle, primarily dairy cattle.

The cow virus, or Bovine Leukemia Vinus (BLV) theory has hinged gingerly on its possible transmissibility. BLV causes bovine lymphosarcoma (BLS), a cancer of the lymphatic system in cattle (29,30,31,32,33). BLV is passed freely among cattle by direct contact (34) through their milk or possibly by

blood sucking insects (35). Scientists also conclude that it can pass *experintenlaly to other species, including sheep (36) and goats (37). There is also little doubt about the virus' prevalance among cattle. One New York state study showed it present in 15% of the cattle and in every herd sampled (38).

The link between this virus and human cancer is, however, more tenuous. There are three general theories of how BLV can be transmitted to humans: through consumption of raw milk; through direct contact with infected animals; and by bloodsuck ng nsects. Some areas with high frequency of BLS also have significantly high rates of human leukemia (12,39,40). Nonetheless scientists have not proven that BLV can be transmitted to humans, and some scientists generally conclude that it is not (41,42). The closest BLV has been traced to humans is their primate relative, the chimpanzee (43,44).

Nonetheless, interest in further research of a viral cause of leukemia has been spurred by recent reports of a human leukemic virus resembling BLV (45). So, in May, 1983, the National Cancer Institute held a "state of the art" conference to discuss the topic. While formal conclusions are not reached at such con erences, the mood of several of the participants was that further research on the virus and its behavior may be warranted, but that, in the absence of more evidence that it transmits directly to humans, further efforts to link it to human leukemia is not. NCI officials are careful not to discredit the possibility of a BLV-human leukemia connection, but they are not enthusiastic about it, either.

The University of Iowa, whose research has shown a connection, is continuing its line of inquiry. A three-year study using the state's cancer registry as a source of subjects to interview is attempting to identify possible casual links between dairy farming and the incidence of acute lymphatic leukemia (ALL). The focus on that particular form of leukemia, which predominately occurs among children, ha been prompted by an earlier Iowa study which showed an unusually high risk of that cancer among rural males both under age 20 and over age 60. Among males li ing n counties with large numbers of cattle, chances of incurring ALL were 40% greater, especially in counties with both large numbers of dairy cattle and documented occurrence of BLS (66% excess risk) (12).

The current University of Iowa study will attempt to isolate various environmental factors which might contribute to the excess risk or which might shed light on a means by which BLV is transmitted from cattle to humans. It is probably the only research on this issue in process. It results will not be known until 1984.

Is It Farmers Or Farming?

This pattern of associations between farming and leukemia, though mixed in particulars, has been consistently reinforced in the medical literature. Some studies have affirmed one or more dimension of the relationship while not confirming others, but few have found that farmers actually have a reduced risk of leukemia (46).

Now comes the New York State Department of Health with a study funded by the National Cancer Institute (as many of the others have been) that reaches

just that conclusion.

Though the study findings have not yet been published, the principal researcher, Dr. Alice Stark, shared her findings informally in a telephone interview. The New York study uses significantly different methodology to compare the incidence of nearly all cancers (not mortality from cancer) among farmers with the incidence among people who live in the same communities as the farmers in the study.

The study used a farm organization membership list with over 20,500 names for the years 1973-79, about half of whom could be classified as to type of farm (about 56% of those that could be classified were dairy farmers), and Department of Motor Vehicle information to determine residence and age. This list was then matched with the state's tumor registry and death certificate files. All kinds of cancer were considered among white males over age 30. The results were that farmers are significantly less likely to contract nearly all kinds of cancer including leukemia, and the related diseases than other people who live in farm areas. Only genital-urinary cancers (especially prostate and bladder) showed an elevated risk for farmers. Dairy farmers were no different from other farmers in their low incidence of cancer compared to their neighbors.

The New York study implies that farming practices which may increase the risk of cancer among farmers in other parts of the nation either do not in New York, or may increase the risk equally to all persons living in a New York farm environment. If either is true, then it is evident that the relationship between farming practices and other environmental factors determines the risk elevation of farmers and others who live in farm communities. What might corn and dairy production in Iowa, Nebraska, and Wisconsin have in common that elevate the risk of leukemia among farmers in those states that does not affect farmers or other rural people in New York?

One possibility is nitrogen, specifically, nitrate-nitrogen in drinking water. High nitrate levels are locally significant in drinking water supplies in Nebraska, Iowa, and Wisconsin, because nitrogen fertilizer used extensively in corn production seeps through the surface soil into the underground water supplies in portions of those states, and because animal waste, also rich in nitrogens, runs off fields into streams and shallow drinking water wells on farms and in some small towns. This is a particular problem in diary regions because of the density of the cattle population and tendency to concentrate the animals near milk facilities. Both the closeness of the water table to the surface and the relatively porous soil materials covering it increase the risk of nitrate pollution of drinking water from these sources.

Because nitrate is toxic if consumed at certain dosage levels, public drinking water supplies are monitored for it. Many in Nebraska and Iowa exceed the recommended public health maximum levels of nitrate-nitrogen and many more approach that limit. In Nebraska, the nitrate levels are particularly high in communities along the central Platte River Valley, he area whi is also the high risk "leukemia belt" in the state. In Iowa, cancer researchers have postulated that nitrate levels may be correlated to the incidence of stomach cancer in that state, as well. Farmers in Iowa have a 32% elevated risk of dying from stomach cancer, and that risk is higher among some age groups in counties with high corn, milk, and cattle production (1).

Nitrate in drinking water is a rarity in New York (except in some portions of Long Island), according to Peter Smith of that State's Bureau of Public Water Supply, because wells tend to be deep wells that go beneath rock formations which shield the water from nitrate runoff or filtration. Only one community in the state reports nitrate levels above the public health standard.

High nitrate levels can be dangerous in many ways. Primarily, public concern centers on the fac that nitrate converts to nitrite during digestion, and nitrite reduces the capacity of blood to carry oxygen to the tissue. Children are particularly susceptible to this condition, called *methemoglobinemia.

But this toxic effect of nitrate tends to overshadow other potential health problems associated with it, including its possible role in cancer. In fact continuous sub-toxic level doses of nitrate in drinking water may significantly increase the risk of several forms of cancer.

When nitrite (derived from nitrate during digestion) interacts with other secondary nitrogen compounds (such as amines) in the body, yet other secondary ni ogen compounds are formed (grouped under the general term N-Nitroso compounds N-Ni roso compounds cause cancer in laboratory animals (47). Some N-Nitroso compounds cause cancer at locations where they occur in the body; others produce cancerous tumors elsewhere in the body. Moreover, the same compound will produce cancer n different locations in different animals (48). Thus, the indiscriminate nature of these carcinogens makes it difficult to rule out their association with any form of cancer in any particular species.

Most of the studies on the cancer-nitrate relationship have been done outside the United States and address the relationship between nitrate and stomach cancer. In Chili, a series of studies have linked stomach cancer to fertilizer use (49,50,51), though not to high nitrate levles in drinking water. Significantly, stomach cancer rates in Chili have declined in recent years except in parts of the country where fertilizer use is high. In Columbia, stomach cancer rates are high among people who used well water more frequently as infant and several of the high risk areas of the country have nitrate concentrations as high as 300 milligrams per liter (mg/l), about six times the level recommended as safe by the World Heal h Organization (50). In Japan, people who use well water, especially farmers, had a greater risk of stomach cancer than people who used public water supplies, though the level of nitrate pollution in the well water was not determined (52). And in Worksop, England, where drinking water averaged nine times the nitrate level of a group of control communities studied, stomach cancer mortality rates were significantly higher (53).

The one study on this topic done in the United States considered groups of communities in Illinois and found no elevated risk of cancer mortality in communities with different nitrate levels in drinking water (54). The study has been criticized, however, for inadequate nitrate and population data (55).

All this leads to a plausible hypothesis that stomach cancer is related to nitrate levels in drinking water. Water, of course, is not the only source of nitrate. Indeed, in most situations, nitrate is ingested primarily from vegetables. But in areas where the nitrate content of water is as high as 100

mg/l, as much as 70% of daily intake can be from water. And the indiscriminate nature of N-Nitroso compounds leaves open the possibility that leukemia and other related cancers can be caused by nitrate delivered to water supplies by agricultural practices.

It is also plausible, that other materials in the drinking water of regions with high leukemia rates are responsible. Uranium is present in some locations, especially in Nebraska, for example, where high leukemia rates are found, though other areas in the same state where uranium is present do not have high leukemia rates.

The high rate of leukemia in North Central states has prompted more studies in Iowa, Minnesota, and Kansas, all funded by the National Cancer Institute. These studies build upon earlier epidemiologic studies like those summarized in table 2 by using similar statistical methodology but by also using cancer registries in these states to identify and interview cancer patients about factors in their environment which may have led to the disease. Special attention is being given to herbicides and insecticide exposure and to animal exposure. Data are also being gathered on drinking water source, although funding was not approved for water quality analysis that would have provided more precise information about the nitrate connection. Therefore, when these studies are completed and the results published in several years, there will still be no epidemiologic study of nitrates and cancer in the United States, despite the fact that nitrate pollution of drinking water is substantial in the Midwest farming states where cancer mortality is high.

Several proposals from the University of Iowa to study the relationship between the incidence of cancer and nitrate in drinking water have been rejected by both the National Cancer Institute and the Environmental Protection Agency.

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The Hidden Health Effects of Pesticides

Marty Strange, Liz Krupicka and Dan Looker

Pesticides are toxic chemicals deliberately used to control plant and animal pests which compete with crops for soil nutrients and solar energy, spread diseases among those crops or consume them directly as food. At first, pesticides were used occasionally and only to control a pest infestation which threatened to cause a catastrophic loss of crop. They are now used routinely to prevent pest populations from developing, whether damage is imminent or not.

World War II produced an abundance of applied research on chemicals which was successfully adapted to agricultural uses later. The miracle pesticide DDT (and some related compounds) became an overnight success not only in controlling malaria, yellow fever, and typhus in the third world, but also in reducing crop and livestock pests, launching an era of pesticide enthusiasm in the process which has never subsided. The research which led to this impressive use of DDT won a Nobel Prize for the scientist responsible*.

Further research has multiplied the uses of various pesticides, developing more sophisticated applications of an ever growing number of chemical pest killers. Today, about two thousand pesticides are used in the United States, although the top 43 account for over 80% of the usage (2). They are used most intensively on food crops where the damage from pests is particularly expensive, but they are used almost universally on basic field crops such as

*Applied research, of course, depends on underlying basic research, which rarely receives such acclaim. The German student who first developed the chemical compounds of which DDT is a family member (chlorinated hydrocarbons) in the 1870's got nothing more than a doctorate degree for his effort (1).

corn, soybeans, and cotton, too.

The last two generations of farmers in this country have come to depend on pesticides so much that few know how to farm without them.

This ubiquitous use of pesticides has proceeded nothwithstanding the growing public concern about thei health and environmental effects. Evidence of the persistence of the chlorinated hydrocarbons in the environment, their capacity to nger in the food chain, and their carcinogenic (cancer-causing) properties, prompted government regulations which led to the severe restri tion or banning of several of the most "effective" insecticides. Many of the first-wave pesticides were curbed DDT was banned in 1972. Dieldrin aldrin, heptachlor chlordane, mirex, and most recently toxaphane and 2-4-5t have been banned or severely restricted by the Environmental Protection Agency (EPA). There is now relatively little use of chlorinated hydrocarbons in the U.S.

While this environmental concern was producing such restrictions, there was also growing concern among farmers about the steadily increasing cost of pesticides. More started talking in the mid 1970's about "organic" farming, and some research showed that organic farmers in the Midwest were already as well off financially as their pesticide using neighbors, because the increase in production made possible by chemical pest control no longer offset the cost (3).

Despite restrictions on pesticides and the growth of interest in organic farming, pesticide use has grown. From 1972, the year DDT was banned, until 1980, pesticide use increased by 75%. In the same period, the amount paid by American farmers for the pesticides quadrupled.

During this period, several notable changes in the kinds of pesticides applied and the way they are used have occurred which are of special significance to Midwestern agriculture.

There has been a shift from chlorinated hydrocarbon insecticides which persist in the environment and tend to be carcinogens, to organophosphates and carbamates, which are less environmentally hazardous but generally more toxic to direct contact.

The use of herbicides has increased rapidly. In 1972, herbicides were used on 68.5% of the corn acreage in the U.S. Today, they are used on 93%. Similar figures apply to soybean acreage. Herbicides now account for 57% of the $3.7 billion farm pesticide market (4).

There has been a marked trend toward reduced tillage farming systems which tend to foster plant disease and increase insect populations, requiring 30% more use of pesticides than conventional tillage (4).

The growing use of some pesticides which adhere in the soil and adversely affect crops which might subsequently be planted in rotation (called "pesticide carryover") has d scouraged crop rotation, encouraging more repetitive planting of the same crop (monoculture) which requires more use of the same or related pesticides to protect.

Many insect species, and now many weed species, have developed genetic

resistance to pesticides, requiring either stronger pesticides or ever stronger applications of the same pesticides.

These trends, in combination, mean that more farmers routinely use and are increasingly dependent on pesticides which are becoming less cost-effective, and many of which are more toxic to the user.

How Pesticides Work

Most pesticides commonly used in agriculture work either on the nervous system or growth regulators of pests. All of the commonly used insecticides in the Midwest, for example, inhibit a nerve enzyme, cholinesterase which regulates nerve impulses by breaking down acetycholine a substance which transmits them. When the pesticide inhibits cholinesterase acetycholine accumulates at nerve junc ions, impeding transmission of nerve impulses to the muscles. Organophosphates which were derived from nerve gases) and carbamates are both cholinesterase inhibitors.

The herbicides either act as hormones, inducing uncontrolled growth and leaf dropping, or "starve" the plant by blocking the process of photosynthesis by which plants convert sunlight to cellulose.

Pesticides have a tremendous range of toxicity. Some are lethal to humans at doses of two grams or less. Some are no more lethal than table salt. Most cases of acute poisoning involve either accidental direct contact by farmers, farmworkers, children, or others, or suicide attempts. The cases of accidental poisoning of farm people are legion and have been reported in many news accounts. Some are dramatic. Less noted, but more common, are the flu-like symptoms experienced ommonly by farmers who use pesticides. These symptoms re rarely reported o medical authorities and are frequently not identified with pesticide use when they are. In 1978, the University of Nebraska Medical Center tudied 98 farmers and commercial pest applicators and found significant reductions in cholinesterase activity in 30 percent of the individuals tested, and symptoms of mild poisoning in 22%. None of the study subjects brought these symptoms to the attention of a doctor (5).

Farmers are exposed whenever they use pesticides. When they buy and transpor them when they mix and load them, when they apply them, and when they re-enter the field to examine crops after pesticides have been applied. The Occupa ional Safety and Health Administration regulates the time of re-entry for hired farmworkers on farms which employ ten or more workers, but it has greatly relaxed those standards recently. It has nothing to say to farmers or farmworkers on farms with fewer than ten employees.

To the extent that pesticides remain in or on food produced under their treatment, farmers, like everyone else who eats, are also exposed.

Pesticides and Cancer

Pesticide poisoning worries some farmers, as it should. In one sense, they have a right to feel that society has turned the pesticide problem "in" on them by forcing a shift from the chemicals which break down more slowly in the environment to those which degrade more rapidly but are frequently more toxic to the user. In another sense, many farmers and others would say that if this

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they are not the people most exposed to pesticides. Commercial pesticide applicators presumably have far greater exposure, and studies have shown them to be more likely than most to die of lung cancer (11,12); in one case, twice as likely (13). These studies echo a fairly consistent finding that the earlier in life and the longer the exposure to pesticides, the greater the risk of death from cancer. Commercial applicators also show elevated risk of skin and bladder cancer (12), and of hematopoietic (blood) cancers (14).

Perhaps the strongest case associating cancer with farm chemicals comes from Sweden, where people exposed to herbicides were found to have five times the risk of malignant lymphoma (15).

Cancer is not the only disease risk, of course. Pesticides are also possible causes of birth defects. In a California study, children born of agricultural workers were found to have deformed limbs at a rate of 5.2 per thousand, 13 times the expected rate among others (16). In Florida, a five year study also relates birth defects to heavy pesticide spraying (17). There might be some consolation in the knowledge that cancer is frequently a slow developing disease with a latency period of many years. Many of the studies linking pesticides with cancer and with farming may reflect early exposure to the chlorinated hydrocarbons which were prevalent in the pre-1972 era (or to the arsenic group of pesticides which were used even earlier).

But there is, nonetheless, the knowledge that pesticides have profound effects on human biology, especially the central nervous system. The impact of the organophosphates (which are now used on over 20 million acres) on the health of commercial applicators' central nervous system has been well documented since 1964. Studies then reported changes in the brain wave patterns of pilots and a 6 to 12 month recovery period from symptoms of schizophrenia and depression (18). Federal Aviation Administration studies show that the low level doses of organophosphates can reduce crop-dusters' performance (19). Loss of memory and concentration is common (20), as is an increase in anxiety (21).

There is little doubt but that these substances represent a potential long-term health risk to users. Which substances present which risks, and how great are they? It is surprising to know how much is known about these risks. And given how much is known, it's just as surprising to find out how many questions are raised for which there are no answers.

Protecting Farmers (and Others) From Long Term Health Risks of Pesticides

Pesticides cannot be sold, shipped or delivered in the United States unless they are registered by the Environmental Protection Agency (EPA). Before registering a pesticide, EPA is to determine that it will perform as intended without causing "...any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits..." Deciding what is and what is not reasonable burdens EPA with the mission of balancing two interests: the control of pests who compete with humans for food crops using products in which there is a substantial commercial interest, and the health of both the human population and the natural environment. That these interests are at odds is taken for granted, and it is assumed that there will be a health risk "cost" to individuals and society of using them. EPA's job is to weigh the benefits of chemical use against these

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waiver of these tests permanent. Its rationale is that farmers and other users won't buy chemicals that don't work, and if they o, the manufacturer is potentially liable for damage suits. This confidence in he market place as a determinant of the efficacy of potentially dangerous products has not been accepted by other agricultural regulatory agencies, notably the Food and Drug Administration which requires independent laborator confirmation of the claims of manufacturers of animal feed additives which might leave a residue in food.

Assuming, as it does, that every chemical marketed is effective, EPA only needs to determine whether the benefits from the use exceed the cost of the health risk which society assumes in exposing people and the environment to it. This cost-benefit analysis is done only on pesticides which tests reveal to be relatively high-risk pesticides. Basically, the benefit is calculated as the economic loss to society of banning the use of the chemical, and considers primarily the extent of the chemical's use and the existence of safer substitutes. The cost is measured in health and medical costs and potential loss of life. These delicate balances are weighed by EPA during its pesticide registration process.

The Status of Some Commonly Used Pesticides

EPA's registration process has evolved during a period characterized by three trends: a growing general public concern about the health e ects of pesticides; a rapidly increasing sophistication in the scienti ic procedures for testing health effects; and an environment of government deregu ation in almost all areas. In order to describe how these trends have worked together to produce important gaps in the confidence which farmers can enjoy in he use of pesticides, we have analyzed the registration status of f teen commonly used pesticides in Midwestern agriculture. Of the fifteen, ten are herbicides and five are insecticides. Table 1 identifies these pesticides by both generic and brand names, their chemical family and manufacturers, extent of use, and acute toxicity. Pesticide use is, of course, dynamic, and these chemicals are by no means the only widely used chemicals in Midwestern agr ulture nor are they particularly more or less suspect on health grounds tha are other pesticides. Farmers wi l recognize hem howeve and by reviewing the status of health ef ec s research on each of hem, can better understand both the nature of pesticide-related health risks generally, and the effectiveness of government regu atory procedures in controlling those risks. It should be noted that in is repor we are focusing attention on the health risks which farmers are exposed to both as a result of direct contact with these chemicals and as part of the consuming public. We have not analyzed these chemicals with respect to the risk they pose to other species or to the general environment.

TABLE 1 PESTICIDES COMMONLY USED IN THE MIDWEST

Common Name	Brand Name/Manufacturer	Type of Compound	Estimated Acres (million ac)	Acute Toxicity
Insecticides				
carbofuran	Furadan (TM)/FMC	carbamate	10.2	moderate
terbufos	Counter (TM)/American Cyanimid	organo-phosphate	7.9	high
fonofos	Dyfonate (TM)/Stauffer Chemical	organo-phosphate	6.1	high
phorate	Thimet (TM)/American Cyanamid	organo-phosphate	3.9	high
chlorpyrifos	Lorsban (TM)/Dow Chemical	organo-phosphate	2.7	moderate
Herbicide				
alachlor	Lasso (TM)/Monsanto	amide	27.6	high
trifluralin	Treflan (TM)/Elanco	dinitrotoluidine	24.1	moderate
atrazine	Aatrex (TM)/Ciba-Geigy	triazine	23.1	low
bentazon	Basagran (TM)/BASF Wyandotte	thiadiazin	12.3	moderate
2-4-D	numerous products	chlorophenoxy	10.6	low
metirbuzin	Sencor (TM)/Bayer A.G., Mobay Chemical	triazine	9.6	moderate
butylate	Sutan (TM)/Stauffer Chemical	carbamate	7.9	low
cyanazine	Bladex (TM)/Shell	triazine	6.1	moderate
dicamba	Banvel (TM)/Velsicol Chemical	chlorophenoxy	4.4	low
linuron	Lorox (TM)/E.I. du Pont de Nemours	phenylurea	3.6	low

Note: The initials (TM) have been used throughout the text to designate the standard registered trademark symbol.

What the Public Knows (or can find out)

Independent scientists usually working for government agencies or universities have conducted a substantial number of studies on the health effects and other properties on many pesticides, though most of these studies have been done on older chemicals whose formulas are known to the public. In many cases, those chemicals are no longer widely used as pesticides. Newer chemicals, whose formulas are protected as trade secrets, have been less subject to health studies by independent scientists. Nonetheless, the pesticide science literature yields some piecemeal information about the health effect properties of many of the commonly used pesticides in the Midwest. Some of these research findings are noted in Table 2, column I. The studies referenced in this table are cited on the page following the table. It should be pointed out that evidence of helath risk for a generic pesticide does not necessarily mean that all commercial products which use this pesticide as a principal ingredient have the same health risks.

Naturally, this scientific literature is obscure to the average person, and highly technical. Its presence does little to assure that pesticide users will be well-informed about the health risks they are assuming. Instead, the public faith is vested in government, specifically the EPA, which is supposed to know all about this literature, to evaluate it, to require additional scientific studies where they are needed to fill the many gaps in this literature, and to determine whether these risks are worth taking. But how well does the EPA manage this pursuit of information on pesticide health effects?

TABLE 2

HEALTH RECORD OF PESTICIDES COMMONLY USED IN THE MIDWEST

PESTICIDE	RESEARCH SHOWS THAT THIS PESTICIDE... (I)	IBT STUDIES AS A BASIS FOR EPA REGISTRATION: Extent of reliance on invalid IBT major health tests (II)	Corrective Measures (III)	EPA STATUS (Jan., 1984) (IV)
INSECTICIDES				
carbofuran	breaks down under conditions like those found in the human stomach forming chemicals which are highly mutagenic (1).	18 of 39 tests were done by IBT, including 5 of 8 on reproductive effects and 5 of 9 on neurotoxicity. Only 3 IBT tests were valid, and 2 of these did not meet regulatory data requirements.	most of the tests have been replaced or partially replaced. Some are no longer required by EPA.	EPA plans to issue registration standard in 1984 and says the data base is complete.
terbufos	causes mutations directly and after metabolized by animals (2). EPA says desirable data on turbufos as potential cause of birth defects, cancer and mutations are lacking and that it has been shown to effect reproduction.	1 of 18 tests were done by IBT. It was an invalid birth defect study.	manufacturer has not agreed to replace the test and EPA has not required it to do so.	EPA issued a registration standard in 1983 granting a temporary data waiver.
fonofos	causes mutations directly and after metabolized by animals (2).	No IBT tests.	No IBT tests.	EPA plans to issue registration standard in 1984 and needs 2 cancer and 2 birth defects tests.
phorate	causes damage to the liver and testes of animals (3) and and attacks nerve cells in chickens (4).	1 of 21 tests were done by IBT. It was one of 17 neurotoxicity studies and was invalid.	manufacturer has not agreed to replace the test and EPA has not required it to do so.	EPA plans to issue registration standard in 1984 and needs 2 cancer tests, 2 birth defect tests and 1 long-term feeding test.
chlorpyrifos	attacks nerve cells in chickens (4).	No IBT tests.	No IBT tests.	EPA plans to issue a registration standard in 1984 and says data base is complete.

TABLE 2
HEALTH RECORD OF PESTICIDES COMMONLY USED IN THE MIDWEST

PESTICIDE	RESEARCH SHOWS THAT THIS PESTICIDE... (I)	IBT STUDIES AS A BASIS FOR EPA REGISTRATION: Extent of reliance on invalid IBT major health tests (II)	IBT STUDIES AS A BASIS FOR EPA REGISTRATION: Corrective Measures (III)	EPA STATUS (Jan., 1984) (IV)
HERBICIDES				
alachlor	causes lung, nose, stomach, and thyroid cancer in rats and mice (5).	10 of 20 tests were done by IBT, including 5 of 8 on mutagenicity. Three (all mutagen tests) were found valid but were improperly designed. The other seven were invalid.	2 tests have been replaced and accepted by EPA; 4 more replacement tests are under review; the manufacturer has not indicated whether it will replace 3 others; 1 is no longer required.	EPA plans to issue a registration standard in 1984 and consider data base complete.
trifluralin	is contaminated with traces of N-nitroso protein (NDPA) known to cause cancer. Tests with mice show that trifluralin itself may also cause cancer (1). It is also a mutagen (6).	No IBT tests	No IBT tests.	EPA concluded in 1979 that trifluralin contaminated with NDPA exceeded acceptable cancer risks and has required a reduction in the level of NDPA in the product. EPA also required tests on mutagenicity, reproductive and environmental effects, and birth defects.
atrazine	causes mutations in plants (7).	2 of 17 tests were done by IBT. They were partially valid and could be used independently to supplement the findings of other labs.	1 test has been replaced and is being reviewed by EPA. The manufacturer has not agreed to replace the other.	EPA issued a registration standard in 1983 and says it still needs a cancer test and 2 birth defects tests.
bentazon	little or no research published.	No IBT tests.	No IBT tests.	EPA plans to issue a registration standard in 1984 and considers the data base complete.

TABLE 2

HEALTH RECORD OF PESTICIDES COMMONLY USED IN THE MIDWEST

PESTICIDE	RESEARCH SHOWS THAT THIS PESTICIDE... (I)	IBT STUDIES AS A BASIS FOR EPA REGISTRATION: Extent of reliance on invalid IBT major health tests (II)	IBT STUDIES AS A BASIS FOR EPA REGISTRATION: Corrective Measures (III)	EPA STATUS (Jan., 1984) (IV)
HERBICIDES (continued)				
2-4 D	Causes birth defects and still births (3) and mutations (8,4) and has been linked to neurological problems of Vietnam veterans (9). Epidemiologic studies in Germany link it to bronchial cancer (10) and in Sweden to elevated risk of soft-tissue sarcoma among lumberjacks (11,12).	No IBT tests.	No IBT tests.	EPA says it needs cancer, birth defect, reproduction and neurotoxicity tests and won't issue a registration standard for some time.
metribuzin	little or no research published. Chemically close to atrazine and cyanazine.	5 of 21 tests were done by IBT, including 3 of 6 on birth defects. All were invalid.	4 tests have been replaced and are being reviewed by EPA; the other is being conducted by the manufacturer.	EPA plans to issue a registration standard in 1984 and considers the data base complete.
butylate	little or no research.	No IBT tests.	No IBT tests.	EPA issued a registration standard in 1983 and says it needs tests on cancer, reproduction, birth defects, and long term feeding effects.
cyanazine	causes mutations in plants and animals (13).	2 of 8 tests were done by IBT, including 2 of 3 on on birth defects. Both were invalid.	Manufacturer plans to replace both invalid tests.	EPA plans to issue registration standard in 1984 and needs a cancer test and 2 birth defect tests.

TABLE 2
HEALTH RECORD OF PESTICIDES COMMONLY USED IN THE MIDWEST

PESTICIDE	RESEARCH SHOWS THAT THIS PESTICIDE... (I)	IBT STUDIES AS A BASIS FOR EPA REGISTRATION: Extent of reliance on invalid IBT major health tests (II)	Corrective Measures (III)	EPA STATUS (Jan., 1984) (IV)
HERBICIDES (continued)				
dicamba	little or no research published. Chemically close to 2-4 D.	6 of 19 tests were done by IBT, including 3 of 4 on mutagenicity. All were invalid.	Manufacturer plans to replace 1 test, 1 is no longer required, 2 the manufacturer will not replace, and 2 it has not indicated its intentions.	EPA issued a registration standard in 1983 indicating data base is complete.
linuron	little or no research published.	No IBT tests.	No IBT tests.	EPA has not yet scheduled this chemical for re-registration and has not evaluated the adequacy of its data base on health effects.

Citations for Table 2

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Oversight of Health Effects Tests

Scientific testing of pesticides is not done by independent scientists nor are results currently made available to the public, and EPA has had serious lapses in its own oversight of company testing.

The tests done to evaluate the health risks of chemicals seeking registration are done by the companies who seek to register the chemical or by laboratories which they hire to do the tests. When FIFRA conferred regulatory authority over pesticides to EPA, the act also specified that health and safety test results were to be accessible to the public.

In 1979, however, Monsanto Company, a major pesticide manufacturer, filed suit against EPA to prevent it from releasing to the public information about the health effects of one of its products, a commercial formulation of the pesticide glyphosate. Monsanto argued that since had paid for the health effects research, that research was its property which he government had no constitutional right to release to the public. Monsanto further argued that information contained in these studies might be used by competition and their release might therefore damage Monsanto. A federal district court agreed issuing an injunction prohibiting EPA from releasing such data on any chemical. EPA has appealed to the U.S. Supreme Court and the case is pending Unless and until this appeal is decided in favor of EPA, pesticide health test results are not subject to the scrutiny of independent scientists. Only EPA and reviewers chosen by the agency see the test data and analysis. This falls considerably short of the peer review and publication requirements normally associated with professional science.

The absence of rigorous scientific quality controls in the research used to support pesticide registrations increases the risk that shoddy or even deceptive findings might be used to support erroneous conclusions about a chemical's safety. In 1977, that possibili became a reality. That year, Industrial Bio-Test Laboratories (IBT), a commercial testing laboratory specializing in pesticide registration tests, was found to have been falsifying test results and fabricating data for major health effect studies on a routine basis. In fact, an EPA audit revealed that nearly three-quarters (594) of the 801 major studies done by IBT in support of 140 chemical registrations held by 38 companies were found on review by the agency to be invalid. It was an open case of massive fraud, and in October, 1983, a federal jury found three former IBT officials guilty of multiple counts of fraud in the registration testing for just four of those chemicals.

The case was a shock to the federal pesticide regulatory system, revealing just how much the system depended on the good will, integrity, and honesty of the regulated and the independent laboratories frequently hired to provide the test studies. The extent of the scandal threw into question the credibility of the registration process itself. Though few chemicals were registered solely on the basis of IBT tests (5 were), the large number of invalid studies created huge gaps in the data on health effects of 140 chemicals. For example, glyphosate, the chemical which Monsanto sought to protect from public scrutiny, was heavily dependent for its registration data on invalid IBT studies. Twenty-five of 34 IBT studies in support of glyphosate were invalid, and though all those invalid tests still required by EPA have been replaced by Monsanto since, none of them have been accessible to the public or to independent

scientists outside EPA. Similar gaps are present for many pesticides. Over one-fourth (45 of 163) of the health studies done in support of the registration of the ten leading herbicides and five leading insecticides used in Midwestern agriculture were IBT studies. Only six of the pesticides were free from IBT studies and all but one of the IBT studies were invalid. Nonetheless, none of the chemicals registration was suspended or revoked.

Many of these chemicals are now undergoing the process of being re-registered by EPA, during which some of these studies will be replaced by the company which registers the chemical, while others will not. EPA has simply dropped the requirements for some kinds of studies The extent to which the original registration of 15 common Midwestern chemicals was based on invalid IBT studies and the dates of corrective measures are shown in Table 2, Columns II and III.

As a result of this experience, EPA and the Food and Drug Administration (FDA) (which regulates similar testing procedures established a laboratory audit program designed to spot check testing laboratories and spec fic pesticid tests each year to assure high standards for research on health effects. EPA has been a less than vigorous user of the lab audit program. FDA has conducted over 5 times as many spot checks as EPA which is still reviewing 13 lab audits which indicated problems prior to 1982, 22). Meantime, the agency has not changed its general policies regarding the independence of research and the Supreme Court has not yet decided whether to uphold the lower court ecision protecting the results from the general public under the excuse that they might reveal trade secrets.

Registration Lag

Man pesticides now commonly used in agriculture were registered using health effects data which were produced using scientific testing methods and analytical procedures which are now outdated. Moreover, some were originally registered when health effects test requirements were not as rigorous as they are now As a result, many pesticides are on the market and commonly used which have met less stringent health testing standards than currently required of pesticides. This lag in the scient ic evaluation of registered pesticides was recently analyzed by he staff of a congressional subcommittee which reviewed the files of 60 active chemical ingredients. t foun that only 52% of the required cancer studies, 62% of the birth defects studies, and 52% of the reproductive impairment studies were on file with EPA (23).

This gap in the health effects studies of older chemicals long on the market is a serious one. To correct it, EPA has instituted a re-registration process that requires each currentl registered chemical to be re-examined according to current scientific standards for evaluating health effects. Similar products using the same active ingredients are combined - there are about 600. A key document in this process is the "registration standard", which analyzes available data on the chemical and specifies the required data which the agency does not have in its files. To give ea ly warning to manufacturers of the test gaps in a pesticide's registration file, EPA has instituted a "data-call-in" program by which the companies and the public are notified of missing studies prior to the issuance of a registration standard. All chemicals subject to re-registration have been grouped according to their use into 48 clusters, (for example, cluster #1 consists of insecticides used on

corn, alfalfa and sorghum) so that competing products are re-registered in roughly the same period and pesticides most extensively used can be re-registered rs Some chemicals will not be re-registered for several years, ring which time they will presumably continue to be sold and used by farmers absent a complete review of their health effects. The re-registration status of commonl used pesticides in Midwestern agriculture is shown in Table 2, Column V The table ndicate when EPA intends to ssue registration standards on the pesticide if t has no already done so, and what data requirements have been "called-in" for use in preparing the registration standard.

Of the 15 common pesticides used in the Midwest, the data base is complete on only six. For eight of the 15, substantial health test data is missing and has been requested of the companies. One of the 15 pesticides has not yet been scheduled for registration standard issuance (i.e., it is in a lower ranking cluster of chemicals), and an assessment of its health effects data has not yet been made by the agency.

Not surprisingly, as new data on pesticides already registered and commonly used trickles in, there are instances when the evidence warns of previously unknown health risks. What then?

Learning Something New Everyday

If the data gathered in support of a registration standard for a pesticide indicates that EPA's risk criteria are exceeded and that there may be an "unreasonable adverse effect" on people or the environment if the pesticide continues to be used as it is now, the agency conducts a "special review." This new, simpler name, replaces a more suggestive one previously used to describe the same process. It used to be called a Rebuttable Presumption Against Registration RPAR).. If a special review is conducted it is because EPA has good cause to believe that health or environmental effects are serious, and that the risks may exceed the benefits of continuing to use the pesticide. The burden is on EPA, however, to prove its case before taking any action to further restrict the chemical.

During special review, EPA analyzes the scientific data to calculate public exposure to the pesticide and to estimate the risk to the public and the environment. It also considers the benefits of continued use of the pesticide. An initial regulatory position is established and published (ca led a "Position Document #1"), up to 105 days are provided for public comment (primarily used by the manufacturer to present rebuttal information) and EPA then either drops s stated concerns ("Position Document #2") or specifies the corrective action it feels must be taken "Position Document #3"). Among the possibilities: cancel the pesticide's registration, reclassify it, restrict its uses, or change labeling requirements (which usually means changing the product chemically). The full record is sent to a Science Advisory Panel and the Department of Agriculture for review, and again public comment is solicited. After considering it all, EPA issues its final position ("Position Document #4").

That's the textbook version, anyway. In fact, the process is deliberate, but it's also very technical. Participation is generally limited to the registrant, its competitors, USDA, the Science Advisory Panel, and EPA. A few environmental groups intervene on occasion.

Key to the success of this process, however, is the initial determination by EPA that a pesticide warrants such careful scrutiny. Absent such a determination, a risk assessment is not done, benefits are not calculated.

EPA has come under considerable riticism for the manner in which it evaluates data in determi ing whether a special review is needed. A congressional subcommi tee staff nvestigation (23) recently concluded that policy changes within EPA have had the effect of substantially lowering the public guard against pesticides which may cause cancer. The policy question is one in which EPA considers the "weight of the evidence" before deciding that a chemical deserves special review.

Under the weight of the evidence approach, the congressional subcommittee staff concluded that EPA:

**allows a test which shows positive findings of a cancer risk to be offset by a number of negative tests. "Limited evidence" of risk is equated to limited risk.

**uses mutagenicity tests to decide whether a chemical which is cancer-causing in animals is one which also affects the genetic structure of the animal or does not. If it does not, its risk of causing human cancer is considered less serious.

**has increased the level of risk of cancer which is considered "tolerable." Risks ten to 100 times greater than those previously accepted are now considered tolerable.

**now no longer considers a significant increase in benign tumors (cancers which do not spread to other parts of the body) as sufficient evidence to trigger special review.

If despite this generous attitude on the part of EPA, a chemical fails to quiet the concern of EPA regulators, a special review takes place. The case of one of the 15 commonly used pesticides in Table 1 describes the special review process.

Trifluralin is a herbicide used extensively for weed control in soybeans, cotton, and other crops. Its principal registrant is Elanco Products Co., a division of Eli Lilly. Trifluralin is the active chemical ingredient in Elanco's brand name herbicide, Treflan (TM).

Trifluralin has been registered for many years and pesticides formulated from it are preferred by many armers who rotate crops because it does not leave a "carryover" residue in the field that would be toxic to crops in the rotation. Its health effects were not considered significant until 1977.

That year, suspicion about Treflan (TM) began to mount, however, when it was learned that highly carcinogenic compounds called nitrosamines were present in trifluralin. The particular nitrosamine of concern was N-nitroso-di-n-propylamine, or NDPA.

Petitions were filed by several environmental groups and some members of

Congress to suspend Treflan's (TM) registration, and EPA agreed that the presence of NDPA as a contaminant warranted a special review of all pesticides containing trifluralin. On August 30, 1979, EPA issued a notice to that effect.

In its initial review of trifluralin, EPA concluded that manufacturers had to reduce the amount of NDPA in trifluralin to not more than 1 ppm. In addition, EPA was prepared to require a battery of long term health effect testing -- cancer, reproduction impairment, mutation, and birth defect tests.

During the final stages of the special review process, however, Elanco submitted to EPA the results of a test in which animals were fed trifluralin over a ong period This chronic feeding test was required as part of the re-registration process and was significant because it involved feeding of nearly pure trifluralin not contaminated with NDPA (that is, NDPA level was less that of the level at which EPA proposed to set its limit). The test results showed that trifluralin itself, without NDPA, caused significantly increased rates of cancer in the kidneys, bladder, and thyroid glands of rats.

This presented EPA with a problem. Until now, the agency had considered only NDPA to be a health problem in Treflan (TM). Now the principal ingredient itself trifluralin was implicated. Moreover more new information was received: NDPA was not the only nitrosamine in trifluralin Even more carcinogenic compounds (called simply C7 and C8 nitrosamines for the number of carbon atoms in each were present The previous anal sis of exposure and risk which the agency had done to reach its preliminary conclusion that manufacturers had only to reduce NDPA levels to 1 ppm to make the cancer risk of using trifluralin acceptable, was invalid.

Elanco, however, came forward with yet more new information. It had decided to reduce the amount of NDPA in Treflan (TM) even below the 1 ppm level proposed by EPA. To permit recalculation of the risk/exposure level, Elanco submitted an analysis of 635 samples of its reformed product showing average NDPA residues of 0.1 ppm. Since trifluralin constitutes about 44.5% of the ingredients in Treflan (TM), this was equivalent to a level of about 0.2 ppm NDPA in trifluralin.

EPA's new analysis, therefore, had to take into consideration three new variables not considered in its initial analysis:

- **sharply lower levels of NDPA in Treflan (TM)-- from 5 ppm used in initial analysis to 0.1 ppm.
- **sharply higher cancer risk than earlier assumed for trifluralin itself, a risk which proved to be much more serious than the risk associated with NDPA
- **a new contaminant (C7/C8) which though present in much smaller amounts than NDPA, is a more potent carcinogen

Meantime, EPA approved registration of Treflan (TM) for additional uses for weed control in barley and grain sorghum.

By reducing the NDPA contamination level in Treflan (TM) from 5 ppm to an average of 0.1 ppm, Elanco was reducing the level of NDPA by a factor of 50.

EPA assumed that the trifluralin risk exposure was therefore reduced by a factor of 50 also. Accordingly, its earlier conclusion that the overall risk to the public (both from worker exposure and dietary consumption of the chemical by the general population) of getting cancer from Treflan (TM) was simply reduced to a level of risk almost too small to measure.

Likewise, using Treflan (TM) samples which showed C7/C8 contamination at 0.02 ppm, risk was calculated as extremely low from that source.

At the same time, the agency then recalculated the risk of cancer from exposure to trifluralin itself, which it had previously consi ered to be non-existent, and concluded that the new risk, based on Elanco's chronic feeding study, was 1.08 in 1,000,000. Adding the new, lower risk level associated with a reduced level of NDPA with the new, higher risk level for exposure to trifluralin itself, EPA came to the conclusion that the overall revised risk of cancer from exposure to Treflan (TM) was about twice as great as it had thought initially. But because the risk was sti only about one in a million, EPA found that "The overall risk has not changed significantly..." and that "the added risk due to exposure to trifluralin is offset by the reduction of NDPA..."

Then, strangely, EPA decided to permit manufacturers to let the level of all nitrosamines in trifluralin reach 0.5 ppm, roughly two and a half times the level which it had used in its analysis of cancer risks. Moreover, recognizing that NDPA is sometimes produced naturally when trifluralin is formulated into commercial pesticide products, EPA also decided to permit the nitrosamine level to double during processing.

This in effect means that the cancer risk associated with nitrosamines in trifluralin is two and one-half times greater than reported in the final position document used as the basis for completing the agency's special review.

EPA's review of the benefits associated with trifluralin pesticides did not change significantly. The product is therefore considered safe -- that is, EPA has established that if nitrosamine levels are kept below 0.5 ppm in trifluralin, and if products using that chemical do not more than double the level of nitrosamines during processing, the cancer risks associated with it are acceptable given the benefits which are attributed to the pesticide's use.

The agency will, however, still require that missing health tests be conducted on trifluralin's potential for causing birth defects, reproduction impairment, and mutations. And tests wi also be required which analyze the chemical's ecological effects, which became suspec as well during the special review. Those tests are all due over the next couple years. If they contain more surprises, trifluralin may be subjec o another special review. Meantime, the special review triggered by NDPA contamination is complete, and the pesticide has been returned to the regular re-registration process.

More significant, perhaps, is the fact that for many years, farmers have been using trifluralin-containing pesticides which had substantially higher cancer risks than was known at the time. If reducing the NDPA level in trifluralin was necessary to protect people in 1982, it was necessary long ago as well.

Special Local Needs and Emergency Exemptions

The FIFRA regul tory scheme with its deliberate testing requirements and decision-making procedures assumes that pesticide use is routine and predictab e and that users can anticipate need sufficiently enough in advance o complete the process. Some pesticide uses, however, are more emergency in nature or respond to peculiar local needs which ma or may not reflect national use patterns. In the interest of regulator effi iency, Congress permitted EPA to exempt state and federal agencie rom normal registration procedures and requirements when serious pest outbreaks occur in a state for which there are no effective registered pesticide uses (section 18 of the act). These emergency exemptions are subject to EPA approval, but they have become an important registration avenue for newer products to penetrate the pesticide market before a thorough sc entific evaluation is completed under normal procedures. States may also grant regist a ion for pesticides for special local needs (section 24(c)). These registrations are for new and/or ifferent uses than those for which a pesticide is already registered at he federal level. These emergency and special local need (SLN) registrations do not carry with them additional requirements for health effects testing, and constitute a considerably less burdensome registration process than normal registration procedures. One insecticide which initial tests ndicated showed significant evidence of causing cancer was held up in normal registration process for four years, but in the meantime, was granted 140 emergency exemptions and over 300 SLN registrations. Not surprisingly, these kinds of registrations have proliferated in recent years as a means of circumventing the more stringent regular process.

Between 1978 and 1982, the number of "emergency" requests increased from 199 per year to 724 (264% increase). While many of these exemptions were for the use of pesticides on high value specialty crops rather than the standard row crops of the Midwest, that was not entirely the case. For example a new insecticide, permethrin (marketed by two companies under the trade names Ambush (TM) and Pounce (TM)), was granted 28 emergency exemptions for se on corn in 14 states and 22 emergency exemptions for use on soybeans in 10 states (23).

The same is true of special local need (SLN) exemptions. Nearly one fifth of SLN registrations were granted for use in corn and wheat belt states (23). There should be no mistake about who has defined a "special local need." While the act permits farmers, farm organizations, government agencies, or pesticide producers to request SLNs a study by the Rural Advancement Fund, a rural advocacy group North Carolina, showed that 91% of the SLN registrations granted in 25 states studied were requested by the chemical manufacturer. Only 2% were requested by farmers or farm organizations. Moreover half the 2,089 SLN's granted in these states were for use on extensively planted crops (soybeans, small grains cotton alfalfa, and corn), livestock and forests, the kinds of uses for which specia local need is dubiou . Further, it should come as no relief to farmers tha 43% of all SLN registrations granted in 1981-82 were tested for health effects by IBT, the laboratory whose health studies were found to be overwhelmingly invalid (24).

I

99TH CONGRESS
1ST SESSION

H. R. 1416

To protect the American public from consuming potentially unsafe pesticide residues on imported foodstuffs; to foster prudent and equitable regulatory requirements and standards for United States producers of agricultural commodities competing with producers in other countries in international and domestic markets; and to improve the international exchange of scientific information on the properties, safety, benefits, and risks of pesticide use.

IN THE HOUSE OF REPRESENTATIVES

MARCH 5, 1985

Mr. HEFTEL of Hawaii (for himself, Mr. BARNES, and Mrs. BURTON of California) introduced the following bill; which was referred to the Committee on Agriculture

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A BILL

To protect the American public from consuming potentially unsafe pesticide residues on imported foodstuffs; to foster prudent and equitable regulatory requirements and standards for United States producers of agricultural commodities competing with producers in other countries in international and domestic markets; and to improve the international exchange of scientific information on the properties, safety, benefits, and risks of pesticide use.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. This Act may be cited as the "Pesticide Import and Export Act of 1985".

SEC. 2. (a) Section 7(c)(1) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136e(c)(1)) is amended by striking out "and" at the end of subparagraph (B), by striking out the period and inserting "; and" at the end of subparagraph (C), and by adding after subparagraph (C) the following:

"(D) which he has exported during the past year, and the destination of the exports, including shipments of pesticide active ingredients, intermediates, or formulated products to subsidiaries or other companies engaged in a business relationship with the producer.".

(b) Section 7(c)(1) of such Act is further amended by striking out the last sentence and inserting in lieu thereof the following:

"The information required by this paragraph shall be kept current and shall be submitted to the Administrator annually as required under such regulations as the Administrator may prescribe. The Administrator shall require pursuant to subparagraph (D) of this paragraph, to the extent practicable in light of the transshipment of pesticides and the availability of this information to the producer, information on the nature and quantities

of pesticides exported, the destination of the exported pesticides, and the uses of the exported pesticides. The Administrator shall cooperate and collaborate with the Secretary of Agriculture, Secretary of State, and the Commissioner of the Food and Drug Administration in identifying overseas pesticide use patterns on food crops exported to the United States. An annual report shall be prepared by the Administrator for submission to the Congress and to the United Nations, and for release to the public and other interested parties summarizing the information received under this paragraph. The report shall include the scope, frequency, and results of any pesticide residue monitoring tests conducted by the Food and Drug Administration and the United States Department of Agriculture on food imported by the United States. The report may include any recommendations the Administrator may wish to offer for improving the reliability and usefulness of the information received under this section and section 17 of this Act.".

(c) Subsection (d) of section 7 of such Act is amended to read as follows:

"(d) CONFIDENTIAL RECORDS AND INFORMATION.—

"(1) Except as provided in paragraph (2), any information submitted to the Administrator pursuant to

subsection (c) shall be kept confidential and shall be subject to section 10.

"(2) The Administrator may disclose to the public—

"(A) the names of the pesticides or active ingredients submitted under subsection (c) which are produced or used in producing pesticides produced, sold, distributed, or exported by an establishment; and

"(B) any information the Administrator determines is necessary to submit under subsection (c)(1)(A)(iv).

"(3) The Administrator shall take such steps as are necessary to limit the disclosure of commercial information submitted by producers when such disclosure is not necessary to carry out this section or section 17.".

PESTICIDES AND DEVICES INTENDED FOR EXPORT

SEC. 3. (a) Subsection (a) of section 17 of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136o(a)(2)) is amended to read as follows:

"(a) PESTICIDES AND DEVICES INTENDED FOR EXPORT.—

"(1) IN GENERAL.—Notwithstanding any other provision of this Act, no pesticide or device or active ingredient used in producing a pesticide intended for

export to any foreign country shall be considered in violation of this Act—

"(A) if such pesticide, device, or ingredient is prepared or packed according to the specifications or directions of the foreign purchaser, except that producers of such pesticide, device, or ingredient shall be subject to sections 2(p), 2(q), 7, and 8 of this Act; and

"(B) in the case of any pesticide for which any use or formulation has been cancelled, suspended, or denied under this Act by the Administrator or voluntarily cancelled or suspended, any pesticide identified by the Administrator as an acutely toxic pesticide, and any pesticide classified for restricted use under section 3(d), if the Administrator, after consultation with the Secretary of State and the Secretary of Agriculture and before export, determines that appropriate officials of the foreign country have—

"(i) submitted a request to the Administration that such pesticide be exported to such country;

"(ii) disclosed to the Administrator the specific intended use of such pesticide in such country, including the nature and quantity of

the pesticide and the crops on which it will be used;

"(iii) provided the Administrator with a full description of the procedures instituted by such country to educate users of such pesticide in the safe handling, application, and disposal of such pesticide; and

"(iv) in the case of a pesticide used on food crops exported in commercial quantities to the United States, inform the Administrator of any regulatory requirements established in such country which impose conditions on the use of such pesticide in the country that might affect the nature and level of pesticide residues on such crops, including the nature and level of pesticide residues allowed in such country and the nature and findings of any routine residue testing done on such crops prior to export.

"(2) INFORMATION.—Upon the receipt from a foreign country of any information required to be provided under paragraph (1)(B), the Administrator shall provide such country with information regarding—

"(A) any restriction or prohibition on any use of such pesticide in the United States;

"(B) the nature and estimated severity of any unreasonable adverse effects on man and the environment identified by the Administrator during the course of considering the regulatory status of the pesticide in the United States;

"(C) the availability, upon request made to the Administrator and subject to section 10 of this Act, of regulatory and scientific documents concerning such pesticide; and

"(D) in the case of any acutely toxic pesticide, the acute hazards associated with exposure to such pesticide.

"(3) DEFINITIONS.—As used in this subsection:

"(A) The term 'acutely toxic pesticide' means a pesticide which—

"(i) has an acute dermal lethal dose as formulated of no more than 40 milligrams per kilogram;

"(ii) has an acute dermal lethal dose as diluted for use in the form of a mist or spray of no more than 6 grams per kilogram; or

"(iii) has an inhalation lethal concentration as formulated of no more than 0.04 milligrams per liter.

"(B) The term 'cancelled, suspended, or denied' means the cancellation, suspension, or denial of any use with respect to that pesticide and includes the voluntary withdrawal of the registration of such pesticide under this Act, or of an application to register such pesticide under this Act—

"(i) if such withdrawal occurs after the issuance by the Administrator of a notice of intent to—

"(I) deny the registration of such pesticide pursuant to section 3(c)(6); or

"(II) cancel the registration of such pesticide pursuant to section 6(b)(1); or

"(ii) if such pesticide is voluntarily withdrawn after it exceeds any of the R-PAR (Rebuttable Presumption Against Registration) or Special Review risk criteria, set forth in 40 CFR 162.11.".

(b) The table of contents in subsection (b) of section 1 of such Act (7 U.S.C. 121) is amended by striking out the item relating to subsection (a) of section 17 and inserting in lieu thereof the following new item:

"(a) Pesticides and devices intended for export.
"(1) In general.
"(2) Information.
"(3) Definitions.".

SEC. 4. Section 5(b) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136c(b)) is amended by inserting before the period at the end thereof the following: ", except that a temporary tolerance shall not apply to pesticide residues on imported foodstuffs or feed".

SEC. 5. Section 6 of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136d) is amended by redesignating subsection (f) as subsection (g) and by inserting after subsection (e) the following new subsection:

"(f) REVOCATION OF TOLERANCES.—

"(1) The Administrator shall revoke tolerances established under the provisions of the Federal Food, Drug, and Cosmetic Act when—

"(A) the uses of a pesticide associated with the tolerances have been cancelled or suspended or denied under this section; or

"(B) in the case of a pesticide registration or registration application voluntarily withdrawn, if the Administrator determines that the tolerance is no longer needed or supported by the available scientific data.

If the Administrator fails to revoke any tolerance within 180 days after the cancellation or suspension of use of a pesticide referred to in subparagraph (A) or in the case of a voluntary withdrawal of a pesticide regis-

tration or registration application referred to in subparagraph (B) then such tolerance shall automatically be revoked at the close of such day.

"(2) The Administrator shall establish a residue action level at the time a tolerance is revoked for the purpose of enforcing the provisions of the Federal Food, Drug, and Cosmetic Act if the Administrator—

"(A) determines that residues of the pesticide will unavoidably persist in the environment; and

"(B) makes a determination that such action levels will not pose an unreasonable adverse effect on man or the environment.

In establishing or revoking a tolerance, the Administrator shall take into account any probable impacts of such actions on the competitiveness of agriculture production in the United States in world and domestic markets, with the goal of eliminating, to the extent practicable inequitable burdens on United States producers caused by pesticide regulatory actions and standards established by different nations.".

COOPERATION IN INTERNATIONAL EFFORTS

SEC. 6. Subsection (d) of section 17 of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136o(d)) is amended to read as follows:

"(d) COOPERATION IN INTERNATIONAL EFFORTS.—The Administrator shall—

"(1) in cooperation with the Department of State, other appropriate Federal agencies, and nongovernmental and international organizations, actively participate in, encourage, and cooperate with international efforts to develop improved and uniform pesticide research and regulatory programs, particularly efforts to promote uniformity in the labelling and application of, and setting of tolerance standards for, pesticides; and

"(2) provide countries which import pesticides from the United States with technical assistance, including—

"(A) the establishment of education and safety training programs for the use, handling, and disposal of pesticides; and

"(B) the development of comprehensive regulatory programs, including the monitoring of pesticide residue levels on food crops.".

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●HR 1416 ■

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99TH CONGRESS
1ST SESSION

H. R. 1910

To amend the Federal Insecticide, Fungicide, and Rodenticide Act to provide that pesticides that are used in agricultural production do not endanger human health.

IN THE HOUSE OF REPRESENTATIVES

APRIL 2, 1985

Mr. SEIBERLING (for himself and Mr. WEAVER) introduced the following bill; which was referred to the Committee on Agriculture

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A BILL

To amend the Federal Insecticide, Fungicide, and Rodenticide Act to provide that pesticides that are used in agricultural production do not endanger human health.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. REGISTRATION OF PESTICIDES.

Section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act is amended—

(1) in the first sentence thereof by striking out "and" at the end of clause (C), by striking out the period at the end of clause (D) and inserting in lieu thereof "; and", and by inserting at the end of such sentence the following:

"(E) when used for agricultural production in accordance with widespread and commonly recognized practice has been determined by the Administrator that it is not likely to endanger human beings (including children who are permitted under the Fair Labor Standards Act (20 U.S.C. 201 et seq.) to work in areas treated with pesticides)."; and

(2) by inserting after the first sentence thereof the following new sentence: "In determining whether a pesticide is likely or not likely to endanger human beings under subparagraph (E) of the preceding sentence, the Administrator shall conduct appropriate laboratory tests as the basis for ascertaining the potential long-term and acute effects of the pesticide on human beings (including but not limited to oncogenicity, mutagenicity, fetotoxicity, reproductive effects, and behavioral effects).".

SEC. 2. REREGISTRATION OF PESTICIDES.

Section 3(g) of the Federal Insecticide, Fungicide, and Rodenticide Act is amended to read as follows:

"(g) REREGISTRATION OF PESTICIDES.—

"(1) The Administrator shall accomplish the reregistration of all pesticides used for agricultural production in accordance with this subsection.

"(2)(A) Within 120 days after the date of the enactment of this subsection, the Administrator shall publish in the Federal Register a list of pesticides used for agricultural production in the order of their priority for reregistration under this Act.

"(B) In establishing the list, the Administrator shall—

"(i) give the highest priority on the list to pesticides used in substantial volumes that result in a postharvest residue in or on food or feed crops or in postapplication residues in potable ground water; and

"(ii) include among the pesticides accorded the highest priority on the list the pesticides shown to cause mutagenic effects in an appropriately designed and conducted experiment using a bacterial test system.

"(C) The establishment of the list by the Administrator shall not be subject to judicial review.

"(3) In accordance with the schedule prescribed in paragraph 2(A), the Administrator shall conduct appropriate laboratory tests of each such pesticide as a basis for ascertaining the potential chronic and acute effects of the pesticide on human beings (including but not

limited to oncogenicity, mutagenicity, fetotoxicity, reproductive effects, and behavioral effects).

"(4) The Administrator may not reregister any pesticide contained in the list published under paragraph (2), unless the the Administrator determines, on the basis of the laboratory tests conducted under paragraph (3) with respect to such pesticide, that the use of such pesticide for agricultural production in accordance with widespread and commonly recognized practice is not likely to endanger human beings (including children who are permitted under the Fair Labor Standards Act (20 U.S.C. 201 et seq.) to work in areas treated with pesticides). The Administrator shall notify the registrant of his decision and of his reasons therefor. The Administrator shall promptly publish in the Federal Register notice of such denial of reregistration and the reasons therefor.

"(5) Effective 3 years after the date of enactment of this subsection, the registration of any pesticide contained in the list published under paragraph (2) is revoked unless the Administrator has determined pursuant to paragraph (4), based on laboratory tests conducted under paragraph (3) with respect to such pesticide, that such pesticide is not likely to endanger human life. The Administrator shall notify the regis-

trant of the revocation and shall promptly publish in the Federal Register notice of such revocation.

"(6) The Administrator shall accomplish the reregistration of all pesticides other than pesticides used for agricultural production in the most expeditious manner practicable, except that, to the extent appropriate, any pesticide that results in a postharvest residue in or on food or feed crops shall be given priority in the reregistration process.".

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DEPARTMENT OF AGRICULTURE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20250

July 22 1985

Honorable E (Kika) de la Garza
Chairman, Committee on Agriculture
U. S. House of Representatives
Washington, D. C. 20515

Dear Mr. Chairman:

This is in response to your request for a report on H.R. 1910, a bill "To amend the Federal Insecticide, Fungicide, and Rodenticide Act to provide that pesticides that are used in agricultural production do not endanger human health."

The Department does not recommend enactment of this bill.

The bill is designed to make several revisions to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). These changes would shift costs for laboratory testing from industry to the Federal Government, be prohibitively expensive for the Federal Government, be extremely time consuming and, in the final analysis, could have significant negative impacts on the costs of food, feed, and fiber production due to reduced ability to control agricultural pests.

Sections 1 and 2 of the bill would require the Administrator of EPA to conduct "appropriate" laboratory tests in the areas of oncogenicity, mutagenicity, fetotoxicity, reproductive effects, behavioral effects, and other unspecified testing. Some of these tests are long-term, measured n years, and quite expensive. The burden for providing this data has in the past been borne by industry. The costs for shifting this burden to the EPA could be better estimated by them, but we believe it will be prohibitively costly. Although industry might gain by reducing costs of registration testing, the Federal Government gets no offsetting benefits from taking over the burden of paying for data to support reregistration.

Section 2 of the bill also requires the Administrator to make a priority listing of all agricultural pesticides within 120 days of enactment, and then to test all listed agricultura chemicals prior to reregistering them. Any chemical not so reregistered at the end of three years would be barred from further use. Because of the physical and practical impossibilities of accomplishing such a task, it could be anticipated that large numbers of agricultural chemicals would be taken from the market with a concomitant decrease in productivity due to pest losses. The amount of losses would depend on the number of chemicals.

Honorable E (Kika) de la Garza

As a minor point, Section 2 would require that mutagenic tests be done through "an appropriately designed and conducted experiment using a bacterial test system." The specific test system should not be specified in law, as it might not be the best measure in all circumstances. Fixing scientific state of the art by legislation will not solve problems and may add new ones.

The Office of Management and Budget advises that there is no objection to the presentation of this report from the standpoint of the Administration's program.

Sincerely,

John R. Block

John R. Block
Secretary

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99TH CONGRESS
1ST SESSION

H. R. 2482

To amend the Federal Insecticide, Fungicide, and Rodenticide Act, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MAY 14, 1985

Mr. BEDELL (for himself and Mr. ROBERTS) introduced the following bill; which was referred to the Committee on Agriculture

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A BILL

To amend the Federal Insecticide, Fungicide, and Rodenticide Act, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1985".

REFERENCES TO THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

SEC. 2. Except as otherwise specifically provided, whenever in this Act an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a

section or other provision of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.).

DEFINITIONS

SEC. 3. (a) Section 2(e) (7 U.S.C. 136(e)) is amended—

(1) in paragraph (1) by deleting the second sentence thereof.

(2) by deleting paragraph (4).

(b) Section 2(l) (7 U.S.C. 136(l)) is amended by deleting the words "cancellation proceeding" and substituting therefore the words "a cancellation proceeding under section 6 (b) and (d) or a rulemaking proceeding under section 6(a).".

(c) Section 2(n) (7 U.S.C. 136(n)) is amended to read as follows:

"(n) INGREDIENT STATEMENT.—The term 'ingredient statement' means a statement which contains—

"(1) the name and percentage of each active ingredient in the pesticide product;

"(2) the name (and, to the extent found necessary, the percentage) of each inert ingredient which the Administrator determines must appear in the ingredient statement because of the hazard which the Administrator has determined may be posed by the presence of that ingredient;

"(3) the total percentage of all inert ingredients in the pesticide product;

"(4) if the product contains arsenic in any form, a statement of the percentages of total and water soluble arsenic, calculated as elementary arsenic; and

"(5) any other information concerning the chemical composition or identity of any active ingredient of the product (for example, information on chemical equivalency) which the Administrator requires to appear on the ingredient statement in order that the nature of the active ingredient is accurately represented.".

(d) Section 2(u) (7 U.S.C. 136(u)) is amended by inserting after the words "or desiccant;" the words "or (3) any substance or mixture of substances which contains an active ingredient and which any person distributes or sells in any State for use in manufacturing or formulating a pesticide or for repackaging as a pesticide;".

(e) Section 2(ee) (7 U.S.C. 136(ee)) is amended—

(1) by inserting at the end of clause (1) thereof the words "unless the labeling specifically prohibits deviation from the specified dosage, concentration, or frequency;"; and

(2) by deleting the word "or" in clause (3) thereof and substituting therefor the words "unless the labeling specifically states that the product may be applied only by the methods specified on the labeling; or".

(f) Section 2 is further amended by adding at the end thereof the following new subsections:

"(ff) TO DISTRIBUTE OR SELL.—The term 'to distribute or sell' (and grammatical variations thereof) means to distribute, sell, offer for sale, hold for distribution, hold for sale, hold for shipment, ship, deliver for shipment, release for shipment, or receive and (having so received) deliver or offer to deliver: *Provided*, That the term does not include the holding or application of registered pesticide products or use dilutions thereof by any applicator who provides a service of controlling pests without delivering any unapplied pesticide to any person so served.

"(gg) PESTICIDE PRODUCT.—The term 'pesticide product' means a pesticide in the particular form (including composition, labeling, and packaging) in which it is (or is proposed to be) distributed or sold. The term 'pesticide' as used in this Act shall mean 'pesticide product' when the context so indicates.

"(hh) PESTICIDE TESTING FACILITY.—The term 'pesticide testing facility' means any person that conducts any test, study, survey, or investigation of the properties, effects, or behavior of any pesticide (or any ingredient, metabolite, or degradation product thereof) for or on behalf of any registrant, applicant for registration, or other person who sells or distributes the pesticide (or contemplates selling or distribut-

ing it): *Provided,* That the term does not include any person solely on account of such person's participation as a cooperator in field testing of a pesticide in compliance with an experimental use permit under section 5 of this Act.

"(ii) TERMS OF REGISTRATION.—The term 'terms of registration' means the requirements imposed on a pesticide product under this Act concerning the product's composition labeling, and packaging, and the restrictions on its distribution, sale, and use.".

REGISTRATION OF PESTICIDES

SEC. 4. (a) Section 3(a) (7 U.S.C. 136a(a)) is amended to read as follows:

"(a) REQUIREMENT OF REGISTRATION.—Except as provided by this Act, no person in any State may distribute or sell to any person any pesticide which is not registered under this Act.".

(b) Section 3(c) (7 U.S.C. 136a(c)) is amended—

(1) in section 3(c)(1)(D)(ii) by striking out all of the fourth sentence after "findings and determination of the arbitrator" and all of the fifth sentence, and in section 3(c)(2)(B)(iii) by striking out all of the second sentence after "findings and determinations of the arbitrator" and all of the third sentence, and by substituting in each case therefor the words "shall be reviewable only in the United States court of appeals for the circuit in which the petitioner resides or has its principal

place of business, or in the United States Court of Appeals for the District of Columbia, upon a petition for review filed with the court by a party to the arbitration within 60 days after the entry of the arbitrator's determination or within 60 days after enactment of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1985 whichever date is later. For purposes of section 2112 of title 28, United States Code, the arbitrator's determination shall be treated as if it were an order of an administrative agency. The parties to the arbitration shall share equally in the fee and expenses of the arbitrator, including any expenses of the arbitrator associated with judicial review."; and

(2) in section 3(c)(3) and 3(c)(6) by adding the words "or (7)" after the words "paragraph (5)".

(c) Section 3(d) is amended—

(1) in section 3(d)(1)(A) by deleting the words "on the initial classification";

(2) in section 3(d)(1)(C)(i) by deleting the words "by or under the direct supervision of a certified applicator." and substituting therefor the words "by a certified applicator or under such degree of supervision of a certified applicator as the Administrator may specify.";

(3) in section 3(d)(1)(C)(ii)—

(A) by deleting the words "by or under the direct supervision of a certified applicator" and substituting therefor the words "by a certified applicator or under such degree of supervision by a certified applicator as the Administrator may specify";

(B) by deleting the last sentence thereof and substituting therefor the words "Any such regulation shall be issued under section 6(a) of this Act.";

(4) in section 3(d)(2) by deleting the words "he shall notify the registrant" and all that follows and substituting therefor the words "or that additional restrictions are required to prevent such effects, the Administrator may act to provide such restrictions under section 6(a) or 6(b)(1)(B) of this Act."; and

(5) in section 3(d)(3) by deleting the last sentence thereof and substituting therefor the words "A petition under this paragraph shall be treated as an application to amend the registration and to modify or rescind any regulation involved.".

ADMINISTRATIVE REVIEW; SUSPENSION

SEC. 5. (a) Section 6(a) (7 U.S.C. 136d(a)) is amended to read as follows:

"(a) RULEMAKING PROCEEDINGS TO DETERMINE WHETHER PEODUCTS CAUSE UNREASONABLE ADVERSE EFFECTS ON THE ENVIRONMENT.—

"(1) The Administrator may by regulation determine—

"(A) that a use (or proposed use) of a pesticide product (or category of products) causes or will cause unreasonable adverse effects on the environment; and

"(B) the terms of registration, if any, under which the pesticide product (or category of products) may be distributed, sold, or used.

"(2) As part of a rulemaking proceeding under this subsection, the Administrator may by order require that one or more issues shall be determined solely on the basis of substantial evidence of record presented in a hearing conducted in the manner prescribed by subsection (d) of this section.

"(3) Any regulation issued under this subsection (and any refusal of a petition to modify or rescind such a regulation) shall be reviewable only as provided by section 16(e) of this Act.

"(4) The Administrator may not issue a notice of intent to cancel the registration of a product (or to cancel it unless the terms of registration are modified)

for one or more uses under subsection (b)(1) of this section unless—

"(A) the Administrator has published a final rule under this subsection which concludes that one or more uses of the product poses unreasonable adverse effects on the environment; or

"(B) the Administrator determines that the question of whether one or more uses of the product poses unreasonable adverse effects on the environment can be answered more quickly and efficiently in an adjudicatory hearing under subsection (d) of this section than in a rulemaking proceeding, taking into account the cost to the Government and to other parties and the time required for resolution of issues; or

"(C) the notice is issued on or before October 2, 1988, and concerns a product (or category of products) which was the subject of an administrative investigation or proceeding or investigation commenced on or before October 2, 1986.

"(5) If a hearing results from a notice under subsection (b)(1) or (b)(2) of this section or section 3(c)(6) based on a pesticide's failure to comply with a regulation issued after October 2, 1985, under this Act, the scope of the hearing shall be limited to—

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"(A) whether the product complies with the regulation;

"(B) whether the regulation by its terms is applicable to such a product; or

"(C) whether, because of significant information that was not (and could not reasonably have been) presented in the proceeding wherein the regulation was established, it would be unreasonable to require such a product to comply with the regulation.".

(b) Section 6(b) (7 U.S.C. 136d(b)) is revised to read as follows:

"(b) CANCELLATION.—

"(1) NONCOMPLYING PRODUCTS.—If the Administrator determines that any of the terms of registration of a registered pesticide product (or category of such products) does not comply with the provisions of this Act or any regulation issued under this Act, or determines that use of a registered pesticide product (or category of such products) in accordance with widespread and commonly recognized practice generally causes unreasonable adverse effects on the environment, the Administrator may issue a notice of intent—

"(A) to cancel the registration; or

"(B) to cancel the registration unless specified modifications to the terms of registration of the product(s) are requested by the registrant(s).

"(2) IMPROPER APPLICATION, ETC.—The Administrator may issue a notice of intent to cancel the registration of a pesticide product, or to cancel the registration unless specified modifications to the terms of registration of the product are requested by the registrant, if the Administrator determines that the product was registered (or that its registration was amended)—

"(A) in response to an application that contained or cited any information or representation which the applicant knew or reasonably should have known, at the time of filing the application, was false, inaccurate, or misleading; or

"(B) in response to an application that contained or cited any information which was required to be submitted and which was false, inaccurate, or misleading, if the Administrator determines that cancellation of the registration would be in the public interest, taking into account the need to use the data to determine whether the product may cause unreasonable adverse effects on the environment if used during the period required for replacement of the information and the

degree of care which the applicant exercised in obtaining and submitting the information; or

"(C) in response to an application that did not comply with the requirements of the Act or regulations issued under the Act and that was mistakenly approved by the Agency because of clerical error or other improper ministerial Agency action; or

"(D) in response to an application that was approved on the basis of the prior approval of another application that the Administrator determines is described by subparagraph (A), (B), or (C) of this paragraph, if a notice of intent to cancel the registration resulting from that other application has been issued.

"(3) NOTICE; REQUIRED CONTENTS.—Each notice issued under paragraph (1) or (2) of this subsection shall state the reasons for and factual basis of the notice. Each notice issued under paragraph (1)(B) or (2) of this subsection shall specify each required modification in the terms of registration.

"(4) PUBLICATION OF NOTICE.—A notice of denial, notice of intent to cancel, notice of suspension, or notice of intent to suspend issued under this Act shall be published in the Federal Register and shall be

sent by certified mail, return receipt requested, to the registrant's or applicant's address of record on file with the Agency. If the mailed notice is returned to the Agency as undeliverable at that address, if delivery is refused, or if the Agency otherwise is unable to accomplish delivery of the notice to the registrant or applicant after making reasonable efforts to do so, the notice shall be deemed to have been received by the registrant or applicant on the date the notice was published in the Federal Register.

"(5) REVIEW BY SECRETARY OF AGRICULTURE.—At least 60 days prior to issuing a notice under paragraph (1) or (2) of this subsection, the Administrator shall provide the Secretary of Agriculture with a document containing the substance of the actions proposed and the reasons therefor and an analysis of the impact on the agricultural economy of the actions that could result from issuance of the notice and any resultant hearing or order: *Provided*, That such document need not be furnished if the notice implements a regulation issued under subsection (a) of this section upon which opportunity to comment has been furnished to the Secretary under section 25(a)(2) of this Act. If the Secretary comments in writing to the Administrator regarding the document within 60 days

after receiving them, the Administrator shall publish such comments and any Agency response in the Federal Register with the notice. The comment period established by this paragraph may be waived or modified by agreement of the Administrator and the Secretary. Notwithstanding any other provisions of this subsection (b) or of section 25(d) or (e), if the Administrator determines that an immediate suspension under subsection (c) is necessary, the Administrator may waive the requirement of advance notice to the Secretary under this paragraph and to the Scientific Advisory Panel under sections 25(d) and 25(e), and may proceed in accordance with subsection (c).

"(6) REQUEST FOR HEARING; EFFECT OF FAILURE TO REQUEST HEARING.—The action proposed by a notice of intent to cancel issued under paragraph (1)(A), (1)(B), or (2) of this subsection shall become final and effective at the end of 30 days from the date of receipt of the notice by the registrant or from the date of publication of the notice in the Federal Register, whichever occurs later, unless within that time the Administrator receives—

"(A) a request from the registrant (or from any person adversely affected by the notice) for a hearing concerning the product, if the notice did

not specify modifications in the terms of registration that could be made in lieu of cancellation; or

"(B) with respect to each term of registration found to require specified modifications in a notice issued under paragraph (1)(B) or (2) of this subsection, either a request from the registrant (or from any person adversely affected by the notice) for a hearing concerning the product, or an application from the registrant to amend the terms of registration in the manner specified in the notice.".

(c) Section 6(c) (7 U.S.C. 136d(c)) is amended—

(1) in section 6(c)(1) by deleting the second sentence thereof and substituting therefor the words "A suspension order may prohibit the distribution or sale of the pesticide product, may prohibit use of the product, or both. No suspension order may be issued under this subsection unless the Administrator has issued or at the same time issues either (A) a notice of intent to cancel the registration of the pesticide product under subsection (b)(1) of this section, or (B) a notice commencing a rulemaking proceeding with respect to the product under subsection (a) of this section."; and

(2) in section 6(c)(4) by deleting the word "classification" and substituting therefor the words "the terms of registration".

(d) Section 6(d) (7 U.S.C. 136d(d)) is revised to read as follows:

"(d) PUBLIC HEARINGS AND SCIENTIFIC REVIEW.—

"(1) If a hearing is requested pursuant to subsection (b) or (e) of this section or section 3(c)(2)(B)(iv) or 3(c)(6) of this Act, or if the Administrator convenes a hearing under subsection (a)(2) of this section, a hearing shall be held after due notice for the purpose (subject to subsection (a)(5) of this section) of receiving evidence relevant and material to the issues raised by the request for hearing, or to the issues stated by the Administrator if the hearing is convened under subsection (a)(2) of this section. Any interested person may intervene in such a hearing. The hearing shall be held in accordance with the provisions of subchapter II of title 5 of the United States Code, except that the burden of persuasion in a hearing held in response to a notice issued under subsection (b)(1) of this section or under section 3(c)(6) of this Act or convened under subsection (a)(2) of this section shall rest with the party or parties contending that use of the pesticide product does not cause unreasonable adverse effects on the environment.

The Administrator may by regulation prescribe rules of procedure for hearings under this subsection.

"(2) Upon a showing of relevance and reasonable scope of evidence sought by any party to a public hearing, the Administrative Law Judge shall issue a subpoena to compel testimony or production of documents from any person. The Administrative Law Judge shall be guided by the principles of the Federal Rules of Civil Procedure in allowing and controlling discovery and in making any order for the protection of the witness or the content of documents produced and shall order the payment of reasonable fees and expenses as a condition of requiring testimony of the witness. On contest, the subpoena may be enforced by an appropriate United States district court in accordance with the principles stated herein.

"(3) Upon the request of any party to a public hearing and when in the judgment of the Administrative Law Judge it is necessary or desirable, the Administrative Law Judge shall at any time before the hearing record is closed refer to a committee of the National Academy of Sciences relevant questions of scientific fact involved in the public hearing. No member of any committee of the National Academy of Sciences established to carry out the functions of this

section shall have a financial or other conflict of interest with respect to any matter considered by such committee. The committee shall report in writing to the Administrative Law Judge as soon as practicable after such referral on these questions of scientific fact. The report shall be made public and shall be considered as part of the hearing record. The Administrator shall enter into appropriate arrangements with the National Academy of Sciences to assure an objective and competent scientific review of the questions presented to committees of the Academy and to provide such other scientific advisory services as may be required by the Administrator for carrying out the purposes of this Act.

"(4) As soon as practicable after completion of the hearing (including the report of the Academy), the Administrator shall evaluate the record of the hearing and any findings and conclusions of the Administrative Law Judge and—

"(A) if the hearing was requested in response to a notice under subsection (b) of this section or section 3(c)(2)(B)(iv) or 3(c)(6) of this Act, the Administrator shall issue an order either revoking the notice, canceling or denying the registration, or requiring modification of the terms of registration of the product. Such order shall be based

only on substantial evidence of record and shall set forth detailed findings of fact upon which the order is based; or

"(B) if the hearing was convened under subsection (a)(2) of this section, the Administrator shall make and set forth detailed findings of fact based only on substantial evidence of record and shall include such findings, and the record of the hearing, in the record of the rulemaking being conducted under subsection (a) of this section.".

(e) Section 6 is further amended by adding at the end thereof the following new subsections:

"(g) FINALITY; REOPENING OF PROCEEDINGS.—The Administrator may issue regulations governing the right to a hearing under this section with regard to the denial of any application for the registration of a product containing an ingredient which was the subject of a prior notice of intent to cancel. Under such regulations, due weight shall be given to the desirability of finality of prior proceedings and determinations and to the extent to which the applicant had a prior opportunity to participate in earlier proceedings.

"(h) GENERAL.—

"(1) VOLUNTARY CANCELLATION.—A registrant may at any time request that any of its product registrations be cancelled or be amended to delete one or

more uses. The Administrator shall approve such a request unless the product is the subject of a cancellation proceeding under section 6 and the Administrator determines that the public interest would be served by disapproving the request and continuing such cancellation proceeding.

"(2) CANCELLATION AFTER FIVE YEARS.—The Administrator shall cancel the registration of any pesticide at the end of the five-year period which begins on the date of its registration (or at the end of any five-year period thereafter) unless the registrant, or other interested person with the concurrence of the registrant, before the end of such period, requests in accordance with regulations prescribed by the Administrator that the registration be continued in effect.

"(3) EXISTING STOCKS.—The Administrator may permit the continued use, the continued distribution or sale, or both, of existing stocks of a pesticide product whose registration is suspended or cancelled under any provision of this Act to such extent, under such conditions, during such periods, and for such uses as he may specify if he determines that such distribution, sale, or use is not inconsistent with the purposes of this Act and will not cause unreasonable adverse effects on the environment.

"(4) PETITION.—Any person may petition the Administrator to cancel or suspend the registration of a pesticide product, or to issue, modify, or rescind a regulation under this Act.

"(5) ADDITIONAL INFORMATION.—If at any time after the registration of a pesticide the registrant has additional information regarding unreasonable adverse effects on the environment of the pesticide, he shall submit such information to the Administrator. For purposes of this paragraph, 'information' shall include factual information and expert opinion regarding risks or benefits.".

RECORDS

SEC. 6. Section 8 (7 U.S.C. 136f) is amended to read as follows:

"SEC. 8. RECORDS.

"(a) AUTHORITY TO REQUIRE RECORDS.—The Administrator may by regulation require any producer, registrant, applicant for registration, applicant for or holder of an experimental use permit, pesticide testing facility, or commercial applicator, or any person who distributes or sells any pesticide—

"(1) to prepare, and to maintain for reasonable periods of time, such records as the Administrator finds to be necessary for the effective implementation or enforcement of this Act;

"(2) to furnish to the Administrator reports stating the location where the records are maintained; and

"(3) to furnish a copy of any such record to the Administrator upon written request.

"(b) LIMITATIONS.—The Administrator may not, under the authority of this section, require any person to maintain records of—

"(1) financial data or pricing data;

"(2) personnel data, except for data concerning exposure of employees to pesticides or ingredients of pesticides, or concerning health effects on employees that could reasonably be attributable to such exposure; or

"(3) research or test data (other than data relating to registered pesticide products, data relating to any products for which an application for registration or for an experimental use permit has been filed, or data relating to the conduct of testing at a pesticide testing facility).".

INSPECTIONS

SEC. 7. (a) Section 9(a) (7 U.S.C. 136g(a)) is amended to read as follows:

"(a) AUTHORITY TO ENTER, INSPECT, AND COPY.—Officers or employees of the United States or of any State, duly designated by the Administrator, are authorized at reasonable times, as provided by this section—

"(1) to enter any place where any pesticide, active ingredient, or device is distributed or sold, in order to inspect and obtain samples of any pesticide, active ingredient, or device being distributed or sold at such place, or of any packaging or labeling of any such pesticide, active ingredient, or device;

"(2) to enter any place where there are located any records required by or under this Act, or any place reported pursuant to section 8(a) as a location where such records are maintained, in order to inspect and obtain copies of such records;

"(3) to enter any pesticide testing facility, in order to inspect the facility and the testing being conducted at the facility, and to inspect and obtain copies of any records required by or under the authority of this Act to be maintained by the pesticide testing facility; and

"(4) to enter any place where such officer or employee has probable cause to believe that the Act has been or is being violated by any person other than a person acting in the capacity of a private applicator, in order to inspect such place to obtain evidence of such violation.".

(b) Section 9(b) (7 U.S.C. 136g(b)) is amended to read as follows:

"(b) WARRANTS.—Officers or employees of the United States or of any State or political subdivision thereof, duly designated by the Administrator, are empowered to obtain and to execute warrants authorizing—

"(1) entry for the purposes of this section;

"(2) inspection and copying of all records required under this Act; and

"(3) seizure of any pesticide or device which is in violation of this Act.".

(c) Section 9 is further amended by adding at the end thereof a new subsection, to read as follows:

"(d) PROCEDURE.—Before any entry or inspection of any premises not open to the general public is made under this section, the person conducting the inspection shall present to the person in charge of the premises appropriate credentials, and a written statement of the reason for the inspection and whether a violation of the law is suspected. Each inspection shall be commenced and completed with reasonable promptness. If the person conducting the inspection obtains any samples of pesticides or devices, prior to leaving the premises he shall give to the person in charge of the premises a receipt describing the samples and, if requested and practicable, a portion of each such sample equal in volume or weight to the portion retained. If an analysis of any such sample is made, a copy of the results of such analy-

sis shall be furnished on request to the person in charge of the premises.".

PROTECTION OF TRADE SECRETS AND OTHER INFORMATION

SEC. 8. (a) Section 10(d) (7 U.S.C. 136h(d)) is amended in paragraph (3) by deleting the word "If" in the first sentence thereof and substituting therefor the words "Except with respect to determinations requiring disclosure of information in inert ingredient statements in accordance with section 2(n) of this Act, if".

(b) Section 10 (7 U.S.C. 136h) is further amended by adding at the end thereof the following:

"(h) DISCLOSURE TO STATES.—The Administrator may disclose to any State any data or information acquired under the authority of this Act if the Administrator has first determined that the laws and regulations of the State prohibit disclosure of the data to any person who would not be entitled to obtain the data from the Administrator under this Act.".

(c) Section 10 (7 U.S.C. 136h) is further amended by adding at the end thereof the following:

"(i) DISCLOSURE TO FOREIGN GOVERNMENTS.—Notwithstanding any other provision of this Act, the Administrator may disclose data or information obtained under the authority of this Act to the government of another country if—

"(1) a bilateral treaty or agreement exists between the United States and that country authorizing the mutual exchange and protection of data and information pertaining to pesticides; and

"(2) the Adminstrator, after consultation with the Secretary of State and after notice and opportunity for public comment, has determined that the laws of that country provide protection equivalent to that provided by this Act against disclosure of the data or information and against use of the data or information to support any application for, or decision to grant, any license, permit, or other action to allow the production, distribution, or sale of a pesticide under the laws of any country; and

"(3) the Administrator determines that the particular disclosure is in the national interest; and

"(4) the Administrator notifies any applicant or registrant who submitted the information or data of the disclosure.

"(j) INFORMATION RECEIVED FROM FOREIGN GOVERNMENTS.—Notwithstanding any other provision of this Act, section 552 of title 5 of the United States Code, or any other provision of law, the Administrator shall not be required to disclose any data or information concerning pesticides if—

"(1) the Administrator obtained the data or information from the government of another country;

"(2) that government required the Administrator to agree not to disclose the data or information to the public as a condition of furnishing it to the Administrator;

"(3) the Administrator could not otherwise obtain the data or information; and

"(4) that government has not informed the Administrator that the data or information may be disclosed to the public.".

UNLAWFUL ACTS

SEC. 9. (a) Section 12(a) (7 U.S.C. 136j(a)) is amended—

(1) in subsection (a)(1) by deleting the words "distribute, sell, offer for sale, hold for sale, ship, deliver for shipment, or receive and (having so received) deliver or offer to deliver, to any person—" and substituting therefor the words "to distribute or sell to any person—";

(2) by revising subsection (a)(1)(A) to read as follows:

"(A) any pesticide product which is not registered under section 3 or whose registration has been cancelled or suspended, except to the extent

that distribution or sale otherwise has been authorized by the Administrator under this Act;";

(3) by revising subsection (a)(2)(B) to read as follows:

"(B) to refuse to (i) prepare, maintain, or submit any records required under this Act or by regulations issued pursuant to this Act, (ii) submit any reports required by this Act or by regulations issued pursuant to this Act, or (iii) allow any entry, inspection, copying of records, or sampling authorized by this Act.";

(4) in subsection (a)(2)(F) by deleting the words "to make" and substituting therefor the words "to distribute or sell, or to make";

(5) in subsection (a)(2)(J) by deleting the words "section 6" and substituting therefor the words "this Act";

(6) by amending subsection (a)(2)(K) to read as follows:

"(K) to violate any cancellation order issued under this Act;";

(7) in section (a)(2)(M) by deleting the words "section 8" and substituting therefor the words "this Act";

(8) in subsection (a)(2)(O) by deleting the word "or" at the end thereof;

(9) by striking the period at the end of subsection (a)(2)(P); and

(10) by adding at the end thereof the following:

"(Q) to violate any regulation prescribed by the Administrator to carry out good laboratory practice standards;

"(R) to distribute or sell, to make available for use, or to use any pesticide product which is the subject of an exemption under section 18 in violation of the terms of the exemption;

"(S) who is a registrant, an applicant for registration, or a pesticide testing facility, to falsely or misleadingly represent any information relating to the testing of any pesticide (or any ingredient, metabolite, or degradation product thereof), including the nature of any protocol, procedure, substance, organism, or equipment used, observation made, or conclusion or opinion formed if such representation is made to the Agency, or is made in any document or record which the person making it knows or reasonably should know will be furnished to the Agency or will become a part of any records required to be maintained by this Act or by regulations issued under this Act; or

"(T) who is a registrant, an applicant for registration, or a pesticide testing facility, or who distributes or sells any pesticide, or who is a commercial applicator, or who applies any pesticide for hire, to violate any regulation issued under the authority of this Act.".

(b) Section 12 (7 U.S.C. 136j) is amended by adding at the end thereof a new subsection (c) to read as follows:

"(c) ACTS OF OFFICERS, AGENTS, ETC.—When construing and enforcing the provisions of this Act, the act, omission, or failure of any officer, employee, agent, or other person acting for or employed by any person shall in every case be also deemed to be the act, omission, or failure of such person as well as that of the person employed.".

PENALTIES

SEC. 10. (a) Section 14(a) (7 U.S.C. 1361(a)) is amended—

(1) in subsection (a)(1)—

(A) by inserting after the words, "commercial applicator," the words "applicant for registration, or any pesticide testing facility, or any";

(B) by deleting the word "distributor" and substituting therefor the words "person who distributes or sells any pesticide or device,";

(C) be deleting the words "$5,000" and substituting therefor the words "$25,000";

(D) by adding after the words "offense." the words "Each day such a violation continues shall, for the purposes of this subsection, constitute a separate offense.";

(2) in subsection (a)(2)—

(A) by deleting the words "$1,000" each time they appear and substituting therefor the words "$5,000";

(B) by deleting the words "$500" and substituting therefor the words "$2,500";

(C) by adding at the end thereof the words "Each day such a violation continues shall, for the purposes of this subsection, constitute a separate offense."; and

(3) in subsection (a)(3) by deleting the period at the end thereof and substituting therefor the words ": *Provided*, That if the person neither resides nor has his principal place of business in the United States, the Administrator may designate a site for the hearing in the United States which is reasonably convenient for the parties."; and

(4) in subsection (a)(4) by adding the words "the economic benefit (if any) resulting from the violation," immediately after the words "to continue in business," in the first sentence thereof.

(b) Section 14(b) (7 U.S.C. 1361(b)) is amended—

(1) in subsection (b)(1)—

(A) by inserting after the words "commercial applicator the words "applicant for registration, or any pesticide testing facility, or any";

(B) by deleting the word "distributor" and substituting therefor the words "person who distributes or sells any pesticide or device,";

(C) by deleting the word "misdemeanor" and substituting therefor the word "felony";

(D) by deleting the words "one year" and substituting therefor the words "two years"; and

(2) in subsection (b)(2)—

(A) by deleting the words "30 days" and substituting therefor the words "one year";

(B) by deleting the words "$1,000" and substituting therefor the words "$5,000"; and

(3) by deleting subsection (b)(4).

(c) Section 14 is further amended by adding at the end thereof the following new subsection:

"(c) SUBPOENAS.—The Administrator may, in connection with administrative proceedings under subsection (a) of this section, issue subpoenas compelling the attendance and testimony of witnesses and subpoenas duces tecum, and may request the Attorney General to bring an action to enforce

any subpoena under this section. The district courts shall have jurisdiction to enforce such subpoenas and impose sanctions.".

INDEMNITIES

SEC. 11. Section 15 (7 U.S.C. 136m) is amended by adding a new subsection at the end thereof to read as follows:

"(c) LIMITATION.—Notwithstanding any other provision of this Act, no indemnity payment under this section shall be made on account of any suspension of registration of a pesticide product which occurs after the effective date of this subsection.".

ADMINISTRATIVE PROCEDURE; JUDICIAL REVIEW

SEC. 12. Section 16 (7 U.S.C. 136n) is amended by adding at the end thereof a new subsection, to read as follows:

"(e) REVIEW OF REGULATIONS.—(1) Any regulation issued under this Act and first published in the Federal Register in final form after the effective date of this subsection or any refusal of a petition to modify or rescind such a regulation shall be reviewable only as provided by this subsection. Any person may obtain judicial review of such a regulation or refusal by filing a petition for review in the United States court of appeals for the circuit wherein the person resides or has its principal place of business, or in the United States Court of Appeals for the District of Columbia. Any petition under this subsection for review of a regulation shall be filed

within sixty days from the date of promulgation of the regulation as determined by the Administrator in the Federal Register. Any petition under this subsection for review of a refusal to modify or rescind a regulation shall be filed within sixty days after such refusal. The scope of review shall be as specified in section 706 of title 5, United States Code. The commencement of proceedings under this paragraph shall not, unless specifically ordered by the court to the contrary, operate as a stay of the regulation.

"(2) Action of the Administrator with respect to which review could have been obtained under paragraph (1) of this subsection shall not be subject to judicial review in any suspension, cancellation, or denial proceeding under this Act or any appeal therefrom, nor in any proceeding under section 13, 14, or 16(c) of this Act or any appeal therefrom.".

DISPOSAL AND TRANSPORTATION

SEC. 13. Section 19(a) (7 U.S.C. 136q(a)) is amended by inserting after the words "canceled under section 6(c)" the words "on or before October 1, 1985".

DELEGATION AND COOPERATION

SEC. 14. Section 22 is amended by adding at the end thereof a new subsection, to read as follows:

"(c) EFFECT ON CERTAIN OTHER LAWS.—In exercising any authority under this Act, the Administrator shall not, for purposes of section 653(b)(1) of Title 29, United States Code, be deemed to be exercising statutory authority to pre-

scribe or enforce standards or regulations affecting occupational safety or health.".

AUTHORITY OF STATES

SEC. 15. Section 24(c) (7 U.S.C. 136v(c)), is amended in subsection (c)(1) by deleting the period at the end thereof and substituting therefor the words "*Provided*, That such a registration shall expire and be of no further effect, without further action by the Administrator—

"(A) at the end of the period, if any, provided as the duration of the registration by the State which approved it; or

"(B) 10 days after the date the Administrator publishes in the Federal Register a notice stating that the State which issued the registration has informed the Administrator that the State no longer desires the registration to continue in effect.".

AUTHORITY OF ADMINISTRATOR

SEC. 16. (a) Section 25(a) (7 U.S.C. 136w(a)) is amended by revising subsection (a)(4) to read as follows—

"(4) CONGRESSIONAL REVIEW OF REGULATIONS.—Notwithstanding any other provision of this Act, simultaneously with the promulgation of any rule or regulation under this Act, the Administrator shall transmit a copy thereof to the Secretary of the Senate and the Clerk of the House of Representatives. The rule or regulation shall not become effective until the

passage of 60 calendar days after the rule or regulation is so transmitted.".

(b) Section 25(c) (7 U.S.C. 136w(c)) is amended—

(1) by inserting after the words "notice and opportunity for hearing," the words "or by issuance of regulations,"; and

(2) by deleting the words "prescribe regulations requiring" in paragraph (5) thereof and substituting therefor the word "require".

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FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

TUESDAY, MAY 21, 1985

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON DEPARTMENT OPERATIONS,
RESEARCH, AND FOREIGN AGRICULTURE,
COMMITTEE ON AGRICULTURE,
Washington, DC.

The subcommittee met, pursuant to recess, at 9:40 a.m., in room 1302, Longworth House Office Building, Hon. Berkley Bedell (chairman of the subcommittee) presiding.

Present: Representatives Brown, Staggers, Volkmer, Roberts, Morrison, Gunderson, Evans of Iowa, and Combest.

Also present: Representative E (Kika) de la Garza, chairman of the committee, and Representatives Heftel and Synar.

Staff present: Phillip L. Fraas, counsel; John E. Hogan, minority counsel; Mark Dungan, minority associate counsel; Glenda L. Temple, clerk; Bernard Brenner, Nick Ashmore, Timothy J. Galvin, and Gary R. Mitchell.

Mr. BEDELL. The subcommittee will come to order.

There is a Democratic caucus on and some of the other members had other things to do, but I am sure they will come here as we proceed.

This is a continuation of the hearings that we had all day yesterday on FIFRA. I understand that our colleague, Mike Synar, will be our first witness this morning.

First of all, we are privileged to have the chairman of the full committee with us.

Mr. de la Garza, do you have any statement you wish to make?

The CHAIRMAN. No.

Mr. BEDELL. Mr. Combest, do you want to say anything?

Mr. COMBEST. No, Mr. Chairman.

Mr. BEDELL. If not, we are glad to have you here, Mike. We look forward to hearing from you.

STATEMENT OF HON. MIKE SYNAR, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OKLAHOMA

Mr. SYNAR. Thank you very much, Berkley.

I will enter my prepared remarks into the record and just summarize.

The purpose for which I come to the hearing this morning is not to endorse any particular proposal but to share with you the results of an extensive investigation of EPA's pesticide registration

activities conducted by the Environment, Energy, and Natural Resources Subcommittee, which I have the honor of chairing. It is my hope that this information will be useful to this subcommittee in formulating sound legislative proposals.

Our investigation identified a number of serious weaknesses in EPA's pesticide registration activities which are summarized in a report approved unanimously by the Committee on Government Operations last October. Most of these weaknesses were not due to deficiencies in the law, but rather to inadequate administration, implementation, and enforcement of the law. For this reason, the committee's report made a number of recommendations for administrative improvements, but noted that, if EPA's response to the recommendations was inadequate, Congress might find it necessary and appropriate to address these problems legislatively.

Berkley, I will admit that some improvements have been made. However, these changes are really insufficient. Therefore, I think legislation should be enacted to mandate further improvements.

I understand that EPA has prepared a legislative proposal which the administration refused to allow the Agency to submit to Congress, but you and Mr. Roberts from Kansas introduced the proposal as a basis of debate, and I want to commend you and him for that, and also your other work.

Unfortunately, EPA's proposal may not go far enough in that it merely gives the Administrator additional discretionary authority without really providing any assurance that that new authority will be used effectively.

The investigation which we did revealed that the flexibility which Congress has provided to the Administrator of EPA in enforcing the law has provided a cover for bureaucratic footdragging, inefficiency, and inaction in the face of resistance from the regulated industry. As a result, the original intent of Congress, the elected representatives of the people, has been thwarted by unelected officials. It is for that reason, Mr. Chairman, that I would like to make the following recommendations:

I recommend that the subcommittee incorporate in its legislative proposal certain specific mandates and, where necessary, deadlines for their achievement. A good example is the re-registration of older pesticides. Twelve years after that legislation was enacted, registration standards have been set for only 76 of more than 600 chemicals, out of an estimated 50,000 registrations subject to the re-registration requirement. I urge the subcommittee to consider reestablishing a reasonable deadline with appropriate milestones for completion of the re-registration process.

Now a similar problem exists with respect to the special review process. Originally it was devised by EPA to provide more expeditious decisionmaking than was possible under the normal adjudicatory process. Our investigation showed that the special review process has, in fact, lengthened the period of time required to reach final determinations.

I would recommend that the subcommittee consider incorporating into the law a specific timeframe during which EPA must act at each stage of the special review process, similar to the legislative deadlines now imposed on outside parties in the special review process.

Another area which has caused our subcommittee concern was EPA's failure to act promptly to cancel registrations for products when it found that any one of the essential safety studies was based upon falsified or misleading data submitted by International Biotest Laboratories. This is a situation which I hope your subcommittee will act to rectify legislatively.

Another area which I hope this subcommittee will address is how to assure that, once a pesticide registration has been canceled, imported food products which have residues of such pesticides above normal background levels will not be allowed into this country.

As your subcommittee is aware, this has occurred with DDT and EDB. This not only presents an unwarranted risk to the American consumers, but I think even a more significant point is that it places our American farmers at a competitive disadvantage in the marketplace.

Now I know the subcommittee is aware of the serious problems that we are facing with regard to ground-water contamination. For this reason, I would also ask you to consider including language to insure that information be required on the ability of all pesticides, including those currently registered, to contaminate ground-water by leaching into the soil and that, unless adequate labeling can be devised and enforced to prevent such occurrences, the registration will be canceled.

Finally, Mr. Chairman, the subcommittee may want to consider inclusion of legislative provisions to insure a community's right to know about the potential dangers of pesticide manufacturing operations in their area.

I know these recommendations represent very strong medicine, but, as one who grew up on a farm and who comes from a family of farmers and ranchers, I firmly believe that farmers and other users of pesticides, as well as consumers of agricultural products, have a right to expect that their pesticides will be safe and effective when used according to the EPA-approved labeling.

I want to thank you, Mr. Chairman, and the other members who are here today for your time on this very important issue.

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

Mr. BEDELL. Thank you very much, Mike.

Mr. de la Garza, do you have any questions?

The CHAIRMAN. No.

Mr. BEDELL. Mr. Combest.

Mr. COMBEST. No, Mr. Chairman.

Mr. BEDELL. I don't have any questions, except I need to alert you to a problem we face, and that is that one of the major problems we face is lack of financial resources in order for EPA to do the job properly in the timely fashion that you are suggesting. I guess a concern that I would have is if we put in specific time requirements but, we don't give them the money with which to do the job, we have a heck of a problem on our hands. I presume you are aware of that difficulty.

Mr. SYNAR. We are, and that is usually the answer we get from EPA when they come down here.

A couple of things I might note: EPA, as an agency which has a responsibility to protect the health and safety of individuals, has a

higher responsibility, I think, to make the demands on OMB to give them the type of resources necessary. The reason they have that responsibility is simply because it is impossible for any of us in this body to put an economic value on human life. Yet, with the continuous exposure which the American public has to pesticides, it may be penny wise and pound foolish to not make the necessary resources available.

I am aware of those budget restraints. I hope that EPA will continue to fight for additional resources and make this a priority item.

Mr. BEDELL. We certainly appreciate your suggestion. I would hope you would keep track of what is happening in our subcommittee and in our full committee. If there are things that you think we are missing in what should be done, I hope you would at least talk to me, Mike, or check with our subcommittee or some of the members of the subcommittee or the full committee. We are going to try our darnest to do what is best. Our plans are definitely to move forward with FIFRA legislation; at least that is certainly the chairman's plan, to try to move forward.

Thank you very much for your testimony and for your interest in this issue.

Mr. SYNAR. Thank you.

Mr. BEDELL. We next have a panel consisting of Al Meyerhoff, senior attorney, Natural Resources Defense Council, San Francisco; Ms. Nancy Drabble, director of Public Citizens' Congress Watch, Washington, DC; Mr. Brian Turner, director of legislation and economic policy, Industrial Union Department, AFL–CIO; Mr. Jack Sheehan, legislative director, United Steelworkers of America; and Mr. Jay Feldman, Coalition Against the Misuse of Pesticides.

Will all of you come forward?

We have a large number of witnesses today, and we need to get through by 12 o'clock. We are going to require that you stay within your 5-minute period. When that time is up, I will simply have to mention it to you. If you need two or three more sentences, that is understandable, but we are going to have to stick to our time.

In the meantime, the ranking minority person on our subcommittee, who is a real great help in this particular issue, Mr. Roberts, has arrived.

Do you have anything that you want to say, Pat?

Mr. ROBERTS. No, Mr. Chairman.

Mr. BEDELL. We will go ahead, then, with Mr. Meyerhoff first.

STATEMENT OF ALBERT H. MEYERHOFF, SENIOR ATTORNEY, NATURAL RESOURCES DEFENSE COUNCIL, INC., ACCOMPANIED BY LAWRIE MOTT, PROJECT SCIENTIST

Mr. MEYERHOFF. I will try to keep my remarks very brief, Mr. Chairman.

My name is Albert Meyerhoff. I am a senior attorney with the Natural Resources Defense Council. With me is Lawrie Mott, project scientist, to answer any questions of a technical nature that you might have.

We appreciate the opportunity to testify at these important hearings on necessary amendments to the Federal pesticide law, FIFRA.

As Congressman Synar noted, it is the position of the Reagan administration that FIFRA should be reauthorized for 3 years without change. This essentially echoes the views of the chemical and food industries, although it is reported that they are seeking legislation through both FIFRA and the farm bill that would preempt State authority to regulate pesticides in food and local authority to regulate pesticides.

In a statement provided to this subcommittee in writing from the Environmental Protection Agency, FIFRA was characterized as a fundamentally sound environmental law, one of our biggest assets. Of course, all of this flies in the face of reality. An unbroken litany of reports from congressional subcommittees, from the GAO, from the National Academy of Sciences, and elsewhere have all documented that FIFRA has failed. It provides, at best, an illusion of safety, no more than that.

Consider ground water protection. For many years we thought that pesticides did not provide any significant threat to ground water. The finding of DBCP in ground water in California in 1979 broke that false sense of security. A recent report released last month entitled, "The Leaching Fields," from the California Assembly Office of Research, found 57 different pesticides in more than 3,000 wells.

The chart that I brought this morning documents where those pesticides have been found in 28 of California's counties. They include such pesticides as DBCP, EDB, DDT, 2,4,5–T. You can almost pick your poison throughout the valley. Fifteen hundred or more of those wells have been found unfit for human consumption, for washing, and for other use.

We think California is a harbinger and that, if FIFRA is not amended to specifically address ground water now, we are going to have an environmental time bomb on our hands.

A Cornell study last year found that 67, 68 percent of rural Americans have pesticides in substantial quantity in their groundwater, 75 percent of people living in the West. We think this is intolerable and we would urge the Agriculture Committee and the Congress to adopt specific amendments to address the threat to American health posed from ground water.

Of course, the remaining issues of consumer protection, the food chain, and farmworkers—all of which, again, are a case study in failure. Take the food chain. We found that EDB, after 10 years of having been found by the National Cancer Institute to be a probable human carcinogen, was finally pulled off the market. It remains in the food chain.

EDB was not an aberration. Consider the EBDC's, for alphabet soup, if you will. EBDC's are one of the most widely used fungicides in the country. They are used on one-third of our tomatoes, over half of the potato crop, two-thirds of the mushrooms, 100 percent of all the bananas brought into the country. They have been linked to birth defects, cancer, genetic mutations.

When you cook a product containing the EBDC's, it breaks down into another chemical, ETU, also a carcinogen. There are no toler-

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ances for ETU in the food. DuPont did one study. They found that 23 percent of the canned fruits and vegetables they tested contained ETU—again, not an aberration. There are literally dozens of pesticides in fresh and processed foods that are known or suspect carcingens for which tolerances have been set with false or fraudulent data or no data at all, an illusion of safety.

Then there is consumer protection. I will give just a couple of examples, and I will be brief.

Pentachlorophenol: In 1978 the Environmental Protection Agency placed penta into RPAR, as you know, an expedited process to get particularly suspect chemicals regulated as quickly as possible. RPAR was originally intended to be completed within 300 days. No RPAR has ever been completed within 300 days. Seven years after penta went into RPAR a final decision was released by the agency.

First, in 1981 EPA proposed a decision that would prevent over-the-counter sale of penta. The reason for that was that as early as 1974 HEW in studies found penta linked to birth defects. In 1978 there was additional data demonstrating that a dioxin contaminant contained in penta might cause cancer. So in 1981 EPA said, "Well, let's get this off the market at least for home use. Let's not have consumers buying this over the counter."

Thirty-two or thirty-three closed meetings then occurred between EPA officials and representatives of the wood preservant industry. Another decision was issued in 1974, this time on industry letterhead. When there was a flurry of controversy, that decision was withdrawn.

Last year we received a final decision that was reported in the New York Times and the Washington Post indicating that penta should no longer be sold over the counter; it should be restricted; there should be a Consumer Awareness Program.

I have with me this morning a can of pentachlorophenol bought at a local hardware store. You can still buy this product. You can put it on your deck. You can put it on your children's playground. You can do whatever you want with it. That is because this decision, this 8-year process, has now been challenged in the courts and before EPA as having been unfair to the industry.

This is the consumer protection we were getting from EPA. There are many other examples of this. We have a statute here that is fundamentally deficit. It is not protecting the public health. It deserves immediate attention by the subcommittee and amendments that will do so.

Thank you.

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

Mr. BEDELL. Thank you.

We will now hear from Ms. Nancy Drabble.

STATEMENT OF NANCY DRABBLE, DIRECTOR, PUBLIC CITIZEN'S CONGRESS WATCH, ALSO REPRESENTING CONSUMER FEDERATION OF AMERICA AND PUBLIC VOICE FOR FOOD AND HEALTH POLICY

Ms. DRABBLE. Thank you, Mr. Chairman.

I am Nancy Drabble. I am the director of Public Citizen's Congress Watch. Public Citizen is a nationwide consumer organization with 80,000 members. I am also speaking today on behalf of the Consumer Federation of America and Public Voice for Food and Health Policy, two other major consumer organizations.

Our groups have worked for many years on food safety issues, and we became particularly concerned about pesticide residues on food in 1983 when we observed the EDB debacle and the failure of testing of pesticide residues used on food.

However, the core statute regulation pesticides, the Federal Insecticide, Fungicide, and Rodenticide Act, remains unchanged. After many years of documentation of FIFRA's failures and several congressional reports and critical analyses by the National Academy of Sciences and GAO, nothing has happened.

However, we applaud the intention of your subcommittee to move ahead to amend FIFRA this year. Our coalition of 40 consumer, environmental, labor, religious, and health groups has united together to express support for the bill that Congressman George Brown and Senator William Proxmire will be introducing soon to correct the fundamental defects in FIFRA. I have a letter here today that we have sent off to the Agriculture Committee describing this bill and endorsing it, which I would like to submit for the record.

Mr. BEDELL. Without objection, it will be entered in the record.

[The letter follows:]

CAMPAIGN FOR PESTICIDE REFORM

May 20, 1985

Dear Representative,

The Agriculture Committee will soon begin action on amendments to FIFRA (The Federal Insecticide, Fungicide and Rodenticide Act). This year, environmental, consumer, health, religious and labor organizations have joined in the Campaign for Pesticide Reform to support FIFRA reform amendments being sponsored by Congressman George Brown (D-CA). These critically needed amendments will make the use of pesticide chemicals less dangerous by improving the FIFRA law through the following health and environmental protections:

1. EPA must require pesticide manufacturers to complete health and safety tests under deadlines.

These studies are necessary to determine whether pesticides cause cancer, infertility, sterility, birth defects, nerve damage, genetic mutations, or chronic diseases. Congress mandated these tests in 1972, but 13 years later EPA has full health and safety data on only 6 out of 600 active ingredients used in pesticides. These untested pesticides remain on the market even though EPA lacks critical information on health risks.

A 1982 study by the House Agriculture Subcommittee on Department Operations, Research, and Foreign Agriculture reported that 84% of registered pesticides lack adequate cancer tests, 93% lack adequate genetic mutation tests, and 70% lack birth defects tests. The National Academy of Sciences reported in March 1984 that only 10% of pesticides have health and safety data sufficient to assess health hazards. The Brown bill requires pesticide manufacturers to conduct the necessary tests under deadlines and allows EPA to bill registrants for the cost of the tests if they are not initiated promptly.

2. EPA must prevent further pesticide contamination of groundwater.

According to EPA, 16 different pesticides have been detected in the groundwater of 23 states. For example, an April 1985 study of Iowa wells found pesticide contamination in 40% of the public drinking water supplies analyzed. The potent carcinogen EDB has been discovered in water in Connecticut, Massachusetts, Georgia, South Carolina, Florida, Texas, California, and Hawaii. A California legislature study found 57 pesticides in 28 counties.

Under the Brown bill, when EPA detects pesticide contamination of groundwater from agricultural use, it must start proceedings to cancel the pesticide within four to six months, unless the affected state develops a plan to prevent additional contamination or the registrant amends the pesticide label to prevent future contamination. For example, the label could be amended to prohibit application in areas with a high water table or with sandy soil.

3. EPA must not register pesticides that cause birth defects.

The California Department of Food and Agriculture has identified 22 pesticides which may be teratogens (cause birth defects). EPA finally banned the herbicide 2,4,5-T mainly because of its teratogenic hazards, but it delayed years after laboratory tests indicated birth defect potential and only acted when humans suffered birth defects. Only one exposure to a teratogenic pesticide at an early stage of pregnancy can cause birth defects, stillbirth, or spontaneous abortion. These pesticides can also cause sterility or infertility in prospective parents.

The pesticide reform bill stops the problem of pesticide-induced birth defects by prohibiting registration of teratogens. Given the availability of numerous effective non-teratogenic pesticides, no justification exists for the continued home and agricultural use of this relatively small, but dangerous, group of pesticides.

4. Food with residues of banned pesticides must not be imported into the United States, and foreign countries must receive better notification before U.S. companies export dangerous or banned pesticides.

Imported food with residues of cancelled pesticides arrives at the dinner tables of Americans regularly, endangering consumers and harming American farmers. EPA has allowed tolerance residue limits to remain on the books even after a pesticide has been cancelled. For example, EPA failed to eliminate tolerances for DDT for more than 10 years after cancellation. These amendments prohibit tolerances for banned pesticides except when residues unavoidably persist in the environment, and prohibit the import of food with residues exceeding the tolerance.

U.S. export of banned, unregistered and highly toxic pesticides has caused fatal injuries and environmental destruction abroad. In addition, the residues of such pesticides return to the U.S. on imported food. Devoloping countries in particular need timely warning when hazardous pesticides are being shipped to them. In addition, these countries need information about why these chemicals are restricted or banned in the U.S. The current law requires shipment-related notification of the receiving country only for cancelled or suspended pesticides (which may not be the most hazardous), and the notice usually arrives after the shipment. Under the Brown reform bill, pesticide manufacturers would notify the EPA of exports annually, and EPA would provide the relevant foreign country with information about the pesticide, allowing that country the opportunity to request the import of the banned, suspended or restricted pesticide.

5. Communities should have a right-to-know about pesticides produced in their area.

The pesticide reform bill establishes a public right-to-know of the identities and health hazards of pesticides manufactured in local communities. Residents would also be able to obtain information on the proximity of pesticide plants to residential neighborhoods and plans for emergency evacuation in case of an accident.

6. EPA must establish a worker protection program.

In 1972, Congress gave EPA jurisdiction over pesticide safety for workers, but 13 years later EPA has not established an occupational health program. These amendments require EPA to start such a program and to adopt worker safety regulations.

7. EPA's procedures to remove dangerous pesticides from the market must be streamlined.

EPA's pesticide cancellation process is notoriously cumbersome and lengthy, sometimes taking up to 10 years. Just the cancellation hearing for a single pesticide can take two to four years. In the meantime, people suffer continued exposure and eat food with residues of the dangerous pesticide. Also, the fact that cancellation hearings take so long and cost so much money acts as a disincentive to start a hearing in the first place.

The Brown reform bill simplifies cancellation hearings, gives citizens the right to initiate and participate in such hearings, and sets deadlines on completion of each phase of the hearing process.

* * *

Despite repeated critical analysis, the EDB fiasco, the Bhopal disaster, and calls for reform from the National Academy of Sciences, the GAO, and several Congressional committees, the nation's pesticide law remains fundamentally flawed. Consumers, workers, and farmers continue to be subjected to unknown health risks because of grave deficiences in the law. This illusion of safety must not continue. We urge you to join with us to work for passage of a reform bill this year.

Sincerely,

Nancy Drabble
PUBLIC CITIZEN'S
CONGRESS WATCH

Al Meyerhoff
NATURAL RESOURCES
DEFENSE COUNCIL

Jay Feldman
NATIONAL COALITION AGAINST THE MISUSE OF PESTICIDES

Barbara Bramble
NATIONAL WILDLIFE FEDERATION

Victor W. Sidel, M.D.
AMERICAN PUBLIC HEALTH ASSOCIATION

Brian Turner
INDUSTRIAL UNION DEPARTMENT, AFL-CIO

Terry Shafer
SIERRA CLUB

Mary Lou Licwinko
ASSOCIATION OF SCHOOLS OF PUBLIC HEALTH

Ralph Lightstone
CALIFORNIA RURAL LEGAL ASSISTANCE FOUNDATION

Scott Martin
LEAGUE OF CONSERVATION VOTERS

Gene Kimmelman
CONSUMER FEDERATION OF AMERICA

John Sheehan
UNITED STEELWORKERS OF AMERICA

Deborah Berkowitz
FOOD AND ALLIED SERVICE TRADES DEPARTMENT, AFL-CIO

Tani Adams
TEXAS CENTER FOR RURAL STUDIES

Tom Dawson
WISCONSIN PUBLIC INTERVENOR

Juanita Cox
TEXAS CHAPTER, UNITED FARMWORKERS OF AMERICA, AFL-CIO

Shirley Briggs
RACHEL CARSON COUNCIL

Dave Conrad
FRIENDS OF THE EARTH

Ann Brown
AMERICANS FOR DEMOCRATIC ACTION

Norma Grier
NORTHWEST COALITION FOR ALTERNATIVES TO PESTICIDES

Ellen Haas
PUBLIC VOICE FOR FOOD AND HEALTH POLICY

Greg Humphrey
AMERICAN FEDERATION OF TEACHERS

Michael Jacobsen M.D.
CENTER FOR SCIENCE IN THE PUBLIC INTEREST

Charlie Horowitz
FARMWORKER JUSTICE FUND

Francisco Gonzalez
SU CLINICA FAMILIAR, BROWNSVILLE, TEXAS

Mike Kerr
AMERICAN FEDERATION OF STATE, COUNTY AND MUNICIPAL EMPLOYEES

Eric Jansson
NATIONAL NETWORK TO PREVENT BIRTH DEFECTS

Mike Lemov
FOOD RESEARCH ACTION CENTER

Rodney Leonard
COMMUNITY NUTRITION INSTITUTE

Cathy Lerza
RURAL COALITION

Steve Meili
INSTITUTE FOR PUBLIC REPRESENTATION

David Raphael
RURAL AMERICA

Eric Schulman
NATIONAL COUNCIL OF SENIOR CITIZENS

Allen Spalt
RURAL ADVANCEMENT FUND

Dan Swartz
RELIGIOUS ACTION CENTER

Jeff Tryens
CONFERENCE ON ALTERNATIVE STATE AND LOCAL POLICIES

Barbara Warden
NATIONAL CONSUMERS LEAGUE

Dick Warden
INTERNATIONAL UNION, UNITED AUTO WORKERS

Floyd Zahn
TEXAS PESTICIDE ABUSE COALITION

Ms. DRABBLE. Thank you.

This legislation which has half the number of amendments of last year's FIFRA bill represents a lean and serious effort to correct the fundamental flaws in the law. Five key parts of the bill would curb pesticide contamination of ground water, stop the exposure of Americans to imported food that contains residues of banned pesticides. It requires pesticide manufacturers to finish long overdue health and safety tests. It gives local communities a right to know about dangerous pesticides produced in their areas. It also provides for more public participation in the rulemaking process.

Let me briefly outline those key sections of the bill. I would mention before I go ahead, though, that unfortunately the EPA draft bill failed to address even one of those questions.

First, the bill would prevent future contamination of ground water. Nearly half the Nation gets its drinking water from ground water. Many people are increasingly concerned over the chemicals in the water they drink. EPA has identified 16 pesticides in the ground water of 23 States. A study that just came out of Iowa just last week found pesticides in 40 percent of the wells that were sampled. It found six commonly used pesticides that are used in Iowa, including the herbicide atrazine, which was found in 35.9 of the wells sampled.

Under the Brown reform bill, we tackle this problem by saying that EPA would have to move to cancel a pesticide found in ground water unless the affected State could take steps to eliminate future contamination or the label could be changed to stop additional contamination. Label restrictions could include restrictions on geographical areas where the pesticide could be applied or restrictions on use in certain kinds of soil like sandy soil or where there was a high water table. We think such kinds of restrictions can work.

While we cannot eliminate the current pesticides that have already leached down through the soil into the ground water, at least we should try to prevent further damage.

Second, the bill prevents approval of pesticides that cause birth defects. The California Department of Agriculture has identified 22 pesticides which may cause birth defects.

In our society we place a high value on making sure that women, pregnant women, are not exposed to substances which may cause miscarriage, stillbirths, or spontaneous abortions, but under the current law EPA can approve pesticides which cause birth defects, but why should we accept the risk from this small, but dangerous group of pesticides when alternatives exist?

We advocate a strict approach to pesticides that may cause birth defects because it takes only one exposure at an early stage of pregnancy to produce tragic results.

Third, the bill requires better notification of foreign countries of pesticide exports and stops import of food with residues of banned pesticides. A recent Harris poll revealed that the public ranks pesticide residues on food as the No. 1 hazard in food. Now this outranks cholesterol, salt, sugar, artifical coloring, artificial flavors, or any other hazard in food. Pesticide residues were ranked No. 1.

Consumers are clearly fed up with the daily dose of pesticides that they are getting at the dinner table. The Brown reform bill

would prohibit imports of food with residues exceeding tolerance limits.

Fourth, the bill requires EPA to finish getting the missing health and safety data on pesticides. They were told to do this back in 1972, but as of today they have only got complete health and safety data on 6 out of the 600 pesticides that are subject to reregistration. This is a scandal, and in the bill that Congressman Brown will be introducing they are put on a tight schedule so that they would finish getting those tests back in in the next 6 years.

Last, the bill gives local communities a right to know about pesticides produced in their neighborhoods, and other witnesses will address that.

We believe that now is the time to act on FIFRA reform. In the last year the news that the public has gotten about pesticides has been all bad from the EDB debacle to the Bhopal disaster to stories about the dangers of chemicals on lawns.

This subcommittee has an opportunity to play a historic role in leading the way to modernize FIFRA. We stand ready to help in any way we can, and we look forward to working on the issue with you.

Thank you.

[The prepared statement of Ms. Drabble appears at the conclusion of the hearing.]

Mr. BEDELL. Thank you.

Mr. Turner.

STATEMENT OF BRIAN TURNER, DIRECTOR, LEGISLATION AND ECONOMIC POLICY, INDUSTRIAL UNION DEPARTMENT, AFL-CIO

Mr. TURNER. Thank you, Mr. Chairman.

I am here today on behalf of the Industrial Union Department, representing 55 national and international unions and their 5 million industrial workers who are affiliated with us.

The Industrial Union Department strongly supports the package of FIFRA amendments about to be introduced by Congressman Brown and Senator Proxmire with support from the campaign for pesticide reform.

Our testimony here will select out the issues of community right to know for special attention.

Let me point out, sir, that workers are particularly vulnerable to the failures of FIFRA to adequately protect public health in the use and production of dangerous pesticide chemicals. Workers don't just occasionally use a pesticide product; they come into contact with these chemicals on a daily basis, often on a level of contact which goes far beyond anything that the normal public or the general public would experience.

However, there is a dangerous lack of information on the health hazards of the massive quantities of chemicals being used as pesticides and used in the United States. All too frequently, the public and the press only focus on these dangers, however, after some terrible tragedy. The recent case of Bhopal has been mentioned already and will be again.

Let me remind you of the story of ethylene dibromide, which I think is a terrible and classic example in that regard. In the early

1970's, after the OSHA act was passed, a standard for ethylene dibromide exposure was adopted by OSHA that was called an industry consensus standard; that is to say, the industry suggested level which they considered to be safe. It was a small number of parts per million.

In 1981 research was done at NIOSH showing that for every 1,000 workers who were exposed at the then-approved level in production and use of EDB, for every 1,000 exposed at the approved level, 999 of them would develop cancer and die as a result of that exposure. Yet, for 2 years after that information became available OSHA did nothing. At the end of that 2-year period some States and counties started removing food products from the shelves of their grocery stores because they were concerned about tiny, minute bits of EDB that might show up in a cake mix or a pancake mix.

Then after EPA had banned the use, and FDA had banned the use of EDB in a number of applications, even then the protection for workers was denied as the Occupational Safety and Health Administration refused to implement an emergency standard for EDB. This is a tremendously deadly carcinogen.

We only got a standard on worker exposure to EDB's after going to court at the end of this incredible sequence of events where the threat to life and health couldn't have been more clear.

Now we know already that some States and localities have succeeded in passing right-to-know laws. Many others have been defeated in that effort by opposition from the chemical industry, and others have succeeded in part as a result of actions through the courts.

This bill establishes a critically needed Federal right to know which will complement existing provisions in the Clean Air Act, the Clean Water Act, and RCRA. Specifically, the Brown amendment to section 7 of FIFRA would require all pesticide producers in the United States to submit to EPA the type and amounts of pesticides and intermediate chemicals which they produce annually; a summary of the health and environmental risks posed by these chemicals and an assessment of their potential for public exposure; the location of all pesticide manufacturing plants in the United States and abroad; and information on the proximity of those plants to populated areas; plans for evacuation, where appropriate, in the event of a health emergency; and information on the type, quantity, uses, and destination of pesticides being exported from the United States to other countries.

We commend the subcommittee, Mr. Chairman, for holding these hearings to focus on the weaknesses of the Nation's major pesticide law. We urge the committee and Congress to adopt a Federal right to know and other amendments which will soon be introduced by Mr. Brown.

Both public and worker concern is at a very high level, and this is the year we believe for comprehensive FIFRA reform.

Thank you.

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

Mr. BEDELL. Thank you very much.

Mr. Sheehan.

STATEMENT OF JOHN J. SHEEHAN, LEGISLATIVE DIRECTOR, UNITED STEELWORKERS OF AMERICA

Mr. SHEEHAN. Thank you, Mr. Chairman.

My name is Jack Sheehan. I am the legislative director of the Steelworkers Union.

The union strongly supports the campaign for pesticide reform amendments to FIFRA which Congressman Brown will soon introduce. The amendments address the numerous areas in which the FIFRA law is weak.

As my colleague, Mr. Turner, has just pointed out, it is all too often that the Federal Government and industry fail to act to protect worker health until the public perceives a general health threat and applies pressure in a crisis atmosphere.

It is our hope that we can prevent fatal worker accidents and dangerous working conditions through improvements to the Nation's primary pesticide law before the crisis occurs.

Our organization is particularly concerned about the current lack of protection for workers from health hazards posed by pesticide usage and production. Though Congress gave EPA jurisdiction over pesticide safety for workers back in 1972, the Agency has never enforced a worker safety regulation. The few regulations they have adopted are ineffective due to the fact of the Agency's self-doubt about enforcement authority. Though the Agency is in the process of developing new worker safety standards and regulations, they still remain doubtful about their ability to enforce these measures.

The package of amendments we support provides for the establishment of a worker protection program at EPA. Specifically, this includes the founding of an occupational health program staffed with health professionals who can develop and implement pesticide exposure standards and safe work practices. These amendments clear up ambiguity in this area and remedy a regulatory situation which leaves workers unprotected.

Mr. Brown's bill specifically would, No. 1, require EPA to establish an occupational health program for protection of workers who are involved in the manufacturing or application of pesticides.

Two, require EPA to coordinate its worker health and safety standards and enforcement activities with standards and enforcement activities undertaken by OSHA.

Three, issue regulations for the protection of employees who are exposed to pesticides. Such regulations would include, for instance, requiring protective clothing, protective equipment, procedures for emergency medical treatment, medical surveillance, and so forth.

Now, in addition, this bill will provide antiretaliation or antiblackmail protection for pesticide workers. This provision protects workers through a provision which makes it an offense to discharge or adversely affect the employment status of any employee because the person filed a complaint against his or her employee or exercised other rights under FIFRA.

Mr. Chairman, a number of the environmental regulations now include the antiblackmail provision, as also does, for instance, the primary labor protection act, OSHA.

In conclusion, we urge the subcommittee to adopt these worker protection provisions. Working people should no longer bear the brunt of a weak national pesticide law. Congress should take the corrective measures and actions through the adoption of the comprehensive improvements to FIFRA being sponsored by Congressman Brown, known as the Federal Pesticide Reform Act of 1985.

Thank you.

Mr. BEDELL. Thank you.

Mr. Feldman.

STATEMENT OF JAY FELDMAN, NATIONAL COORDINATOR, NATIONAL COALITION AGAINST THE MISUSE OF PESTICIDES

Mr. FELDMAN. Good morning.

I am Jay Feldman, national coordinator of the National Coalition Against the Misuse of Pesticides. We are a membership organization of some 300 community-based organizations across the country, including farmers, farmer organizations, consumers, and victims of pesticide exposure. Several of our members testified yesterday, and I believe expressed to you some of their concerns from their own individual experiences.

What you have heard so far during this hearing does not describe a situation that is new. It is just one that is worse than last time we were here.

The victims of pesticides who call NCAMP on a daily basis cry out and are now in larger and larger numbers demanding that there be adequate controls in place both to protect exposure on the farm and in their homes. People want controls and assurances that this subcommittee cannot now offer them under the existing FIFRA statute, including protection from pesticide contaminated air, water, and food. As a result, these people have taken the pesticide issue to town councils, city halls, State legislatures, and, where possible, the courts. Clearly, the protection emanating from this subcommittee and the Congress is not sufficient. The deficiencies exist in many areas which I would like to discuss.

What I would like to do, however, in first getting to this issue is to start with the public disclosure. Some of the other issues which other members of this panel have addressed such as the ground water contamination are also of great concern today and, given the limited time to talk, I won't touch on some of those that have already been addressed.

We have today a serious breach of the American public's trust in the U.S. Environmental Protection Agency, the U.S. chemical corporations, and, in fact, the operation of the Federal pesticide control law.

The public does feel misled by the marketing of chemical products that it assumed were fully tested and determined to be safe by the Government. Those who have been harmed have asked questions on health effects to which there are no answers.

While people are told to trust the EPA and chemical manufacturers, some inside the Agency, inside the EPA, continue to this day to point out serious deficiencies in the Agency's reviews of safety studies, maintaining that, and I am quoting an EPA staff person, "Trust conferred on the Agency may have been misplaced."

I have provided to you this morning a memo, a March 20 memo, that has been given to us from inside EPA, not the publication, from someone working inside EPA.

We implore this subcommittee not only to investigate the recent allegations on faulty EPA reviews, which I will discuss below, but consider the importance of allowing the public to review and discuss without FIFRA-imposed constraints all matters pertaining to health and safety studies on which EPA makes its critical toxic pesticide use decisions.

You have in front of you evidence, I believe, of bogus EPA reviews which continue to underlie safety decisions. I would like to provide you with an astounding example of the extremely important need for openness in this area of EPA decisionmaking, openness which we don't have today.

It goes back to the cut-and-paste reviews of industry and safety studies in which EPA quotes verbatim and without attribution the registrant's own evaluations. The implications of this are somewhat unbelievable. It now appears that at least of the six pesticides that EPA tells the public on a daily basis is fully registered, fully reregistered, that that one pesticide of the six that we know of, its registration has been based on a bogus evaluation by the Agency. This is a pesticide called metalaxyl. It is a fungicide widely used in agriculture today.

In discussing this matter, I leave out any reference to individuals involved since this example is being raised to illustrate to the subcommittee that the system in place is not adequately protecting the public.

Contained in the March 20 memo is a reference to not only metalaxyl, but another insecticide, also the subject of bogus reviews.

What you see here is a pattern of inadequate reviews, lack of access on the part of the public to actually review in a public forum that same underlying data, public exposure on a daily basis to these same pesticides without any knowledge that in fact the product may not be fully tested.

In this case, in terms of the memo you have in front of you, you have a scientist saying that the determinations made by the Agency were wholly inadequate and not based in fact.

In conclusion, and the reason I focus so much on this particular memo is that it suggests that we have a system in place that is plagued and riddled by inadequate oversight, inadequate protection, inadequate public review. Our feeling is that you can act quickly and fully in this area by looking at these amendments that have been referred to today, by looking at this situation referred to in the memo, and open up the process for public review, right to know, in a very serious way.

I appreciate the opportunity to be here today and look forward to working with you in the future to work out some of these problems.

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

Mr. BEDELL. Thank you, Mr. Feldman.

Mr. Combest.

Mr. COMBEST. Thank you, Mr. Chairman.

Mr. Meyerhoff, in your statement where you were talking about the issue of ground water, you indicated that it was nearly impossible to clean up following contamination. Do you feel that there should be some standards set for tolerance levels in ground water?

Mr. MEYERHOFF. It is our position that the tolerance system in the food chain has been an unmitigated disaster and that the American public is not prepared at this time to accept a certain level of EDB or DBCP or any other pesticide chemical in ground water; that if we take steps now at the supply side, if you will, to prevent the contamination of ground water, that is a much better course.

It is the farm community here that is most at risk. About 90 percent of rural America gets its drinking water from the ground water. This report that I mentioned from California, I think, was telling. At one point it refers, just looking at it, talking about drinking water and it says:

> The agricultural community also suffers an intangible but important loss by being associated with the pollution of a public resource that is valued for its purity. The agricultural community withstands a great deal, even if it is not deserved, by being identified as an accomplice in the contamination.

I think that the duty to protect ground water from contamination lies squarely with the petrochemical industry. They have to take sufficient steps in testing their products for environmental fate and for toxicological effects to insure that that water is not going to be polluted in the first place, at least to the best practical means.

Mr. COMBEST. But you really don't feel the tolerance levels have sufficient improved protection——

Mr. MEYERHOFF. The Safe Drinking Water Act, which is the primary statute dealt with by Congress to protect ground water, has addressed 6 pesticides, 6 out of more than 600 active ingredients; three of those have already been canceled. At this time, no, I don't think it has.

There is legislation in California that on Friday passed the agriculture committee—it has the support of the Governor in that State—that is similar to the legislation that Congressman Brown and Senator Proxmire are introducing here.

For those chemicals that are likely to get into ground water, it provides that if there is contamination, and either the State or the registrant doesn't take steps to prevent further contamination, then that pesticide is canceled for that use.

Mr. COMBEST. You mentioned home use of pesticides in your testimony, as well. In some of yesterday's testimony we heard continuing suggestions from people who wanted to further regulate and license certain commercial home lawn care companies to require various types of additional restrictions. Do you feel that there would be a potential—in short, if we impose further regulations, that what it is going to do is affect considerably the cost and is going to drive people into using their own—individuals going in and spraying their own yards, gardens, whatever; that in reality what we may be ending up with is people who have absolutely no knowledge of the use of the pesticides; and that we might really be looking at a potential that could cause contamination worse than it is now without further regulation?

Mr. MEYERHOFF. I think that is already happening. I think that the home use products that the consumer can buy over the counter now are frequently unsafe or potentially unsafe. The average consumer goes into a market or a store and he or she is under the belief that the product has been tested, that it has been found safe, approved by the Government. Nothing on the label would indicate otherwise, and nothing is further from the truth.

Captan, which I have here in my hand, a very widely used agricultural pesticide, is a home use product. It is a relative of thylidamide. It has been linked to birth defects, cancer, a variety of other potential chronic health effects. You can buy it over the counter.

The studies that were done originally on captan were done by IBT. They were found to be invalid. The chemical was put into RPAR in 1980, 5 years ago. We are still waiting for a decision.

Whether the product problem is an untrained applicator, the product problem is an untested chemical you buy over the counter, or the problem is the chemical getting into the drinking water and the food supply, we have this parade of horribles because the statute is deficient, in my judgment.

Ms. DRABBLE. Also, if I might comment on that briefly, the provisions in the Brown reform bill that would affect commercial applicators are really quite modest. There are two major ones. One would require commercial applicators to keep records of their applications, which under good business practice they ought to be keeping now anyway. The requirement for records does not apply to farmers or private applicators, so it does not affect them.

Second, it gives EPA the authority to set standards for indoor exposure, which is an area which EPA has neglected. It does not mandate that EPA do that, but it gives them that authority.

In addition, it says that commercial applicators should make sure that their employees are trained, and I think right now that they would say they should be training their employees to apply pesticides in the most safe way. The amendments make that requirement for some training explicit.

Mr. COMBEST. Mr. Chairman, may I please finish this question?

Mr. BEDELL. Of course.

Mr. COMBEST. On the ground water protection section in your statement, where you indicate that a State should develop a plan to prevent further contamination, do you have any idea about what something of this nature might cost? Is is just a suggestion? Do you have actual implementation suggestions of how one would go about in the State developing a plan that would prevent further contamination potential?

Ms. DRABBLE. I think one thing we can do is look at the State of Wisconsin. They passed a ground water law there, and they are trying to prevent further contamination of their ground water. The kind of plan that a State would develop is to look at the different kinds of soil, look at the geographic areas in their State, and see where they have a problem with the pesticide leaching down into the soil, and then either prohibit the use of the pesticide in certain areas that are particularly dangerous, where it is going to get into the drinking water, or place restrictions on the label so that people who are using the pesticide make sure that they don't use it in certain areas, or use it in such a way—for example, not irrigating for

a few days after application of the pesticide—that it won't leach down into the soil; it would have time to evaporate.

Mr. COMBEST. Is there any estimate of the cost incurred? Was that Wisconsin, did you say?

Ms. DRABBLE. No, I don't think so, because that is a relatively recent law. It has only been in place, I would say, less than 1 year right now.

In cost I would say, whatever costs there are—and no doubt there will be some—they have to be balanced against the importance of preventing the contamination of drinking water, which is a very high priority and also can have some very heavy costs in terms of people's health and hospital bills along down the line.

Mr. COMBEST. How would you suggest that cost should be spread? Would you think it should be done by taxpayers' expense in the States? Should it be done by industry? Should it be done by agriculture? How would you suggest that that cost be spread or borne?

Ms. DRABBLE. Well, the cost would be—there would be restrictions placed on the pesticide. Those restrictions would indicate when the pesticide should or should not be used. I don't know that it is a matter of assigning the cost in any way other than that.

Mr. MEYERHOFF. Clearly, the cost of conducting the relevant tests of environmental fate and toxicity should be borne by the chemical company itself, in my opinion. That is what the law should provide.

Mr. COMBEST. They should bear the cost of testing to see whether or not there is a contamination?

Mr. MEYERHOFF. If their product is going to get into the drinking water in the first place.

Ms. DRABBLE. In some instances right now, EPA is requiring tests to find out whether pesticides are leaching down through the ground water for new registrations of pesticides, and in some instances, on an ad hoc basis, EPA has imposed some restrictions on the label on the use of the pesticide to try to make sure it doesn't get down into the ground water. Some of those tests are already being done, and they are part of the normal obligation under FIFRA. But under our legislation, that would be done on a more systematic basis.

Mr. MEYERHOFF. One problem is that with point source pollution it is easier to know who the culprit was, if you will, to be able to define some responsibility. But with nonpoint source pollution, with pesticide type of contamination, it is harder.

Is it the farmer's fault that he applies a pesticide according to the directions on the label and with the Government's approval? Is it what chemical company actually produced a particular product that is being found in ground water in the central valley? Who is going to pay for the cleanup? All of those issues are very difficult issues.

Mr. COMBEST. Mr. Chairman, thank you. I apologize for using my time. I would like to pursue that further, but I appreciate your indulgence.

Mr. BEDELL. Mr. Roberts.

Mr. ROBERTS. I have no questions.

Mr. BEDELL. Mr. Evans.

Mr. EVANS OF IOWA. No questions.

Mr. BEDELL. Mr. Gunderson.

Mr. GUNDERSON. No questions.

Mr. BEDELL. Do you have more questions, Mr. Combest?

Mr. COMBEST. No, thank you.

Mr. BEDELL. You have some products there that are apparently sold over the counter that you feel are health hazards; is that correct?

Mr. MEYERHOFF. They are products that we think EPA has dragged its feet on, has not made a final decision on that protects the public, or, where EPA has made a decision, that industry has then blocked that decision in the courts.

Pentachlorophenol is one example of that. As I said, early data in 1974 linked it to birth defects. Adioxin is a contaminant; yet, you can buy it off the shelf and put it on your deck. A pregnant woman could be using this or a 2-year-old child could be exposed to it. We think that that is unconscionable.

It is the same thing with captan. There are questions about captan that need to be answered. It is taking 5 and 6 years to answer them or more since it even went into RPAR; yet, I can buy it over the counter with no warning on the label, no indication that it is a potential teratogen, no indication that it could cause birth defects.

Mr. BEDELL. I assume that EPA did check that and registered it for sale; is that correct?

Mr. MEYERHOFF. Well, it was certainly registered for sale, based upon primarily IBT studies that were found to be invalid, when it was originally registered. Then, in 1980, it was put into this RPAR process, the special review, to determine whether or not it should be restricted or taken off the market. We are still waiting with bated breath for EPA's decision.

I want to make one other point, too. I was looking at this captan. Eighty-eight percent of what is in this particular product is an inert ingredient. EPA, under FIFRA, has systematically failed to require any chronic health data for the inerts, the so-called inerts, that are in pesticide products. Those are inert as to pests. Likewise, under the Food, Drug, and Cosmetic Act, more than 500 pesticide inert ingredients have been given blanket exemptions from the tolerance requirements of that act. Some of those inerts—and a full list is appended to my testimony—include such chemicals as vinyl chloride, a very probably human carcinogen; benzene; the glycol ethers; ethylene dichloride; formaldehyde—all bad actor chemicals, a variety of solvents. Yet, EPA requires no chronic data and exempts them entirely from the tolerance requirements. We find that to be totally unphantomable.

Mr. BEDELL. One of the issues is apparently this issue of private right to sue. I need to understand that better, as to just what the concern is and what changes you would like to see in that regard.

What is the issue here? You can sue at this time. What is it you want different about it?

Mr. MEYERHOFF. I am sorry, I couldn't hear the question.

Mr. BEDELL. Right now you can bring suit if you feel you have been harmed, as has already happened. What is it that you would like to see different about the opportunity to sue?

Mr. MEYERHOFF. The thrust of the private right-of-action provision is that right now we can't depend upon EPA to even enforce

the provisions of FIFRA as written. The private right of action would give the citizen both the right to bring a tort action, if he or she chose to do so, but also to sue concerning the misuse of a product, if it was used in violation of a label; if, under the FIFRA, it had an unreasonable adverse effect—to bring a suit directly, rather than waiting for the Government to act.

Mr. VOLKMER. Would the gentleman yield?

Mr. BEDELL. I would be glad to yield.

Mr. VOLKMER. Suit against whom?

Mr. MEYERHOFF. It could be against the applicator. It could be against a chemical company. It could be against the Government.

Mr. BEDELL. Can't you do that now if you feel you have been damaged?

Mr. MEYERHOFF. You can bring a—go ahead.

Ms. DRABBLE. You can only bring an action for damages if you feel that your property has been damaged or you have been personally injured. You can bring a personal injury action against whoever you feel has harmed you. But what you cannot do is bring an action saying that that corporation or that person has disobeyed the law and has failed to comply with the law.

One of the things under the private right-of-action section we do is say that, if someone wanted to sue an applicator other than a commercial applicator, they would have to notify the State and EPA for 60 days before bringing the suit, to give EPA or the State an opportunity themselves to bring an enforcement action, to allow them to enforce the law. It was only if the State or EPA failed to enforce the law that then the private citizen would have a chance to go ahead and bring the suit.

Mr. BEDELL. The whole issue is not damage; the whole issue is that now you can sue if you feel you are damaged, and you would like to see the law changed so you could bring suit to see that the law was enforced, even though you may not have been damaged; is that what the issue is?

Mr. MEYERHOFF. No, you would be damaged.

Ms. DRABBLE. Yes; usually there would be two parts to it. You would have been damaged, but also there would have been a violation of the law.

Mr. BEDELL. If you have been damaged, right now you can bring suit, can you not?

Ms. DRABBLE. Right; but part of that suit cannot be an allegation that the law was disobeyed.

Mr. MEYERHOFF. You can bring an action in tort but you cannot bring an action for violation of FIFRA. If a product was misused—say, drift on a home in a suburb, something like that——

Mr. BEDELL. Mr. Volkmer, do you have any questions?

Mr. VOLKMER. No.

Mr. BEDELL. Mr. Morrison.

Mr. MORRISON. No, Mr. Chairman.

Mr. BEDELL. We appreciate your testimony. It is a very difficult issue for many of us.

Mr. MEYERHOFF. I have a free can of pentachlorophenol for any member of the subcommittee who——

Mr. BEDELL. I beg your pardon?

Mr. MEYERHOFF. I have a free can of pentachlorophenol if anyone would like to have it.

Mr. BEDELL. I think you've got us all scared to use it now. [Laughter.]

Thank you for your testimony.

Next we have a panel: Jack Early, president, National Agricultural Chemicals Association; accompanied by Carl Kensil, vice president, Ciba-Geigy Corp., and vice chairman of the NACA board of directors; and Scott Ferguson, general counsel for NACA.

We are having to hold our testimony to the 5-minute period, Mr. Early.

Mr. EARLY. I understand that, Mr. Chairman, yes.

Mr. BEDELL. We would appreciate it if you would try to hold to your time. You may proceed.

STATEMENT OF JACK D. EARLY, PRESIDENT, NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION, ACCOMPANIED BY CARL J. KENSIL, VICE PRESIDENT, BOARD OF DIRECTORS, AND W. SCOTT FERGUSON, GENERAL COUNSEL

Mr. EARLY. Thank you, Mr. Chairman.

Good morning, Mr. Chairman and members of the subcommittee.

I am Jack Early, president of the National Agricultural Chemicals Association. I am accompanied this morning by Mr. Carl Kensil, on my left, vice chairman of our board of directors and the president of the Ciba-Geigy Corp., agricultural division, and on my right is Scott Ferguson, our general counsel.

You, Mr. Chairman, and others on your subcommittee have called upon all of us—industry, agriculture, government, and special interests—to be part of a process to address some of the nagging concerns in pesticide regulation. We are here today to help, Mr. Chairman.

In giving our pledge to help, we add one observation: We believe, as we think many here do, that any amendments to FIFRA should reflect the testimony given before the subcommittee last month by EPA's Dr. John Moore, that FIFRA, and I quote, "is fundamentally sound environmental law." This statement reinforces comments made last year before this subcommittee by EPA's then-Administrator William D. Ruckelshaus, who testified that FIFRA is, and I quote, "basically a sound and workable statute which gives EPA authority to act on several fronts without waiting for changes in legislation."

We agree with these EPA views and urge the subcommittee not to make extensive revisions to FIFRA suggested in H.R. 2482, H.R. 1416, and H.R. 1910, and other bills that we believe will yet be introduced.

We understand that H.R. 2482 has been introduced as a bipartisan effort to encourage constructive dialog on FIFRA. While this bill may achieve that laudable objective, enactment of the bill, the Heftel and the Seiberling bills, would cause severe injury to our industry and perhaps to our agricultural customers.

FIFRA currently strikes a careful balance among many legitimate concerns and interests. Changes proposed in bills before this

subcommittee would upset that important balance. Let me give you some examples.

Scrapping the present cancellation procedures in favor of rulemaking would speed removal of products from the market, but at the cost of procedures that ensure due process, where literally millions of dollars of investment, crops, health, and the livelihood of thousands of members of the public ride on the product's registration.

Wholesale data disclosure to foreign governments would make EPA's administration of FIFRA easier, but may cause data owners to lose their intellectual property rights and their investment in the data.

Abolishing indemnification to those injured by the Federal suspension-cancellation actions and imposing fees on the registration of pesticides may appeal to the Federal budget-watchers, but would expose pesticide manufacturers and distributors to potentially catastrophic financial risks and operating costs.

These are just a few examples of the highly objectionable modification proposed in H.R. 2482, H.R. 1416, H.R. 1910. The proposals simply go too far. Some modest changes to FIFRA are worth considering. However, we would submit that major amendments are not only unnecessary, but also potentially dangerous.

I would like to turn now, briefly, Mr. Chairman, to an assessment of EPA's implementation of the current law and how it relates to the decision on the scope of FIFRA amendments.

As EPA has previously testified, the agency has embarked on a vigorous program to address administratively the longstanding concerns in pesticide regulation. This effort has gone a long way in restoring EPA's credibility and the timeliness and scientific quality of its regulatory decisions. I will not repeat now the specifics of what progress EPA has made, other than to observe that this painful administrative process has relieved Congress of the need for making many statutory changes.

But, some modest legislative work remains that will still retain the carefully crafted balance in FIFRA that has served us so well.

I would like now, in my remaining minutes, to discuss areas for constructive FIFRA amendments. We are not asking for a so-called wish list, Mr. Chairman, of improvements, solutions to remote problems, or ways to make our lives any easier. Instead, in the spirit of compromise, we offer ideas of FIFRA changes that are not in our special interest and may assist you in preparing an acceptable bill.

The suggestions which follow are prepared in our firm conviction that FIFRA should not be open to substantial changes, in whatever form. If our understanding is mistaken and FIFRA is, indeed, to be overhauled substantially, we, too, have ideas to amend FIFRA in the public interest and to maintain proper balance.

For example, there are ambiguous FIFRA provisions affecting the use of data supporting registrations, compensation for data, and responsiveness of competing registrants to data call-ins. There are local jurisdictions and communities which supersede this Congress' judgment in FIFRA and EPA's scientific and regulatory assessments with their own. There are potential conflicts and gaps among the Federal statutes affecting many of these issues.

We do not plan to pursue these issues, Mr. Chairman. We believe that FIFRA can function well with a few changes. Let me recommend just a few changes, if I may.

No. 1, imposing stiff penalties on those who would willingly falsify any data to support a pesticide registration.

No. 2, immediate suspension of pesticide registrations if EPA learns that the registrations were obtained on the basis of deliberately falsified data.

Three, mandatory timetables for identifying and filling the data gaps.

Four, EPA inspection authority for laboratories developing data in support of registrations.

Fifth and finally, Mr. Chairman, congressional authority to increase funds for EPA that is dearly needed to increase their resources to deal with the issues.

Mr. Chairman, this completes our testimony. We would be delighted to respond to any questions you may have.

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

Mr. BEDELL. Thank you very much, Dr. Early.

Mr. Roberts.

Mr. ROBERTS. I have no questions.

Mr. BEDELL. Mr. Evans.

Mr. EVANS of Iowa. I have no questions.

Mr. BEDELL. Mr. Gunderson.

Mr. GUNDERSON. Thank you, Mr. Chairman.

Just one question: we all recognize the need for additional funding at EPA. We all recognize the budget problems. Do you have any suggestions other than general revenue on how we might deal with that? I know it is an unpleasant task. I am afraid what we are going to face in this Congress, if you have watched the history thus far, is every authorization bill that has been in front of the Congress thus far has frozen the funding level for 1986 at 1985. I think the chances are better than—much better than—50-50 that we will freeze EPA's funding.

How do you respond to that? If we freeze it, is it going to present real problems in the review and certification of chemicals? I just would like to hear some comments from you, Doctor.

Mr. EARLY. Mr. Gunderson, we have addressed that area of pesticide fees and other issues. Let me read you where we stand on that.

It is our view, first, that a system of pesticide registration fees would dramatically increase product costs, resulting in increased consumer prices, and it would have an unfair and disproportionate impact on small business.

Second, a user fee such as registration fee is a revenue-raising measure that would require additional review with attendant delays by appropriate House and Senate committees other than these committees.

Third, such fees would impermissibly and inevitably move more decisions on funding, the scope and direction of EPA's pesticide regulatory activities from Congress to the regulated community. It is in the public's and the industry's interest that an independently-functioning and financing EPA continue to exist.

Finally, the cost of operating the pesticide program confers no direct pesticide benefit on the pesticide applicants, but rather meets the responsibility of the Federal Government that requires this registration process.

I don't think we have any ideas, Mr. Gunderson, that we think that this ought to come from private funding. We think it is in the public's interest. I recognize the dilemma that you are facing and that we are facing, too, in trying to find additional resources and funding for an area that probably requires more funds and more resources.

Mr. GUNDERSON. I think you would agree, though, that based on the position you have, you are really saying you are content to live in 1986 with the 1985 funding level. You are a pro around here. Really don't you think that is what is going to happen?

Mr. EARLY. I think EPA is going to have to make some choices on what issues and what areas they pursue, because their funds and resources are going to be limited.

Mr. GUNDERSON. Thank you.

Mr. BEDELL. Mr. Volkmer.

Mr. VOLKMER. I have no questions.

Mr. BEDELL. Mr. Morrison.

Mr. MORRISON. No questions.

Mr. BEDELL. Dr. Early, you said you weren't going to submit all your ideas for improvement. I would urge you to do so. We want to hear all of the suggestions people may have for improvement. We may not do everything you would like to see us do, but we would urge you to do that.

How large is your industry? At the manufacturing level what is the annual dollar sales?

Mr. EARLY. The last figures we had, Mr. Chairman, it was something in the neighborhood of $5 to $6 billion, I believe.

Mr. BEDELL. $6 billion?

Mr. EARLY. Yes. That would be domestic and export market combined.

Mr. BEDELL. If we were to have a small tax, percentage tax, on that, we could get the needed money we cannot get out of Government, and it would appear to me that that could be small enough that it would not impose a big burden upon the user.

What would be your reaction to that?

Mr. EARLY. I think obviously I would have some concerns about that, imposing a tax on my industry.

Mr. BEDELL. Well, 1 percent would not be—I would think would not be—a terrible burden to any manufacturer. One percent, if you are right, would bring us $60 million, which would do a big job for us.

Mr. EARLY. The tax perhaps would show as a much greater burden on some of our smaller companies and some of the small businesses that are in the process of——

Mr. BEDELL. One percent?

Mr. EARLY. It would certainly increases the prices that would be passed along.

Mr. BEDELL. I understand. I am not trying to sell it. It just seems to me, if your industry is that big and if we do have this terrible problem of inadequate funds to properly review the things that

need to be checked, we should at least consider the idea. If it was a $100-million industry, then I would see the idea as unfeasible, but with your industry that large, I would think there would be some merit to the proposal.

Mr. EARLY. Let me assure the chairman that we and our industry would be delighted to work with you to see if there are some ways that we could explore some opportunities on how we might be able to fund the agency, either through additional Government funding or some other way. We would be glad to work with you, Mr. Chairman, on that.

Mr. BEDELL. You talked about falsified data. I can understand the concern if somebody deliberately falsified it, but I assume that if the data is false, whether it was deliberate or not, the problem to the public would be the same; would it not?

Mr. EARLY. I think this goes back to a problem that we developed during the IBT case, and you are familiar with that, I believe. It has been referred to several times.

Unfortunately, what happened with IBT is that most of my industry was caught up in the process also unknowingly, having data generated for them, and they submitted it in good faith.

Mr. BEDELL. Sure.

Mr. EARLY. I think that we say it should be willingly and knowingly false data. If someone submits data, you or I submit data to the agency in good faith and we believe it is in good faith, why should we have to pay the penalty for that? That is why we are saying to go back to those that knowingly and willingly put that information forward.

Mr. BEDELL. I understand from the manufacturer's standpoint, but I am asking from the public's standpoint. If the data was false and you, therefore, have something on the market that should not be there, from the public's standpoint it would not really matter whether it was knowingly or unknowingly; the effect is still the same on the public. If our concern has to be with the public, there maybe should be some different consideration for the manufacturer as to what is to be done, but as far as the chemical being used by the public, it would seem to me it would be the same. Do you disagree with that?

Mr. EARLY. I don't know that I really disagree with that. I think that EPA has the authority now under existing law that if they believe that data that was submitted to support that registration is false, for whatever reason, they have the authority to deal with it appropriately. They can either ask for additional data or they can cancel, suspend, or declare an imminent hazard. They can do a lot of things. They have a lot of authority in that area.

Mr. BEDELL. The witness in the previous panel indicated he had a chemical that the EPA had not thoroughly reviewed, although, it is still being sold. Do you know if that is a common problem or not?

Mr. EARLY. Not to my knowledge, Mr. Chairman. I have not seen that internal memo that was referred to. I have not had a chance to read it.

Mr. BEDELL. No, no, not the memo. He had a can of something there; I don't know what it was. He said it was registered at a time when they did not have as much knowledge about the chemical.

Mr. EARLY. Oh, the captan.

Mr. BEDELL. It is still available for sale without any marking on the product, as I understood him.

Mr. EARLY. It may be a difference in judgment on whether or not something in the scientific evidence supports moving ahead by cancellation or suspension or whether it does not. In other words, there may be a difference of opinion, depending on your viewpoint.

I assume that EPA has their scientists evaluating that process. If they reach a decision that a product should not be sold across the counter, they take steps to stop that.

Mr. BEDELL. You are proposing mandatory time tables, I think, are you not?

Mr. EARLY. Yes. Yes.

Mr. BEDELL. In those timetables, what would you do if EPA doesn't keep to the timetables?

Mr. EARLY. I think we have some language we would be glad to share with you in that area. I think the Administrator should have the authority to cancel or suspend the product if they do not meet those timetables. You have to be pretty severe.

If we are serious about filling the data gaps, we have to put an obligation on our registrants that says either you do or you get your product off the market.

Mr. BEDELL. Thank you very much.

Are there any further questions?

If not, we appreciate your testimony.

Mr. EARLY. Thank you, Mr. Chairman.

Mr. BEDELL. Thank you.

Our next panel consists of Ms. Maureen Hinkle, National Audubon Society; Ms. Barbara Bramble, National Widlife Federation; Mr. Robert Wasserstrom, senior associate, World Resources Institute; and Mr. Charles Horwitz, Farmworker Justice Committee.

STATEMENT OF MAUREEN K. HINKLE, DIRECTOR, AGRICULTURAL POLICY, NATIONAL AUDUBON SOCIETY

Ms. HINKLE. Mr. Chairman, I have with me today Edith Meacham, who is my associate, and she directs the international pesticides program for Audubon. She will give testimony on international pesticide regulation.

Mr. BEDELL. My understanding is you are going to take 5 minutes between you, and we don't care if you have 1 or 10 as long as you only take 5 minutes total.

Ms. HINKLE. I think I have a good record of using less than my time. I hope so.

Mr. Chairman and members of the subcommittee, I was glad to hear that Jack Early agrees with the Congressman from Oklahoma, Mr. Synar, on the data gap situation and imposing a mandatory time table on the fulfilling of data gaps.

I would also like to comment on the registration fee that you discussed with Jack Early. Audubon is in favor of Congress mandating to EPA to impose a system of registration fee collection. OMB in 1980 passed back EPA's request for additional appropriations saying that no additional funds would be approved until a registration fee system was imposed. The philosophy was that the beneficiary should pay for the cost of the review of the pesticides.

Industry does benefit from this review because they have a shorter review period and they, therefore, have a longer marketing life. They have earlier market entry and a longer patent term if they have a more efficient review.

It is interesting for us that there are various interpretations of whether FIFRA is an adequate piece of legislation or not. It seems, in our view, it is a pendulum. In 1981 industry said, "Please change it. It needs to be changed." Then in 1982 they said, "We don't need a change at all." Now again they are saying, "We don't need a change at all."

We believe that EPA has made steady progress in pesticide regulation after the Gorsuch-Burford backsliding of 1981 to 1983. They have taken some initiatives in ground-water contamination by pesticides as well as regulation of toxic inerts contained in pesticide regulations.

However, we believe that legislation is required for both groundwater contamination by pesticides and inert ingredients in order to keep EPA on track on these two issues.

EPA has given support for the concepts of providing citizen standing to initiate cancellation hearings and also to strike the indemnification clause, which is section 15. This gives Congress every reason to act on those two issues.

Congress needs to give EPA a harder push to establish a provision to enact a community right to know and to place a lid on special local registrations.

We also hope that you will legislate in the area of false, misleading, and fraudulent data, since we are all in agreement on that.

In regard to Jack Early's statement that data sharing with foreign governments is not required, we respectfully disagree and have a section in our testimony that would show that this would not be a wholesale disclosure to foreign governments, but there are adequate reasons for sharing data with State governments and with certain foreign governments.

I would like to comment on H.R. 2339, which was introduced on May 2 by Barbara Kennelly of Connecticut. This would authorize the Secretary of Agriculture and the Administrator of EPA to study methods to accelerate the use of integrated pest management and to discourage the use of pesticides to meet domestice cosmetic marketing standards.

In view of the fact that EPA essentially regards its mandate as a licensing authority for four past decades and they have only had it for one decade, the authority for regulating pesticides for one decade, nevertheless, the sale and use of pesticides has continued to increase every year for 40 years. At the same time our understanding of the environmental and health implications of this increase in chemicals has remained inadequate.

In view of the fact that pesticides are ending up in our drinking water and in our blood and our fat tissue and in our food, this H.R. 2339 would initiate positive steps for reducing the unnecessary use of pesticides. Therefore, we are extremely enthusiastic about H.R. 2339 and urge you to incorporate it in H.R. 2355, which is the authorization for this fiscal year, or to include it in a comprehensive way in legislation this year.

[The prepared statement of Ms. Hinkle appears at the conclusion of the hearing.]

Ms. HINKLE. Could Ms. Meacham have 2 minutes?

Mr. BEDELL. Ms. Meacham, I don't mean to be difficult. How long is your statement?

Ms. MEACHAM. Very, very short.

Mr. BEDELL. My understanding is it was understood that you had 5 minutes and you could take part of it. We will give you a few minutes here.

STATEMENT OF EDITH D. MEACHAM, AGRICULTURE POLICY ASSOCIATE, NATIONAL AUDUBON SOCIETY

Ms. MEACHAM. Thank you.

If I may just briefly outline our interest in international pesticide export controls and present a few suggestions which we believe will help improve the situation.

First, we would urge you to tighten loopholes in the current pesticide export notification system by enacting a policy of informed request. This provision would require that foreign governments submit a request for a canceled or suspended pesticide to EPA before the pesticide shipment leaves this country. This would allow importing governments greater control over what enters their country.

Further, we would urge you to expand the categories which require notification by including voluntarily withdrawn, restricted use, and acutely toxic pesticides.

The problem of monitoring on imported produce for illegal pesticide residues also disturbs us. We would urge you to improve the Food and Drug Administration's ability to carry out its monitoring responsibilities by requiring importing countries to disclose the intended use of canceled or suspended pesticides which they import.

Further, we would ask that U.S. chemical companies be required to submit an annual report to EPA stating the amount and destination of any pesticides, intermediaries, or formulated products which they have exported.

Finally, we would ask that Congress enact provisions which would require U.S. agencies to work through international channels to help developing countries set their own research and regulatory programs.

Pesticide use in developing countries is growing exponentially. We feel that the United States must work with both industrial and developing nations to insure that this growth does not result in an explosion of problems.

The United States has played a leadership role in this area before, and we believe that it is time to take up thise role once again.

I would like to submit for the record an article on this subject which I wrote for Audubon Action, our bimonthly newspaper which goes out to our half million members.

Mr. BEDELL. Without objection, it will be entered with your prepared statement.

Ms. MEACHAM. Thank you.

I think it will further demonstrate our interest in this issue.

Thank you for the opportunity.

[The prepared statement of Ms. Meacham appears at the conclusion of the hearing.]

Mr. BEDELL. Thank you.

Ms. Bramble.

STATEMENT OF BARBARA J. BRAMBLE, DIRECTOR, INTERNATIONAL PROGRAM, NATIONAL WILDLIFE FEDERATION, AND ON BEHALF OF THE INSTITUTE FOR PUBLIC REPRESENTATION

Ms. BRAMBLE. Thank you, Mr. Chairman.

I am director of the International Program of the National Wildlife Federation. The federation is the Nation's largest conservation organization. It has over 4.5 million members and supporters who are dedicated to the wise use and management of natural resources.

The federation's constituency has had a longstanding awareness of the strong link between sustainable development and intelligent use of natural resources.

I am also speaking here this morning on behalf of the Institute for Public Representation, which is a public interest law firm formed by Georgetown University Law School and the Ford Foundation.

We are dismayed by the proliferation of pesticide use that is destroying fish and wildlife, poisoning humans, and threatening the natural balance of predators and prey. We, therefore, support the pesticide reform legislation which is being sponsored by Representative George Brown and Senators Proxmire and Harkin, which will strengthen the Federal Insecticide, Fungicide, and Rodenticide Act.

The principal provisions of that legislation would increase protection of developing countries against pesticide misuse, augment the control of pesticides that endanger U.S. citizens, and assure public participation in important decisions concerning pesticides.

I would also like to mention that there are some similar provisions in H.R. 1416 which has been introduced by Representative Cecil Heftel, which addresses some of the same import and export issues.

While these bills will not solve all pesticide-related problems, they are needed efforts to address some of the known inadequacies in the current FIFRA legislation.

The National Wildlife Federation endorses the whole package of the FIFRA reform bill that will be introduced by Representative Brown, but we are particularly concerned about the export of hazardous pesticides to developing countries where they are often misused causing acute poisonings as well as long-term health effects and environmental contamination.

Canceled and suspended pesticides are routinely allowed to be exported from the United States, but, moreover, the current export notification provision does not give developing countries sufficient or timely warning of the hazards of pesticides that they are receiving. This leads to several problems.

First, I am sure you all have heard of the circle of poison in which pesticide residues which have been used on food crops in foreign countries may remain as residues and imported into this coun-

try on food products. FIFRA does not now require the automative revocation of food tolerances, the legally permitted amounts of pesticide residues in food, when a pesticide is canceled or suspended.

In addition, this means that an imported food shipment may legally contain as much residue of a canceled pesticide as was permitted when that pesticide was used in the United States prior to the cancellation.

But even where the residue exceeds the tolerance or there has never been a tolerance set for that pesticide on a particular food product, we have found in several research efforts that the FDA does not always act to preclude the shipment entering the country.

The Brown bill would require the revocation automatically of tolerances after a cancellation, and it would also prohibit an import shipment when the residues exceed a tolerance.

Mr. Chairman, you have also suggested an alternative method of reaching this same result, which would be to only permit a food import, shipment import, if a country has a regulation to keep canceled and suspended pesticides from being used on that crop. This alternative is also worth pursuing.

I want to turn now just briefly to the misuse of pesticides in developing countries themselves. As you probably know, safe use of pesticides is hard enough in this country, but in developing countries pesticide misuse is magnified by poverty, illiteracy, the high cost of protective gear, the lack of water for washing after pesticide use, and inadequate, if any, training for applicators.

To add to these enormous obstacles, this country and several other pesticide exporting countries have adopted a double standard which specifically exempts pesticides made for export from important legal safety requirements. For example, under section 3 of FIFRA pesticides made only for export need not go through the registration process. This means that even if an importing country asks EPA for information about the health and safety effects or the efficacy of certain products, EPA has no information to give.

In addition, not all of our pesticide container labeling requirements apply to exported pesticides. Manufacturers for pesticides destined for abroad need not label them with instructions for proper use.

There is a notification system in the FIFRA legislation now, but it is faulty in several ways. The shipment-related notice is not required to precede the shipment. Therefore, the importing country is not given the opportunity to consider the hazards of the chemical before receiving the pesticide.

The one further problem I would like to point out is that, despite the fact that we do give notification for suspended and canceled pesticides, we do not routinely do so for restricted use. Those are the chemicals which are, in fact, most dangerous to use.

You will find that, while DDT would normally have a notification to a foreign importing country, parathion would not. That pesticide alone may be responsible for as much as 80 percent of the pesticide poisonings in Central America.

I would like to endorse the amendments which are in the Brown bill, particularly with regard to notification, broadening the notification system to developing countries, and requiring compilation of information on pesticide exports.

Thank you very much, Mr. Chairman.

[The prepared statement of Ms. Bramble appears at the conclusion of the hearing.]

Mr. BEDELL. Thank you.

Mr. Wasserstrom.

STATEMENT OF ROBERT WASSERSTROM, SENIOR ASSOCIATE AND PROJECT DIRECTOR, WORLD RESOURCES INSTITUTE

Mr. WASSERSTROM. Thank you, Mr. Chairman.

My name is Robert Wasserstrom. I am a senior associate and project director at the World Resources Institute Public Policy Research Center here in Washington.

In collaboration with Richard Wiles, I have recently completed a study of pesticide regulation and farmworker safety in the United States which will be published by WRI within the next few days.

I appreciate this opportunity to offer my views to the subcommittee.

Since FIFRA was enacted in 1947, American agriculture has become heavily dependent on synthetic pesticides which now represent a $4.1 billion a year market for chemical manufacturers.

Because EPA has been unable to codify appropriate uses for these chemicals as the law requires, significant problems of human health and safety, particularly for farmers and agricultural laborers, remain.

In part, such problems stem from the ambiguous nature of FIFRA itself and from the agency's convoluted efforts to balance the price of pest control against the need to limit human exposure. This difficulty has recently been underscored by specialists at EPA's own Economic Analysis Branch.

"While pesticide producers, users, and consumers benefit from the use of pesticides," they wrote, "costs are distributed disproportionately throughout the population in terms of acute and chronic toxic effects such as cancer."

Although conclusive proof is not available, ample evidence suggests that such costs are borne mainly by farmers, field hands, and agricultural laborers.

In our view, the following recommendations would lead to a more effective national policy concerning agricultural workers and pesticide safety:

One, EPA should calculate occupational exposure levels for all workers employed in agriculture. These standards should be at least as high as those developed by OSHA. Even better, EPA might use the so-called "will endanger" test taken from section 211 of the Clean Air Act. This test enables the agency to act on the basis of risk alone without a strict assessment of economic benefits.

To carry out its mandate, EPA should create a new Occupational Health and Safety Branch within the Office of Pesticide Programs which would replace the existing one-person Farmworker Safety Unit.

Revised standards for both acute and chronic exposure must be set as soon as the relevant data are collected and should assure that agricultural workers receive the same degree of protection as other workers enjoy under OSHA.

If such data are not forthcoming in a timely fashion, the agency should adopt a procedure now used in California under the State's Birth Defects Prevention Act which allows officials there to carry out the necessary studies themselves or contract it through a reputable laboratory at the manufacturer's expense.

Meanwhile, EPA should set emergency regulations by undertaking a worst-case analysis of existing evidence. Should the studies outlined above subsequently indicate that less stringent regulations might apply in particular cases or regions, EPA or State officials may then make the appropriate adjustments.

Finally, responsibility for enforcing these regulations must be transferred from State agricultural officials to health authorities who would adhere to strict Federal guidelines.

Two, classification of pesticides should be tightened or reflect the new standards and additional resources must be allocated to accomplish this task expeditiously. All pesticides should be grouped into three major categories depending on their relative toxicity, the danger of human exposure, and epidemiological evidence of intoxication.

Thus, for example, chemicals which do not appear to be particularly harmful in laboratory studies may turn out to cause significant damage when actually used in the field. Such information should figure into EPA's calculation of how dangerous these chemicals are and who should be permitted to apply them.

Furthermore, we support the idea that EPA should require manufacturers to pay a registrant's fee for each new compound placed on the market. Such fees would be higher for chemicals in category 1 than for those in categories 2 or 3 and would effectively share the burden of epidemiological surveillance and monitoring with the chemical industry.

Three, the best scientific information currently available suggests that protective clothing does not shield either applicators or field hands who must return to treated areas before the corresponding reentry periods have expired. Until safer methods are developed, EPA should enforce reentry rules with no special allowance for protective clothing except where positive scientific evidence shows that it is effective.

Since very few agricultural tasks must be performed immediately after pesticides are applied, this procedure is unlikely to represent a severe hardship for most farmers and would rectify one of the most glaring inconsistencies in current regulation.

Four, under existing procedures certified applicators exercise general responsibility for supervising the laborers who mix, load, and spray pesticides but need not be present when treatments occur. To solve this problem, EPA should immediately assure that everyone directly involved in handling such chemicals undergoes a degree of training at least equivalent to what certified applicators now receive.

Whether these measures succeed will depend largely on EPA's willingness to develop and implement a coherent national program. As past experience with FIFRA has demonstrated, partial remedies are not the answer. Pesticide misuse cannot be corrected by putting more detailed instructions on product labels.

We urge Congress to take the steps that an effective national strategy demands. Like medicines, pesticides are both a vital part of modern life and a potential hazard. In neither case can narrow interests be allowed to set the terms of public policy.

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

Mr. BEDELL. Thank you, Mr. Wasserstrom.

Mr. Horwitz.

STATEMENT OF CHARLES HORWITZ, FARMWORKER JUSTICE COMMITTEE

Mr. HORWITZ. Thank you, Mr. Chairman.

My name is Charles Horwitz. I am speaking for farmworkers, clients who have been injured by pesticides in the course of their employment. Farmworkers are the No. 1 occupational health victims of pesticides.

I have represented farmworkers in pesticide poisoning cases and also death cases since 1976 for the Migrant Legal Action Program and recently for the Farmworker Justice Fund.

All of the farmworker laborer and human protective provisions in the Brown-Proxmire bill are necessary, we believe, to insure minimal labor occupational health and safety protections for farmworkers under FIFRA.

FIFRA is the main labor protection statute that I believe your Agriculture Committee deals with. Yet, how many members of the Agriculture Committee regard FIFRA as a labor protection statute, since FIFRA never mentions farmworkers, workers, employers, or occupational safety or health. Take a fresh look at FIFRA, I urge you, and try to find one clue that this law is supposed to be a labor protection statute.

The lack of enforcement of FIFRA for farmworkers and the general public is a very serious problem. Mr. Wasserstrom has documented in his paper recent lack of enforcement, reduced enforcement of FIFRA by EPA which shows a bad situation is getting even worse.

What the Brown-Proxmire does is to try to remedy these problems with several labor protection provisions which require EPA, one, to enact enforceable worker protection regulations. Right now EPA says that the regs at 40 CFR 170 are not enforceable even though they have been on the books since 1975.

It would create an occupational safety and health unit within EPA. EPA does not have such a unit right now. They have no industrial hygienist that we know of, for example, no medical doctors who work on the issue of worker protection within EPA.

It would provide for an antiretaliation provision and it would also provide for a private right to sue, which, as you remember, this subcommittee in 1981 passed and it also passed the entire House, although it did not pass the House Agriculture Committee by one vote, 21 to 20. Similar provisions such as those we are supporting today, as I said, were passed by your subcommittee and by the full House.

Because of the lack of time, I am just going to focus on the private right to sue, the citizens' suit provision, and I am going to give several reasons why we think it is essential to be passed.

In this era of reduced Government support at all levels for regulatory enforcement, it is essential to give private citizens the means to help themselves and not have to beg the Government to help them. Citizens should be able to have this kind of protection because, without it, they are going to have to rely on EPA and the States which the GAO in 1981 and many similar studies have shown that simply has not been up to the job.

Recently EPA has made it even more difficult for anyone to find out how many pesticide injuries occur in this country. Section 20 of FIFRA requires EPA to monitor pesticide exposure, "pollution of man and the environment."

Unfortunately, EPA is not performing this function and EPA has no record of how many enforcement actions it has taken against pesticide applicators who have injured human beings, livestock, or the environment. Although the EPA's Pesticide Instant Monitoring System, PIMS, has recorded over 60,000 injuries over the past several years, the system was not programmed to disclose how many of these incidents involved humans nor to describe how many workers, residents, or other pesticide victims have been injured. Recently, EPA stopped any further public dissemination of PIMS material and PIMS is now closed. The EPA is sort of a blind guardian. It has closed its eyes and does not try to get this information anymore on a regular, voluntary basis.

We have urged unsuccessfully that EPA mandate pesticide reporting requirements in a petition in 1979 which they rejected.

I urge you to vote for the private citizen suit provision because of the serious practical difficulties victims, not only farmworkers, face in litigating pesticide poisoning cases. This bill provides a Federal forum which is a very small but helpful step in the right direction.

It is true, as some of you have mentioned and asked Mr. Meyerhoff and others earlier, that victims can go into court and sue on tort damages if they are injured, but they cannot go into Federal court now unless they have diversity of citizenship.

Let me share some of the background of the problems which farmworkers face. First of all, 65 percent of all pesticide poisonings that are agricultural involves crop-dusting pilots who negligently permit spray drift to injure people and the environment. Yet, very often victims such as farm or forestry workers and rural residents cannot afford to take time off from work even though they are severely poisoned. Only a few report involuntary pesticide poisonings to governmental authorities.

For example, in California they have about 1,500 cases a year reported to the State officials. That is only 1 percent of the total number.

I am just going to conclude by saying that, with this provision, it would make it a little bit easier for a farmworker in one State to sue in Federal court where right now he only has the option of going into State court or begging EPA or the States to help him. We believe that asking the Government so far to help them with pesticide poisonings is a futile gesture.

Thank you.

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Mr. BEDELL. Thank you very much.

Mr. Combest.

Mr. COMBEST. No questions.

Mr. BEDELL. Mr. Roberts.

Mr. ROBERTS. Yes, Mr. Chairman. I think I should say at this juncture that my lack of questions does not indicate lack of a keen interest or some pertinent questions that I do have of the witnesses dating back to a several year period. However, in the interest of time, I am deferring those questions in that I do want all members of the panel that have been scheduled to have their say.

I want to say at this juncture, which I should have said at the beginning of the hearing, that I welcome all the witnesses to this process and thank them for their input. We share your sense of concern. Mr. Bedell and I have introduced a bill that hopefully will be a vehicle for improvement for all parties.

With that, Mr. Chairman, I would yield back.

Mr. BEDELL. Thank you, Mr. Roberts.

Mr. Morrison.

Mr. MORRISON. Mr. Chairman, just a question of Mr. Horwitz based on his last comments.

You indicated that a very small percentage of farmworkers supposedly injured by pesticides actually recorded that injury and that they did not take time for treatment because they could not afford to. Whatever happened to industrial insurance or workers' compensation? My experience is that payments are made immediately if someone is actually injured.

Mr. HORWITZ. Sir, in 25 States farmworkers are explicitly or implicitly excluded from workers' compensation. That is No. 1.

No. 2, studies have shown that farmworkers simply do not know about their rights to workers' compensation for various reasons. The fear of retaliation of complaining to the grower is a real problem. Testimony in California and many other States has shown that, if you want to be foolish, you complain and then you are out of a job. Farmworkers cannot afford to take that kind of risk. The antiretaliation provision that is in this Brown-Proxmire bill would provide that kind of protection, the antiretaliation provision.

Mr. MORRISON. Aren't the major agricultural areas covered, though, with industrial insurance? I know certainly the State of Washington is, as well as California.

Mr. HORWITZ. It is true. Texas just recently passed one. So now the major agricultural States have it, but, mind you, migrant farmworkers by definition migrate from Texas up the Middle West where many States don't have it, from Florida on the east coast, and they don't have protection in those States. Some farmworkers migrate 3, 6, or 9 months out of the year, and they are in those States without protection of workers' compensation. Like I say, workers' compensation studies have shown it is simply not known as an available remedy for farmworkers and they do face the risk of being fired if they complain.

Mr. COMBEST. As a farmer for 30 years, I have never seen the particular problem that you point out as severe, but I am going to take your word for it because your testimony is part of what we are taking under consideration, as Mr. Roberts has indicated.

Mr. HORWITZ. Thank you, sir.

Mr. BEDELL. Mr. Volkmer.

Mr. VOLKMER. No questions.

Mr. BEDELL. On the export of chemicals that some of you talked about earlier, is what you want simply notification of the danger of using that chemical? Is that as far as you wish to go?

Ms. Bramble, I think you talked about it.

Ms. BRAMBLE. Yes, I did. Thank you.

We have talked about it over a long period of time, about how far we think we can go with that concept. Obviously, a lot of people have suggested that we should simply prohibit the export of pesticides which are totally cancelled for use here. That would be simple and it would certainly be something we could justify.

There has been a lot of thought given to whether that is realistic, what would happen if you did that. There certainly are producers in many other countries who are exporting the same chemicals. Frankly, unfortunately, more and more of some of the bad actors are being made in developing countries themselves.

I think in the long run the only solution is going to be sensible development of regulatory systems in each country. If we can promote that by the process of an improved notification system with timely notification, with technical assistance from EPA and AID here in this country for the AID countries, we would probably go more in the long run toward alleviating the human health and environmental problems in developing countries than a simple, perhaps emotionally satisfying, but not particularly helpful straight ban. That is at least where I come out now.

Mr. BEDELL. Mr. Wasserstrom, you talked something about protective clothing. I am sorry, I did not comprehend what you said. What was that all about?

Mr. WASSERSTROM. In the rush to abbreviate my remarks, I think I probably truncated the point I was trying to make.

Currently, EPA has adopted a procedure of establishing reentry intervals for farmworker protection, certain intervals of time, 24 hours, 48 hours in some cases, after which the pesticide has to dry or settle before workers can be ordered to return to a field. In most cases that provision is suspended if the farmer provides his workers with so-called adequate protective clothing.

In reviewing the scientific evidence about protective clothing, the rate at which pesticide residues penetrate protective clothing and so on and so forth, it turns out that there is very little evidence to support that kind of waiver. It seems that most protective clothing in fact is easily penetrated by available pesticides. What we are urging is that that kind of exemption be abolished, except where scientific evidence becomes available to show that it is viable.

Mr. BEDELL. Thank you very much.

Are there any further questions?

If not, we appreciate your testimony very much. Thank you.

Our next panel is Mr. Lloyd Cline, National Cotton Council, and Mr. Harold Collins, National Agricultural Aviation Association.

Mr. Combest has asked permission to introduce Mr. Cline. We will recognize Mr. Combest.

Mr. COMBEST. Mr. Chairman, I appreciate that very much.

I am certainly proud to introduce to this subcommittee one of my constituents from Lamesa, TX, a gentleman who is not only widely

recognized for his expertise in agriculture in west Texas, but across this country and is here today representing the National Cotton Council.

I would like also to acknowledge the participation and attendance of Mr. Shelton from Hereford, TX, who is here with the National Agricultural Aviation Association. We welcome both of you gentlemen from Texas to Washington.

Mr. CLINE. Thank you.

Mr. COMBEST. Thank you, Mr. Chairman.

Mr. BEDELL. Thank you, Mr. Combest.

As chairman, I would like to thank you for your participation and attendance with this subcommittee.

Mr. Cline, I can assure you that he is very conscientiously working in his duties on this subcommittee.

STATEMENT OF LLOYD CLINE, VICE PRESIDENT, NATIONAL COTTON COUNCIL, ACCOMPANIED BY JIM BROWN

Mr. CLINE. Thank you very much.

I am Lloyd Cline of Lamesa, TX. I am testifying today both as a concerned farmer and as a vice president of the National Cotton Council which represents cotton producers, processors, and handlers in 18 of these great States of ours here in the United States.

I also have with me Dr. Jim Brown with the National Cotton Council, to my left, who is here to assist me in answering any questions that might be of a technical nature that you might raise.

We have submitted copies of a more detailed statement that we would like to have considered and put into the record.

Mr. BEDELL. Without objection, your statement will be entered in the record.

Mr. CLINE. Thank you, sir.

My comments here today will be a summary of that statement.

Basically, Mr. Chairman, we support a simple 1- or 2-year reauthorization of FIFRA. Should the act be open for amendments, however, we respectfully suggest that consideration be given to the following concerns:

We strongly believe that the Federal Government should retain sole authority for setting pesticide residue tolerances. Allowing States to set tolerances would result in mass confusion. One pesticide could have as many as 50 different tolerances of that same commodity.

By the same token, we believe overall authority for regulating pesticides should remain in the hands of the Federal and State governments rather than at the county and the city level.

We think Congress was right in allowing restricted-use pesticides to be applied either by a certified applicator or under his supervision. We believe this provision should be retained.

Congress also was right in providing that a pesticide should not be denied registration just because another pesticide is already registered for that use. Yet, EPA is using this so-called lack of essentiality as a consideration for cancelling pesticides and for decisions on conditional registration of new products. We think Congress should make clear to EPA its intent in this regard.

We support keeping the requirement that EPA compensate owners of pesticide stocks whose registration has been suspended and later canceled, and pay for their disposal.

We strongly favor requiring all imported farm commodities and products processed from them to meet our residue tolerance standards.

We further believe that FIFRA should be amended to make clear that EPA has statutory authority to set pesticide action levels as well as the tolerances.

We strongly oppose any amendment to insert a so-called "private right-of-action" provision in FIFRA. Instead of enhancing protection under FIFRA, such a provision would only serve to encourage additional lawsuits.

For similar reasons, we also oppose any new provisions to give the public standing to initiate suspension or cancellation hearings.

On the matter of registration guidelines, considerable progress has been made toward developing them in such a way that potential pesticide registrants will know what registration requirements are. However, there appear to be continuing incidents of registration being delayed because requirements not covered in the guidelines have been added. In the case of pond or aquatic studies, the agency doesn't seem to know what the requirements should be.

We strongly oppose transferring any authority over the farm use of pesticides from EPA to OSHA. Such action would only increase Federal costs and place additional regulatory burdens on farmers.

We believe the present Federal pesticide applications standards are adequate, and we oppose establishment of unnecessary buffer zones, unworkable notification requirements, and other standards without valid scientific proof as to their necessity.

We also oppose any increase in pesticide registration fees. They would result in higher pesticide costs that would be passed on to farmers and ranchers.

We also have serious reservations about eliminating adjudicatory hearings because of the serious consequences on farmers and ranchers. We think the current two-stage process is neither too long nor unfair.

Finally, Mr. Chairman, we want to commend EPA for the new approach it took in revising the section of FIFRA relating to exemptions for emergency use of pesticides. Instead of developing and proposing new regulations on its own, the agency established a 21-member negotiating committee to write them. The committee included representatives of farm organizations and other user groups, environmental organizations, the farm chemical industry, State pesticide and health agencies, USDA, and EPA.

We would hope to see EPA take such an approach on more of the major pesticide regulatory issues.

Mr. Chairman, thank you for allowing us to be here today and to express our views and concerns in this matter.

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

Mr. BEDELL. Thank you, Mr. Cline.

Mr. Collins.

STATEMENT OF HAROLD COLLINS, EXECUTIVE DIRECTOR, NATIONAL AGRICULTURAL AVIATION ASSOCIATION

Mr. COLLINS. Mr. Chairman, thank you for giving the Agricultural Aviation Association an opportunity to testify today.

Along with the testimony, we have made two attachments to it which we would like to offer for your further consideration in the record, sir.

Mr. BEDELL. Without objection, the attachments will be entered in the record.

Mr. COLLINS. Thank you.

My name is Harold Collins. I am employed as the executive director of the National Agricultural Aviation Association, headquartered in Washington, DC. The organization is a federation of State and regional associations throughout the United States. The members of the association include individual agricultural aviation businesses, agricultural pilots, allied industries who supply the products and services we use, international persons and companies from 18 nations around the world.

In this country we represent about 3,000 operating companies who own and operate approximately 10,000 agricultural aircraft, of which 900 are helicopters and the rest are fixed wing.

During the course of a normal year, whatever that is, we fly approximately 2,600,000 hours. We consume approximately 90 million gallons of aviation fuel, which we believe to be very energy efficient. We apply seed, fertilizer, and crop protection chemicals.

With regard to the hearing, NAAA, sir, has not had time to communicate with its board of directors and the legislative committee on the recently introduced legislation.

As a consequence, Mr. Chairman, we respectfully request that we might be able to provide you with additional comment in the future in a timeframe consistent with your subcommittee's needs, if that would be appropriate.

Yesterday, based on the testimony of Representative Seiberling, I want to relate to the subcommittee that EPA did not ban the aerial application of Lasso or Alachlor, as had been suggested. That was entirely a Monsanto decision, according to Mr. Steve Shatzow, who is EPA's Director of the Office of Pesticide Programs. Immediately following Mr. Seiberling's testimony yesterday, I went and explained the situation to him and he is consistent with that now.

In fact, Monsanto has recently supplied new data to the agency which may, indeed, result in the reinstatement of the aerial application method to the Lasso label.

For future consideration, we would like to offer the following thoughts to the committee: Earlier this year NAAA participated in and was one of the numerous sponsors of a pesticide waste disposal conference held in Denver, CO. Attendees to this conference included numerous State, Federal, and public entities, all of whom were vitally concerned with pesticide waste disposal, as we are.

Our observations from that conference are attached to this testimony, which is copied from our association magazine. We hope you will find that helpful.

Based on ideas generated at this conference, NAAA would like to suggest that the subcommittee consider requiring that pesticide

waste disposal be regulated exclusively under section 19 of the FIFRA rather than the Resource Conservation and Recovery Act.

We believe that private and commercial pesticide applicators alike are simply unable to comply with RCRA. If we use the existing technology available to us today to create waste disposal regulations under FIFRA that are both practical and attainable, I believe the agricultural community would welcome the opportunity to be able to comply with the law for the first time.

Mr. Chairman, it also seems to our association that medical studies of long-time pesticide users in the agricultural community could provide strong evidence of health consequences associated with pesticide exposure. Such a study might even reduce the conjecture associated with laboratory animal test data which we are invariably trying to extrapolate into human terms. We certainly would end up knowing more than we know today by such a study.

NAAA would like to suggest that EPA conduct a nationwide health study of pesticide users. We suggest this because we as a group are voluntarily and repetitively exposed to pesticides at levels greater than the general public. If you can agree with that and agree with the dose-response relationship, it seems to us that we would be able to provide some valuable medical knowledge to the world.

In 1978 we funded, as an organization, an epidemiological study of pilots, their spouses, and children. We funded the study because the Government at that time was totally disinterested in such information. The control group in this study was the siblings of agricultural pilots, their spouses, and their children as long as they had no involvement in aerial application or pesticides.

The ultimate benefits of that study showed that there was no significant difference between the agricultural pilots with exposure levels and their siblings with no exposures. We think that the lack of a difference was important, and that was, indeed, the conclusion of that study.

Finally, sir, we appreciate the work this committee has accomplished on pesticide legislation over many, many years. We commend and support your continued singular oversight on these issues.

We thank you.

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

Mr. BEDELL. Thank you very much, Mr. Collins.

Mr. Combest.

Mr. COMBEST. Thank you, Mr. Chairman.

Mr. Cline, on the original testimony which you submitted to the subcommittee that we had looked through, on page 2 you were talking about buffer zones. It seems to me, if my memory serves me correctly, that a few years ago there were some States that were proposing buffer zones which would have, in effect, in a 160-acre field only have allowed about 40 acres of that to be sprayed or be treated. Do you know where that issue stands today? Where are they on that issue as far as proposed buffer zones? Do you know?

Mr. CLINE. Dr. Brown, are you in a position to answer that question?

Mr. JIM BROWN. There are buffer zones established by certain pesticides. The State of Texas just this past year—well, it went into effect, I believe, in January—buffer zones for certain categories of pesticides.

Mr. COMBEST. How extensive are those, Mr. Brown? In some of those areas is there a criterion or what are the criteria for establishing that buffer zone? Is there an amount of a field, for example, that is not allowed to be sprayed on the exterior or toward——

Mr. JIM BROWN. It is a distance, and it is basically—excuse me.

Mr. COMBEST. I am sorry.

Mr. JIM BROWN. It is based not only on the pesticide, but the proximity to such facilities as school grounds, public playgrounds, hospitals, and this type of facility.

Mr. COMBEST. Different States, though, are adopting different types of buffer zone programs?

Mr. JIM BROWN. Yes.

Mr. COMBEST. The second question, Mr. Cline: In the testimony of supporting Federal preemption for tolerance setting, do you feel that most States have the capability, scientific capability, of establishing tolerances?

Mr. CLINE. I don't believe they do. I would recommend that the Federal Government set those tolerances, so you would not have a conflict between the different States on the different tolerances that would be allowed.

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

Mr. BEDELL. Thank you, Mr. Combest.

Mr. Roberts.

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

Mr. BEDELL. Mr. Volkmer.

Mr. VOLKMER. I have no questions.

Mr. BEDELL. Mr. Morrison.

Mr. MORRISON. Thank you, Mr. Chairman.

Mr. Collins, I was interested in your medical study that had been done. I would like to have you amplify a little on that.

I have attempted to skim through the results, conclusions, and so forth. In essence, I sense that the report said that there is no significant difference on the total health systems between aerial applicators, as exposed as they are on a daily basis to these pesticides we have been hearing about today, and their families.

Mr. COLLINS. That is correct, sir.

Indeed, if I may add to it, this survey was replicated by the U.S. wheat growers' organization. Their conclusions were identical to ours. However, the difference in health was statistical significant between the wheat grower who had the better health and the control group who were not involved with pesticides.

More recently, and as yet unreported formally, there is work going on at the University of Nebraska by Drs. Gold and Olson, two of the gentlemen I know involved, where they have been studying commercial applicators for the past 3 years. Their data tends to support this data which was done earlier in that there are no significant differences in the health of persons who are highly exposed versus those who have what might be considered standard exposure through diet or occasionally driving through the country.

Mr. MORRISON. One other question not related to the study: my understanding in talking with aerial applicators in our area is that there is increasing difficulty in getting insurance to cover the problems with perhaps spraying near someone else's property or a home, that sort of thing. Is that accurate?

Mr. COLLINS. Yes. Insurance premiums have been increasing. One of the problems, however, is the source of underwriting has been principally Lloyds of London. There are domestic underwriters, but Lloyds is the principal. They have found underwriting other forms of insurance is more profitable.

Many of our people this year are paying premiums no different than they were several years ago. Many, however, have had their premiums tripled. In some cases this might be due to problems that they have had—hull problems, the airplane crashed, or drift problems where material left the target cite and did, indeed, cause damage.

Mr. MORRISON. Is it fair to assume, then, that the legal remedies that someone would have under today's ground rules are working?

Mr. COLLINS. Yes, sir, they are.

Mr. MORRISON. In essence, what that is saying, if it is more difficult to get insurance in this area, it must reflect that there have been greater losses where in fact materials have left the target, to use your term.

Mr. COLLINS. One of the problems, as like all insurance, I suppose, is the difference of opinion between the plaintiff and the defendant in the degree of damage that was done, if any, and sometimes, sadly, in the insurance industry there is a payout, an out-of-court settlement which occurs in spite of the fact that there was perhaps no damage, but it is cheaper than litigating. The insurance industry is not prone to spending more money to win when it can spend less money and admit guilt. That is sadly the case in some situations.

Mr. MORRISON. Thank you very much.

Thank you, Mr. Chairman.

Mr. BEDELL. Thank you, Mr. Morrison.

Mr. Collins, do you have studies or reports that you could submit to the subcommittee that indicate those who have had high exposure do not necessarily show any greater health effects than those that have not?

Mr. COLLINS. Yes, sir. The one report that our association conducted is attached to the testimony. I would be more than happy to provide one accomplished by the Wheat Growers Association, and I will be receiving a copy from the University of Nebraska in the near future, because they are concluding a 3-year study right now.

Mr. BEDELL. The reason I ask is that our job is to try to learn as much as we can and be as objective as we can.

Mr. COLLINS. Yes, sir.

Mr. BEDELL. Mr. Feldman, in his prepared statement, said, and I probably ought to read the paragraph here:

> The public interest concern is not an abstract concern of numbers. A January 1981 report issued by the Council on Environmental Quality, "Chemical Hazards to Human Reproduction," cites various studies of male and female workers exposed to pesticides. These studies report impotence, chromosome aberrations, infertility, miscarriages, and other adverse effects on reproduction.

A University of Iowa study in 1982 found that Iowa farmers faced greater risk of six types of cancers than city dwellers. According to researchers, the cancer rate is an occupational hazard of farming not related to smoking, as confirmed by other studies around the world.

I don't know if that is right or wrong. Our job is to try to sort out the facts and try to be as objective as possible. Any studies that you have I think we should get, so that our staff can look at them, and then we should give him the opportunity to give any studies that he has that we could look at, to try to determine whether or not the concern, as is expressed by many people, is justified.

Any further questions?

If not, the subcommittee will be adjourned until 2 o'clock this afternoon.

I want to thank everybody for their great cooperation this morning.

[Whereupon, at 11:40 a.m., the subcommittee recessed to reconvene at 2 p.m. the same day.]

AFTERNOON SESSION

Mr. BEDELL. The subcommittee will come to order.

I know there are other committee meetings taking place, so we may have our members in and out.

Mr. Brown, do you have a statement before we start?

Mr. BROWN. No, Mr. Chairman.

Mr. BEDELL. If not, we are pleased to have our colleague, Cecil Heftel, here from Hawaii.

I might tell you, Cec, first of all, how pleased we are with the recovery that you have seen since your accident.

Mr. HEFTEL. Thank you.

Mr. BEDELL. We are awfully glad to have you back. We look forward to your testimony.

STATEMENT OF HON. CECIL (CEC) HEFTEL, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF HAWAII

Mr. HEFTEL. Thank you very much, Mr. Chairman, committee members.

I would like unanimous consent to summarize and have my statement placed in the record.

Mr. BEDELL. Without objection, that will be done.

Mr. HEFTEL. H.R. 1416 was drafted by me in response to inadequate pesticide monitoring system on the part of our EPA. EPA does not collect sufficient information about pesticide products leaving this country. FDA cannot adequately monitor residues when it has so little information about what to look for.

We offer a plan, if you will, which would enable FDA to monitor what it is that is coming into this country that has already used a pesticide that may have been banned in the United States. Ideally, we should ban the export of any pesticide that is not registered for use in the United States and ban the import of any food commodity that has been treated with a pesticide not registered here, but this would be politically unfeasible.

Congress would be accused enacting trade barriers. U.S. pesticide manufacturers would threaten to move their operations abroad.

So the provisions of H.R. 1416 are designed not to hamper American export of pesticides but the bill would increase the amount of information EPA receives about which pesticides are exported from the United States, their destination, and the products to which they will be applied; require nations importing pesticides not registered for use in the United States to acknowledge that they understand the dangers of the pesticides and how to safely use and dispose of them.

The enactment of the provisions of H.R. 1416 would ideally assure American citizens that their health is not being compromised, assure farmers that they are competing on an equal basis with their foreign counterparts, and make the United States a better trading partner by taking the lead in promoting pesticide safety standards and showing that they do not wish to treat the rest of the world as a dumping ground.

Simply stated, we would know more about what is happening to pesticides banned in the United States which are exported for use and make sure that we have a system of protecting ourselves from receiving commodities that have been treated abroad by those pesticides to come back in for consumption in the United States, when the original purpose in banning the pesticide was to avoid consumption of commodities involving those pesticides.

I thank you, Mr. Chairman, and would be delighted with any dialog you wish to enter into.

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

Mr. BEDELL. Thank you very much.

Mr. Brown.

Mr. BROWN. Mr. Heftel, could you give me an indication of what led to your concern about this issue?

Mr. HEFTEL. I had a meeting with our farmers in Hawaii about 4 years ago and, by accident, found out that pesticides were being used on products being imported by us that were banned in the United States. So we were receiving agricultural products which had been treated with pesticides that are not permissible for use in the United States, and that just didn't make any sense. That is what commenced my interest, and then I did further investigation and found out that it was fairly prevalent that pesticides were finding their way abroad and then used on commodities coming back into the United States from such places as Mexico, right across the border, which you perhaps would be more familiar with than I in terms of that occurrence.

Mr. BROWN. I am familiar with it. I am familiar with the problem. I think it does need to be addressed, and I want to commend you for making the proposal that you have in H.R. 1416.

It is a complex problem, and I am not sure how well we will be able to address it here, but I think you have helped to focus our attention on it. I hope we will be able to take some action.

Mr. HEFTEL. I would appreciate the committee's input and modification in redesign or totally new design of legislation that would address the problem. I would not be as intimately aware of all the facts as I think you people are, and particularly yourself in California, but I do know it is a problem that should be addressed. I think it can be addressed. I would hope that the committee would provide

that leadership, because all I am really doing is sort of starting the dialog.

Mr. BROWN. Well, we appreciate that and we will make every effort to carry on that effort.

I have no further questions.

Mr. BEDELL. Cec, does your bill simply call for notification in case these chemicals are sold to foreign countries.

Mr. HEFTEL. Yes.

Mr. BEDELL. Notification of the dangers involved?

Mr. HEFTEL. Yes. We haven't gotten into the question of sanctions at all.

Mr. BEDELL. But that is all it does——

Mr. HEFTEL. Yes.

Mr. BEDELL. It is just notification?

Mr. HEFTEL. That is correct; yes.

Mr. BEDELL. Have you found anybody who is opposed to that?

Mr. HEFTEL. I have not found anybody opposed because it is hard to be opposed to a statement which says we don't want products to come in with pesticides that were banned in the United States because they are harmful to the health of the people of the United States, only to be imported on products produced abroad.

Mr. BEDELL. We had some testimony in opposition, but I am not sure I understand it, if all it is notification, if it is simply a requirement that any foreign purchasers be notified that that product is banned and there could be some health problems with it.

I guess that is all you are asking, as I understand it.

Mr. HEFTEL. Well, plus beefing up the way that we know how to examine products coming back to determine whether or not you have those pesticides on those products, but that is an internal administrative problem for us. It certainly would not involve either private industry or the foreign governments. It would just basically protect us from those products coming in, and knowing how to find out whether or not they have, in fact, been treated with the illegal pesticides and should not be permitted for importation.

Mr. BEDELL. Or if they contain residues of that pesticide?

Mr. HEFTEL. Yes; well, residues.

Mr. BEDELL. That is what you meant?

Mr. HEFTEL. Yes; a method for determining what your residue is.

Mr. BEDELL. The only problem we have is that it does take money to properly check all that.

Mr. HEFTEL. Where have I heard that before?

Mr. BEDELL. And we have a heck of a problem getting the money we need.

Mr. HEFTEL. I think we ought to at least start by having the notification program and putting the ideal program in place pending funding.

Mr. BEDELL. Sure.

Mr. HEFTEL. Even the threat perhaps, though I don't think we would carry it out, but perhaps it should be entertained in the dialog, of simply saying, "We're not going to permit the sale of pesticides abroad that are produced here," but I don't think that that accomplishes anything. You force your pesticide manufacturers abroad, and you just do a lot of things that are not going to work as a practical matter.

I think we should at least have dialog pointing out that we have gone through the scenario and do understand why that would be undesirable and want to use the more moderate approach.

Mr. BEDELL. Mr. Evans, do you have any questions?

Mr. EVANS of Iowa. No, I have no questions.

Mr. BEDELL. We thank you very much for your effort, and we will certainly be following your work.

Mr. HEFTEL. Thank you.

Mr. BEDELL. Our next panel consists of Mr. Milan Yager, legislative director, United Fresh Fruit & Vegetable Association, and Mr. Lawrence T. Graham, executive vice president of the National Food Processors Association.

Mr. Graham is accompanied by Clausen Ely, I believe it is, counsel for the National Food Processors.

Mr. Yager served on my staff for some long time. I have never had an opportunity to really go after him with questions before. [Laughter.]

We will hear from you first, Milan.

STATEMENT OF MILAN P. YAGER, LEGISLATIVE DIRECTOR, UNITED FRESH FRUIT & VEGETABLE ASSOCIATION

Mr. YAGER. Thank you, Mr. Chairman.

I am Milan Yager, legislative director of United Fresh Fruit and Vegetable Association. It is an honor for me to appear before you today and this subcommittee and to share with you the thoughts of United's membership.

I am going to summarize my statement and, with permission of the chairman, I would like to submit the formal statement for the record.

Mr. BEDELL. It will be entered in the record.

Mr. YAGER. Thank you.

United is the national trade association of the fresh produce industry, with 2,500-member companies throughout the United States and in 14 countries. We are involved in all facets of the fresh produce industry including growing, shipping, wholesaling, and retailing of fresh produce. United's members handle over 80 percent of all fresh produce marketed commercially in the United States.

We agree with the Assistant Administrator John Moore when he testified before this subcommittee and stated that the FIFRA was a fundamentally sound environmental statute. However, our membership also believes that FIFRA is a sound agricultural statute.

American farmers produce the safest and most wholesome food in the world under this statute, food that is abundant, available, affordable, and appealing. As users of federally registered pesticides, consumers of food products, and citizens concerned about our environment, let me share with you some concerns of our membership.

Under the legislation introduced by Congressman Roberts and yourself, changes are made regarding applicators under supervision. Our memberships is currently reviewing your proposal and will provide members of the committee copies of our report when it is finished.

However, United's current policy is that existing law and regulations for private applicators provide the needed protection to insure the safety of farmers, farmworkers, and the environment.

Under 40 CFR 171.6(a), the availability of a certified applicator must be directly related to the hazard of the situation. Where the certified applicator is physically not present, verifiable instructions to a competent person must be provided detailing guidance for applying the pesticide.

Furthermore, under section 2(e)(4) of FIFRA, the Administrator may require by the label the actual physical presence of the certified applicator.

Our members are also concerned about sections 11 and 13 of your legislation which eliminates indemnity payments as well as the Administrator's authority to provide the safe and proper disposal of hazardous pesticides.

It is in the public's interest that when all scientific and legal safeguards fail, the production, sale, and use of hazardous pesticides be immediately halted and that these products be safely disposed. Farmers who purchase federally registered pesticides should not suffer the economic loss of these cancellations.

Please note that we are talking about a limited Federal financial exposure since we are only talking about pesticides that were cancelled to prevent an imminent hazard. We believe this is a small price to pay for the elimination—and, mind you, the safe disposal—of hazardous pesticides.

Finally, Mr. Chairman, let me comment on an area of great concern to the food industry which we suggest needs to be addressed in your amendments.

The Administrator of EPA has the responsibility for registering pesticides, establishing conditions for their use and application, and also the authority and responsibility to establish tolerances for pesticides on raw agricultural products. A tolerance is the maximum residue level that the crop may contain at the time it leaves the farm gate under the most strenuous conditions of pesticide use. The tolerance thus represents a level of residue that provides the consumers with the safest possible food products. The establishment of a tolerance for a particular pesticide commodity is a scientific and technical task that requires the funding, staffing, and facilities of the quality of the Environmental Protection Agency and the Federal Government.

Consumers throughout the United States rely upon EPA to guarantee the safety of raw agricultural products. Products safe to be sold in one market or region of the country should be safe throughout the United States.

Statutory language is needed to continue to assure consumers of uniform safe tolerances throughout the United States. Section 24 of FIFRA should be amended to prevent multiple pesticide commodity food tolerances in different areas of the country, a possibility that destroys consumer confidence in Government regulatory food safety, hampers interstate commerce, artificially inflates food prices, and frustrates and disrupts the agricultural marketing practices.

To avoid this regulatory chaos, language is needed to be adopted to section 24 of FIFRA to assure consumers of safe, wholesome food under a national uniform tolerance.

Mr. Chairman, all of us—Government, industry, farming, and public interest groups—have a common responsibility to respect and protect our environment and to provide consumers healthy and safe food. To this end, we pledge our cooperation.

I would be happy to answer questions.

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

Mr. BEDELL. Thank you very much, Milan.

Mr. Graham.

STATEMENT OF LAWRENCE T. GRAHAM, EXECUTIVE VICE PRESIDENT, NATIONAL FOOD PROCESSORS ASSOCIATION, ACCOMPANIED BY CLAUSEN ELY, COUNSEL

Mr. GRAHAM. Thank you, Mr. Chairman.

I am Larry Graham, the executive vice president of NFPA. I am accompanied today, on my right, by Clausen Ely, legal counsel to NFPA with Covington & Burling.

The National Food Processors Association is a scientifically and technically based association that represents about 450 member companies that pack processed prepared fruits, vegetables, meat, fish, and specialty products including canned, frozen, aseptic, dehydrated, pickled, and other preserved food items. In addition, we have about 150 member companies that manufacture packaging and processing equipment, and supplies, or provide services to the food processing industry.

It is very important to our membership, which includes some of the largest food processing companies, that they have an abundant selection of quality raw agricultural products for the production of a wide variety of processed food products.

For this reason, FIFRA is an important agricultural statute not just to the farmer who needs the maximum possible yield per acre, but also to the food processor who needs an economical, high quality, raw ingredient for his food products. Our members process these raw products into a wide variety of food products which are distributed across State lines.

During such processing, pesticide residues are usually significantly reduced by washing, trimming, peeling, and other operations. For many pesticides, the residue levels are reduced below the level of detectability. For others, residues can be detected, but the levels are significantly less than the amount that was on the raw product before processing. EPA establishes, as you know, the tolerance for safe levels of pesticide residues that may enter into State commerce.

Today I would like to just briefly comment on four issues that we have identified as of special interest to the food processing industry: The national standard for pesticide residue tolerances, lack of essentiality, indemnification, and applicator certification.

The vast majority of NFPA members produce food products sold in more than one State. In fact, most are active in the national market. To be efficient, food production, distribution, and process-

ing must be a national undertaking. Interstate commerce should not be disrupted. The ease of shipment across State lines must be assured.

For these reasons, NFPA requests that this subcommittee amend FIFRA to provide that no State or local jurisdiction may issue a pesticide tolerance in addition to or different than one established by EPA.

FIFRA is a comprehensive pesticide regulatory statute. Section 24 governs the Federal-State relationship in regulating pesticide use and prescribes in detail permissible State pesticide regulatory and enforcement activities.

Section 24 already prohibits State pesticide labeling or packaging requirements in addition to or different from those required under FIFRA. It should also prohibit additional or different State or local residue tolerances.

Only the Federal Government, in our opinion, has the resources and expertise to gather and evaluate the relevant safety, residue, and economic data to determine an appropriate national residue limit. There must be only one standard for pesticide residues in food, and that standard should be established by EPA and not by 50 different States or thousands of local jurisdictions.

The States would retain full authority to enforce pesticide residue tolerances and to coordinate with EPA in setting appropriate national tolerances.

Section 3 of FIFRA prohibits the Administrator of EPA from denying registration of any pesticide simply because another pesticide is registered for the same use. This is referred to as lack of essentiality. We feel strongly that FIFRA section 24(a) should be amended to provide that States are also prohibited from using lack of essentiality as the sole criteria in denying registration of a pesticide. Alternative pesticides are essential for maximum flexibility and pest management programs.

I do want to emphasize that NFPA is not asking that section 24(c) be amended. A prohibition against use of lack of essentiality would not impair State authority to deny approval for pesticides on other grounds other than lack of essentiality.

The food processing industry must have the assurance of safe agricultural products. We, therefore, would support stricter certification programs for pesticide applicators, including better guidelines for the individual applicator.

If all the scientific and legal safeguards fail, and a pesticide is banned on the basis of new data, there should be a mechanism for the orderly marketing of existing food stocks treated with that pesticide. Otherwise, FIFRA should be amended to provide for indemnification of food processors for the fair market value of existing stocks of food products to which pesticides were legally applied but which are rendered illegal by subsequent regulatory action.

FIFRA currently provides for indemnification of pesticide manufacturers for the existing stocks of suspended pesticides, but there is no comparable protection for food processors whose products are produced in compliance with all legal guidelines.

That concludes my testimony. I would be happy to answer any questions.

Mr. BEDELL. Thank you, Mr. Graham.

Mr. Brown.

Mr. BROWN. I would like to say that the testimony from both of you gentlemen seems imminently reasonable and suggests some things that——

Mr. BEDELL. Would the gentleman yield?

Mr. BROWN. Yes.

Mr. BEDELL. That's because I trained Milan in my office. [Laughter.]

Mr. BROWN. I hope we can include your recommendations in the bill as we go through markup.

Mr. Graham, the problem of indemnification is going to be a sticky one, however, because obviously we are not consistent at the present time. We are indemnifying manufacturers or distributors when a pesticide is banned; we are not indemnifying the people in your industry who may suffer even greater loss.

Could you refresh my memory as to how the problem was handled in the case of the EDB ban last year or a year or two ago?

Mr. GRAHAM. Congressman, I was not around then, but I think Mr. Ely would be happy to answer that question.

Mr. BROWN. Mr. Ely.

Mr. ELY. As you note, the statute currently provides for indemnification of those who possess the chemical that is suspended, which would include manufacturers, distributors, and users of the chemical. It is my understanding that those individuals who owned existing stocks of EDB at the time it was suspended did make claims for indemnification. I don't know whether they have been paid yet. But those food companies that were in possession of products that were rendered illegal by removal of the tolerance exemption for EDB, to the extent they had to destroy their food products, of course, they did not qualify for indemnification and did not ask for any.

Mr. BROWN. How did they handle their losses?

Mr. ELY. I don't know.

Mr. BROWN. Ate them?

Mr. ELY. I think so.

Mr. BROWN. What I'm really trying to get at is whether the ordinary process of business insurance may have covered some of that loss. I am sure you gentlemen recognize that EPA has recommended not to extend the indemnification program but we curtail the indemnification program.

Mr. GRAHAM. We do recognize that.

Mr. BROWN. Can you tell me if, from your knowledge, the industry was able to spread its losses through insurance?

Mr. GRAHAM. I don't know the answer to that. We can certainly provide you the answer to that question. I don't know if they have insurance that covers——

Mr. BROWN. I think it would be useful if we could determine whether or not that was an insurable loss. It does not make the loss any less, but it means that it is covered as a part of your normal payments to your insurance carriers as a business—whatever.

Mr. GRAHAM. We would have to ask a few of our member companies to see what happened in that situation.

Mr. BROWN. All right. If you could do that, I would appreciate it.

Mr. GRAHAM. Sure.

Mr. BROWN. I appreciate your testimony. Thank you.

Mr. BEDELL. Mr. Evans.

Mr. EVANS of Iowa. I have no questions, Mr. Chairman.

Mr. BEDELL. Mr. Staggers.

Mr. STAGGERS. I thank the two gentlemen for their testimony, but I have no questions, Mr. Chairman.

Mr. BEDELL. Do you know how effectively the FDA is conducting the tests of your fruits and vegetables?

Mr. YAGER. Are you speaking of domestic products?

Mr. BEDELL. Yes. If I am growing vegetables for the domestic market and I am selling them to the local stores, and so on, is it likely that those will be checked for residues of chemicals? I presume that requires a test by a chemist somehow.

Mr. YAGER. The FDA does monitoring samplings throughout the United States to guarantee the consumer that products that are marketed in the United States meet those residue tolerances.

I do not have the statistics on how many products they actually sample. It is a small number, but it is a number sufficient to guarantee the consumer that those products are meeting the residue standards.

They do the same thing on imported products. They do samplings at all the ports.

Mr. BEDELL. We understand that at least in the case of some imported products—such as pork from Canada—the fact of the matter is that there is very little testing occurring.

I guess the concern I would have—and I don't know if it is even a legitimate concern—would be that certainly the amount of residue on cabbages, if you want to use that, would I think vary greatly according to the individual farmers. Some farmers possibly would use a great deal more than others. If you only have spot checking, I would think there would at least be the possibility that we could be getting vegetables that would have way more than the allowable minimums of residues on them. I don't even know how big a problem that is or if that occurs.

Mr. YAGER. Pesticides are an expensive item of the production cost, just one of a number of different items. I think that it is the responsibility of the farmer to try to produce that product as low as possible cost. They probably are not going to apply additional pesticides than they need to.

Second, the adage that some is good and a lot is a lot better does not work with pesticides because too much can often damage the product.

Third, if too many pesticides are applied to a product and they are rendered adulterated, then the entire product is lost and that could be an expensive hazard to the farmer's entire crop. The farmer has that responsibility to try to keep those residue levels down.

Last, Mr. Chairman, is that when a residue is set for a particular product, it is set at the highest maximum residue level at the farm gate, not necessarily at the market, such that we determine the maximum number of applications, the closest period of time that the pesticide can be applied to the product before it is harvested, and all these tests are made at the maximum level. Rarely, if ever,

FDA has testified before this committee last year—very seldom do products ever even reach that residue level. The residue levels are normally set very high in protection of the public.

Mr. BEDELL. Any further questions?

If not, we appreciate your testimony very much.

Mr. YAGER. Thank you.

Mr. BROWN. Mr. Chairman, may I ask unanimous consent to include in the record at this point a statement by the CRS on this subject of FDA monitoring which occurs on page 14 of the study. The study is a part of the record, I presume, but this deals specifically with the level of monitoring, the number of samples, and so forth. I think it would be relevant.

Mr. BEDELL. Without objection, that will be made part of the record.

[The material follows:]

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FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT REAUTHORIZATION ISSUES BEFORE THE 99TH CONGRESS

Prepared at the Request of the
House Agriculture Subcommittee on Department Operations,
Research, and Foreign Agriculture

James Aidala
Analyst
Environment and Natural Resources Policy Division
February 27, 1985

At that time, after the Registration Standard has been issued, the registrants will be required to develop the necessary data.

III. FOOD WHOLESOMENESS--PESTICIDE RESIDUE TOLERANCES

As part of a registration decision for pesticides used on food, EPA makes a determination of what level of a pesticide residue is safe for the eventual consumers of the treated crop. EPA grants a "tolerance" for allowable pesticide residues which will adequately protect public health. This is an amount EPA calculates as safe, assuming a lifetime of exposure to the treated crops. EPA also assumes, as part of this calculation, that all of the crops which the pesticide might be used on are treated. In this way, EPA tries to assure a wide margin of safety, as these assumptions are intentionally conservative.

A. Federal Agency Coordination

EPA determines the tolerance, but monitoring and enforcement of these limits is done by the Food and Drug Administration (FDA). For raw agricultural commodities, such as unprocessed fruits and vegetables, the tolerance is established under authority of FIFRA. For processed foods, such as grain flours and processed vegetable products, the tolerance is established under authority of the Food, Drug, and Cosmetic Act (FDCA). This is because a pesticide residue is considered a "food additive" after the raw commodity has been processed. Section 409 of the FDCA includes the Delaney Amendment, which prohibits food additives which have been identified as animal carcinogens. However, Section 402 of the FDCA states

that a foodstuff cannot be considered edulterated if the residue level in the processed food is the same or less that the level allowed on the raw agricultural commodity. So the Delaney Clause prohibition only applies if the pesticide residues concentrates in higher amounts in the processed food.

This regulatory situation has been controversial for years, and the EDB incident in 1984 raised a variety of questions about the current system for tolerance assessment and monitoring. Subjects of concern included the adequacy of FDA methods (both sampling and analysis) and EPA's assessment of allowable residues.

Monitoring actual residue levels is the responsibility of the FDA. The FDA collects samples of food sold in interstate commerce from various parts of the country, and analyzes the food to see if allowable residue levels have been exceeded. However, FDA states that it does not have the capability to routinely analyze foods for the presence of over half of the pesticides registered for use on food (over 300 active ingredients are used on food products). Furthermore, FDA reports that the usual number of pesticides analyzed is far less than this number. FDA was especially criticized for these policies during hearings before the House Energy and Commerce Committee during the summer of 1984. These findings were presented at hearings held to consider a bill to accelerate the generation of chronic health data about food use pesticides (H.R. 5495).

Also criticized at the hearing was the usually low number of samples taken each year by FDA (approximately 10,000), and FDA's ability to track

down contaminated shipments of food (especially imported commodities). Currently FDA allows shipments to continue through the marketing chain after a sample is taken (to avoid spoilage of the shipment while waiting for the results of the analysis). FDA responded that more extensive sampling was very expensive, and that it had developed a system based spot checking of shipments and previous experiences with particular foreign producers to prevent contaminated shipments with a minimum of program expense and delay in the marketing of agricultural products.

B. EPA Tolerance Reviews and Exemptions

The 1982 DORFA Subcommittee staff report criticized the Agency review procedures and policies for setting tolerance levels, claiming that EPA had increased allowable risk levels from residues, and had permitted the use of animal carcinogens on processed foods (which would make the residue a food additive and subject to the restrictions of the Delaney Amendment). EPA was also criticized for allowing the sum of Theoretical Maximum Residue Concentrations (TMRC--the level of a pesticide which would be eaten if all of the commodity consumed contained the pesticide) to be greater than the Allowable Daily Intake (the amount determined to be the maximum which can be safely consumed on a daily basis). These issues may be revisited during the FIFRA reauthorization debate.

Another related issue, highlighted by the EDB situation, is the existence of exemptions from tolerance requirements for a variety of pesticides. For a time, if it was believed that residues of the pesticide dissipated after application or during processing, the pesticide

Mr. BEDELL. I would also, without objection, ask that a statement by our colleague, Frank Horton, be entered into the record. Without objection, it is so ordered.

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

Mr. BEDELL. We next have a panel consisting of Mr. George Miller, Pesticide Producers Association, accompanied by Bob Hasness; Mr. Kenneth Weinstein, McKenna, Conner & Cuneo; and Mr. Ralph Engle, president of the Chemical Specialties Manufacturers. I understand he is accompanied by Charles Frommer.

Mr. ENGEL. Mr. Chairman, we just need to change one name. Mr. Frommer is not with us; Mr. Stickle has joined me.

Mr. BEDELL. We're stuck with Stickle, are we? [Laughter.]

Thank you.

We will have Mr. Miller or Mr. Hasness first. We are asking everybody to hold to the 5-minute timeframe.

STATEMENT OF ROBERT HASNESS, PRESIDENT, PESTICIDE PRODUCERS ASSOCIATION, ACCOMPANIED BY GEORGE MILLER, CHAIRMAN, LEGISLATIVE COMMITTEE

Mr. HASNESS. Good afternoon, Mr. Chairman and members of the subcommittee.

My name is Bob Hasness of Terra Corp. of Sioux City, IA. I am the current president of the Pesticide Producers Association. Accompanying me is Mr. George Miller of Trans Chemic Industries, who is the chairman of our legislative committee.

The PPA is a nonprofit trade association made up primarily of small-to medium-sized businesses engaged in the formulation, manufacture, and distribution of agricultural chemicals in the United States. For the majority of their business, our members rely upon the production of generic pesticides. Those are those products on which the patent has expired.

Our membership provides a much needed service to the agricultural community in securing and distributing those chemical tools necessary to allow all of us to enjoy an abundance of agricultural products at a fair and competitive price.

We regret that we are unable to provide the committee with our complete written testimony today, but we just received a copy of the bill last Friday. We do have a request that the record be held open for a short period of time so we can provide you with our detailed information.

We will briefly address those areas which we believe will present problems to us. No. 1, we are opposed to the listing of inerts in the ingredients statements of pesticide labels. The original intent of the ingredients section of the label was to provide information to the consumer on the amount and type of active ingredients in a product in order to protect him from fraudulent manufacturers. The inclusion of inert ingredient information on the label will not provide the consumer any additional information of value in making an informed purchase. It will only add useless information to a label which is already confusing enough.

To include inert ingredient information on the label will, however, provide the competitors of a manufacturer with trade secret in-

formation and the opportunity to duplicate months of someone else's formulation development in only a short period of time.

Also, a variety of manufacturers produce, under various trade names, inerts which give similar results in formulations. Formulators often continually switch inerts based on pricing and availability. In addition, the ratio of inerts used often varies from day to day.

Under these proposed amendments, each pesticide-producing establishment would almost need a full-time printing operation just to handle the various labels which would be needed on a daily basis.

No. 2, the proposed changes to the restricted use classification system could require that anyone applying a restricted use pesticide be certified. This is not practical on today's farms which are large and operated by families in which not only the head of the farm applies the necessary pesticides, but also uses the assistance of other members of the family. Under the proposed changes, every working member of the farm family may be required to obtain certification for the application of restricted use pesticides in order to work in the production of their own crops.

In situations where commercial applicators are involved, the required mandatory certification may be advisable and practical since these individuals are applying pesticides as their primary source of income. Proper certification of such individuals should be required, much as we require the licensing of our health care professionals.

No. 3, the proposed amendments to section 6 of FIFRA may have inequities which can and would affect the formulator who relies upon data submitted by others for the registration of their products. Under proposed language, a company who cites data submitted by another could lose his registration if he should rely upon a piece of data which, in the future, proved to be inadequate or fraudulent, even though he has never had direct access to the data.

While we believe that there may be some merit to this amendment, we would suggest that the language be carefully examined and modified to protect individuals who did not submit the original data from the possible cancellation of their labels.

No. 4, we oppose the deletion of the indemnification and disposal sections of the law for those products which are suspended and cancelled by the agency. Manufacturers do not in general benefit from such indemnification payments. Those who have purchased the products receive the majority of the benefit. By providing the encouragement to return and properly dispose of suspended and cancelled pesticides, we prevent the improper dumping of these products.

Mr. Chairman, we were not aware that H.R. 1416 and 1910 were to be considered by the subcommittee at this time. We have not prepared any comments. We will address both of those bills in our written testimony.

However, there are several areas which have not been addressed by H.R. 2482 which are affecting the operation of the pesticide industry and in many cases has reduced competition.

It is important to have a healthy, competitive market in order to provide a reasonably priced product to the public. When there is

limited competition or even a monopoly, the public suffers through inflated prices. FIFRA is one of the few laws in America which presents barriers to entry beyond a 17-year patent period. We believe that the following items should be addressed by the committee in order to protect the viable competitive marketplace:

No. 1, section 3(c)(2)(B) should be amended to provide for the formation of mandatory task forces to produce those data necessary to continue the registration of a pesticide product. Currently, there is no such provision within FIFRA for such mandatory task forces. Without the support of the total industry and the production of new data required to continue the registration of a pesticide product, a registrant with a major portion of a market can freeze out a minor producer.

No. 2, we believe that Congress must, once and for all, address the problem of defining reasonable compensation under section 3(c)(1)(D) of FIFRA. For too long we have been groping in the dark trying to allow the settlement of a few cases to determine the definition of this term. To date, we have had three decisions handed down by either the Administrator or the arbitrators with none of them being the same.

PPA has developed a constructive definition of reasonable compensation for the use of data. We will provide this for you with our written testimony.

No. 3, PPA supports an amendment to section 2(ee) of FIFRA to provide for the common industry practice of repackaging or reformulation of a purchased registered end-use product into another registered end-use product.

Finally, PPA also supports amendments to section 3(c)(2)(D) of FIFRA to exempt the formulator from the submission of data for the registration of pesticide products. The current trend within the pesticide industry is for me-too registrants to enter the market only after the initial period of exclusive use or patent has expired. These registrants are not introducing new products to the market, nor are they increasing the exposure to the pesticide, since the products they are producing and registering are for established use patterns.

PPA supports amendments to FIFRA which would limit the need for me-too registrants of end-use products to submit or cite data necessary for registration or reregistration of a pesticide product unless the formulation or use pattern is new and different.

Mr. Chairman, we wish to thank the subcommittee for this opportunity to present our views on the proposed amendments to FIFRA and look forward to working with the committee in the coming weeks to resolve many of the problems addressed during the past 2 days. At this time I will be glad to respond to any questions from the members.

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

Mr. BEDELL. Thank you.

Mr. Weinstein.

STATEMENT OF KENNETH W. WEINSTEIN, ON BEHALF OF ABBOTT LABORATORIES, CIBA-GEIGY CORP., E.I. DU PONT DE NEMOURS & CO., ELANCO PRODUCTS CO., FMC CORP., MONSANTO CO., RHONE POULENC INC., ROHM & HAAS CO., STAUFFER CHEMICAL CO., UNIROYAL, INC., VELSICOL CHEMICAL CORP., AND ZOECON CORP.

Mr. WEINSTEIN. Thank you, Mr. Chairman.

My name is Kenneth Weinstein, and I am testifying on behalf of a group of companies who are presently involved in a case before the U.S. Supreme Court entitled *Thomas* v. *Union Carbide Agricultural Products Co.*

The issue in that case before the Supreme Court is the constitutionality of the arbitration provision of FIFRA for determining compensation for the use of research data. The Supreme Court is expected to hand down a decision in that case by this July.

The only point that I am addressing today is the provision of H.R. 2482 that provides for judicial review of arbitration awards. The reason that this is in the proposed bill apparently is an attempt to address the constitutional problems that are before the Supreme Court at the present time.

We would suggest, however, that because of the imminence of the Supreme Court's ruling and the fact that we really don't know what the problems are with the arbitration provision until the Supreme Court rules, it would make more sense to wait a few weeks until the court issues its opinion and then to try to formulate a provision to deal with the constitutional issues that have been defined by the Supreme Court.

One of the problems that we foresee is that this judicial review amendment that is in H.R. 2482 will not cure the problem. We had the same problem with the bankruptcy courts that the Supreme Court struck down. In that situation there was judicial review of decisions of bankruptcy court judges. Despite that fact, the Supreme Court said that that system was unconstitutional, even though there was judicial review.

If the Supreme Court was to rule the same way in the *Union Carbide* case, then this amendment providing for judicial review in H.R. 2482 would not resolve the unconstitutionality of the arbitration provision. We would still be left with an unconstitutional statute.

A second problem with the provision that is also before the Supreme Court is that, as has been mentioned today, there is no standard for determining what compensation is in FIFRA. The arbitrator who is supposed to determine compensation does not know what it is; the user who offers to pay compensation does not know how much he has to pay; and the manufacturer who generates the data does not know how much he is entitled to receive. When you make an offer to pay compensation, it is like signing a blank check.

The Supreme Court is going to decide, or at least it is before the Supreme Court to decide, whether the lack of a standard for compensation renders this statute unconstitutional. We think that the subcommittee ought to wait until the Supreme Court rules before trying to remedy this provision, and then we will know what kind of problem we have.

Third, wholly aside from the constitutional problems with this statute, as a matter of policy, there is widespread dissatisfaction with the current provision. The manufacturers don't like it; the me-too registrants and formulators don't like it. Businessmen cannot operate in a context where they don't know how much their liability is going to be and how much compensation they will be entitled to receive when others use their data. They cannot plan their investments in research and they cannot decide what markets to enter into.

This is a problem that really is not addressed but papered over by the judicial review provision in H.R. 2482, and we would urge the subcommittee to look into that after the Supreme Court renders its decision.

Thank you, Mr. Chairman.

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

Mr. BEDELL. Thank you, Mr. Weinstein.

Mr. Engel, why don't you go ahead and we will still be able to make our vote on the floor.

STATEMENT OF RALPH ENGEL, PRESIDENT, CHEMICAL SPECIALTIES MANUFACTURERS ASSOCIATION, ACCOMPANIED BY WARREN STICKLE, DIRECTOR, LEGISLATIVE AFFAIRS

Mr. ENGEL. All right, sir.

Good afternoon, gentlemen.

My name is Ralph Engel, and I am president of the Chemical Specialties Manufacturers Association, CSMA. I am accompanied, as I indicated, by Warren Stickle, our director of legislative affairs.

CSMA represents 400 firms engaged in the manufacture, formulation, distribution, and sale of nonagricultural pesticides, including disinfectants and sanitizers, home and garden pesticides, and a wide variety of other pesticides for home, industrial, and institutional uses.

We are here today to review some of the areas raised in H.R. 2482 and to address as well some of the concerns we have with the existing statute.

Time does not permit to go through everything, but I have raised in our testimony five areas with H.R. 2482—data sharing; indemnification and disposal; cancellation due to false, misleading, or inaccurate data; special reviews; and inerts—as the areas of concern. Let me address just two of them.

Cancellation due to false, misleading, and inaccurate data: EPA would like to more easily cancel a product registration when the Agency discovers that the data or a portion of the data supporting a registration is based on false, misleading, or inaccurate data. The Agency, however, already has sufficient existing authority to start a cancellation proceeding if the data for any reason are not sufficient to support a determination that a pesticide is safe to use.

CSMA in no way countenances the intentional submission of false or misleading data and would sanction a quick and deliberate response by the Agency. On the other hand, when the Agency determines that data submitted is inaccurate and concludes that it does not make a significant impact on the overall data submitted

for a registration, then the Agency should seek to fill the gaps with new studies, rather than immediately beginning a cancellation proceeding. In short, a reasoned judgment should prevail.

Moving now to inerts, under FIFRA as presently written, an inert ingredient is a component of a pesticide other than the active ingredient added to be active on a specific pest or pests. Under current law pesticides are generally required to be labeled with only their active ingredients. We support the present statutory provisions for active ingredients and do not believe that FIFRA should be amended to include specific inerts on the label.

Under the provisions of H.R. 2482, FIFRA would be amended to require the listing of inerts on the label if the inert is determined by EPA to be of toxicological concern. We have several concerns with this proposal.

First, we believe that many inerts and intermediates could be regulated under sections 4 and 5 of the Toxic Substances Control Act [TSCA], rather than under FIFRA, because they are not pesticides, and in many cases the potential pesticidal use is only a small fraction of its total use. EPA has the authority to request toxicological data if the Agency feels it needs it.

Second, disclosure of inert ingredients on the label seriously compromises the confidentiality of the final product in our industry. Consumer products are directly affected. In many cases the essential difference between one consumer product and another is the inert ingredient. The use of a particular surfactant, for example, may determine the performance of the product and give the product a competitive advantage in the marketplace. Disclosure of the name of the inert on the label would, in fact, alert the competition to the key difference in the product formulation.

When Congress originally enacted FIFRA, it correctly stipulated that inerts needed to be treated confidentially and most certainly did not require that they be specifically named on the label.

Although the amendment to section 2(n) deals only with labeling provisions for inerts, it also raises a fundamental concern about testing of inerts. What information does the Administrator need to determine if a hazard exists? Who should provide the data request, test studies, or information? The basic manufacturers or the marketers or distributors of the finished products? Who should pay for such data, test studies, or information, and how would it be apportioned? What statutory language needs to be created to put in place on an appropriate system for compensation of data? In essence, many questions about testing and compensation are raised by the language in H.R. 2482, but none are answered.

Rather than starting a new program, the Agency might conduct a study to resolve many of the unanswered questions and deal with such controversial areas as confidentiality and compensation for data as it pertains to the testing of inerts. There is already a drain on the resources of the Agency, as I have been hearing for 2 days.

Now although we have serious problems with a number of provisions of H.R. 2482, we welcome an opportunity to work with the members of the subcommittee regarding this proposed legislation in the hope that we can resolve some of our difficulties.

We are equally concerned, Mr. Chairman, however, that the present and potential legislative discussions to date have not ad-

dressed several other pressing problems with FIFRA. There are a number of these in our testimony, and I am going to ask that they be submitted for the record rather than cover them.

Mr. BEDELL. Without objection, they will be entered in the record.

Mr. ENGEL. Finally, we understand that a revised version of H.R. 3818 in the 98th Congress and perhaps other amendments are likely to be introduced in the near future. We request that additional hearings be held to examine these amendments in some depth before they are considered by the subcommittee. This policy would be consistent with a longstanding tradition of the committee.

Finally, Mr. Chairman, CSMA is committed to work with this subcommittee to help resolve some of these important concerns where we can.

Thank you very much.

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

Mr. BEDELL. If it wouldn't impose too much upon you folks, we would appreciate it if you would wait so that we could have some questioning after we return from the vote. We are going to have to run now in order to catch the vote that is on the floor of the House.

The subcommittee will be in recess for about 15 minutes while we go vote.

[Recess taken.]

Mr. BEDELL. I have a number of questions, and I think maybe I could go through those while we wait for some of the other members to return.

The first question I have has to do with the inert ingredients that we have talked about here. Mr. Engel, you state that, "If an inert is determined by EPA to be of toxicological concern," then it has to be listed. It would seem to the chairman that if it is of concern that it ought to be listed on the label. Do you feel that it should not be even if the statute were to say that if it is of concern, as EPA may determine it must be named on the label? We had testimony earlier indicating, and I don't remember all of the items, but one was vinyl chloride which was listed as one of those inerts. This person would not consider vinyl chloride as an inert, if it is indeed.

Mr. ENGEL. Mr. Chairman, first, let's again look at the fact that we are representing the consumer end of the business, the nonagricultural end, if you will. That is important to keep in mind.

Therefore, inerts—one single inert can make the difference in the competition between products. Let me give you an example.

A cleanser, a toilet bowl cleanser, for example, may have a surfactant in it which makes it better than any on the market, and listing it on the label will just have everybody have the same product, so competition will be lost.

Again, I say this is for nonagricultural or household products. When the agency really finds a bad actor, a toxicologically bad actor—as you mentioned, vinyl chloride—the listing on the label may not be the answer. In fact, they did discontinue its use, took it off the market. That does not say that we have to list it on the

label. An action in a bad actor like that does not necessarily mean listing on a label.

Mr. BEDELL. You may be unfortunate to have me as chairman because you are going to have to show me or prove to me that some laboratory cannot very easily analyze that and find out exactly what is in that formula.

I know I was with a major producer here within the last week, and they said they have no trouble taking any item and tearing it down and seeing what is in it. I have a fishing tackle factory that is not exactly the place you would expect to have the greatest expertise in chemicals; they can do it. They can take any chemical you want to give them and they will tell me exactly what is in it. They may not tell me the exact proportions, but they will tell me what is in it.

Do you think that I am wrong about that?

Mr. ENGEL. I think that most—not most, I would say a good percentage of—really good laboratories could break down the general active ingredients.

Mr. BEDELL. Yes.

Mr. ENGEL. But they cannot get the percentages to the point where they will make a significant difference.

Mr. BEDELL. Would you feel that this would be all right if we had the percentage range somehow in there so that we did not have to have the exact percentage?

Mr. ENGEL. The position of our association, Mr. Chairman, is that we would be opposed to putting inerts on the label, because we are a different animal, if you will.

Mr. BEDELL. I understand. See, to me, that is unreasonable. To me, it is unreasonable for you to argue you cannot put it in because then it lets people know what is in there. My argument would be, if there is some way you can convince me that I cannot take any item you've got and take it to a laboratory and have them tell me what is in it, then I think that argument holds up, but otherwise it sounds like you are trying to fool people and this subcommittee when you tell us you cannot do it because it would let your competitors know what is in there, if your competitors can easily find out what is in there anyway.

Mr. ENGEL. I hear you.

Mr. BEDELL. Also, Mr. Hasness, you made the same statement. Unless there is something I don't understand or unless I am wrong about something—then I need to be corrected if I am wrong—but my understanding is that a laboratory can quite easily take that product and tell you what is in it.

Mr. MILLER. Mr. Chairman, that is very true, but in one part of the bill that is being introduced you do put down that the Administrator could also ask for percentages. Now if you have the inert ingredients plus the percentages there, I could go along and duplicate that formulation very easily without half trying.

Mr. BEDELL. You think that the laboratories cannot determine what percentage of the inert is in the product?

Mr. MILLER. Not very accurately unless they go into, we will call it, very sophisticated research. They can find out what the constituents are, but the amounts are more difficult.

Mr. BEDELL. So you would have no particular problem if it listed the items but it was not so specific in regard to the inerts in regard to the exact percentages?

Mr. MILLER. I still see a problem, Mr. Chairman, in the fact that I don't understand why inerts have to be listed, if they are an inert.

The true definition of an inert.

Mr. BEDELL. We said only if it is of toxicological significance.

Mr. MILLER. Toxicological significance.

Mr. BEDELL. Yes.

Mr. MILLER. All right, if it is of toxicological significance, it does not belong in the formulation. Unless you want to make it an active ingredient.

Mr. BEDELL. Do you want us to do that? Do you want us to say—I wouldn't think you would——

Mr. MILLER. No; I would rather put it in the active ingredients statement then.

Mr. BEDELL. Well, you understand our problem.

Mr. ENGEL. Yes, I do——

Mr. BEDELL. We are trying to work something out that makes sense. We are not trying to go in one direction or another.

Mr. ENGEL. I do understand.

Mr. BEDELL. We do have to be reasonable on both sides.

If vinyl chloride was at one time considered an inert, then I think that is of significant concern, frankly. I think you would agree with me, Mr. Engel, would you not?

Mr. ENGEL. Yes; let me read something to you. This is important, I think. Again, we go back to what the Administrator is able to do today.

If the Administrator feels he has concern over a potentially troublesome inert, he has used his authority to request that information be placed on the label. In at least three cases to date the Administrator requested that products containing chloroflorocarbons, CFC's, be so identified on the label; that certain products containing petroleum distillates carry a warning on the label; and that all products containing sodium nitrate stabilizers be identified on the label. In essence, the Administrator really has the ability to act quickly in an emergency situation.

All we are saying is we don't want it to be a rule that, indeed, every inert has to end up being on a label when the Administrator can act if he needs to do so.

Mr. BEDELL. Let me ask you another question. I don't know the answer to this necessarily.

Suppose I knew that I was allergic to kerosene, and kerosene was in there as an inert. Wouldn't it be fairly important for me to know that that was in there if that did not present problems to almost anybody but for me; I happen to be an individual that, if I have kerosene on my hands, it would cause me to break out and cause me difficulty? Don't you think that would be of concern?

Mr. ENGEL. I understand. I suspect, however, it wouldn't say kerosene; it might say petroleum distillate products.

Mr. BEDELL. OK, petroleum distillate.

Mr. ENGEL. What I am trying to say by that is it is not the fact that there is anything being hidden from the consumer, because

these things—the names of these products—probably would not mean anything to the consumer anyway as chemical names.

Mr. BEDELL. I think it would. I don't know, but I assume there are people who are allergic to some of these items that are used as inerts.

I don't understand your great objection to their being listed. I don't see what is wrong with listing them. If they are inert and don't cause any trouble, why is it you are so uptight about listing them?

Mr. ENGEL. Our industry is uptight, in essence, to protect the competitive edge from one product to another.

Mr. BEDELL. But you have already admitted that they can find that out without any trouble.

Mr. ENGEL. Let me give you an example. Our industry essentially is developing new products every day. If I market a product and have a competitive edge on day 1, it may be 5, 6 months' edge before a competitor can go out or would go out and analyze that product to see what the ingredient is. That is just one example.

I hear your dilemma, and I guess the object of this exercise now is to see if we can work something out between us, so that perhaps both of us are somewhat protected here.

Mr. BEDELL. I guess, honestly, my problem goes further than that. I think we have to have reasonableness, but there is a lot of dichotomy here. I see polarization on two sides. It seems to me we have to have reasonableness.

Mr. ENGEL. I hear you.

Mr. BEDELL. I don't particularly like the fact—and I don't mean to go after you, but I don't like the fact that you come in and say we have to do it because otherwise our competitors will find out what is in it, when the reality is that I happen to have enough knowledge of chemistry to know that they can find that out anyway. That really waves a great big red flag, let me tell you, over my thinking on this situation.

We are trying to get people together, if we possibly can. If we are going to do that, we are going to have to be honest with each other; we are going to have to honestly face what the problems are; and we are going to have to try to work them out.

I don't doubt for 1 minute but what the other side is going overboard in some directions, but if they try to mislead us in any way, I am going to be equally upset.

Mr. ENGEL. I am not trying to mislead you, sir. I am just trying to give you an industry posture.

Mr. BEDELL. Sure.

Mr. ENGEL. And I hear you.

Mr. BEDELL. Another concern I have is that in regard to the arbitration, Mr. Weinstein, you had said that:

> The subcommittee should instead give consideration to an alternative mechanism that will achieve Congress' purposes in a manner that is satisfactory to the regulated community.

Can you tell us what that would be or can you send that to us? What can you do?

I do not like the idea of saying, "Don't do it yet because the Supreme Court is looking at it," and so on. We can always find ex-

cuses not to do something. At least this chairman's attitude is we should go forward and we should try to do something. If there is something wrong with the arbitration procedure as it is now, then we ought to address that problem and try to do what we can about it.

I think, if we are going to do that, we need to have some proposals from some people about what should be changed about it and how it should be handled.

Mr. WEINSTEIN. The committee did adopt an amendment in 1982, and the House of Representatives passed that amendment in H.R. 5203, and that was a repeal of the compensation and arbitration provision. They substituted in its place a greater exclusive use period, with certain other changes to the compensation provisions. There compensation was phased out over a period of years. That was passed by the House.

Mr. BEDELL. Under those circumstances, it gave greater exclusive use but said that, after that period, then anybody could use that data; is that what it said?

Mr. WEINSTEIN. That is correct.

Mr. BEDELL. Can you get that to us, as to what that proposal is, so we can give it consideration?

Mr. WEINSTEIN. I think we can do that.

Mr. BEDELL. Mr. Volkmer.

Mr. VOLKMER. I have no questions.

Mr. BEDELL. What do we want to do? Do we have some of the others coming back? Do we want to proceed? What would you suggest, Harold?

Mr. VOLKMER. Pardon?

Mr. BEDELL. Shall we dismiss this panel?

Mr. VOLKMER. I would say just go ahead and dismiss them and call your next panel.

Mr. BEDELL. OK; fine. We do appreciate your testimony. We are trying to work things out. I hope you will understand we want to work out these things to the best interest of everyone. I guess I would hope there would be some flexibility on everyone's part as we try to work these things out and try to get the best answers for everyone.

Mr. VOLKMER. I would like to ask—in view of what Mr. Weinstein said—in regard to what we passed back in 1982—and I remember that—does anyone else on the panel have any problems with that proposal that passed the House in 1982?

Mr. MILLER. The Pesticide Producers Association would like to submit their own proposal. Even though we went along with 1982, we feel we have a better one now.

Mr. BEDELL. Good.

Mr. VOLKMER. As far as having the longer period of time for exclusive use.

Mr. Engel, do you have any problem with that?

Mr. ENGEL. I would like to reserve those comments, Congressman Volkmer, to review 1982 again. I do believe we did have some problems, yes.

Mr. VOLKMER. All right. Thank you, Mr. Chairman. I would like to know what they were.

Mr. BEDELL. I am glad we got complete agreement on that.

Well, we thank you very much for your testimony.

Our next panel consists of Mr. Richard Kelley, environmental specialist, Iowa Department of Water, Air, and Waste Management, and Dr. Leon Burmeister, Department of Preventive Medicine and Environmental Health, University of Iowa.

This is our Iowa panel.

Mr. Kelley, you will be first. Even though you are from Iowa, we are going to ask you to limit your testimony to 5 minutes, as we have done to everybody else.

STATEMENT OF RICHARD D. KELLEY, ENVIRONMENTAL SPECIALIST, IOWA DEPARTMENT OF WATER, AIR AND WASTE MANAGEMENT

Mr. KELLEY. My name is Richard Kelley. I am an environmental specialist with the department of water, air, and waste management, State of Iowa.

I appreciate this opportunity to inform you of the work recently conducted in Iowa related to ground water contamination. I would like to focus on one aspect of the results of a recent survey of public water supplies in the State and related research conducted in northeastern and north-central Iowa. Specifically, I will address the subject of the appearance of pesticides in the ground water.

I have supplied the panel members with a copy of the survey and a related paper on "Agricultural Chemicals and Ground Water Quality in Iowa." I would supply a copy for the record, with the permission of the Chair.

Mr. BEDELL. Without objection, they will be entered in the record.

Mr. KELLEY. Thank you.

Between May 1984 and March 1985, the department of water, air and waste management sampled 128 wells from 58 public water supplies for the presence of frequently detected synthetic organic compounds. Seventy of these wells were also monitored for the presence of 34 commonly used pesticides. Twenty-eight of the 70 wells monitored for pesticides were found to have one or more of the pesticides present in measurable concentrations. The 28 wells represented 18 public water supplies. Of the 34 pesticides that we analyzed for, only Atrazine, Bladex, Lasso, Dual, Sencor, and the insecticide Dyfonate were found.

However, Atrazine turned out to be the most frequently detected contaminant of the survey, being found in 24 wells and 14 public water supplies. In addition, Atrazine was the only pesticide detected in the finished water of any of the supplies surveyed.

There was a clear relationship between the depth of the wells and the appearance of pesticides. Nineteen of the wells with Atrazine were alluvial wells and the other five were bedrock wells. However, three of the five bedrock wells were open to the overlying shallow formations. Furthermore, 14 of the 19 alluvial wells that were sampled were less than 50 feet deep.

Neither the occurrence of these six particular pesticides nor the relationship between their appearance and well depth is surprising. The work conducted by the Iowa Geological Survey has shown that the most commonly used herbicides are being found in the shallow

ground waters of the State. Further, it has been shown that between 80 percent and 100 percent of the pesticide concentrations in ground water are being delivered through infiltration.

Pesticides detected in the survey of public water supplies are identical to those found in studies conducted by the Geological Survey and the concentrations are all within the range of values found in the course of their studies. The concentrations of pesticides that we typically found were between 0.1 and 5 micrograms per liter. These are all well below values that we commonly encounter as a result of spills.

The public water supplies survey suggests that as many as one-half of Iowa's shallow ground water supplies may have low concentrations of pesticides present. However, I would like to point out that this may be a low estimate of the actual number of drinking water supplies with measurable concentrations of pesticides present. Between 70 and 80 percent of all the wells and springs sampled in northeastern Iowa by the Iowa Geological Survey have been found to have detectable concentrations of pesticides over the course of a year.

There is evidence to suggest that if nitrate concentrations of greater than 10 milograms per liter occur in the water well samples, there is a very good likelihood that the ground water will contain detectable concentrations of pesticides. Nitrate concentrations of 10 milligrams per liter or more are commonplace in the shallow ground water systems of the State of Iowa and cannot be attributed to natural processes.

Both the work conducted by the Iowa Geological Survey and the survey of public water supplies suggest that Atrazine is likely to be present throughout the year. To date, however, the analyses have only been for the parent compounds, and it is not known if metabolites or breakdown products of these or other pesticides are occurring in our ground water.

Pesticide concentrations we have routinely detected in Iowa are far below toxic levels and generally below levels which are thought to contribute to long-term health problems. However, we feel there is legitimate concern for public health over the long term if they continue or they increase.

There are a great many uncertainties with regard to long-term exposures to low levels of concentrations of combinations of pesticides and possibly other metabolites. At the present time it seems as though only the relatively shallow aquifers are being affected. However, work conducted in the Big Spring Basin in northeastern Iowa suggests that between 1 and 5 percent of the pesticides applied to that basin are lost to the surface and shallow ground water. At the same time I would like to point out that shallow ground water systems are the most heavily utilized source of drinking water in the State.

If pesticides continue to enter and persist in the shallow ground water, they will over time be transmitted to the deeper formations. Therefore, it is important that activities be undertaken to identify a means of eliminating this loss.

While the recommendations resulting from our survey of public water supplies may not be directly applicable to FIFRA regulations, it is my hope that the subcommittee will find the results of

this survey and related work in Iowa helpful in its efforts to address a very difficult problem.

Thank you.

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

Mr. BEDELL. Thank you, Mr. Kelley.

Can you wait while we run over and vote? We have another vote on the floor.

Mr. KELLEY. Sure.

Mr. BEDELL. Can you wait, Mr. Burmeister?

Mr. BURMEISTER. Sure.

Mr. BEDELL. The subcommittee will be in recess for about 15 minutes while we go vote.

[Recess taken.]

Mr. BEDELL. The subcommittee will come to order.

Dr. Burmeister, we will now hear your testimony.

STATEMENT OF LEON F. BURMEISTER, PROFESSOR, DEPARTMENT OF PREVENTIVE MEDICINE AND ENVIRONMENTAL HEALTH, UNIVERSITY OF IOWA

Mr. BURMEISTER. Mr. Chairman and members of the subcommittee, I appreciate the opportunity to appear before you.

My name is Leon F. Burmeister, and I am a professor in the department of preventive medicine and environmental health in the University of Iowa's College of Medicine.

My colleagues and I have published several epidemiological studies concerning cancer and agricultural practices in Iowa farmers. Several additional studies are currently being completed. I would like to describe today the general results of these studies.

I must emphasize that for all types of cancer combined, mortality in adult, male Iowa farmers is significantly lower than in Iowa nonfarmers.[1] This is due primarily to significantly lower mortality rates for smoking-related cancers: Lung, esophagus, mouth other than lip, and other respiratory cancers.

However, the following cancers caused significantly higher mortality rates in Iowa farmers: lip, stomach, prostate, leukemia, multiple myeloma, and non-Hodgkin's lymphoma. It is important to note that these cancers have also caused significantly increased mortality rates in farmers in other States.[2]

Subsequent studies have evaluated the association of mortality rates in farmers and agricultural practices by county. Mortality in Nebraska farmers from leukemia was elevated in 30 counties of 93, with the greatest corn production and highest insecticide usage.[3] However, mortality from leukemia was not elevated in the remaining counties. Furthermore, it was elevated only in farmers born after 1900.

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[1] Burmesiter, LF. Cancer mortality in Iowa farmers. 1971-78. Journal of the National Cancer Institute, 66(3):461-464, 1981

[2] Blair, Malkar, H, Cantor, K, Burmesiter, L, Wiklund, K. Cancer among farmers: a review. Submitted to the Scandanavian Journal of World Environmental Health.

[3] Blari, A, Thomas, TL. Leukemia among Nebraska farmers: a death certificate study. American Journal of Epidemiology, 110:264-273, 1979.

A comparable study in Iowa produced remarkably similar results.[4] Mortality from leukemia was elevated in farmers living in the 33 of 99 counties having the greatest corn production and the highest use of herbicides. In the other counties, leukemia mortality was not significantly different for farmers and nonfarmers. In Iowa, only farmers born after 1890 were subjected to higher leukemia mortality rates.

This consistency with the aforementioned Nebraska study can be interpreted as an implication of modern—that is, post-World War II—farming methods. Extensive herbicide and insecticide use are two such methods.

Similar results have been found in Iowa farmers for mortality from non-Hodgkin's lymphoma and multiple myeloma.[5] Multiple myeloma mortality was elevated only in farmers born after 1890 and was similarly associated with insecticide and herbicide use. Non-Hodgkin's lymphoma, although showing increased mortality in farmers only for those born before 1900, was associated with herbicide use. It also had an increase in statistically nonsignificant mortality only in the high usage counties for those born after 1900. No such associations were found for prostate cancer and stomach cancer. Lip cancer was not further investigated because it causes relatively few deaths and is thought to be related to sun exposure.

The above studies are ecologic and relate countywide characteristics which assume that all the individuals within a county are similar. To overcome this limitation, case control studies of leukemia, multiple myeloma, and non-Hodgkin's lymphoma have been funded by the National Cancer Institute and are currently undergoing statistical analyses.

Based on preliminary analyses, it appears that certain histological types of these three reticuloendothelial or hematological malignancies are associated with exposure to specific types of herbicides and insecticides. Each of these reticuloendothelial cancers is relatively uncommon. Consequently, their simultaneous increase and association with pesticide usage may signify a common etiological link.

The possible role of insecticides and herbicides in development of and subsequent mortality from selected cancers in farmers is one that has generated a high level of interest. Consequently, it seems prudent to evaluate mechanisms that may cause farmers to be at higher risk for some cancers.

One such mechanism may be the infusion of agricultural runoff, including pesticides, into shallow farm wells. It is hoped that future research will suggest other mechanisms that might play a role in the development of the suspected cancers in farmers. Only then is it likely that the appreciable risks currently facing farmers for mortality from selected cancers will be reduced.

In summary, I just would like to say it is obvious from just being here for a couple hours today that there are many very complicated aspects of the questions that you are facing. Those of us at the

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[4] Burmeister, LF, Van Lier, SF, Isacson, P. Leukemia and farm practices in Iowa. American Journal of Epidemiology, 115:720–728, 1982.

[5] Burmeister, LF, Everett, GD, Van Lier, SF, Isacson P. Selected cancer mortality and farm practices in Iowa. American Journal of Epidemiology, 118:72–77, 1983.

University of Iowa, and I think the National Cancer Institute and other places, are really very concerned about the health of the farmers who are doing the work not only in our State but other States as well.

Mr. BEDELL. Thank you, Dr. Burmeister.

Mr. Roberts.

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

Mr. BEDELL. Mr. Kelley, you have done a study of what these different levels are. Are those levels at this time dangerous levels in some of the places you have tested?

Mr. KELLEY. None of the levels that we have seen so far would be high enough that we would consider them to be an immediate threat to human health, in that they are all well below acute toxicity. They are all below chronic toxicity. Our concern is the fact that we don't know what long-term exposure to low levels of multiple pesticides means in terms of implication to human health.

Mr. BEDELL. I take it, Dr. Burmeister, that your studies would indicate that very possibly there are some problems associated with long-term exposure; is that correct?

Mr. BURMEISTER. Yes; and the emphasis must be on the possible part of it, too, because these are associations, not results of studies conducted in an experiment sense in a laboratory. They are merely associations. But we are concerned about these possibilities.

Mr. BEDELL. How will we know on this? Is there monitoring to see what occurs in the future or what?

Mr. BURMEISTER. The most honest answer to that is probably that we will never know with certainty, but the case control studies that are currently reaching completion I think will be very informative along these lines.

Mr. BEDELL. Yes; Mr. Roberts.

Mr. ROBERTS. On page 2, Doctor, you are talking about those farmers born after 1890. Where on Earth did you find that test group that is 95 and older?

Mr. BURMEISTER. Pardon me?

Mr. ROBERTS. On page 2 you talk about farmers born after 1890. Was there a test group where they were 95 and older?

Mr. BURMEISTER. It is very hard to summarize detailed studies of which there are several referred to in here, but basically these were people that died in Iowa from 1964 through 1978.

Mr. ROBERTS. I see.

How does this square with the other testimony given by the representative of the agriculture air force in regard to the spray?

Mr. BURMEISTER. I honestly cannot attest to that because I was not privileged to hear that testimony.

Mr. ROBERTS. Is the Nebraska study the same one that was referred to—you say "the aforementioned Nebraska study." Is that one that was referred to——

Mr. BURMEISTER. It was previously mentioned only in my testimony.

Mr. ROBERTS. I see.

Mr. BURMEISTER. I did not mean to infer that it was mentioned in anyone else's testimony.

Mr. ROBERTS. Then we have two Nebraska studies, Mr. Chairman—one good news and one bad news. Take your pick.

Mr. BEDELL. Mr. Kelley, what do you think we ought to do about the ground water problem? Apparently your studies indicate quite clearly that there is some leaching of some of these chemicals into the ground water. Is that accurate?

Mr. KELLEY. That is an accurate statement, yes.

Mr. BEDELL. What do you think we ought to do about it?

Mr. KELLEY. I think there are several actions that you can take or that can be undertaken on a State level.

The one thing I don't think that you can do is regulate the solution. I know that in earlier testimony there was a great deal of discussion about establishing water quality standards for ground water. I don't think that that in itself is a real answer to the problem.

The problem that you have out there is the misuse or inappropriate use of an agricultural chemical. When it appears in the ground water, that is purely an indication that that misuse or inappropriate use has taken place.

To set ground water standards does not solve your problem. The problem is still existing out there. I think that the only way that you are going to do that is to solve the problem itself, and the only way you are going to solve that problem is to change human behavior. You change human behavior through public education efforts.

One of the things that we are proposing to do in northeastern Iowa in the Big Springs study basin is to go in with the cooperation of every farmer within that basin and look at current farming practices, look at alternative farming practices, look at the attitudes and behaviors of those farmers now. We want to change their farming practices and then find out how those attitudes and behaviors have changed. We think we can adequately address the problem if we change farming practices.

Mr. BEDELL. Have you started to do that yet? Have you started to have those meetings and so on?

Mr. KELLEY. The Carstadt ad hoc committee was set up about 2, 2½ years ago. Some of our preliminary work has begun. We have research proposals out at the present time that are being considered by EPA. EPA, however, has not been exceptionally speedy in responding to us, and so we are——

Mr. BEDELL. We are awfully glad you came to inform us of that very important fact, we weren't aware that EPA is not real speedy. [Laughter.]

Mr. KELLEY. Sometimes I have a tendency to state the obvious.

Mr. BEDELL. Excuse me. I didn't mean to interrupt you.

If I understood you correctly, you are trying to meet with farmers and convince them it is in their own interest to keep their ground water at safe levels and that they should adopt practices that do that; is that what you are saying?

Mr. KELLEY. That is exactly what I am saying.

Mr. BEDELL. The question is, How successful have you been at that?

Mr. KELLEY. We are just beginning right now. I can't give you a definitive answer, but we have every reason to believe that we will succeed in it.

They are causing the problem. They are the primary users of the water. It is a problem they have to deal with daily. It is in their best interest to change their practice.

Mr. BEDELL. Mr. Roberts, do you want to be recognized?

Mr. ROBERTS. Yes, Mr. Chairman.

Just a couple questions: when you say "we," you are obviously referring to the Iowa Department of Water, Air, and Waste Management. Is your budget such on a State level that you feel you can proceed along these lines?

Mr. KELLEY. We operate on a balanced budget in the State. Our budget is extremely strapped. If you want to be honest, we are bankrupt.

Mr. ROBERTS. Well, that is our story back here, but we don't have a balanced budget. [Laughter.]

You have truth in spending there. We just have a printing press here.

Go ahead.

Mr. KELLEY. We have cut every corner. At this point we have committed $2.4 million in staff and analytical free time, as it were. We have manned the research station. We have people in the fields. We are still short about $4.2 million to complete the project, but we do have every reason to believe we are going to raise that.

Mr. ROBERTS. In the other body—which is the way we refer to the Senate—in the Senate Environment Committee they did not go down the road that you—let me rephrase that. They went down the road that you suggested. They did not get into standards so much as they mandate within 18 months that States come up with plans such as these, and there is approximately $300 million available in matching funds to do that chore. Then they put a timetable on it of 18 months to get your house in order and have a good, workable plan.

You are thinking along those lines, then?

Mr. KELLEY. Yes.

Mr. ROBERTS. That is a better approach to this whole problem.

Mr. KELLEY. Yes, I believe it is.

Mr. ROBERTS. OK. Thank you, Mr. Chairman.

Mr. BEDELL. Mr. Volkmer.

Mr. VOLKMER. I would like to know, just out of curiosity, what practices of the farmers would you change?

Mr. KELLEY. We are looking at changing application rates, changing application times, going in different rotations. Much of the basin that we are looking at right now is in corn all the time. The fact of the matter is we don't need it.

Mr. VOLKMER. What do you mean? You don't need what?

Mr. KELLEY. We don't need the corn.

Mr. VOLKMER. Are you talking to the farmers, then, about producing soybeans?

Mr. KELLEY. In the basin that we are looking at we are not talking about beans primarily because there are not beans produced in that region.

Mr. VOLKMER. What are we talking about other than corn then?

Mr. KELLEY. There is a pretty good sized dairy industry, meadow-type crops, those sorts of things.

Mr. VOLKMER. We are talking about hay?

Mr. KELLEY. Yes, right, hay.

We are also pushing for conversion of some of the land back to woodland.

Mr. BEDELL. Would the gentleman yield?

Mr. VOLKMER. Are you talking also about perhaps not using herbicides, pesticides at all?

Mr. KELLEY. We are talking about being very selective in the herbicides that you use. Don't run out and buy Dyphanate and use it because you think you have a rootworm problem. Find out if you have a rootworm problem before you run out and buy the insecticide; the same way with the herbicides.

We are also suggesting that they stay away from—we are trying to commit the farmers to staying away from those herbicides that have a problem with persistence. A lot of the herbicides, particularly Atrazine, has a carryover problem, but many more of them, such as Dyphanate—and I am not particularly picking on Dyphanate; it is just a name that comes to mind, one that shows up in the ground water—Dyphanate likes to—they don't hesitate to advertise that they will last longer than anybody else. We would just as soon that they didn't.

Mr. VOLKMER. It sounds like you are basically analyzing the life of an insecticide or herbicide and then determining also the ability to permeate or leach through the soil, that type of thing?

Mr. KELLEY. That is true. Leaching information is particularly interesting for us. If there is a real shortfall in information, it falls in two basic areas—one being, of course, public health and the other one being the leaching characteristics of particular herbicides. There is very, very little information as far as we are concerned on leaching characteristics, and we want more.

Mr. VOLKMER. Thank you.

Mr. ROBERTS. Would the gentleman yield?

Mr. VOLKMER. Yes.

Mr. ROBERTS. I have one other question. In terms of the efforts—you see in my country going to more soil conservation practices and minimum tillage. We are anticipating the increased use of herbicides and pesticides, more especially due to the economic adversity that we are going through, and farmers are really not willing to take a gamble, as you have indicated; they wait to see if there is a problem. Unfortunately, you get into the idea that if a little will do a little good, a lot will do a lot of good. That is exactly what we want to avoid.

Do you have any thoughts—I know that the State of Iowa is especially hard hit in terms of farm income. Are you seeing your individual farmers much aware of this and willing to go forward with these kinds of practices?

Mr. KELLEY. Well, yes, we are. We have had a very interesting response when we have gone to the farmers. When we have gone to the farmers, we said, "Look, here's a problem and here's why the problem exists. This is why we think it is a problem." Then we tell them how we think they might change their practices to improve the situation. They have been very adaptable. We have gotten an excellent response from the farmers that we have talked to about this.

I think for the most part, as a general rule, the farming community is going to be very receptive provided, of course, we can back up what we are saying with sound science.

Mr. BEDELL. Do you work with the Extension Service on this?

Mr. KELLEY. Yes; the work that we are doing in northeastern Iowa and proposing to do is actually a cooperative effort. The Extension Service is involved with it, SCS, EPA, the Geological Survey, the Department of Preventive Medicine, the Department of Agriculture. In fact, all resource and academic institutions in the State are trying to cooperate on it.

Mr. BEDELL. Is the Extension Service's purpose to a large extent trying to get information to the farmers? Are they working on this project with you so they are trying to disseminate information?

Mr. KELLEY. Yes; they are. They are doing a great deal of work.

Mr. BEDELL. That is working out fine?

Mr. KELLEY. Yes.

Mr. BEDELL. Fine. Are you going to continue your work, Dr. Burmeister, or is it pretty well done? The problem we have as a committee is that we get the applicators in here and they say, "Look, our people are not showing any health effects, and they are dealing with these chemicals every day." Then your study would indicate that there are some problems with it, with those farmers who are exposed only part of the year. We have to try to put together what the truth is in these things. I hope you understand.

Mr. BURMEISTER. I can certainly understand. It is a very difficult task.

Speculation only—applicators and farmers, what they have in common is the period of application, of course. There always has been concern that maybe the farmers are not going to proper care in the application season.

Maybe there are other aspects to this. One of the things that would be under the heading of other aspects would be the chronic exposure through the drinking water that the farmers have.

Mr. BEDELL. That would be full time, wouldn't it?

Mr. BURMEISTER. Yes; it would. So it may not be just the application.

Mr. BEDELL. In fact, I guess—is that correct—that your test would indicate that this is not from the air they breathe or from some other cause. You indicated lung cancer was not a major finding.

Mr. BURMEISTER. Lung cancer is very, very low in farmers, very much lower, primarily due to the fact that they are known to be less involved in smoking.

Mr. BEDELL. I am not trying to put words in your mouth; I am trying to learn. Does your testing then indicate that, if there is a problem, it is probably from something that they are either ingesting through their food supply or water supply or——

Mr. BURMEISTER. It would be fair only to say that those are speculations. We really have not tested that in any sense. We are just trying to observe what is going on. Our statements are merely speculative.

Mr. BEDELL. What do you speculate?

Mr. BURMEISTER. My own opinion is that it is probably something more likely to a chronic exposure, perhaps the drinking water, as

opposed to carelessness during the season of application. That is only an opinion.

Mr. BEDELL. Any further questions?

If not, we thank you very much for your testimony. Thank you for being here.

Mr. KELLEY. Thank you.

Mr. BURMEISTER. Thank you.

Mr. BEDELL. The subcommittee will be adjourned.

[Whereupon, at 4:02 p.m., the subcommittee recessed to reconvene at the call of the Chair.]

[Material submitted for inclusion in the record follows:]

TESTIMONY OF HONORABLE MIKE SYNAR, CHAIRMAN
ENVIRONMENT, ENERGY AND NATURAL RESOURCES SUBCOMMITTEE
OF THE COMMITTEE ON GOVERNMENT OPERATIONS,

Mr. Chairman and Members of the Subcommittee, I appreciate the opportunity to testify today on the need for amendments to the Federal Insecticide, Fungicide, and Rodenticide Act. My purpose in doing so is not to endorse any particular proposal but to share with you the results of an extensive investigation of EPA's pesticide registration activities conducted by the Environment, Energy and Natural Resources Subcommittee, which I have the honor to chair. It is my hope that this information will be useful to this Subcommittee in formulating a sound legislative proposal.

Our investigation identified a number of serious weaknesses in EPA's pesticide registration activities which are summarized in a report approved unanimously by the Committee on Government Operations last October.[1] Most of these weaknesses were not due to deficiencies in the law, but rather to inadequate administration, implementation and enforcement of the law. For this reason, the Committee's report made a number of recommendations for administrative improvements, but noted that if EPA's response to the recommendations was inadequate, Congress might find it necessary and appropriate to address the problems legislatively.

EPA's written response to the report indicates that the agency is moving in the right direction and that some improvements are being made. However, in my opinion these changes are insufficient to deal adequately with all of the problems we identified during our investigation, and legislation should be enacted to mandate further improvements.

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1 "Problems Plague the Environmental Protection Agency's Pesticide Registration Activities," Sixty-Third Report by the Committee on Government Operations, House Report 98-1147, 98th Cong., 2nd Sess., October 5, 1984.

I understand that the EPA Administrator testified during your earlier hearings that changes in the law are necessary. I also understand that EPA had prepared a legislative proposal which the Administration refused to allow the agency to submit to the Congress. Mr. Chairman, I share the disappointment you have expressed over that event, and I commend you and the Ranking Minority Member of the Subcommittee, Mr. Roberts, for introducing that proposal as a basis for debate on FIFRA reform. I would also like to commend our colleague, Mr. Brown, who I understand will offer some further FIFRA amendments.

Unfortunately, Mr. Chairman, the EPA proposal may not go far enough, in that it merely gives the Administrator additional discretionary authority in a few areas without providing any assurance that the new authority will be used effectively; and it does not deal with some of the more glaring problems which were identified during our investigation.

In the pesticide field Congress faces the same problem that it has encountered in many other regulatory areas, where it has passed legislation which stated certain desired objectives and granted broad discretionary authority to Executive agencies in order to provide flexibility in achieving those objectives. However, investigation reveals that such flexibility has provided cover for bureaucratic footdragging, inefficiency, and inaction in the face of resistance from the regulated industry. As a result, the original intent of the Congress, the elected Representatives of the people, is thwarted by unelected officials.

For this reason, Mr. Chairman, I recommend that the Subcommittee incorporate in its legislative proposal certain specific mandates, and where necessary, deadlines for their achievement.

A good example is the re-registration of older pesticides. As you know, when Congress strengthened the requirements for proving the safety of new pesticides in 1972, it also required that EPA review the safety data on pre-1972 pesticides to insure that they met the new standards. The legislation gave EPA until October, 1976 to complete this so-called re-registration process. When EPA failed to meet the deadline it was extended to October, 1977 and finally abolished altogether. Unfortunately, our Subcommittee's investigation indicates that EPA has taken advantage of Congress removing this deadline.

As a result, 12 years after the legislation was enacted, registration standards have been set for only 76 of the more than 600 chemicals and estimated 50,000 registrations subject to the re-registration requirement. At that rate, Mr. Chairman, as young as you and I are, we may not live to see the task completed. Consequently, I urge the Subcommittee to consider re-establishing a reasonable deadline with appropriate milestones for completion of the re-registration process. If so, I believe EPA will have to seek and employ the resources necessary to accomplish this task, including outside expert assistance from professional scientific organizations as recommended in our Committee report.

A similar problem exists with respect to the Special Review process, previously known as Rebuttable Presumption Against

Registration, or RPAR process. This process was originally devised by EPA to provide more expeditious decision-making than was possible under the normal adjudicatory process on the status of a previously registered pesticide, whenever new evidence indicated that it might constitute an unreasonable risk to man or the environment because it was suspected of causing certain very serious health problems, such as cancer, birth defects, or reproductive problems. However, our investigation showed that this has not been the case, and that the Special Review process has in fact lengthened the period of time required to reach final determinations on whether to cancel or further restrict the use of a registered pesticide.

Moreover, our investigation found that most of the delays in the Special Review process were caused by EPA's inability or unwillingness to make a final decision. After issuing its initial notice to place a pesticide in Special Review and giving affected parties the specified time to respond, EPA took virtually unlimited time to review the rebuttal information, continuously considered new rebuttal arguments without sufficient evidence of merit, and negotiated endlessly with adversarial parties.

For this reason, Mr. Chairman, I would recommend that the Subcommittee consider incorporating into the law a specific timeframe during which EPA must act at each stage of the Special Review process, similar to the legislative deadlines now imposed on outside parties in the Special Review process.

I also hope the Subcommittee will consider revising the Special Review process so that only the risks, rather than a

benefits-to-risk equation, will be employed to reach a decision in cases where the potential risk is actually life threatening, as in cancer or birth defects. I say that Mr. Chairman, because I simply do not believe that one can reasonably place an economic value on human life.

Another area which caused our Subcommittee concern was EPA's failure to act promptly to cancel registrations for products when it found that any one of the essential safety studies was based on falsified or misleading data submitted by International Biotest Laboratories. Instead, EPA spent years reviewing and validating other studies submitted by that laboratory in support of particular registrations, even after an essential study had been invalidated, and also gave the registrants additional time to replace invalidated studies. This is a situation which I hope the Subcommittee will also act to rectify legislatively.

Another area which I hope the Subcommittee will address is how to assure that once a pesticide registration has been cancelled, imported food products which have residues of such pesticides above normal background levels will not be allowed into this country. As the Subcommittee is aware, this has occurred with DDT and EDB. This not only presents an unwarranted risk to American consumers, but also places American farmers at a competitive disadvantage in the marketplace.

I know the Subcommittee is aware of the serious problems we are facing with regard to groundwater contamination; for this reason, I hope you will consider including language to insure

that information will be required on the ability of all pesticides, including those currently registered, to contaminate groundwater by leaching into the soil and that, unless adequate labeling can be devised and enforced to prevent such occurrences, the registration will have to be cancelled.

Finally, Mr. Chairman, in light of the recent Bhopal tragedy, the Subcommittee may want to consider inclusion of legislative provisions to insure a community's right to know about the potential dangers of pesticide manufacturing operations in their area, and what to do in case an accident occurs. The Subcommittee may also want to consider the inclusion of good manufacturing practices provisions for pesticides similar to those for drugs in the Federal Food, Drug, and Cosmetic Act, as well as worker protection provisions.

Mr. Chairman, I know that these recommendations represent strong medicine and will be opposed by many; but I believe they are necessary. As one who comes from a family of farmers and ranchers, no one knows better than I the importance of pesticides to American agriculture. However, I also realize that they can do great harm if not properly tested, labeled and used. Moreover, whenever a dangerous pesticide like EDB makes national news, faith in the integrity of American agricultural products is eroded both at home and in overseas markets, much to the economic disadvantage of American farmers.

I firmly believe that farmers and other users of pesticides, as well as consumers of agricultural products, have a right to expect that pesticides will be safe and effective when used according to the EPA approved labeling. I also believe that this Subcommittee has a rare and unique opportunity to make an important contribution toward that end.

I thank you for your time.

Testimony of

ALBERT H. MEYERHOFF
LAWRIE MOTT

on behalf of
NATURAL RESOURCES DEFENSE COUNCIL, INC.

> One of our biggest assets in meeting these challenges [of protecting the environment] is the FIFRA itself. In carrying out its legislative mandate for a year and a half, I know that it is a fundamentally sound environmental law.
>
> Formal written statement of John A. Moore, Assistant Administrator for Pesticides and Toxic Substances, EPA, at House Agriculture Subcommittee hearings on April 18, 1985.

> You can only go so far to make a silk purse out of a sow's ear.
>
> Oral testimony of John A. Moore, Assistant Administrator for Pesticides and Toxic Substances, EPA, at House Agriculture Subcommittee hearings on April 18, 1985.

INTRODUCTION

My name is Albert H. Meyerhoff. I am a Senior Attorney with the Natural Resources Defense Council, Inc. (NRDC). With m is Lawrie Mott, an NRDC project scientist. We appreciate the opportunity to testify at these important hearings on necessary amendments to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

The Reagan Administration proposes that FIFRA should be reauthorized for three years without change. This sentiment echoes the views of the multi-billion dollar chemical and food industries which are generally satisfied with the statute as written, although they reportedly are seeking amendments to FIFR and the Farm Bill to preempt state regulatory authority over pesticides in food and all local regulatory authority. In

written testimony presented to the Subcommittee last month, a representative of the Environmental Protection Agency characterized FIFRA as "a sound environmental law," requiring at most some limited improvement. As the Subcommittee is aware, even a modest EPA bill to strengthen FIFRA has been blocked by the White House.[1/]

Of course, all of this flies directly in the face of reality. FIFRA is anything but sound. Indeed, it is charitable even to refer to the statute as an environmental law. An unbroken litany of House and Senate Committee reports, GAO investigations, studies by the National Academy of Sciences and others repeatedly reached the same conclusion: the existing statute has failed.[2/] So has the Environmental Protection Agency, and the public health has been placed in serious jeopardy. In answer to a question from this Subcommittee,

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1/ See H.R. 2482 (Bedell, p. 1a).

2/ See, e.g., Sixty-third Report by the Committee on Government Operations, "Problems Plague the Environmental Protection Agency's Pesticide Registration Activities," 98th Cong., 2nd Sess., (1984), p. 17-18. Synar Report); Subcomm. on Oversight and Investigations of the House Comm. on Interstate and Foreign Commerce, "Cancer-Causing Chemicals in Food," 95th Cong., 2d Sess., at 18 (Comm. Print No. 95-67, December 1978) (concluding that "many pesticides which result in chemical residues in food and animal feed have never been tested for their potential to cause cancer, birth defects, and genetic mutations" ; Subcomm. on Admin. Practice and Procedure Senate Judiciary Comm., "The Environmental Protection Agency and the Regulation of Pesticides, 94th Cong , 2d Sess., at 23 Comm Print 1976); General Accounting Office, "Delays and Unresolved Issues Plague New Pesticide Protection Programs," at 19 (1980) (noting that "the public is exposed daily to many pesticides which are not supported by animal and environmental safety studies").

even EPA Assistant Administrator John Moore candidly acknowledged that "you can only go so far to make a silk purse out of a sow's ear."3/ Enactment of the Federal Pesticide Reform Act of 1985, to be introduced by Congressman George Brown of this Subcommittee, will represent a major step toward remedying what has become an unacceptable status quo.

I.

GROUNDWATER: THE NEWEST THREAT FROM PESTICIDE MISUSE

In the past, the major sources of human exposure to pesticide chemicals capable of causing both acute and chronic health effects were thought to be either the workplace, for agricultural and chemical workers, or through the food chain, for the consuming public. Now, a new and disturbing factor has been added to the equation: the increasing body of evidence that pesticides are contaminating groundwater throughout the United States, groundwater that poses a source of drinking water for roughly 115 million Americans.

For many years, pesticides were not considered a threat to groundwater. This was because they were believed either to degrade in the soil or become trapped by impervious layers of

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3/ "Changes in Pesticide Controls Advocated by EPA, Official Remarks Veer from Administration Line," Washington Post, April 19, 1985 at 7.

soil preventing migration to groundwater supplies.[4/] Thus, groundwater contamination legislation almost exclusively addressed "point" sources such as leaking underground tanks or injection wells or seepage from landfills or surface ponds. Pesticide contamination of groundwater (a "nonpoint" source) was virtually ignored by Congress in such legislation intended to protect water quality as the Clean Water Act, Safe Drinking Water Act, Resource Conservation Recovery Act, and other statutes.

The discovery in 1979 of DBCP, a chemical linked to cancer, human birth defects, male sterility and other maladies, in wells throughout California's Central Valley destroyed this false sense of security. To date, DBCP has forced closure of more than 100 public water wells. The overall number of wells contaminated by DBCP has increased from forty in 1979 to 2,449 in 1984. Currently, 1473 wells in California's Central Valley are unsuited for drinking, cooking or bathing due to DBCP levels in excess of recommended "action levels" of one part per billion (ppb). Many

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4/ For example, a 1972 Stanford Research Institute study concluded that "most data collected imply that the incidence of pesticides in groundwater is low and not a significant environmental contamination factor " Stanford Research Institute, Environmental Indicators for Pesticides (Springfield, VA: National Technical Information Service, U.S. Department of Commerce, 1972). In 1976, a University of Hawaii professor declared that in terms of pesticide residues, potable water in Hawaii is "almost pristine in character." A. Benvenue, "The 'Bioconcentration' of DDT in the Environment," Resources Review, 61:37-112. Hawaii's groundwater is now believed to be so badly polluted from pesticides that much of Oahu's aquifer will soon be designated a Superfund site.

wells have been shut down permanently or relegated to emergency use only, but other contaminated wells are still in full use. Other nematicides, such as ethylene dibromide (EDB) and 1,2-D, have also forced closure of public water supplies in the state.

Data concerning pesticide contamination of groundwater is sketchy at best due to sporadic or nonexistent monitoring. Nonetheless, a 1984 study conducted for the Environmental Protection Agency found that 63 percent of rural Americans may be drinking water that has excessive levels of pesticides or other contaminants. In the West, polluted drinking water is consumed by up to 75 percent of the rural population.5/

A preliminary federal study found 16 different pesticides in the groundwater of 22 states. EDB alone, for example, has been found in groundwater in Connecticut, Massachusetts, California, South Carolina, Texas, Florida and Hawaii.6/

In many ways, the California experience best illustrates the national threat to groundwater presented by pesticides. The drinking water of nearly 13 million Californians is derived

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5/ J.D. Francis, et al., National Statistical Assessment of Rural Water Conditions (Ithaca, New York: Cornell University, June 1984).

6/ Stuart Cohen, Office of Pesticide Programs, Environmental Protection Agency, Speech before National Coalition Against Misuse of Pesticides National Forum, March 2, 1985, Washington, D.C.

from groundwater sources. More than 90 percent of rural Californians depend on groundwater as their primary source of drinking water. California also leads the nation in pesticide use. A recent, jarring report, from the California Assembly Office of Research entitled The Leaching Fields -- A Nonpoint Threat to Groundwater, found that pesticide contamination of drinking water constitutes "a serious threat to public health."7/ This seminal study found that 57 different pesticides have contaminated almost 3,000 wells in 28 counties. At least 22 of those pesticides have thus far been traced to agricultural use and the residues were found both in rural and major urban counties, including Los Angeles, Contra Costa, San Diego and Sacramento.8/

The health threat presented by pesticides in drinking water is obvious. DBCP is known to cause cancer, genetic changes and male sterility and also damage human kidneys, lungs and liver. Increased cancer mortality rates already have been found in parts of California served by wells contaminated by DBCP. A California Department of Health Services epidemiological study found a positive association between DBCP drinking water contamination in Fresno, California and an increased number of deaths from 1970 to 1979 due to stomach cancer and lymphoid leukemia, both linked to

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7/ The Leaching Fields: A Nonpoint Threat to Groundwater, Assembly Office of Research , Joint Publications Office (Sacramento, 1985) at ii.

8/ See chart attached to this testimony as Appendix A.

DBCP in laboratory experiments.[9/] And the pesticide EDB, a "close cousin" of DBCP, was banned last year after being linked to cancer and genetic mutations. Other pesticides found in groundwater include such known or suspected "bad actors" as DDT, aldrin, dieldrin, Lindane, parathion, heptachlor, chlordane, toxaphene and 2,4,5-T. All of these have been linked to serious chronic health effects and have been placed in restricted use, made the subject of an EPA "special review" or have been cancelled entirely.

Congress has fundamentally failed to protect the American public from pesticide contamination of groundwater, despite the enactment of several related statutes. The Safe Drinking Water Act provides a particularly good example. Enacted in 1974 to create an enforcement system to reduce groundwater contamination, the Act requires EPA (1) to identify contaminants that may have an adverse effect on human health and (2) to determine the maximum amount of each contaminant that could safely be consumed in drinking water. All public water supply systems are then to be monitored for each specific contaminant. If the contaminant is above the established maximum contaminant level (MCL) the water supply must be treated or closed down. The EPA has set

9/ Richard J. Jackson, "Literature Review on the Toxicological Aspects of DBCP and an Epidemiological Comparison of Patterns of DBCP Drinking Water Contamination with Mortality Rates from Selected Cancers in Fresno County," California - 1970-79: A Report to the California Department of Food and Agriculture (Berkeley: Department of Health Services, 1982).

MCLs for only six pesticides (less than one percent of all pesticide active ingredients). They are: endrin (minimal use), toxaphene (suspended in 1983), 2,4,5-T (cancelled in 1979 except for a few uses), Lindane, 2,4-D, and methoxychlor. A host of widely-used pesticides, including virtually all that have been found in groundwater, have been ignored by EPA.10/

Similar neglect is found in other applicable federal statutes. The Clean Water Act, regulating waste discharges in surface water, has been interpreted not to apply to agricultural irrigation return flows, a primary source of pesticide contamination. The Resource Conservation and Recovery Act (RCRA) has almost no effect on pesticides (as a nonpoint source) because it ragulates the disposal of solid and hazardous waste. And Superfund, while it theoretically applies to pesticide contamination of groundwater, has never been invoked for that purpose. To be fair, EPA is seriously considering five different Superfund sites in Hawaii where groundwater has been seriously contaminated with the pesticides DBCP and EDB. In response, the Reagan Administration is seeking to amend the law and write pesticides out of that statute as well. Unfortunately, closing our eyes to pesticide contamination of groundwater will not deny its reality. Regressive amendments to statutes cannot change

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10/ New proposed amendments to Safe Drinking Water Act would require issuance of MCLs for twenty additional pesticide chemicals. See, H.R. 1650 (Madigan, R. I. at p. 1) and S. 124 (Durenberger, Minn.).

he chemical composition of polluted water.

Another way to state the foregoing is that the principal statutes enacted to protect groundwater have as their major emphasis the control of point source pollution; they ignore nonpoint sources of pollution. It is significant that a point source of contamination, such as a leaking tank or surface impoundment, can be repaired to contain the problem and responsibility is narrowly applied. But responsibility for nonpoint pesticide contamination is more difficult to ascertain and impossible to control without limiting or prohibiting the use of the substance endangering groundwater. It has become a truism that once a groundwater aquifer is contaminated, it is very difficult to restore it to a useable condition. Natural processes such as precipitation recharge usually take decades to flush out the contamination. Pesticide use on a major scale has really been a phenomenon of only three decades in the United States; it took thousands of years for rainwater to reach many of the nation's deeper aquifers.[11/]

Of course, the statute enacted primarily to protect the environment and public from health risks posed by pesticides is the FIFRA. It contains no mention of groundwater or drinking water whatsoever. Even today, very little environmental fate data have been generated since the overwhelming majority of

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11/ Vladimer Novotny and Gordon Chesters, Handbook of Nonpoint Pollution, New York, Van Nostrand Reinhold Company, 1981, p. 270.

pesticides in use in the United States were initially registered in the 1950s and 60s. This lack of data, together with the enormous "data gap" regarding the potential human health and environmental effects of these chemicals discussed below, truly represent a time bomb, particularly in rural America. We believe that it is especially important to emphasize to this Committee that it is probably the nation's farmers that are most at risk because farm families are almost totally dependent on groundwater for their drinking water supply. As the California Assembly Office of Research found:

> In addition to the cost of containing and eliminating existing contamination and the long-term cost to public health, the agricultural community incurs heavy costs from having pesticides in groundwater.. If contamination renders the water supply useless for agricultural purposes another supply must be found usually by drilling a deeper well which creates higher pumping costs. Groundwater contamination also can contribute to reduced productivity of the land, loss of output due to damaged perennial crops lost revenue from the disposal of contaminated food products, and decreased livestock productivity. As a result, property values will likely decline dramatically. Most importantly, the farm family often depends on well water for all its domestic needs, including drinking water. Pesticide contamination therefore directly threatens the health of farmers and their families
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> The agricultural community also suffers an intangible but important loss by being associated with the pollution of a public resource that is valued for its purity....[T]he agricultural community stands to lose a great deal, even if it is not deserved, by being identified as an accomplice in the contamination

of the state's drinking water. 12/

The responsibility to adequately test their products -- and take all necessary steps to ensure that when used properly, they wil not contaminate groundwater -- falls squarely upon the petrochemical industry. This can be accomplished only by requiring that all pesticide chemicals now being marketed be fully tested to determine their health effects and potential for groundwater contamination by a date certain.

Further, FIFRA should be amended specifically to address the groundwater threat, requiring a series of specific steps once pesticide contamination is discovered. First, the Environmental Protection Agency should immediately notify the state and the pesticide registrant or registrants of the contamination involved. Within six months of such notice, registration of the pesticide found in groundwater should be cancelled for the resulting contamination unless (1) the affected state has developed and implemented a plan to prevent further contamination of the aquifer, or (2) the registrant has appropriately amended the pesticide label to accomplish that result. The Pesticide Reform Act of 1985 would achieve these goals and represents the first serious effort to address the growing threat posed by pesticides in groundwater.

In a very real sense, the actual longterm threat to underground drinking water supplies posed by pesticides remains

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12/ The Leaching Fields: A Nonpoint Threat to Groundwater, supra, at 34-35.

unknown. Monitoring of groundwater in the United States for pesticide contamination remains primitive at best. Yet more and more of these chemicals are applied to the land each year -- from approximately 500,000 pounds in 1951 to 1.4 billion pounds in 1977 to an estimated 2.5 billion pounds in 1980.[13/]

The ability of a chemical to migrate to an aquifer is complex, involving both the properties of the chemical itself (e.g., water solubility, volatility, degradability), as well as geologic conditions and the makeup of the soil. What is certain is that it often will take many years for pesticides to reach an aquifer. Yet, we continue to add to the supply of these chemicals in the soil in a helter-skelter fashion, with little knowledge of their potential to reach groundwater and in virtual

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13/ Maddy, "Pesticide Usage in California and the United States," California Department of Food and Agriculture Report, H.S. 1071, January 20, 1983 at p. 3. In recent years, there has been a shift from organochlorines to organophosphates and carbamates. The newer pesticides generally are less persistent in the environment but are more water soluble, more mobile in soil and more acutely toxic. Some chemicals, such as nematicides, are injected directly into the soil. Others are mixed with irrigation water before the water is applied to the land in a process known as chemigation. Conventional irrigation practices, in which such water was applied either by sprinkler, furrow or flooding, increase the likelihood of chemical leaching through the soil and entering groundwater. Also see, Leaching Fields, supra.

ignorance of those chemicals that have already done so.14/

II.

THE FEDERAL PESTICIDE SYSTEM: A CASE STUDY IN FAILURE

In addition to the increasing evidence of pesticide contamination of groundwater, there is, of course, the issue of protecting the American food supply, home, workplace and environment from these hazardous chemicals. Here, too, FIFRA presents a case study in failure.

A. Protection of the Food Chain

Recently, a Harris opinion poll was conducted for the Food

14/ In response to the DBCP discovery in California, that state's Legislature enacted legislation requiring appropriate government agencies to monitor drinking water for a number of organic chemicals. Forty pesticides were identified as presenting the greatest threat to groundwater and are the subject of a monitoring program. None of the forty pesticides is tested for nationally under the Safe Drinking Water Act. The results of the monitoring should be available this summer, but a number of pesticides have already been found in public drinking water including atrazine, simazine endosulfan, 1,3-D, dimethoate and dicofol. Leaching Fields, supra, at 50.

As the Office of Technology Assessment noted in a recent study:

> One of the potentially most important, and as yet relatively unexplored, health issues of groundwater contamination is that contaminated aquifers usually contain more than one substance. Knowledge is almost totally lacking about possible interactions among combinations of substances, such interactions in which subsequent impacts are qualitatively and quantitatively different than expected (and usually greater -- i.e., synergistic) are common in many chemical and biological processes.

Protecting the Nation's Groundwater from Contamination, (Washington DC: U.S. Congress, Office of Technology Assessment, OTA-D-233, October 1984) at 34 (emphasis in original).

Marketing Institute (an industry group) about a variety of food quality issues, such as the use of food additives, cholesterol and the like. Pesticide contamination of the food chain topped the poll by a wide margin. The poll, conducted before the massive publicity over EDB, found a full 77 percent of the American public believes pesticides in food present "a serious hazard."[15/] Substantial evidence supports that belief.

The lack of effective EPA regulation of the pesticide ethylene dibromide (EDB) is now well known. Ten years after the National Cancer Institute first determined that "there is strong evidence that EDB is likely to cause cancer in humans," EPA finally banned its use. Residues of EDB will remain in the food supply for years to come. The failure of EPA to adequately protect the American public from this dangerous pesticide was not an aberration. On the contrary, it was the foreseeable consequence of fundamental deficiencies in the pesticide regulatory process. And, without basic changes in the federal pesticide laws, the EDB debacle, with its attendant public fears, disruption of commerce and serious health risks, will most certainly be repeated.

Just by way of example, consider the ethylene bisdithiocarbamates, or the EBDCs. This family of six different chemicals are among the most widely used fungicides in the United States, the 30.6 million pounds applied in 1978, constituted

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15/ See Appendix B, attached to this testimony.

one-third to one-half of all fungicides used in American agriculture. Ethylene thiourea (ETU) a degradation product, metabolite and contaminant of each of the EBDCs is formed readily in processing and cooking. The EBDCs are used on more than 30 percent of American tomatoes, tobacco, spinach and apples, as well as fifty percent of the potato crop, two-thirds of the mushrooms and one hundred percent of imported bananas. According to EPA documents, "dietary exposure [to the EBDCs and ETU] potentially affects [sic] the entire US population." A duPont study of ETU in processed foods and canned vegetables and fruits found 23 percent of its sample contained ETU. ETU also has been found in foods where no tolerances exist such as meat, milk and eggs.

Both the EBDCs and ETU cause cancer, birth defects, genetic mutations, thyroid effects, and are acutely toxic. EPA documents quantify these risks at very high levels, acknowledging general dietary cancer risks as great as $5x10^{-4}$ (or 100,000 additional cancers over a lifetime in the American population), thyroid risks at $4x10^{-3}$, applicator cancer risks in the 10^{-2} range, with margins of safety for some applicators of less than ten. In six separate cancer studies, ETU and the EBDCs were found to cause liver, lung and thyroid tumors. EPA documents also show ETU to be teratogenic.

The EBDCs were placed into special review or RPAR by EPA in 1977 -- eight years ago. Following a series of private meetings with registrants of the chemicals, the EBDCs were returned to

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general registration with minimal protections for applicators and no steps addressing the contamination of food. EPA has now agreed to "reassess" this decision by December 31, 1986, after obtaining more scientific data. In the interim, exposure to these dangerous chemicals in the food supply continues unabated. "Safe" tolerance levels for the carcinogenic EBDCs remain undisturbed. No tolerance has ever been established for ETU.

The EBDCs/ETU are not unique. They are the norm. Dozens of examples exist of pesticides found in the American food supply that are known or suspect carcinogens or mutagens, that have "safe" tolerances set with false or fraudulent scientific studies, or that have not been tested at all.16/

Recently, a list of some 100 inert ingredients believed or suspected by EPA of being "toxicologically significant" was submitted to the EPA Science Advisory Panel. While that list was the subject of testimony from EPA Assistant Administrator John Moore at the April 18 hearings before this Subcommittee, it has nonetheless still not been made public. Yet, much of the American public is regularly exposed to these "toxicologically significant" chemicals in their food.

The issue of toxic inerts is not limited to dietary exposure. Recently, it was learned that the widely-used

16/ See, Mott, Lawrie, Pesticides in Food: What the Public Needs to Know, (San Francisco, 1984); also see Section III, below: "The Data Gap: Blind Regulators Cast Adrift in a Sea of Ignorance."

pesticide dicofol, a home use and agricultural pesticide that has also been found in groundwater, contains the banned pesticide DDT, as an inert and contaminant. In March 1984, EPA issued a special review of dicofol because, due to its DDT contamination, its use posed a threat to wildlife, particularly bird populations. When DDT was canceled in 1972, EPA went through their files to look for uses of DDT -- but their files were not indexed to reflect inert compounds. Therefore, it was not until 1979 when the Agency commenced a registration standard review that DDT was "discovered" in dicofol -- even though the registrants had been submitting confidential statemants of formula since 1957 indicating the presence of DDT.[17/] Despite the knowledge in 1979 that an RPAR trigger of hazard to wildlife had been exceeded, EPA did not initiate special review until 1984. All dicofol products contain approximately ten parcent DDT impurities.[18/] It is unlikely that workers manufacturing or applying dicofol -- or consumers using it ins their homes -- knew that they were working with DDT.

The dicofol incident underscores the systemic failure of EPA to evaluate the safety or otherwise regulate the so-called inert ingredients contained in all pesticide products. While these substances may be inert as to pests, many are not as to

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17/ Synar report, supra, pp. 17-18.

18/ 49 Fed. Reg. 39822 (October 10, 1984).

humans. They include such known health threats as the glycol ethers, benzene, formaldehyde, vinyl chloride, ethylene dichloride, hydrazine, and epichlorohydrin.[19/] In deciding whether to register, restrict or cancel a pesticide, FIFRA requires EPA to determine whether the product will have "an unreasonable adverse effect on man or the environment." For reasons that are far from clear, the Agency simply chooses not to require registrants to submit chronic health and safety studies of inert ingredients. Further, the Agency has granted blanket exemptions from the tolerance requirements of § 408 of the Food, Drug and Cosmetic Act to approximately 500 different inert ingredients. All of the chemicals listed above, for example, have been exempted from food tolerance requirements, with little or no data concerning their toxicological effects or residues in the food chain.[20/]

FIFRA should, therefore, be amended to direct the Administrator to carry out duties already imposed by existing law, prohibiting the registration or reregistration of a pesticide chemical containing an inert that causes unreasonable adverse effects on humans or the environment. The Administrator should be further required, no later than July 1, 1986, to

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19/ Epichlorohydrin was listed as a potential RPAR candidate in 1978 for oncogenicity, mutagenicity, and other chronic effects. 43 Fed. Reg. 16808 (March 14, 1980).

20/ 40 C.F.R. 108.1001, attached hereto as Exhibit C.

develop a plan to evaluate inert ingredients contained in pesticides already on the market that may cause unreasonable adverse effects on man or the environment and issue appropriate regulations. Exceptions should be provided for inerts that are generally recognized by scientific experts to be safe for use. Health and safety studies on such inerts should be made available to the public pursuant to § 10 of FIFRA provided that the Administrator not disclose the percentage of each inert ingredient unless to do so is necessary to protect the public interest.

B. Home Use: The Hidden Risks

The average American consumer enters a supermarket, garden shop or paint store with a wholly false sense of security -- what some have characterized as an illusion of safety. He or she assumes the product purchased over the counter is safe, tested by the seller, approved by the government. Nothing on the label indicates otherwise. Nothing is further from the truth.

Take captan as one example. Captan is a widely used agricultural pesticide applied to a variety of vegetables and fruits such as apples, peaches and strawberries. It is also sold commonly for home garden use and is an ingredient used in shampoos, cosmetics and mattresses.

Captan was placed into special review or RPAR by EPA in 1980 due to evidence of carcinogenicity, teratogenicity, adverse reproductive effects and mutagenicity. Much of the original health and safety testing performed for captan came from

Industrial Biotest (IBT) Laboratories and has been determined to be invalid. A former Stauffer Chemical Company scientist in a letter to Senator Helms, Chairman, Senate Committee on Agriculture, Nutrition and Forestry, reported that while at Stauffer, experiments he conducted produced results demonstrating that "the mutagenic compound, captan, reaches the gonads of mammals after oral administration." The scientist, Dr. Clifford A. Selsky, told Senator Helms that Stauffer did not allow him to report fully on his findings and that he was asked to resign -- and did.21/

EPA will soon issue a proposed preliminary decision for captan cancelling its use on food crops, continuing its nonfood and home uses and requiring protective clothing for some workers. However, the proposal will be delayed until at least April 1987 to require submission of crop residue data. In the interim, EPA will provide FDA with captan toxicity data for consideration in regulating its use in shampoos and cosmetics. EPA estimates the dietary risk from captan exposure to be $5x10^{-4}$, the risk from its use in cosmetics is $2x10^{-5}$, and for shampoos the estimate is $2x10^{-3}$.22/ Following eventual

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21/ Pesticide and Toxic Chemical News, September 22, 1982 at p. 29.

22/ Pesticide and Toxic Chemical News, March 20, 1985, at p. 3.

issuance of a final decision by EPA, the registrants of captan may still avail themselves of lengthy cancellation procedures, set forth in § 6(b) of FIFRA, and judicial review.

Then there's the case of pentachlorophenol, placed into RPAR seven years ago, in 1978. Penta is used in millions of homes, on telephone polls, childrens' playgrounds, as a general wood preservant and for pressure treating lumber. It is sold over the counter for home use throughout the United States. Initially placed into RPAR due to its teratogenic and fetotoxic effects, penta also contains a dioxin contaminant (hexachlorodibenzo-P-dioxin or HxCDD), a suspected carcinogen. Studies linking penta with birth defects in animals appeared as early as 1974. Eighty-five percent of Americans have penta in their urine. Its residues periodically turn up in samples of meat, poultry and other food stuffs.

In February of 1981, EPA issued a proposed decision on penta, cancelling outright registrations for over-the-counter retail sale and imposing a variety of restrictions on the chemical. In June of 1981, the EPA Science Advisory Panel unanimously approved the proposed decision,

> deplor[ing] the lack of scientific objectivity of the presentations by industry concerning the biological hazards of wood preservatives and find[ing] the industry's denial of scientific data concerning the mutagenicity and carcinogencity of the wood preservatives to be disturbing.

Thereafter, roughly thirty separate private meetings occurred between representatives of industry and EPA. A

subsequent decision released in February 1983, on industry letterhead, was substantially weaker than initially proposed. In response to a letter from Senator Jesse Helms, Assistant EPA Administrator John Todhunter indicated that "we now have a cooperative relationship with industry."

After public criticism and litigation challenging such closed meetings, this agreement was withdrawn. A final decision was issued on July 11, 1984, among other things, limiting the use of penta to certified applicators, requiring a consumer awareness program and reducing the dioxin contamination in pentachlorophenol to 15 ppm immediately and to one ppm within 18 months. This decision has now been contested by the wood preservant industry, which has requested a cancellation hearing. The industry also has filed suit in federal court in Louisiana challenging the fairness of the procedures followed in reaching the penta RPAR decision. Thus, seven years after the RPAR on penta was initiated, the chemical remains on the market without restriction, sold to an unknowing public.

We wish to emphasize that captan and penta are only examples. The EBDCs are sold for home garden use in a variety of products. Lindane, a chlorinated hydrocarbon, has been linked to cancer and chronic reproductive and fetotoxic effects. It is used in everything from pet dip to floor wax. Benomyl, linked to birth defects, reduced sperm count, genetic mutations and cancer, is registered for use on home lawns. The labels of any of these

products offer no hint that these products may be hazardous -- except "to aquatic organisms " or fish.

C. Proposed Reforms of Pesticide Regulatory Process.

As the EDB case and above examples demonstrate, even after serious health hazards become known, it takes many years at best to effectively regulate a pesticide through EPA's RPAR or special review process. And then come lengthy administrative trial-type hearings. And judicial review, yet as a kind of "worst first" system, RPAR or special review was created in 1975 to give expedited attention to those chemicals most suspected of posing the highest degree of health or environmental risk. The entire procedure was designed to take no more than 300 days. In fact, no special review has ever been completed within that time period. Instead, once publicly initiated, special reviews take an average of two to four years to complete and in some cases have dragged on for seven years. Furthermore, it can take several years to commence the public review even though the Agency has data indicating the need for review. For example, EPA received a positive cancer study for EDB from the National Cancer Institute in 1974; yet the RPAR was not initiated until 1977. Internal EPA documents indicate that EPA considered initiating an RPAR review for damirocide as early as 1981; EPA publicly announced the review in July 1984. As of March 1984, after almost ten years since adoption of the procedure, EPA had

completed special reviews for only 19 pesticides.[23/]

Thus, even in the face of substantial evidence of environmental or human health risks, the present statutory schema creates inherent delays of many years before chemicals known to be hazardous can be restricted or removed from the marketplace. The Pesticide Reform Act of 1985 will streamline the entire special review and cancellation procedures by redefining special reviews, establishing specific timetables for their completion, simplifying cancellation procedures, providing for expedited hearings and eliminating oral testimony except in exceptional cases. Judicial review then remains available. Due process requires no more than this, and public health requires no less.

III.

THE "DATA GAP": BLIND REGULATORS CAST ADRIFT IN A SEA OF IGNORANCE

The inability of government bureaucracy to expeditiously

23/ "Status Report on Rebuttable Presumption Against Registration (RPAR) or Special Review Chemicals, Registration Standards Program and Data Call-In Program," (Washington DC: Office of Pesticide Progrsms, EPA, September 1984) pp. 17-26. Until recently, the RPAR process was frequently the vehicle for numerous "sweetheart agreements" between EPA and pesticide registrants, reached in so-called "decision conferences" held behind closed doors. As a result of settlement of a federal lawsuit brought by NRDC and the AFL-CIO, EPA will now reassess such decisions for more than a dozen pesticide chemicals, including the EBDCs, paraquat, PCNB, benomyl and lindane. In addition, pursuant to the settlement, last month EPA issued proposed ragulations to ensure public participation in this special review or RPAR process.

cancel or restrict the use of pesticides known to present serious health hazards is, however, not the most serious deficiency in the federal pesticide regulatory scheme. This is because, in most cases, we are simply acting -- or more correctly, not acting -- out of ignorance. The vast majority of pesticides in use today have not been tested in a manner that EPA can assure the American public that the continued use of these untested chemicals is not creating a toxic time bomb. It is difficult to imagine a situation more fraught with danger.

Central to the failure to effectively regulate pesticides in the United States is the absence of accurate scientific studies addressing tha ability of these chemicals to cause cancer, birth defects, nerve damage, reproductive disorders and other acute and chronic health effects in the human population. The reason for this vast pool of ignorance is that most pesticides were registered in the 1950s and 1960s. Yet, cancer-causing capacity was recognized as a danger only in the mid-1960s; the capacity of pesticides to cause genetic mutations and birth defects was perceived only in the late 1960s and early 1970s. In each case, tests for these dangers were required only prospectively. That is, pesticides registered prior to the adoption of the new testing requirements were inexplicably "grandfathered in." Since most pesticides in use today were registered before the current testing requirements were adopted, we are literally adrift in a vast sea of pesticide ignorance.

Sadly, this is no new revelation. It was first recognized in 1972 when Congress mandated that all the then-presently registered pesticides be retested in light of contemporary standards within five years. What has EPA done under this mandate? In the thirteen years since Congress acted, EPA can now give a full assurance of safety to only six pesticide active ingredients. EPA has projected that they can now (given the very limited personnel resources presently devoted to the effort) reregister 25 pesticides per year. That means it will take until 2003 to complete the job! Most often, Congress is presented with vastly different estimates of the magnitude of a problem. However, in this case, no faction disagrees:

- The EPA concluded in 1981 that "very few of the thousands of pesticides registered between 1947 and 1974 have undergone modern testing for chronic effects." ("Reregistration Standards Evaluation," EPA, October 15, 1981, p. 8.)
- A 1983 staff report by this Subcommittee found that 85 percent of the federally registered pesticides lacked adequate data to assess their ability to cause cancer in humans; roughly two-thirds lack such data to assess teratogenicity, and 93 percent lacked adequate data to assess mutagenicity.
- Most recently, a report from the National Academy of Sciences in 1984 found that the chemical industry had

provided sufficient health and safety data for complete health hazard assessments of only ten percent of pesticides now in use.

- For the vast majority of pesticides widely used in the U.S., "data bases are woefully inadequate and [moreover] the existing data have not been evaluated by current standards." (Statement of John A. Moore, Assistant Administrator for Pesticides and Toxic Substances, EPA, before the DORFA Subcommittee, House Agriculture Committee, April 18, 1985, p. 2.)
- Even when new data has been generated, serious questions exist about EPA's ability to independently evaluate such data. A 1983 Congressional audit uncovered several dozen cases where EPA data analysis were "verbatim transcripts of the applicant's report...and failed to assess the accuracy and completeness of the submission." (Regulation of Pesticides, Appendix to Hearings of the DORFA Subcommittee, House Agriculture Committee, Vol. IV, 1983, pp. 13, 123-24.)

Even the little data that exists is of questionable reliability. Registration of nearly one-third of all pesticides still rests on data supplied by the Industrial Biotest Laboratories (IBT), now known to have systematically submitted a huge number of falsified research studies over an extended period of time. More than 90 percent of the studies conducted by IBT are now known to be invalid. Much of the data have yet to be

replaced. And, while three IBT officials recently began prison terms, chemicals registered with IBT studies remain on the market -- a wide variety of products, including structural pest control agents, home cleansers, wood preservants, hospital disinfectants, as well as poisons used to control many agricultural pests. Hopefully, the IBT criminal prosecution will serve to deter future conduct by other laboratories that place the profit and loss statement above life and health. But what justifiable basis is there for Congress to permit the results of this pervasive criminal conduct to continue to endanger the very health and lives of present and future generations? Surely, the economic well being of the pesticide industry cannot be paramount to the lives and health of the entire American population.

How can we have come to such an extraordinarily dangerous state of affairs? How can it have come to pass that a bureaucratically neutral term such as "data gap" can have evolved to describe this mess? This is not just a problem of inadequate filing systems.

In its 1972 amendments to FIFRA, Congress charged EPA with the duty to reregister pesticides in compliance with the new comprehensive health and safety data requirements. Originally the Agency was to complete the task by October 21, 1976. This deadline was later extended to October 21, 1977 and ultimately eliminated entirely. After numerous false starts, EPA now claims to have the reregistration process operating smoothly through the registration standards program. Yet, by EPA's own admission, it

may take until 2003 to complete all the necessary registration standards, at the current rate of 25 issued per year. (This estimate may be decreased by a few years if registrants voluntarily cancel their older products with limited markets in response to EPA requests to submit data.)

When asked about progress towards reregistration of the approximately 600 older pesticides, EPA will cite statistics concerning its registration standards program. We have examined the registration standard program accomplishments through the end of FY 1984 (September 30, 1984) and have found that EPA's confidence in the approach belies the reality. By the end of FY 1984, 89 "registration standards" had been issued. We closely examined 87 of these standards and found several significant problems. (Two standards -- hypochlorites and potassium iodate -- were not available for review). Only nine of those 87 pesticides had complete health and safety data at the time the standards were issued. Thirteen pesticides had no chronic health and safety data when the standards were completed. For nine chemicals, all chronic health effects data requirements were waived. That leaves 56 pesticides still with data gaps even after the so-called "standards" were issued.

Obviously, the registration standards program is not filling data gaps as many have believed. Moreover, a registration standard no longer means that the chemical has been reregistered. In fact, only six chemicals have been actually reregistered to date, and only two of these had a complete

complement of health and safety data on file when EPA granted reregistration.[24/] In other words, EPA is reregistering chemicals without full scientific information on their health effects. In summary, EPA's current reregistration program through the issuance of registration standards is simply reregistration through semantics.

EPA's registration process for new active ingredients is also seriously flawed. Consider that ten to fifteen new pesticides are registered for use each year. EPA grants "conditional" registrations for about half of these. In other words, EPA is allowing even more chemicals on the market that have never before been used without all the required data.

In FY 1984, registration of new active ingredients took a more astonishing turn when the Agency registered two separate pesticides that had never before been used even though both exceeded RPAR triggers. Ethalfluralin, an herbicide, was found to be oncogenic, and EPA estimated the risk of dietary exposure to be 3.77×10^{-6} excess cancer cases.[25/] Cypermethrin, a synthetic pyrethroid insecticide for use on cotton that would result in meat and milk residues, was found to be oncogenic in mice. Despite acknowledging their potential health risks, EPA did not place either of these chemicals into RPAR or special

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24/ One of these chemicals, Glean, is a new pesticide ingredient that was not originally included in approximately 600 "older" pesticides registered prior to 1972.

25/ 49 Fed. Reg. 391 (January 4, 1984).

review. Then, in a December 20, 1984 Federal Register notice, the Agency counted both chemicals as completed special reviews.26/

The solution to this central weakness in the pesticide regulatory scheme must include the establishment of a specific timetable for submission of full health and safety studies by the pesticide industry to EPA coupled with imposition of a registration fee system generating sufficient funds that the reregistration and special review systems can become self-supporting. It is certainly within the economic self-interest of the pesticide industry to obtain an accurate, honest government "seal of approval." This valuable public endorsement of their products has a price, and they should pay it. Amendments in the Pesticide Reform Act of 1985 would accomplish this result. These amendments are modeled on the California Birth Defect Prevention Act of 1984, Senate Bill 950 (Petris), recently overwhelmingly enacted by the California Legislature and signed into law by Governor George Deukmejian. These amendments would require that for the 300 pesticide active ingredients, most widely in use, all necessary data be submitted to EPA by 1990. Data for all remaining pesticides must be submitted by 1991. If data is not submitted in a timely fashion, EPA shall obtain the necessary data by contracting with private firms, or otherwise, and then assessing the applicable

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26/ 49 Fed. Reg. 49547 (December 20, 1984).

registrants with the testing costs. Finally, a provision is proposed that will eliminate the possibility of data gaps in the future by requiring that tests for newly-perceived dangers of pesticide use be required not just for newly-registered pesticides, but also for all those registered in the past. Congress should never permit this sorry chapter in public policy to be repeated.

IV.

ENHANCED PUBLIC RIGHT TO KNOW AND PARTICIPATE

Even with the changes to increase public participation being made at EPA pursuant to a stipulated court order (in the NRDC-AFL-CIO case), nonetheless the general public remains effectively frozen out of many key stages of the pesticide regulatory process. For example, as currently interpreted, FIFRA § 3(c)(2)(A) denies the public the right to review and comment upon the relevant scientific evidence underlying applications to register pesticides and establish food tolerances until 30 days after the final decision is made by the Agency. As the experiences with EDB, heptachlor, chlordane, DBCP and a host of other chemicals make clear, once on the market, removal of a pesticide's registration or tolerance requires a herculean effort. Moreover, as the result of the U.S. Court of Appeals decision in Environmental Defense Fund v. Costle, 15 E.R.C. 1218 (D.C. Cir. 1980), only pesticide registrants -- and not environmental, consumer or labor groups or other interested members of the public -- may demand a hearing if they are

dissatisfied with the Agency's final determination in the RPAR process or otherwise. Among the results of this slanted system is that the Agency will quite commonly tailor its final RPAR decision in a pro-industry manner, in order to avoid possible challenge in a cancellation hearing.

By amendments to §§ 3 and 6(b) of the Act, the Pesticide Reform Act of 1985, will provide full access to health and safety data prior to granting registrations or establishing food tolerances; a 60-day period would be provided for members of the public wishing to comment. Moreover, by amending § 6(b) of the Act, the general public would be given standing to initiate and participate in cancellation hearings, irrespective of whether they have an economic interest in the pesticide involved. Finally, these amendments would repeal the 1978 Grassley-Allen amendment to FIFRA which has been interpreted by EPA to require the Agency to privately and without public review give registrants an opportunity to rebut evidence of environmental risk even before initiating the RPAR process.

Further, this bill would establish a federal "right to know" for pesticides manufactured in the United States. All pesticide producers registered under FIFRA would be required to submit pertinent information to the Administrator concerning, among other things, the identity of pesticides produced and intermediary chemicals used, a summary of their health and environmental risks, the location of manufacturing plants cited either in the United States or abroad, the proximity of such

plants to residential neighborhoods and plans for evacuation or other measures in case of an emergency. The information would be fully available to appropriate local and state authorities, fire and police officials and members of the interested public. EPA would also issue a report annually providing information concerning the nature, quantity and uses of pesticides in commerce. During recent environmental incidents involving such pesticides as EDB and DBCP, the Agency was unable even to accurately inform the public of the extent to which these deadly toxins were being used or were being found in the American food supply.

VI.

BIRTH DEFECT PREVENTION

Teratogenicity, the ability to produce birth defects, can result from inhaling, eating, or absorbing through the skin, a chemical early in pregnancy. Unlike other health hazards, where repeated exposure may be necessary to produce a result, one single exposure to a teratogen can produce birth defects.

For many years, it has been known that certain pesticides cause birth defects in human beings. The decision of EPA to ban the herbicide 2,4,5-T was based largely upon its teratogenic effects. However, ignoring years of laboratory test data, EPA waited until there was actual evidence that human beings were suffering birth defects before taking effective action against that pesticide.

According to the California Department of Food and Agriculture, only 28 pesticides are suspected teratogens.27/ Given the availability of numerous effective pesticides that are not teratogens, little justification exists for the continued home and agricultural use of a relatively small but dangerous number of chemicals that can cause sterility or infertility in prospective parents and deformities, spontaneous abortions, stillbirths and other severe adverse effects on unborn children.

Experience has shown that existing controls reportedly intended to reduce exposure to pesticides are unreliable and insufficient to prevent the extraordinary human costs and suffering occasioned by birth defects and other reproductive injuries. Until adequate enforcement mechanisms exist, the law must stop the problem of pesticide-induced birth defects at the source -- the registration process.

FIFRA should be amended to prohibit registration of a pesticide shown to cause a statistically significant adverse effect on parental performance and the growth and development of healthy offspring as determined by valid scientific evidence. Pesticides known to cause such reproductive effects should be cancelled.

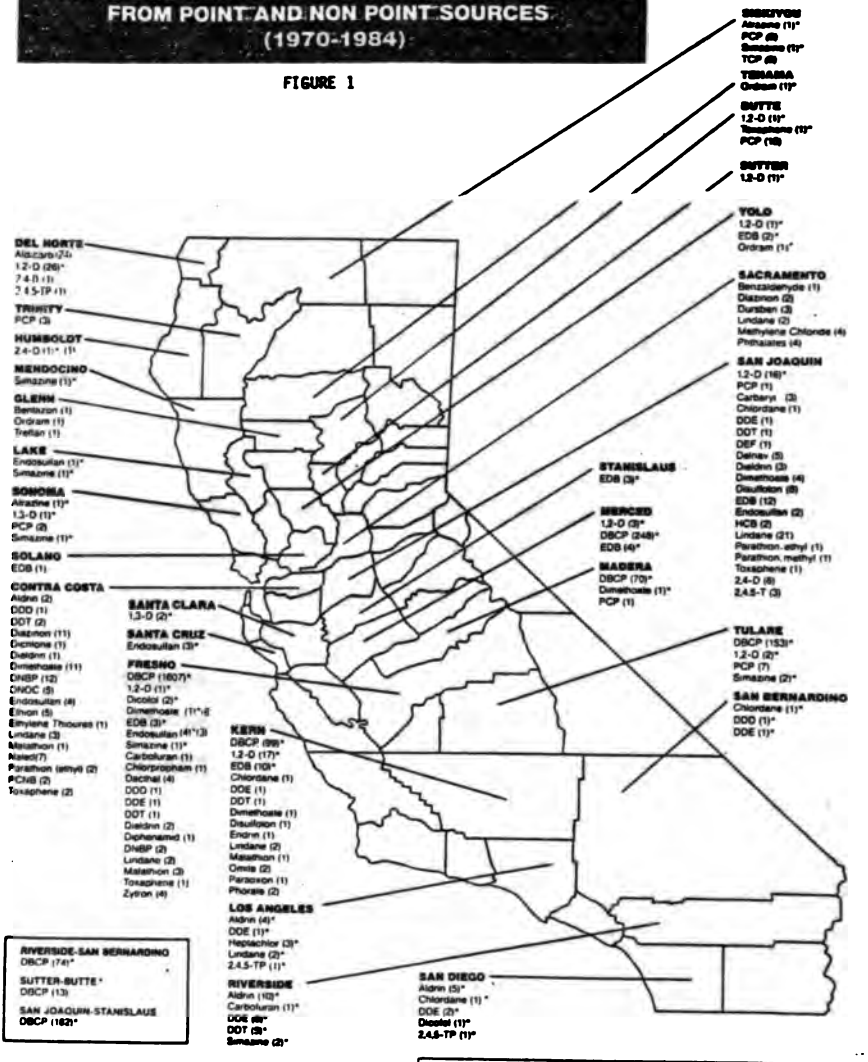
27/ Worker Health and Safety Unit, California Department of Food and Agriculture, "Selected Pesticides for Which There Have Been Some Concerns About a Teratogenic Potential," March 29, 1985.

(Appendixes A and B follow; Appendix C is held in the committee files.)

APPENDIX A

PESTICIDES CONTAMINATING CALIFORNIA'S WELLS FROM POINT AND NON POINT SOURCES (1970-1984)

FIGURE 1



* = Known and suspected non point sources
( ) = Number of contaminated wells

D.B. Cohen and G.W. Bowes, *Water Quality and Pesticides: A California Risk Assessment Program*, California Water Resources Control Board, Dec. 1984, pages 130-141. Draft Update sent Jan. 30, 1985.

APPENDIX B

Table 3

CONSUMER CONCERN ABOUT SELECTED FOOD ATTRIBUTES

Base: The shopping public

Q.: How concerned are you about the following items being in food? Would you [illegible] a serious hazard, somewhat of a hazard, or not a hazard at all?

		Serious Hazard	Something of a Hazard	Not a Hazard at All	Not Sure
Residues, such as pesticides and herbicides	%	77	18	2	3
Cholesterol	%	45	48	5	2
Salt in food	%	37	53	9	1
Additives and preservatives	%	32	55	8	4
Sugar in food	%	31	53	15	1
Artificial coloring	%	26	53	17	5

Table 4

LEVEL OF SHOPPERS' CONCERN ABOUT TAMPERING WITH NONPRESCRIPTION DRUGS ON RETAIL SHELVES

Base: The shopping public

Q.: At this time, are you personally very concerned, somewhat concerned, not very concerned, or not at all concerned about the possibility that nonprescription drugs may be tampered with on retail store shelves?

	1983 %	1984 %
Very concerned	66	50
Somewhat concerned	19	26
Not very/not at all concerned	15	23
Not sure	*	1

*Less than 0.5%.

"Public Attitudes Toward Food Safety," Tim Hammonds, Food Marketing Institute.

STATEMENT OF NANCY DRABBLE
DIRECTOR
PUBLIC CITIZEN'S CONGRESS WATCH

ELLEN HAAS
EXECUTIVE DIRECTOR
PUBLIC VOICE FOR FOOD AND HEALTH POLICY

AND
GENE KIMMELMAN
LEGLISLATIVE DIRECTOR
CONSUMER FEDERATION OF AMERICA

BEFORE THE
SUBCOMMITTEE ON DEPARTMENT OPERATIONS, RESEARCH AND FOREIGN AGRICULTURE
HOUSE AGRICULTURE COMMITTEE

ON
AMENDMENTS TO THE
FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

MAY 21, 1985

Chairman Bedell and members of the subcommittee, thank you for the invitation to testify here today. I am speaking this morning on behalf of three major consumer organizations. I am the director of Congress Watch, the lobbying arm of Public Citizen, a nationwide consumer organization with 80,000 members. Consumer Federation of America is a coalition of over 200 state, local, and national consumer organizations. Public Voice is a research, education, and advocacy group that advances the consumer interest in food, agriculture, and health policy. Our organizations have worked for many years on food safety issues. We became particularly concerned about pesticide residues on food in 1983 when we observed the EDB debacle and examined the inadequate testing of pesticides used on food and The Food and Drug Administration's lax enforcement of pesticide residue limits. Thus, we supported Rep. Henry Waxman's and Sen. David Durenburger's bills to reform the regulation of pesticides residues (H.R. 5495 and S. 3076).

But the core statute regulating pesticides, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), also needs critical amendments. Unfortunately, FIFRA fails to protect consumers, workers and the environment from dangerous pesticides. Riddled with loopholes and industry-oriented provisions, it remains an anachronistic statute which falls far short of other modern health and environmental laws. After many years of documentation of FIFRA's failures and EPA's abysmal record, critical analyses from the National Academy of Sciences and the General Accounting Office, and numerous reports and hearings by several House Committees in the last few years, our national

pesticide law remains unchanged.

We applaud your subcommittee's plan to amend FIFRA this year, and urge you to report out a bill which addresses the core defects in the law. Our coalition of consumer, environmental, labor, religious, health, and farm organizations has formed the Campaign for Pesticide Reform to express united support for the FIFRA reform bill being introduced by Rep. George Brown (D-CA) and Senator William Proxmire (D-WI). This legislation, which contains half the number of amendments of last year's reform bill, represents a lean and serious effort to correct the fundamental flaws in the law. We hope you will support it.

Key parts of this legislation would curb pesticide contamination of groundwater, prevent pesticide-induced birth defects, stop the exposure of Americans to imported food contaminated with banned pesticides, require pesticide manufacturers to finish long-mandated health and safety tests, and give local communities a right-to-know about the dangers of pesticides produced in their neighborhoods.

Unfortunately, the EPA bill fails to address even one of these problems. After years of promising the Agriculture Committee FIFRA legislation, the EPA produced a milktoast bill that could not gain OMB approval. Along with minor improvements in FIFRA, the EPA draft does contain four important amendments. It simplifies the notoriously complex cancellation hearings, eliminates the loophole which allows untrained employees to apply acutely toxic restricted used pesticides, repeals the indemnification system, and makes violations of FIFRA regulations

illegal. The Brown reform bill also amends the law in these areas. I would now like to outline in greater detail some of the amendments in the Campaign for Pesticide Reform legislation:

1. THE BILL REQUIRES EPA TO OBTAIN MISSING HEALTH AND SAFETY DATA ON PESTICIDES.

Most Americans probably assume that all pesticides have been carefully examined by EPA and have passed rigorous health aud safety tests. This is simply not true. According to the December 1982 staff report of this subcommittee, at least 84% of pesticides now in use have never been adequately tested to determine whether they cause cancer. 93% have not been tested for their capacity to cause genetic mutations. 70% lack birth defects tests. On the average, 85% of pesticides currently in use have incomplete health and safety data. Why? Most pesticides came on the market before the requirements for health and safety tests went into effect. The National Academy of Sciences reported in March, 1984 that only 10% of pesticides have sufficient health and safety data for a complete assessment of health hazards.

Under the 1972 amendments to FIFRA, Congress required EPA to "reregister" all pesticides lacking tests for cancer, birth defects, and other hazards. Under the reregistration process, older pesticides must undergo modern health and safety testing. But now, 13 years after Congress passed the reregistration requirement, EPA has a complete data package on only 6 out of the 600 active ingredients used in 40,000 pesticides! This is a scandal. At their current rate, EPA admits that it will finish reregistering pesticides at some

indefinite date well after the year 2000. Meanwhile, we continue to eat foods that contain residues of untested pesticides. Tolerances or exemptions from tolerances remain in effect for these time bomb pesticides, providing false assurance that the government has any idea of their dangers.

EPA attempts to obfuscate its failure at reregistration by pointing to the fact that it has written almost 100 "registration standards." For example, Assistant Administrator Moore said in his April 18, 1985 testimony before this subcommittee, "Of the 600 pesticide chemicals potentially subject to reregistration, the Agency has reviewed and issued registration standards for 98; 47 of these standards have been completed in the last two years." But issuance of a registration standard does not mean that the agency has received, evaluated, and approved the necessary health studies. It only means that the agency has completely reviewed the chemical's file and identified which new studies registrants must conduct; most of the work still remains to be done. Thus, it is extremely misleading for EPA to call issuance of a registration standard "reregistration."

The Brown bill would correct the reregistration problem by requiring EPA to gather the necessary information over the next several years. The amendment is modeled on the California Birth Defects Prevention Act, (California Food and Agriculture Code Section 13121 et seq.), which passed the California legislature with bipartisan support last year and was signed by Republican Governor George Deukmejian.

Under this amendment, the EPA must first identify data gaps

for the 600 active ingredients. The Administrator must issue the first list of 300 by July 1, 1986, giving priority to (a) large volume pesticides used on food, feed, or fish, (b) pesticides with the biggest data gaps, and (c) pesticides which may cause mutations. The second list of 300 must be issued by July 1, 1987.

The EPA would notify registrants on each list that they must complete the necessary tests within a resonable time, not to exceed four years. Six months later, EPA would check to see if the registrant had started the tests and made sufficient progress to ensure completion within 4 years. If it hadn't, EPA would contract with a lab to obtain the necessary test and bill the registrant if the company wanted to continue use of the pesticide. This generous schedule gives chemical companies 5-6 years from this summer to submit health and safety studies which should have been done years ago, and allows ample time for lengthy feeding studies, which can take 2-3 years. It also simplifies EPA's current system, which combines "data call notices"--which only notify companies of missing studies--with the later issuance of "registration standards"--which identify missing and inadequate studies. Even though pesticide registrants are under a legal obligation to fill the data gaps, they sit around and wait for the sluggish EPA to issue data call-in notices and registration standards, knowing they can safely market potentially dangerous pesticides in the meantime. Thus, chemical companies can play the regulatory game to reap profits from suspect chemicals for years before having to submit tests. Then they can wait for EPA to move at its glacial pace to evaluate the data and move to cancel the pesticide.

The bill also requires EPA to revoke any tolerance or exemption based on "false, misleading or inaccurate" data. During 1976 the Food and Drug Administration discovered that many health and safety studies conducted by Industrial Bio-Test Laboratories (IBT) were based on fraudulent, fabricated or non-existent data. On April 9, 1984 a federal judge sentenced three high level IBT officials to prison terms for submitting fraudulent data.

One would expect that any pesticide approved on the basis of an IBT test would be pulled off the market immediately pending new studies, since EPA would have no idea whether food residues were safe. But EPA has allowed IBT-tested pesticides to remain on food, despite the fact that only 3% of the IBT studies are definitely valid, according to a Natural Resources Defense Council analysis of EPA figures. At least 90 pesticides registered with IBT data are used on food, but EPA has not revoked any of the tolerances based on IBT tests. Under the Brown reform bill, EPA would have to revoke any registration based on unreliable data whenever such data was material to the decision.

2. <u>THE BILL WOULD PREVENT FUTURE CONTAMINATION OF GROUNDWATER</u>.

Based on 6,000-7,000 samples collected on a spotty basis, EPA has identified 16 pesticides in the groundwater of 23 states, but has not revealed which communities have contaminated groundwater. Nearly half the nation's population gets its drinking water from groundwater and many people are increasingly

alarmed by chemicals in the water they drink. Unfortunately, more evidence of tainted groundwater appears regularly.

For example, in the April, 1985 study by the Iowa Department of Water, Air and Waste Management, "Synthetic Organic Compound Sampling Survey of Public Water Supplies," scientists found pesticides in 28 of 70 monitored wells, representing 18 public water supplies. The study sampled for 34 pesticides commonly used in Iowa and pesticides detected in earlier studies, and found six. The herbicide Atrazine was detected in 35.9% of the water supplies, outranking all other synthetic organic compounds and pesticides. The sampling also revealed the pesticides Bladex, Lasso, Dyfonate, Dual, and Sencor. The study detected more pesticides in shallower wells, reporting: "Neither the occurrences of these six particular pesticides, nor the relationship between their appearance and well depth is surprising. Work conducted by the Iowa Geological Survey has shown that the most commonly used herbicides are occurring in groundwater." Concentrations of these pesticides ranged from .09 parts per billion to 3. parts per billion, excluding one city's wells, now closed, which produced concentrations of up to 13 ppb.

Iowa Geological Survey studies in northeastern Iowa have found pesticides in 70 to 80% of the wells sampled. By comparison, the April, 1985 study reports somewhat lower percentages of pesticide contamination because the Department took only one or two samples per well, which may not have been collected at the appropriate time to detect all pesticides.

Study author Richard Kelley concludes:

"While concentrations of contaminants detected in groundwater are below known acute and chronic toxic levels, there is a legitimate concern for public health. There is a general lack of information regarding the health effects related to human exposure for many of the contaminants found in this survey.

At the present time relatively unprotected aquifers are being affected by the contaminants found in this survey. However, if such chemicals persist in groundwater they will likely be transmitted to deeper, generally more protected, aquifers and thus expose larger populations over longer periods of time. Therefore, it is important that activities be undertaken to identify and eliminate the sources of the contamination and ensure the adequate detection of contaminants in the future."

The disturbing Iowa study reflects results found in other states. A recently released California legislature study found 57 pesticides in 28 counties. The potent carcinogen EDB has been detected in Texas, California, Connecticut, Massachusetts, Georgia, South Carolina, Florida and Hawaii.

The Brown bill tackles this problem by preventing future contamination of groundwater. Whenever EPA determines that a pesticide has contaminated groundwater because of agricultural use, it must move to cancel the pesticide unless the affected state develops and implements a plan to prevent future contamination or the registrant amends the label to stop additional contamination.

We adopted this approach for three reasons: First, once an aquifier becomes contaminated it is prohibitively expensive and difficult to clean up. Thus, while we can't eliminate the current pesticides which have already leached down through the soil, we should at least try to prevent any further damage. Second, the public expects its drinking water to be clean and will not accept assurances from chemical companies that a "safe" level of

pesticides can be set for pesticides in their water. The public's demand for pure drinking water rests on its understanding that we do not know enough about chronic health hazards of most pesticides in drinking water to set levels to protect public health, particularly when a water supply has traces of several pesticides. Mistakes made in setting any contaminant levels cannot be corrected later. Third, we believe that label amendments to restrict application to certain soil types or geographic areas can be effective in preventing further leaching. The EPA has imposed such restrictions on an ad hoc basis, but must do so more systematically. If the agency or state adopts appropriate measures, we do not believe that a tough approach to groundwater contamination would mean widespread pesticide cancellations.

The Congress must address this issue because EPA seems only prepared to study the issue and occasionally ask for data.

3. THE BILL PREVENTS REGISTRATION OF PESTICIDES WHICH CAUSE BIRTH DEFECTS.

Pesticides which cause birth defects deserve strict treatment in FIFRA. In our society we place a high value on ensuring that pregnant women and their unborn children are not exposed to substances which may cause birth defects, miscarriages, stillbirths, infertility or sterility. But under the current language of FIFRA, EPA can approve pestcides which cause reproductive damage. But why should we accept the use of a relatively small group of teratogenic pesticides when acceptable alternatives exist? How many deformed or dead newborns balance

57-556 O—86——15

out the benefits of one pesticide?

The California Department of Agriculture has recently released a list of 22 potentially teratogenic pesticides, 4 of which have been cancelled or withdrawn ("Selected Pesticides For Which There Have Been Some Concerns About a Teratogenic Potential," March 28, 1985). EPA decided to ban 2,4,5-T mainly because of its teratogenic effects, but waited until it had evidence of birth defects in humans before acting, even though laboratory animal data had indicated teratogenic potential years before. We do not believe that EPA should wait for children to start suffering birth defects before taking action.

The proposed change in the law would prevent the Administrator from registering or reregistering a pesticide that had been shown to cause a statistically significant adverse effect on parental reproductive performance and the growth and development of offspring as determined by the chronic health effect data submitted under section 3(c)(2) or other relevant scientific evidence. The change would also require the Administrator to cancel pesticides that cause reproductive damage.

EPA need not find that workers or consumers have been exposed to any particular dose of the pesticide in their food or workplace. A decade of experience with attempts to reduce exposure has demonstrated that consumers and workers cannot depend on those controls to reduce exposure to teratogenic pesticides--particularly since it takes only one exposure to a pesticide at an early stage of pregnancy to produce tragic

results.

4. THE BILL STREAMLINES THE CUMBERSOME CANCELLATION PROCESS

The procedural labyrinth leading to cancellation of a pesticide which causes unreasonable adverse effects on man or the environment can take ten years. While EPA moves through its absurdly convoluted process, consumers continue to suffer exposure from dangerous pesticides. In addition, EPA's credibility goes downhill when the press reports the many delays. For example, The National Cancer Institute identified EDB as a potent carcinogen in 1974, but EPA did not make a decision to ban the chemical until 1984 after states forced the agency's hand by starting to remove EDB-contaminated products from the shelves.

Consider some of the steps industry can use under current law and practice to delay cancellation:

1. Determination of Significant Evidence of Unreasonable Risks: The Grassley-Allen Amendment. When EPA receives information that a pesticide may be unsafe, it cannot even give that pesticide a Special Review (the Rebuttable Presumption Against Registration (RPAR) or "special review" process) until it has a validated test or other significant evidence raising prudent concerns of unreasonable risks. This restriction was placed on EPA in 1978 by the so-called Grassley-Allen amendment.

2. Pre-Special Review Rebuttal By Industry. While the requirement of a validated test may seem reasonable, FIFRA legislative history also requires EPA to notify a registrant privately before placing a chemical in RPAR. EPA has read the this provision to require it to give the registrant an opportunity to rebut the evidence that EPA is relying on before

it initiates the Special Review. Thus, at the pre-RPAR stage, which can take years, EPA often holds a protracted series of meetings or exchanges correspondence with industry representatives.

3. Special Review Process. Special review is an extra procedural step created by EPA to study the risks and benefits of a pesticide before moving to cancel it. EPA considers benefits again in the cancellation hearing itself. Unfortunately, special review takes an average of 2-4 years and up to 7 years. During this time, EPA prepares four Position Documents (PD 1-4) which analyze the risks and benefits of the pesticide. There is no way to predict if and when EPA will issue any Position Document.

4. Analysis of Impact on Agriculture. Before issuing a notice of intent to cancel, the statute directs the Administrator to consider the impact "on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy."

5. Referral to the Department of Agriculture. 60 days before making a notice of intent to cancel public, the Administrator must provide a copy of the notice and the EPA analysis of the impact on the agricultural economy, and ask for USDA's comments.

6. Referral to Scientific Advisory Panel. Under the same time frame, EPA must also submit its proposed action to the Scientific Advisory Panel for comment on the impact on health and the environment and the quality of EPA scientific analyses.

7. Announcement of Notice of Intent to Cancel. The EPA then issues its notice of intent to cancel the pesticide, which may become final 30 days later if no adversely affected person requests a hearing.

8. Request for Hearing. An adversely affected person has 30 days to request a hearing. The United States Court of Appeals for the D.C. Circuit in the Chlorobenzilate case, Environmental Defense Fund, Inc. v. Costle, held that environmental groups and other interested members of the public have no right under FIFRA to request a hearing when a notice of intent to cancel does not go far enough. This allows EPA to make sweetheart deals at the end of the special review process, shuting the public out of the real decisionmaking.

9. Hearing is Held. A cancellation hearing can take 2-4 years. It is essentially a trial-type proceeding, where parties raise evidence, offer expert witnesses, take depositions, conduct cross-examination, and can ask the Hearing Examiner to issue subpoenas to compel testimony to produce documents. The question of the pesticide's risks and benefits is reconsidered once again.

10. Referral to the National Academy of Sciences. Upon the request of a party to the hearing and when the Hearing Examiner thinks it is necessary or desirable, he can refer "relevant questions of scientific fact" to the National Academy of Sciences. The NAS must then convene a panel to consider the scientific questions and report back to the Hearing Examiner within 60 days.

11. Final Decision of the Administrator. Within 90 days of the completion of the hearing, the Administrator makes his final decision whether or not to cancel the pesticide.

It is bad enough that these tortuous procedures govern the cancellation of pesticides, but they also apply when EPA wants to change the classification of the pesticide to restricted use or order a modification of a pesticide's label or packaging. Thus, these procedural roadblocks act as a substantial disincentive against even making minor label changes.

The Brown reform bill would improve the cancellation process in six ways. First, it would repeal the Grassley Allen amendment and require EPA to issue a notice of intent to cancel a pesticide when a substantial question of safety exists. This should be the threshhold test that initiates a public hearing. The determination of whether risks outweigh benefits should be made in that hearing. Second, a citizen would have an equal right to industry to request a hearing. Third, the cancellation hearings would be simplified while retaining fair due process for all. Rather than a trial-type proceeding, EPA would conduct a hearing without cross-examination or depositions, and would have discretion to permit oral testimony. However, all parties would have an opportunity to present written testimony and arguments and written rebuttal testimony. Fourth, each phase of the hearing would be completed under reasonable deadlines. Fifth, the Hearing Examiner would not make referrals to the NAS. The EPA has rarely availed itself of this time-consuming and expensive procedure, and NAS submissions have had little influence on the outcome. Last, changes in labels or

classification would be made by notice and comment rulemaking rather than through these cancellation procedures.

We also note that H.R. 2482 contains some positive revisions to the cancellation process that deserve careful attention. The EPA has taken an approach analogous to the pesticide reform bill which we plan to study in detail.

5. THE BILL REQUIRES BETTER NOTIFICATION OF FOREIGN EXPORTS AND STOPS IMPORT OF FOOD WITH RESIDUES OF BANNED PESTICIDES.

A Harris poll conducted in January, 1984 on attitudes toward food safety revealed that the public ranks pesticide residues as the #1 hazard in food. In the poll, conducted before the massive publicity about EDB, 77% of the public said pesticides and herbicides were a serious food hazard. Pesticides outranked all other concerns about food additives, preservatives, salt, cholesterol,sugar, and artifical coloring by 30 percentage points.

In a Roper poll conducted in February, 1984, 59% of the public said that government should regulate pesticides more strictly and only 7% said there was too much regulation. These poll results dramatically illustrate the public's insistence that its food not be contaminated with excessive pesticide residues.

The Campaign for Pesticide Reform legislation would tackle this issue in two major ways. First, it would prohibit imports of food crops with pesticide residues exceeding tolerance levels for cancelled, suspended and voluntaily withdrawn pesticides, and would only allow a tolerance to remain in place for such a pesticide when residues unavoidably persist in the environment.

This provision would eliminate EPA's deplorable practice of leaving tolerances on the books for years after a pesticide is off the market. How can EPA permit residues on food when it has cancelled the use of a pesticide? For example, EPA failed to revoke tolerances for the cancelled pesticides DDT, TDE, Aldrin, Dieldrin, and DBCP, among others; last month EPA finally proposed to cancel these tolerances after repeated promises to do so. DDT was cancelled in 1972. The only excuse for retaining a tolerance after the pesticide has been cancelled is if residues unavoidably persist in the environment, in which case the tolerance should be reduced to the level that remains in the environment. In that case, farmers in Mexico would not be able to intentionally use DDT on food going to the United States with impunity because residues would exceed the tolerance level. This protects American consumers and American farmers who are harmed by foreign producers who use cancelled pesticides.

The second major amendment which protects consumers from dangerous imported food residues requires better notification to foreign governments of U.S. exports of cancelled, suspended, or restricted use pesticides. This provision requires U.S. pesticide manufacturers to notify EPA of their exports of such pesticides annually. EPA would then provide the foreign country with a detailed summary of the health hazards of the pesticides and the availability of any regulatory or scientific information. The foreign country would then decide whether to request the export of the pesticide and provide EPA with a description of its registration and labeling requirements,

procedures to educate pesticide users in safe handling, transportation, application and disposal, and how the country controls residues to meet U.S. tolerances, including results of any residue tests conducted over the past two years.

This system of informed consent will provide foreign countries with the information they need to decide whether to import a cancelled, suspended, or restricted pesticide and provide EPA with information on whether foreign countries use any procedures to ensure that their crops do not exceed U.S. tolerences.

6. THE BILL GIVES LOCAL COMMUNITIES A RIGHT TO KNOW ABOUT PESTICIDES PRODUCED IN THEIR NEIGHBORHOODS

People in towns and cities across the country have started a movement to gain the right-to-know about hazardous chemicals produced in their areas. Efforts by state and local right-to-know groups to enact such laws have met with opposition from the chemical industry and, where enacted, have been challenged in court. Thus, Congress should establish a federal right-to-know for pesticides

The pesticide reform bill would require pesticide manufacturers to provide the EPA and local communities with the following information, some of which is currently on file with EPA but has not been made public:

(A) the identity of active ingrediants and intermediary chemicals produced at the plant;

(B) a summary of the pesticide's health hazards and environmental risks;

(C) the location of the company's pesticide plants in the United States and abroad, including information on plant proximity to residential neighborhoods and populated areas and any evacuation plans the company has developed.

* * *

In addition to these highlighted amendments, the bill makes many other important changes that have been emphasized by other witnesses. For example, the legislation requires the EPA to evaluate the safety of long-neglected inert ingredients and list inert ingredients on pesticide labels. It lifts chilling restrictions on peer review and publication of health and safety data, requires commercial pesticide applicators to keep spray records, clarifies the pesticide company's duty to disclose adverse affects data to the EPA, and tightens conditional registration and special local needs exemptions. It also requires EPA to establish a worker protection program, allows citizens to sue to enforce the law, requires better technology to prevent pesticide drift and requires EPA to set standards for indoor exposure to pesticides. Finally, to increase EPA's resources, it repeals the indemnification system and requires registration fees.

Mr. Chairman, we believe that now is the time to act on pesticide reform. In the last year, the news the public has received about pesticides has been all bad, from EDB to Bhopal to stories about the dangers of chemical lawns. We will continue to have shocks of other pesticides pulled off the market at short notice and more public health disasters unless the law is changed. This subcommittee has an opportunity to play a historic role in leading the way to modernize FIFRA. We stand ready to help in any way we can. Thank you.

TESTIMONY ON FIFRA

by
BRIAN TURNER
Director, Legislation & Economic Policy
Industrial Union Department (AFL-CIO)

before the House Agriculture Committee
Subcommittee on Department Operations, Research and
Foreign Agriculture, May 21, 1985

The Industrial Union Department (AFL-CIO) strongly supports the package of amendments to FIFRA (The Federal Insecticide, Fungicide and Rodenticide Act) about to be introduced by Congressman George Brown (D-CA). While we support all of Rep. Brown's proposals, our testimony today will focus on the need for a federal community right-to-know for pesticides.

Workers are particularly vulnerable to the failures of FIFRA to adequately protect public health in the use and production of dangerous pesticide chemicals. Workers do not just occasionally use a pesticide product, they come into contact with these chemicals on a daily basis.

Unfortunately, as a result of fatal accidents in this country and the tragic disaster in Bhopal, India, workers are becoming more aware and less confident that the federal government and the chemical industry are adequately protecting their health during routine operations and in case of accidents.

There is a dangerous lack of information on the health hazards of the massive quantities of pesticide chemicals being manufactured and used in the United States. All too frequently the public and the press only begin to

focus on the dangers posed by exposure to industrial chemicals and pesticides after terrible tragedies -- tragedies that could and should be prevented. The now infamous case of the powerful carcinogen EDB (ethylene dibromide) sadly proves the point. Although unions had struggled in vain for years to have EDB adequately regulated in the workplace, it was not until EDB started showing up in cake mixes and breakfast cereals that public opinion finally forced action by EPA and OSHA. For more than two years before the EDB OSHA standard was tightened, EPA and OSHA knew that for every 1,000 workers exposed at the level of the antiquated OSHA standard for EDB contaminated environments, 999 of them would develop cancer and die as a result of that exposure at the "approved" level.

Some states and localities have successfully passed right-to-know laws; other states and local communities have failed in similar efforts because of strong opposition from the chemical industry and, where they have been successful it has often been the result of actions in the courts. This bill establishes a critically needed federal right-to-know which will complement existing provisions in the Clean Air Act, Clean Water Act and Resource Conservation and Recovery Act.

Section 7 of FIFRA would be amended to require all pesticide producers in the U.S. to submit to EPA:

1. The type and amounts of pesticides and intermediary chemicals which are produced annually;

2. A summary of the health and environmental risks posed by these chemicals and an assessment of their potential for public exposure;

3. The location of all pesticide manufacturing plants in the U.S. and abroad;

4. Information on the proximity of the plants to populated areas;

5. Plans for evacuation in the event of a health emergency, and

6. Information on the type, quantity, uses and destination of pesticides being exported from the U.S. to other countries.

We commend this Subcommittee for holding these hearings to focus on the weaknesses of the nation's major pesticide law. We urge the Committee and the Congress to adopt a federal right-to-know and the other amendments which Rep. Brown will soon introduce in order to raise the level of protection of public health. Both public and worker concern are at a very high level as a result of the EDB crisis and the Bhopal disaster; this is the year for comprehensive FIFRA reforms.

STATEMENT OF JAY FELDMAN
NATIONAL COORDINATOR, NATIONAL COALITION
AGAINST THE MISUSE OF PESTICIDES
BEFORE THE
SUBCOMMITTEE ON DEPARTMENT OPERATIONS,
RESEARCH AND FOREIGN AGRICULTURE
COMMITTEE ON AGRICULTURE
MAY 21, 1985

Mr. Chairman and members of the subcommittee. I am Jay Feldman, National Coordinator of the National Coalition Against the Misuse of Pesticides (NCAMP). NCAMP was formed in 1981 after a series of three public hearings on pesticide use and misuse were held across the country. Since that time, our membership has grown to approximately 300 local community organizations across the country. Our membership spans 49 states, the District of Columbia, Canada, Mexico, as well as other countries around the world.

I would like to introduce you to a typical person in our coalition, but that is not an easy task because the range of people involved vary so widely, including all age groups, backgrounds and political persuasions. There are those who consider themselves victims of pesticide misuse, having been exposed through pesticide use , or drift, or contamination of their home by a structural pesticide application. These people are joined by others such as farmers, genetic toxicologists, cancer researchers, former chemical company scientists, former regulators with state and federal agencies (some currently employed as well), physicians and attorneys.

Because of these people's experiences and knowledge, they have joined together to improve the control of pesticides through improved laws and they have sought to promote alternative pest management strategies, such as Integrated Pest Management (IPM) and nonchemcial pest management, which reduce or eliminate pesticide use while improving protection against pests. The major statute at issue for these people is the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

Our story is not a new one to the Agriculture Committee. In 1981, we were fortunate to have the opportunity to assist this subcommittee in identifying witnesses to tell Congress their story. People then and for this hearing have traveled long distances to describe to you their firsthand experiences with the hazards of the materials over which you have statutory control. People brought to your attention issues of health hazards, damaged crops, drift, ground water contamination, lack of worker protection, poor training of applicators and diminishing returns from pesticide use due to resistance.

What you have heard and will hear during the course of these hearings in 1985 does not describe a situation that is new, just one that is worse than last time we appeared before this subcommittee. The victims of pesticides who call us on a daily basis cry out and are now, in larger and larger numbers, demanding adequate protections from pesticide exposure on the farm and in their homes. People want controls and assurances

that this subcommittee cannot now offer them, including protection from pesticide-contaminated air, water and food. As a result, these people have taken the pesticide issue to their town councils, city halls, state legislatures and, where possible, the courts. Clearly, the protection emanating from this subcommittee and the Congress is not sufficient. The deficiencies exist in many areas which I would like to discuss.

Weak Standards Lead to Human Hardship

The public interest concern is not an abstract concern with numbers. A January, 1981 report issued by the Council on Environmental Quality, Chemical Hazards to Human Reproduction cites various studies of male and female workers exposed to pesticides. These studies report impotence, chromosome aberrations, infertility, miscarriages and other adverse effects on reproduction. A University of Iowa study (1) in 1982 found that Iowa farmers faced greater risks of six types of cancer than city dwellers. According to the researchers, the cancer rate is an occupational hazard of farming not related to smoking and is confirmed by other studies around the world.

In addition, this subcommittee is well aware that pesticides in use are not adequately tested. Your own staff in 1982 documented the lack of long term health and safety studies

supporting the majority of pesticide products registered. (2)

Of important note is the fact that despite these problems and unknowns, exposure to pesticides is widespread and growing. The public is routinely exposed to pesticides through the food supply. A 1983 study by the Natural Resources Defense Council found that 44 percent of the fresh fruit and vegetables they sampled contained residues of 19 different pesticides. Forty-two percent of the samples with detectable pesticide residues contained residues of more than one pesicide; several samples had four different pesticides present. (3) A study on Long Island, New York found that of the 1,100 homes surveyed 33 percent had homes contaminated with chlordane (used for termite control). (4) EPA has now detected 16 pesticides as having contaminated ground water in 23 states. (5) Community spray programs for mosquito control and other pests are widespread as is forestry and right-of way spraying. Chemical lawn services have been growing. One such company, Chemlawn, according to newspaper reports has increased annual sales from $87 million in 1979 to $227.7 million in 1984 with 1.3 million customers in 42 states and Canada. (6) This, on top of normal household use of inadequately tested pesticide products, suggests alarmingly high rates of pesticide exposure.

The Need for a Statutory Response

Failing an adequate response from EPA on a host of issue

over the last 12 years since the federal pesticide control law took its current form, it is our position that statutory steps must be taken now to assure adequate public protection from pesticides. In response to a pesticide problem out of control, we endorse legislation that has been drafted and we understand will be introduced soon in the House and Senate which addresses eight areas of concern and would: (i) establish full public disclosure and community right-to-know; (ii) require complete scientific health and safety testing of all pesticides on the market by a date certain; (iii) prevent pesticide-induced birth defects; (iv) increase protection for workers and the public generally; (v) streamline EPA review procedures to assure timely regulatory response to identified problems; (vi) establish provisions to prevent pesticide contamination of ground water; (vii) strengthen international provisions governing the exportation of pesticides and residues on imported food; and, (viii) increase EPA revenues through registration fees.

The Specifics of the Reform Proposal

While it is not terribly difficult to see the generalized pesticide problem that puts the public at signification risk, I would like to explore some of the specifics of reform legislation with additional background information on the need.

I. Public Disclosure and Community Right-To-Know

We have today a serious breach of the American people's trust in the U.S. Environmental Protection Agency, U.S. chemical corporations and, in fact, the operation of the federal pesticide control law. The public does feel misled by the marketing of chemical products that it assumed were fully tested and determined to be safe by the government. Those who have been harmed have asked questions on health effects to which there are no answers. And yet the ability of these people to make public use of available health and safety data supporting product registrations are stifled. Those wanting to know how EPA arrived at decisions based on manufacturer generated safety data are precluded from doing this in a public forum. And while people are told to trust the EPA and chemical manufacturers, some inside the Agency continue to this day to point out serious deficiencies in Agency reviews of safety studies, maintaining that the "trust conferred on this Agency may have been misplaced."

We implore the subcommittee to not only investigate recent allegations of faulty EPA reviews which I will discuss below, but consider the importance of allowing the public to review and discuss, without FIFRA-imposed constraints, all matters pertaining to the health and safety studies on which EPA makes its critical toxic pesticide use decisions.

A. Bogus EPA Reviews Continue To Underlie Safety Decisions

I would like to provide you with an astounding example of the extremely important need for openness in the area of EPA decision making. On March 20, 1985, an EPA staff person circulated an internal memo in the Agency, which for the first time, to my knowledge, disclosed that EPA continues, to this day, to make decisions based on bogus "cut and paste" reviews of industry health and safety studies, quoting verbatim and without attribution registrants' own evaluations. This subcommittee is aware that the "cut and paste" scandal, according to the Battelle Columbus Laboratories' partial audit, between 1979 and 1982. After the audit was released, Assistant Administrator for Pesticides and Toxic Substances, John Moore, D.V.M., wrote in a letter to Congress, "I trust with the submission of this . . . that we can put the issue of "cut and paste" behind us."

While we are aware that this scandal took place, "we continue to be plagued by this apparently total failure to rectify what had gone wrong," according to the March 20, 1985 memo.

The implications of all this is somewhat unbelievable. It now appears that at least one of only six pesticides in the United States that enjoys the status of being fully registered

by the EPA --metalaxyl-- has been subjected to a bogus evaluation by the Agency. In discussing this matter, I leave out any reference to the individuals involved since this example is being raised to illustrate to the subcommittee that the system in place is not adequately protecting the public. I will, however, be happy to provide the subcommittee with a copy of the memo for further and detailed review. The EPAer's memo states,

> In a memorandum that I wrote . . . April 30th, 1984 I had . . .demonstrated . . . that when the Hazard Evaluation Division had been expressly and explicity directed to carry out a full review of the toxicity for that [the fungicide metalaxyl] product (following an initial "cut-and-paste" and otherwise unacceptable review) even then the reviewers there elected to have reference only to the summary prepared by the registrants rather than address the detailed data contained in the entire report. Because of this, a number of important aspects of the safety of metalaxyl were again glossed over. With reference to yet another "cut-and-paste" review for that same product, metalaxyl -the one-year dog study carried out at International Research and Development Corporation- I have no knowledge that this had been rereviewed by anyone even though I had demonstrated that this too had caused important safety aspects to be similarly "missed" by EPA.
>
> Also in that memorandum . . . I indicated how a number of persons both within the EPA, including the Administrator himself, as well as others outside the Agency had been misled on the impact of the unacceptable manner in which health effects of pesticide products are being evaluated in the Hazard Evaluation Division. (p. 2)

Contained in the March 20, 1985 memo is also reference to another review of a different pesticide, the insecticide oxamyl, also the subject of a bogus review. In this case, the EPAer charges that EPA's

> comments that there was "an independent evaluation" by "the initial TOX Branch review" (presumably "independent" of the registrants) and that the "evidence" for this was the fact that the review in question "included an analysis of the lung tumor data and noted no pesticide-related effects."
> . . .If anyone can demonstrate to me exactly where in that review there is any reference whatsoever to lung tumors, I would be willing <u>not</u> to characterize that assertion as a fabrication out of whole cloth, as a brazen and total falsehood . . . The risks to the consumers of this country apparently can be disregarded in this entirely wanton and reckless manner, so long that no one in the Hazard Evaluation Division can be thought of as having acted in an improper way, and it seemingly does not matter even if it takes outright lies to acheive that end. (pp. 9-10)

These are only two examples of a system that subjects the public to potential long term hazards such as cancer. The problems are not limited in scope because from evaluations such as these EPA has established "acceptable" consumption rates in the form of food residues, proposed final tolerances and issued emergency exemptions from food tolerances. All these decisions directly affect public and user exposure to a chemical that, apparently, was reviewed inadequately.

Not only are we asked to accept this as officials admit that, "Little has been done at EPA over the last year to rectify the "cut and paste" problem." We are also asked to consume these pesticides in our food without the freedom to discuss the data that allowed them to get onto the market and remain on the market!

This society's health should not depend on the diligence and honesty of one EPA staff person to push the system and make

it work through scathing memos, although the public owes a debt of gratitude to the work of this individual and others who see it as their public duty to get this type of information before a hearing such as this. From a policy point of view, we desperately need to open up all the information regarding testing to public scrutiny.

Because of the overwhelming public good associated with the release of health and safety test information on pesticide products, we urge you to repeal Section 10(g) of the Act.

B. Public Disclosure of Health and Safety Test Data

Rather than encouraging openness and public discussion of matters such as those outlined above, current procedures in place at EPA impede open discussion of pesticide health and safety data. NCAMP has an historical commitment to ensuring public disclosure and discussion of the underlying health and environmental information used by EPA to register products. Although the Supreme Court in Ruckelshaus v. Monsanto Company (7) resolved the constitutionality of releasing pesticide health and safety data to the public, the procedures do not facilitate pulbic use of this material once released because FIFRA forbids the disclosure of such data to multi-national pesticide producers.

The data release instructions in place currently will have a chilling effect and seriously curtail important scientific

and public debate on pesticide product safety. We believe, that neither the public nor EPA and State regulators are served by the kind of secrecy which will result from the the current statutory language in FIFRA, Section 10(g) and EPA interpretation which instructs data recipients to consult legal counsel prior to using the public information. We have already been told by industry representatives, given their interpretation of Section 10(g), that disclosure of more than one or two items of raw data would constitute grounds for legal action by EPA or a pesticide manufacturer. Clearly, this is not what Congress had in mind when adopting Section 10 of FIFRA.

C. Access to Pesticide Manufacting and Use Information

Adequate access to information on pesticide manufacturing and underlying health and safety data is central to the decision making process guiding both individual and community choices on the range of pest management strategies. In light of the Bhopal, India disaster, the public has become especially sensitized to dangerous industries that may be operating in their communities and expect an accounting of what is used so that individual assessments and personal choices can be made. Information is also needed on the distribution of pesticides in commerce according to agricultural, household and other use so that hazards can be monitored.

D. Inert Ingredients

Despite the fact that the so-called inert or secret ingredients in pesticide products may be biologically and chemically active, they enjoy a regulatory status that permits widespread public exposure without long term health and safety and ecological effect reviews and public disclosure on product ingredient statements. In October, 1984, EPA identified 85 "toxicologically significant" inerts of some 1000-1200 chemical inert ingredients contained in approximately 49,000 pesticide formulations. (8)

The second class status of inerts in terms of being subjected to the full regulatory review and disclosure provisions of FIFRA is not warranted in light of the hazardous nature of many. Those toxicologically significant pesticides should be subjected to testing and disclosure requirements similar to the active ingredients.

II. Require Complete Scientific Health and Safety Testing of All Pesticides on the Market Within a Date Certain

A. The Slow Pace of Reregistration

At the heart of any discussion of pesticide safety is the status of what we know and do not know about the pesticide products in question. Central to the discussion, of course is the registration status of the product and all that it means.

It is quite possible that EPA in 1985 has actually reregistered no pesticides depending on your definition of "reregistration." Regardless of the way the term "reregistration" is being used by the Agency, we know from reports of the studies supporting the registration of one --metalaxyl (discussed above)-- of the six that EPA says are completely reregistered, that not everyone in the Agency would agree with the official number. Nevertheless, given the fact that there are 600 basic active ingredients requiring reregistration, the reregistration program has not and is not moving with adequate speed.

It is very well known to EPA officials and the U.S. Congress that there exist thousands of hours of Congressional and Agency hearings, numerous U.S. General Accounting Office (GAO) reports, many comprehensive Congressional reports, a National Academy of Sciences study and dozens of confirmed contamination and poisoning cases that tell the tale loud and clear.

The U.S. General Accounting Office in 1975 randomly selected 36 pesticides with established tolerances and in their report, Federal Pesticide Registration Program: Is It Protecting the Public and the Environment Adequately from Pesticide Hazards? (9) found that: seven lacked cancer and reproduction studies, fourteen lacked birth defect studies, and; twenty-three lacked mutation studies. EPA responded by

saying, "GAO's criticims are well-founded, and we are very much concerned about tolerance-setting problems."

The question of health and safety data validity was first brought to light in 1976 by the staff of the Subcommittee on Administrative Practice and Procedure of the U.S. Senate Judiciary Committee. Senator Kennedy introduced the report, entitled, The Environmental Protection Agency and the Regulation of Pesticides (10) saying, "Apparently EPA made a conscious policy decision sometime in 1973 not to evaluate the safety testing data submitted by pesticide manufacturers. The record behind this decision is not entirely clear. What is clear, however, is that EPA had no sound basis upon which to assume that data 15, 20 or 25 years old was generally good and reliable."

A 1980 U.S. General Accounting Office report, entitled Delays and Unresolved Issues Plague New Pesticide Protection Programs, (11) indicates that the deficiencies outlined in the earlier 1975 report had not improved. The report states, "Our 1975 report to Congress stated that the public is exposed daily to many pesticides which are not supported by animal and environmental safety studies. The situation has not improved." The report continues, "According to EPA officials, key tests required under current EPA regulations have not been performed for many of the 514 registration standards. Included are long-term (up to 3 years) animal feeding studies which show

whether a pesticide causes chronic effect, such as cancer or birth defects, in animals. An official told us that EPA needs the results of these tests to make even preliminary decisions concerning a pesticide's safety and whether it should be reregistered."

Finally, two recent reports indicate how little is known about pesticides' health effects. The U.S. House of Representatives' Subcommittee on Department Operations, Research and Foreign Agriculture Staff Report in 1982 cited above reveals discomforting figures indicating: (i) between 79 and 84 percent of the pesticide products on the market have not been adequately tested for the capacity to cause cancer; (ii) between 90 and 93 percent of the same products have not been adequately tested for their ability to cause genetic damage; (iii) between 60 and 70 percent have not been fully tested for their abiliyt to cause birth defects. (12)

In 1984, the National Research Council of the National Academy of Sciences released a 382-page report, entitled Toxicity Testing: Strateiges to Determine Needs and Priorities (13) which says complete health hazard assessments for pesticides and inert ingredients of pesticide formulations are possible for only 10 percent of pesticides.

This, then, serves as the basis for promoting changes to the underlying statute that will allow this state of affairs to

continue for years to come. In April 18, 1985 testimony, the Assistant Administrator for Pesticides and Toxic Substances, John Moore, D.V.M., told DORFA that, of the 600 basic active ingredients that require reregistration, EPA has assessed its file information on 98 pesticides and issued registration standards (14). While EPA has generally referred to these chemicals as having been reregistered, this step of identifying deficiencies in a pesticide's registration package simply enables the Agency to request from the product's manufacturer the necessary studies which will be needed by the Agency to determine product safety and labelling. In rare cases, EPA, in generating the standard, finds enough information to require interim safety measures, such as restricting specific uses or requiring protective clothing for applicators. However, in every case a final determination on safety is years off. EPA is now predicting its ability to generate 25 registration standards a year. Taken together with predictions that 175 pesticides will be dropped by manufacturers who do not want to commit to generating the costly health and safety studies, at this rate, we will be well into the next century before EPA has completed evaluations of the data received from the issuance of standards.

B. Falsified Health and Safety Test Data

A U.S. Food and Drug Administration audit in 1976 revealed that a major independent lab testing firm, the Industrial

Bio-Test (IBT) Laboratores, Inc., was falsifying safety test data being submitted to EPA as part of pesticide product registration. IBT had performed thousands of scientific safety tests used to register hundreds of pesticides. The findings confirmed a situation that was even worse than the Kennedy report revealed.

Despite this, EPA has repeatedly said that it does not have the authority under FIFRA to remove from the market products that have been registered under false pretenses. Reform legislation much provide EPA with this authority.

C. Conditional Registration Loophole

When the reregistration program began in 1977, it was thought that the public would finally be protected from the hazards of pesticides for those new products coming on line. Because of the ability of manufacturers under FIFRA to "conditionally" register their products under FIFRA prior to the completion of all health and safety studies, this has not turned out to be the case.

It appears that between 1978 and March 31, 1985 most, or at least two-thirds, of the approximately 100 pesticide active ingredients registered by the EPA have been conditionally registered. It also appears that since the conditional registration program began, there has been an increasing trend in this type of registration.

Worse yet, three new active ingredients --cromazine, cypermethrin and cyromazine-- where going through an abbreviated Special Review at EPA because of health risk factors at the same time or perhaps even before they were given conditional registration from the Agency.

Given this situation, this program must be overhauled. A registration program must assure compliance with modern safety standards prior the marketing, not after.

III. Improve Protections for Workers and the Public

A. Certification and Training

Since the inception of a cooperative federal-state training and certification program in 1978, move than 1.5 million individuals have been trained and certified to handle chemicals identified by EPA as "restricted use" pesticides or, according to the Agency, the most toxic class of compounds. According the General Accounting Office's 1983 review of the program for certifying and training these individuals to apply pesticides, "certification examinations do not fully conform to the federal requirements and as a result do not provide assurance of an individual's competency." (15) Given underlying problems with the safety of products, the training program becomes more important when considering the problems associated with over application, lack of safety precautions and improper mixing and

loading and storage and disposal of chemicals.

We feel that allowing untrained and uncertified persons to apply the most restricted class of pesticides, or any class of pesticides for that matter, is unprotective of the public health and the environment. Untrained handlers of dangerous materials have led to situations such as the Pratts of Nashua, Iowa whose dairy heard was virtually wiped out after an untrained applicator unloaded a tank of the pesticide atrazine in a roadside ditch adjacent to their farm in 1984. Since this incident, 6 cows have died, another 30 had to be destroyed, 22 claves were still born or died soon after birth and milk production from the cows remaining dropped 75 percent.

The law must be strengthened in this area of certification and training and the existing loophole, allowing untrained applicators to operate under the supervision of those trained, must be striken from FIFRA.

B. Private Right of Action

From an enforcement perspective, an October, 1981 GAO report, entitled Stronger Enforecment Needed Against the Misuse of Pesticides, suggests that the public and the environment are not protected from pesticide misuse because EPA and state enforcement programs exhibit the following characteristics: (i) many enforcement actions are questionable or inconsistent; (ii) some cases are poorly investigated; (iii) some (state) lead

agencies often do not share EPA enforcement philosophy; and, (iv) most states lack the ability to impose civil penalties. (16) In fact, the existing enforcement system does not provide adequate public protection and recourse for pesticide misuse.

We agree with those who would like to provide the public with an alternative means to stop label violations as well as damage or harm associated with pesticide use. The alternative available under almost all other pieces of environmental legislation, such as the Water Pollution Control Act, the Clean Air Act, the Noise Control Act, the Toxic Substances Control Act and the Safe Drinking Water Act, is a citizen suit provision or a private right of action. This, then, would enable, as one alternative, the enforcement of FIFRA through the U.S. District Court system.

C. Prevent Pesticide Drift or Chemical Trespass

The question of drift or chemical trespass is a basic question of exposure. Pesticide drift has long been a public and environmental health concern to those living near sprayed fields and forests as well as farms and rights-of-way. Community and suburban lawn care spray programs have resulted in substantial drift as well. Pesticides are not adequately labelled to control for chemical trespass, but simply instructs users in generally unenforceable terms to "avoid" drift. But studies show that as much as 50 percent and more of the sprayed

57-556 O—86——16

pesticides may not land in the target area.

In a letter to a California state officical, Larry Landis, a commercial cropdusting pilot with over 16 years experience writes,

> . . .In the past 16 years, I have piloted aircraft for agricultural businesses. . .My experiences have led to the realization that the aerial spraying of agricultural chemicals is dangerously close to being completely uncontrolled with regard to health hazards. Applicators in California consistently spray homes, schools, hospitals, highways and waterways, and are virtually unsupervised by the Agricultural Commissioner's staff. . .Because of the lack of enforceable regulations, involuntary exposure to a wide variety of harmful chemicals has become part of the "American way of life!" (17)

Legislation is needed to address this problem, as difficult as it is. Application technologies and standards governing use patterns, including buffer zones, must be adopted to address the problem, rather than ignoring the problem totally.

D. Special Local Need Permits

Section 24(c) of FIFRA permits a proliferation of chemicals that have not been subjected to full and adequate health and safety testing. I would like to remind the subcommittee of a July, 1983 study that was presented to you by the Rural Advancement Fund of the National Sharecroppers Fund (RAF/NSF).

Using a sample of 2,089 special local need (SLN) registrations for 25 states (79 percent of all SLNs granted in

1981-1982, RAF/NSF found that: (i) more than 40 percent of all SLN pesticide registered in the past two years contain chemicals registered on the basis of invalid or fraudulent tests conducted by Industrial BioTest Laboratories (IBT). For example, IBT conducted the safety tests for the three most widely used SLN pesticides (Furadan, Sencor, Paraquat); (ii) a majority of the SLN registrations were issued for major crop use over a wide geographic area. More than 60 percent of all SLNs were issued for use on ten major crops; and, (iii) 90 percent of the registrations are obtained by chemical manufacturers. Five companies received 46 percent fo all SLNs in 1981-1982. (18)

Clearly, the abuses here, which continue, can be corrected with legislation which restricts the expanded uses of products that have not been fully tested across wide geographic regions without any concern for the regional or national scope of the problem.

E. Indoor Exposure

The use of chemicals such as chlordane, which belongs to the organochlorine or DDT family, for termite control continues to attract a lot of public attention because of the widespread contamination of possibly millions of homes in the U.S. As mentioned earliers, a recent survey on Long Island, New York found that of 1100 homes tested 33 percent were contaminated

with chlordane.

Those with residues of chemicals in their home, experiencing chronic low level exposure, often exhibit symptoms of pesticide poisoning, including headaches, muscle aches, nausea, sleeplessness and excitablility. More severe illnesses associated with higher levels of exposure include convulsions loss of consciousness, disorientation, personality changes, psychic disturbances, loss of memory and a variety of blood diseases. It is not uncommon, moreover, for those in a contaminated home to live with a constant fear of long term chemical effects.

Despite the real hazards associated with indoor exposure, EPA has not set standards of safety to protect public health. Instead, for the termiticides, the National Academy of Sciences has established guidelines of no more than five micrograms per cubic meter of air. However, for the range of chemicals used indoors, most often guidelines do not exist.

In a January 17, 1983 letter explaining federal policy, former Deputy EPA Administrator, John Hernandez, said the setting of maximum residual levels or tolerances for pesticides with indoor uses is outside the Agency's legal authority. He states, "Neither the Federal Food, Drug and Cosmetic Act, the FIFRA, nor any other pertinent statutes, provide for setting tolerances for residues of pesticides in air or on surfaces in

buildings."

This state of affairs leaves the public unprotected. Legislation can easily rectify this major deficiency by simply requiring safe residues standards.

IV. Establish Provisions to Prevent Pesticide Contamination of Ground Water

In August, 1984, EPA staff identified some 45 pesticides that "may have the potential to contaminate ground water." (19) At the point the Agency has found 16 pesticide to have contaminated ground water in 23 states. In a recently released report from the California Assembly Office of Research entitled, The Leaching Fields: A Non-Point Threat to Groundwater, 57 pesticides were found to have contaminated 3,000 wells in 28 states.

With approximately 50 percent of the U.S. population relying on underground water from aquifers for drinking, the protection of ground water from pesticides must be a national priority. While there are only six pesticides regulated under the national interim primary drinking water standards, it has become obvious that we must approach this growing problem with a preventive orientation. Cleaning up ground water is virtually impossible. At the least, measures must be instituted under FIFRA to restrict or, if possible, relabel pesticides that have already shown up in the ground water.

Premarket testing of new chemicals must ensure that chemical use patterns will not result in contamination.

V. Strengthen International Provisions Governing the Exportation of Pesticides

Current U.S. pesticide export policy allows for a double standard of control and protection --one of domestic and a weaker one for export. Thus, chemicals which are highly restricted or banned in the U.S. are freely available in developing countries. This situation allows the exportation of hazards to which we do not subject our own country. It furthers subjects the U.S. to a "circle of poison" through the importation of dangerous residues on imported crops. Given the current system, residue tests do not exist to detect many, if not most, of the pesticides being imported into this country on food.

As a result, it becomes especially important to adopt legislative measures which create one standard of protection through a single registration requirement for U.S. manufacturers who market thier product domestically and for export. Some assurance must be provided prior to their exportation that severely restricted pesticides, such as those that do not have registered domestic food uses, will be properly used. A January, 1984 poll for the Food Marketing Institute showed that 77 percent of those interviewed

considered pesticide residues on food a serious hazard. (20) Other provisions improving communication between the U.S. and importing countries will assist in improving the understanding of proper use, but will not ensure compliance with a use pattern that precludes contamination of food imported into the U.S.

Conclusion

We seek a system of pesticide control that is respectful of human life and the protections that the public wants. While there may continue to be resistance from some quarters, our sense is that the overall public sentiment calls for dramatic improvements in the law. This call for improvement is not coming from those who stand to gain economically from pesticide control law, but from a cross section of society, including farmers, workers, consumers, environmentalists and health care professionals, all seeking protection from both known and unknown health and environmental effects of pesticides.

Mr. Chairman and members of the subcommittee, we appreciate the opportunity to present our views and we thank you for your consideration of our national pesticide problem.

FOOTNOTES

(1) Leon Burmeister, "Cancer Mortality in Iowa Farmers, 1971-78," Journal of the National Cancer Institute, March, 1981, Vol. 66, No. 3.

(2) Staff Report, EPA Pesticide Regulatory Program Study, Subcommittee on Department Operations, Research and Foreign Agriculture, U.S. House of Representatives, 98th Congress, 2nd Session, December 17, 1982.

(3) Lawrie Mott with assistance of Martha Broad, Pesticides in Food: What the Public Needs to Know, Natural Resrouces Defense Council, Inc., March 15, 1984.

(4) Nancy Kim, Director of Bureau of Toxic Substance Assessment, New York State Department of Health, Testimony before the New York State Department of Environmental Conservation, Albany, New York, April 4, 1984.

(5) S.E. Cohen, "Ground-Water Monitoring of Pesticides in the U.S.A.," presentation before the 189th National Meeting of the American Chemical Society, Miami Beach, Florida, Abstract # PEST-34, April 30, 1985; and, S.E. Cohen, et. al., Treatment and Disposal of Pesticide Wastes, American Chemical Society Symposium Series #259, chapter 18, 1984.

(6) Geraldine Brooks, "Dispute Erupts Over Lawn-Spray Dangers," Wall Street Journal, October 11, 1984; and, A. David Gram, "Growing Lawn-Care Field Scares Environmentalists," Plain Dealer, February, 19, 1984.

(7) Supreme Court of the United States, Ruckelshaus, Administrator, United States Environmental Protection Agency v. Monsanto Company, No. 83-196, June 26, 1984.

(8) U.S. Environmental Protection Agency, Discussion Paper on Inerts Prepared for the Administrator's Pesticide Advisory Committee, October 25, 1984.

(9) U.S. General Accounting Office, Federal Pesticide Registration Program: Is It Protecting the Public and the Environment Adequately from Pesticide Hazards?, RED-76-42, 1976.

(10) U.S. Senate, Judiciary Committee, The Environmental Protection Agency and the Regulation of Pesticides, 1976.

(11) U.S. General Accounting Office, (Delays and Unresolved Issues Plague New Pesticide Protection Programs, CED-80-32, 1980.

(12) Staff Report, p. 187.

(13) National Research Council, National Academy of Sciences, Toxicity Testing: Strategies to Determine Needs and Priorities, 1984.

(14) John A. Moore, Assistant Administrator for Pesticides and Toxic Substances, U.S. Environmental Protection Agency, Testimony before the Subcommittee on Department Operations, Research and Foreign Agriculture, Committee on Agriculture, 99th Congress, 1st Session, April 18, 1985.

(15) U.S. General Accounting Office, Better Coordination Is Needed Between Misuse Enforcement Programs and Programs for Certifying and Training Individuals To Apply Pesticides, RCED-83-169, July 1, 1983.

(16) U.S. General Accounting Office, Stronger Enforcement Needed Against the Misuse of Pesticides, CED-82-5, October 15, 1981.

(17) Larry Landis, letter to Lori Johnston, Assistant Director, Pesticide Enforcement Unit, California Department of Food and Agriculture, September 9, 1983.

(18) Allen Spalt, A Report on "Special Local Need" Pesticide Registrations, Rural Advancement Fund of the National Sharecroppers Fund, July 27, 1983.

(19) S.Z. Cohen, Ground-Water Team Leader, Exposure Assessment Branch, Office of Pesticide Programs, U.S. Environmental Protection Agency, memo, "List of Potential Ground-Water Contaminants," August 24, 1984.

(20) Tim Hammonds, Senior Vice President, Food Marketing Institute, "Public Attitude Toward Food Safety," 1984.

(Attachments follow:)

Addendum
to Feldman

MEMORANDUM - to :- Kevin Keaney,
Office of Pesticide Programs, (OPP);

copy :- Jay Ellenberger,
Registration Division, OPP;

MAR 20 1985

from :- M. Adrian Gross, BUD, OPP;

subj.:- Okamyl (EI duPont de Nemours) Reg. No. 352-372
PP No. 1F2448
Accession No. 070136-143

Background.

On April the 24th last year I wrote you on the difficulty with the "cut-and-paste" reviews in the Hazard Evaluation Division; the specific problem discussed at that time was malathion which had been signalled by Battelle as having been a case where "EPA copies verbatim registrant's summary (pp 10-11 fiche). There is no evidence of an independent analysis of the document which contains highly suggestive evidence of a dose-related carcinogenic effect...".

This matter was referred to a "Review Group" containing amongst its members two former chiefs of the Toxicology Branch; this strikes me as being rather odd:- after all, Battelle was actually retained by OPP at a considerable cost to conduct an investigation into this matter with the "cut-and-paste" reviews originating in the Toxicology Branch to have the final report of that organization "evaluated", as it were, for its merits by the very people who constituted the target of such investigation does not seem to me to be indicative of any serious concern here that potentially toxic pesticide products may not have been regulated in the optimal manner as a result of those "cut-and-paste" reviews.

If indeed there were such concern in the Office of Pesticide Programs, I should think that at least the following should have happened:-

a) The results of the Battelle investigation (i.e., their final and detailed report) should have been referred for an assessment of its merits to a group which would not have a built-in conflict of interests in this area; the actual "Review Group" which was appointed for this purpose could have been expected to weigh in with comments which were self-serving and whose main purpose was to cover-up the initial failure in that Branch to do the job that one would expect to have been carried out there:- review and evaluate the toxicity reports emanating from the regulated industry in an independent, adequate, objective, and critical fashion, rather than quote verbatim without attribution or "cut-and-paste" those registrants' own evaluations;

b) Inasmuch as Battelle had investigated merely a sample of the reviews emanating from the Hazard Evaluation Division and inasmuch as that very sample itself provided ample evidence that this practice of shoddy reviewing was extremely pervasive there, I completely fail to understand

just why that initial effort was not followed up by a more in-depth or a full account of all pesticide products for which "cut-and-paste" reviews were carried out; this would have enabled one to determine what precisely had been "missed" as a consequence of such reviews and how would this alter whatever regulatory action was undertaken as a consequence of this kind of failure.

The other day I asked Dr. Farber, the new chief of the Toxicology Branch in the Hazard Evaluation Division, what had been done in the way of a follow-up on this problem; he replied that, as far as he knew, nothing had been done in this respect and, moreover, he had no plans at all to undertake any kind of follow-up in the future since he believes that this would create too much work for him and for his people there.

In that memorandum to you of last year that I cited at the beginning here I had demonstrated that the so-called "Regulatory Opinion" reached by the "Review Group" that had been appointed to pass on the Battelle findings was not only self-serving but also totally improper:- malathion in fact manifested highly significant carcinogenic activity in each of three separate bioassays conducted by the National Cancer Institute; in other words, the initial review had "missed" this feature, i.e., we have here a situation in all respects identical to that which I had initially brought to light in October, 1982, for harvade, another product altogether.

In a memorandum that I wrote to Ed Gray less than a week later, April the 30th, 1984 I had also demonstrated (as illustrated by an entirely different pesticide product, metalaxyl, which was not part of the initial Battelle "sample") that when the Hazard Evaluation Division had been expressly and explicitly directed to carry out a full review of the toxicity for that product following an initial "cut-and-paste" and otherwise unacceptable review) even then the reviewers there elected to have reference only to the summary prepared by the registrants rather than address the detailed data contained in the entire report. Because of this, a number of important aspects on the safety of metalaxyl were again glossed over. With reference to yet another "cut-and-paste" review for that same product, metalaxyl the one-year dog study carried out at International Research and Development Corporation - I have no knowledge that this had been re-reviewed by anyone even though I had demonstrated that this too had caused important safety aspects to be similarly "missed" by the EPA.

Also in that memorandum addressed to Mr. Gray I indicated how a number of persons both within the EPA, including the Administrator himself, as well as others outside the Agency had been misled on the impact of the unacceptable manner in which health effects of pesticide products are being evaluated in the Hazard Evaluation Division.

We are now almost a year down the road since I wrote those two memoranda in the Spring of last year and yet, unfortunately, we continue to be plagued by this apparently total failure to rectify what had gone wrong here.

New Information.

Last month I was assigned to a team whose task was to audit a long-term toxicity study of oxamyl in mice.

The review generated by the Hazard Evaluation Division for that study is reproduced in full on the right side of the five pages to follow immediately here; opposite each such page on the right side I have "cut-and-pasted" on the page facing it on the left side excerpts from the registrants' summary to convey the actual source of the reviewer's comments:-

Oxamyl

page four

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

JUN 23 1981

MEMORANDUM

DATE: June 18, 1981

SUBJECT: EPA Reg.#352-372; PP#1F2448; Long Term Feeding Study In Mice with Oxamyl
CASWELL#626A 561A Accession#070136-143

FROM: William Dykstra, Toxicologist
Toxicology Branch, HED (TS-769)
WJD for LOC 6/19/81

TO: Jay Ellenberger (12)
Registration Division (TS-767)
and
Residue Chemistry Branch
Hazard Evaluation Divsion (TS-769)

Recommendations:

1. Oxamyl was not oncogenic up to 75 ppm in the diet of mice for two years. The study is acceptable as Core-Minimum Data.

Review:

1. Long Term Feeding Study in Mice with Oxamyl (WIL 77033; 5/29/81)

Test Material: Technical grade Oxamyl, H#10963, 97.1% purity, white crystalline powder

Three hundred and twenty Charles River CD-1 mice of each sex were selected for study on the basis of body weight gain and findings observed during the quarantine period. The animals were randomized into four treatment groups according to body weight. The randomization process was done separately for males and females.

The mice were housed individually. Fresh water and Purina Laboratory meal were provided ad libitim throughout the study.

The dose levels in the groups were set based upon findings in an eight week range finding study run at WIL, report dated 9/27/77. Four groups consisting of 80 males and 80 females were established and were as follows:

Treatment Group	Dose Level (ppm)	No. of Animals Male	Female
1	0	80	80
2	25	80	80
3	50	80	80
4	100/75*	80	80

*Due to the unexpected high mortality rates in the mid- and high-dose groups during the first few weeks, the 100 ppm group was decreased to 75 ppm on week 6.

Also 22 extra mice, not previously selected for the study but from the same shipment were added 11/28-12/9/77 to provide additional mice for long term evaluation: 721 added to group 2 female 11/28/77; 722 added to group 3 male 11/28/77; 723, 724, 725, 726 added to group 3 female 11 28/77; 727, 728, 729 added to group 4 male 1/28/77; 730, 731, 732 added to group 4 female 11/28/77; 733, 734, 735, 736, 737 added to group 4 male 12/6/77; 738, 739, 740 added to group 4 female 12/6/77; 741 added to group 4 female 12/8/77; 742 added to group 4 female 12/9/77. These animal additions were made at the request of the sponsor after consultation with the study director.

During the study, all mice were observed twice daily for signs of mortality, toxicity and behavioral changes.

All mice were palpated once weekly for the presence of masses. Any positive findings were recorded as to size, location and appearance.

A record was kept on all mice that died or were killed in extremis during the study. Mice which became moribund or had sudden large weight loss were sacrificed by CO_2 asphyxiation and necropsied according to the original protocol. Tissues from animals dying before the end of the study or sacrificed in extremis were preserved for histopathologic examination. A gross pathological examination was performed and the tissues saved in 10% buffered neutral formalin on all animals that died with in the first weeks of dosing. Most of these latter tissues were not evaluated histopathologically as per instruction from the sponsor, since no alterations of a carcinogenic nature were anticipated from such a short exposure to the test diet. A weekly cumulative record of mortality was maintained.

Body weights were measured for all mice once weekly during the first six months (weeks 1 through 29), once every week during the second half of the first year (weeks 31 through 53), and then once a month until study termination (weeks 57 through 105).

Each time the mice were weighed, the amount of diet consumed by each sex of each group was measured. From these data, food efficiency and average intake of Oxamyl per group was calculated.

Ten male and ten female mice randomly selected from each group were bled from the orbital sinus after 1, 3, 6, 12, and 18 months of dosing and prior to termination of the study. Parameters evaluated were: WBC, RBC, hemoglobin, hematocrit, MCV, MCH, MCHC, complete differential WBC.

All surviving mice were weighed, sacrificed with CO_2 asphyxiation and necropsied on November 14, 15 16 and 17, 1979 under the supervision of Dr. Fred W. Sigler. The following organs were weighed: liver, kidneys, tests, brain and stem, and heart.

The following tissue specimens were taken and fixed in 10 to 20 volumes of 10% buffered neutral-formalin:

Brain
(Forebrain, midbrain and hindbrain)
Eyes with contiguous Harderian glands
Pituitary
Salivary glands
Heart
Thymus
Thyroid (Parathyroid)
Lungs
(2 coronal section with mainstem bronchi)
Trachea
Esophagus
Stomach
Intestine, smal and large
Adrenals glands
Pancreas
Liver, 2 lobes
Gall bladder
Kidneys
Urinary bladder
Testes, epididymides
Prostate
Ovaries
Corpus and cervix uteri
Spleen
Lymph nodes
Skin
Sciatic nerve
Mammary gland
Bone, bone marrow, or tibio-femoral joint
Muscle
Aorta
Uterus
*Nasal cavity and paranasal sinuses
*Spinal cord (2 levels)
*Head (3 coronal sections) nasopharynx, middle ear, tongue and oral cavity
*Seminal vesicle
Gross lesions (with normal tissue)

Prior to the issuance of the proposed regulations tissue specimens were collected from animals found dead and sacrificed moribund throughout the study according to the above list expect for the tissues marked with *.

Some animals died early in the first few weeks of the study and only a gross necropsy was performed, no tissues were histologically examined (see Mortality section). These mice were 0, group 2 male; 346, group 3 male; 489, 556, 495, 514 503, 510, 500, 481, 547 492 group 4 male; 269, 308, group 2 female; 438, 409, 436, 410, 443 group 3 female; 570, 606, 624, 626, 616, 600, 738, 592 group 4 female. Also, several mice were judged to be in such an advanced state of autolysis as to preclude histopathologic evaluation. These mice were 540, group 4 male; 111, group 1 female; 308, group 2 female; and 564, 583 group 4 female. Many other mice were found to have advanced postmortem autolysis, but it was not extensive enough to preclude a histopathological evaluation.

One mouse (71, group 1 male) was cannibalized (cages used in the study had center dividers and one mouse penetrated the divider and was canninbalized) and one (600, group 4 female) was not necropsied (technician oversight).

All other mice placed on the study were examined histologically.

Statistical analyses of the data were performed:

Results:

There was no apparent test material-related effect on any clinical observations.

Tissue masses observed and palpated throughout the study and at termination were eva uated histopathologically. No apparent consistent test material-related effect was noted.

Group 4 males mean food consumption was significantly less than that of the control, group , males for weeks 11 through 84 with the exception of weeks 12 and 19. From week 88 through the end of the study there was no significant difference. No pattern was shown throughout the study for the other test groups 2 and 3 males and 2, 3, and 4 females.

The mean body weights for group 3 males were significantly less than those of the control from weeks 1-81 The mean body weights for group 4 males were ignificantly less than those of the control from weeks 2-43 and were variable thereafter to the end of the study. There was no significant difference throughout the remainder of the study The mean body weights for group 3 or 4 females were variably ignificantly different during the first 21 weeks of study but were only sporadically significantly different after week 2 No other consistent pattern was noted in any of the treated groups compared to the controls throughout the remainder of the study.

No consistent test material related effects were noted in the body weight of the treatment groups compared to that of the controls after the first 81 weeks of the study.

The cumulative life graph data reflected the early mortalities. These deaths appeared to be related to the acute toxic effect of the test material in the diet mixture. Subsequently, life table analysis indicated no further increased mortality due to Oxamyl occurred during the remainder of the study.

Sporadic significant differences in hematology parameters were noted throughout the study. These changes are suggestive of a compound related effect upon red cell mass in group 4 males early in the study week 4 but this did not persist.

There was a slight decrease in absolute weight of the liver in group 3 males and a slight increase of the organ to body weight ratios of the kidney for group 4 males. Based on the absence of histologica findings, these effects are not considered significant.

No significant histopathological changes were noted for the test groups when compared to those of the controls except that the chronic interstitial nephritis of the kidney was significantly less for the test groups (group 2, 3 and 4), males, compared te that of the controls. Oxamyl was not oncogenic at any level tested.

Conclusion:

Oxamyl was not oncogenic at dietary levels up to 75 ppm.

Classification: Core-Minimum Data

TS-769:th:TOX/HED:WDykstra:6-18-81:#2

There is a surprising similarity between what is stated (on the left side of the five foregoing pages) by the registrants in the summary of their report with what are allegedly the "independent" assessments of the Hazard Evaluation Division reviewer (given on the right side pages). Quite apart from this feature one may also note the following:-

a) The registrants report is comprised of a total of 2,347 pages; yet the entire review originating in the Hazard Evaluation Division has reference to what is presented merely in the first 14 pages of that report and to nothing else; it appears to me that the balance of 2,333 pages were not even cracked for a mere cursory examination by that reviewer.

b) The initial page of that review (page 4 in this communication) reveals that its author in the Hazard Evaluation Division saw fit to initial for the signature of his own Section Supervisor, perhaps in an attempt to circumvent the latter's possible finding that this was merely a "cut-and-paste" job. Also, although that review is dated June the 18th, 1981, (a date also found on its very last line it was not until the next day when the reviewer apparently had decided to append his own initials for those of his supervisor. Four additional days seemingly elapsed before the entire document was stamped with the date June the 23rd, 1981, perhaps to indicate that t took as long for this review to have "ripened" in the Hazard Evaluation Division or to have been "approved" by the Toxicology Branch Chief or the Director of that Division, even though there is no evidence that any of these actually saw t and agreed with its contents.

It may also be pertinent to add here that the reviewer of record here is by no means some kind of neophyte or a recently recruited employee who may not be familiar with the way things ought be done. I am informed that he is a Ph.D. Toxicologist, that he had recently been promoted to a GS-14 grade level (a category denoting an "expert and that he had recently been recognized as having performed in an "outstanding" fashion for having demonstrated unusual efficiency in carrying out reviews of this sort. It s small wonder that by having reference to less than 1/100-th of the material n a toxicity report and, additionally, by helping himself to or appropriating the registrant s views and representing these as his own, he can be very efficient indeed, in that he took but a few minutes to do what it may take others hours, days, weeks, etc. This is to say nothing of the time that he had "saved" his supervisors at three different levels to oversee the quality of this work.

c) That particular mouse study with oxamyl had been signalled by Battelle to have been subjected to a "cut-and-paste review. am appending here as Attachment a communication addressed to Douglas D. Campt, Director of the Registration Division of February the 3rd, 1984 which carries the signature of Wi liam L. Burnam of the Toxicology Branch, Hazard Evaluation Division and that of John W. Melone, the Director of that same Division which presents the Battelle comments (allegedly, verbatim

In that same communication we also read under "Review Group s comments" that there was "an independent evaluation" by "the initial TOX

Branch review" (presumably "independent" of that of the registrants) and that the "evidence" for this was the fact that the review in question "included an analysis of the lung tumor data and noted no pesticide-related effects".

I have reproduced that review "in toto" here on pages 4 through 8 in this communication. If anyone can demonstrate to me exactly where in that review there s any reference whatsoever to lung tumors, would be willing not to characterize that assertion as a fabrication out of whole cloth, as a brazen and total falsehood. Its only purpose cannot be but to save embarassment for the Hazard Evaluation Division, even at the risk of misleading Mr Campt of the Registration Division the person who would have the ultimate responsibility for setting a tolerance for this pesticide product. The risks to the consumers of this country apparently can be disregarded in this entirely wanton and reckless manner so long that no one in the Hazard Evaluation Division can be thought of as having acted in an improper way, and it seemingly does not matter even if it takes outright lies to achieve that end.

Was Mr. Campt in fact misled in this respect ? Appended here as Attachment 2 is the official document published in the Federal Register which bears his signature and the date December the 4th, 1984. In the last paragraph of its second page we read "The data submitted in the petition and all other relevant material have been evaluated. The toxicological data considered in support of the tolerance included ... a mouse oncogenicity study which was negative ... up to 75 ppm for 2 years." This s reminiscent of what there is in the review originating from the Hazard Evaluation Division:- "Oxamyl was not oncogenic at dietary levels up to 75 ppm under "Recommendations" (first line of the review), "Oxamyl was not oncogenic at any level tested (last line before "Conclusions"), "Oxamyl was not oncogenic at dietary levels up to 75 ppm", the sum total of the "Conclusions" themselves.

This is by no means the first time Mr. Campt had been misled by Mr. Melone, the Director of that Division on the safety of a pesticide. On August 1st, 1983 wrote to Mr Campt a detailed memorandum indicating a similar such situation for the insecticide permethrin; unfortunately, he had not seen fit to even acknowledge receipt of that communication of mine.

I do not know to what extent the other studies mentioned in the Federal Register statement of December 1984, are justified in the sense of their having been based on reviews other than of the "cut-and-paste" type or even f they were not of this variety, they were in fact reliable such reviews; I have not examined those reviews and, therefore, I shall have no further reference to them here Rather for the balance of the present communication, I shall limit my remarks merely to the 2-year mouse study with oxamyl, and, more specifically, I shall discuss only two aspects of it: did the reviewer indeed have reference to more than the initial 14 pages of the registrants report on that study, .e. did he in fact make here a review which was truly "independent" of the evaluations reached by

the registrants and what are some of the examples on what was "missed" in that evaluation.

If, indeed, as the Burnam-Malone communication to Campt given here in Attachment 1 states, the reviewer had in fact addressed the lung tumors noted in the mice in this study, he could not have failed to notice that three of the females at the high level of exposure, Nos. 585, 612, and 587, presented grossly visible "nodules" in the lung which could have turned out to be in fact pulmonary tumors, either benign or malignant and either primary or metastatic to the lung; in fact, however, those grossly-observed lesions were not confirmed as being either tumors or any other kind of abnormality during the microscopic examination of those particular lung sections. This is not something that was discovered by me as a consequence of examining any "internal records" maintained by the laboratory that executed the study; rather, it is present in the final report submitted by the registrants to the EPA which, presumably, was available for the examination of the Hazard Evaluation Division reviewer, had he in fact elected to merely glance at what is beyond the first 14 pages of that report.

Furthermore, and of far greater importance, had the reviewer in fact examined the individual pathology reports of the test animals beyond those initial 14 pages of the report, particularly with reference to the lung tumor data, he could not have concluded that, in the words of Burnam-Malone, there are "no pesticide-related effects" attaching to those lung tumor data; rather, he could have found what I did in that same final report available for his review:-

The female animals with pulmonary adenoma were Nos.:- 640, 724, 315, 155, 310, 448 (dead on 8/31/79), 634, 428, 307 (dead on 6/17/79), 302 (dead on 10/12/79), 423, 632, 628, 422, 297, 82, 637, 295, 413, 619 (dead on 9/25/79), 288, 283, 605, 577 (dead on 10/24/79), 572, 267, 266, 568, 566, 263, 639, 259, 116, and 561.

In addition to those animals, Nos. 419 (dead on 8/3/79), 599 (dead on 3/16/79) and 586 (dead on 5/6/79) manifested malignant tumors primary in the lung, pulmonary adenocarcinomas.

The distribution of those animals amongst the various experimental groups (even if one were to ignore the three animals at the high level of exposure with grossly visible lesions suggestive of pulmonary tumors but which were unconfirmed histopathologically) is such as to yield the following:-

a) For merely the malignant primary pulmonary tumors and taking as the data base all females with lung sections examined microscopically, there is a dose-response slope of 0.000,365 with standard error 0.000,197, yielding a chi square with one degree of freedom of 3.407 whose one-sided probability is only $p = 0.032$ and which is consistent with linearity (chi square with two degrees of freedom of 0.442 whose two-sided probability is as high as 0.802);

b) For all pulmonary tumors primary in the lung regardless of their malignancy status and taking as the data base the same as in (a) above, we have a dose-response slope of 0.001,65 with standard error of only 0.000,698, yielding a chi square with one degree of freedom as high as 5.601, whose one-sided probability is only p = 0.008 97 and which is also consistent with linearity (chi square with two degrees of freedom of 4.074 whose two-sided probability is as high as 0.130). For merely the low level of exposure the probability for the increased incidence of such tumors over the control rate is 0.011,01 + 0.002,21 + 0.000,27 + 0.000,01 = 0.013,51 and for the high level it is 0.001,51 + 0.000,22 + 0.000,02 + 0.000,00 = = 0.001,75;

c) As in (b) above but taking as the data base only those females which completed the full exposure period, there is a dose-response slope of 0.002,800 with standard error of only 0.001,500, yielding a chi square with one degree of freedom as high as 3.483 whose one-sided probability is as low as 0.031 and which is consistent with linearity (chi square with two degrees of freedom of only 3.307, whose two-sided probability is as high as 0.191. For merely the low level of exposure the probability for the increased incidence of such tumors over the control rate is 0.025,01 + + 0.005,12 + 0.000,59 + 0.000,03 = 0.030,75 and for the high level it is 0.006,83 + 0.001,01 + 0.000,09 + 0.000,00 = 0.007,93.

This indicates that no matter how one analyzes the data on pulmonary tumors as a whole, or merely those on the malignant such tumors, we have here a highly significant dose-related increase in incidence amongst exposed animals by comparison with the unexposed control animals.

I should think this demonstrates conclusively and beyond any doubt whatsoever that not only was it not true, as Burnam-Melone stated, that the nitial review made in the Hazard Evaluation Division "included an analysis of the lung tumor data" but t was also not true for them to imply that there are "no pesticide-related effects" related to those data. Consequently, their "evidence" such as this is in reality no evidence whatsoever for what they attempt to convey to Mr. Campt that there was an "independent evaluation made here by the reviewer in their Division.

Actually, if one is concerned with "evidence" in this respect, as Messrs. Burnam and Melone appear to be, there is additional evidence that in fact there was here no evaluation whatsoever which can be thought of as having been "independent" of that made by the registrants. For example:-

Note in the last paragraph before the "Conclusion" on the last page of the review emanating from the Hazard Evaluation Division (page 8 here) that "No significant histopathological changes were noted for the test groups when compared to those of the controls except that the chronic interstitial nephritis of the kidney was significantly less for the test groups (group 2, 3, and 4) males, compared to that of the controls."

Had the reviewer been less eager to call attention merely to what lesions were significantly less for the test groups, i.e., regurgitate

merely the registrants' own evaluation, but instead made an effort to find out what lesions in that very same organ, the kidney, were significantly increased in incidence amongst the exposed animals over their unexposed fellows (which would denote at least some degree of concern on his part with the public health of those humans exposed to this particular pesticide product) he would have made at least a gesture towards examining this toxicity report beyond page 14.

Had he in fact done so, he would have discovered that the distribution of male animals with glomerulosclerosis in the kidneys is associated with a dose-response slope of 0.001,458 with standard error of only 0.000,642, yielding a chi square with one degree of freedom as high as 5.108 whose one-sided probability is as low as p = 0.012 and which was not inconsistent with linearity (chi square with two degrees of freedom of only 1.876 whose two-sided probability is as high as p = 0.391). As in the case of the pulmonary tumors amongst the female animals discussed above, this also indicates that a NOEL was not established in this study.

Another example:-

In the paragraph of the review made in the Hazard Evaluation Division just prior to the one cited above, we find yet another untruth referable to the fact that the reviewer did not see fit to evaluate by himself the actual data submitted by the registrants in this report but, instead, chose to copy their own misleading evaluations. We find there that there was "a slight increase of the organ to body weight ratios of the kidney for group 4 males. Based on the absence of histological findings (in the kidneys of group 4 males, presumably), these effects are not considered significant."

What is clearly not true here is multifaceted:-

a) "Histological findings" in the kidneys were not only present in those of group 4 males but also in the kidneys of all other male mice in this study; moreover, the increase in incidence of glomerulosclerosis in a dose-related manner was not only highly significant but it also resulted in a NOEL not having been established in this study, as I demonstrated just above;

b) For merely the group 4 males, the incidence of renal glomerulosclerosis was increased from 3.80% in the control males to 14.29%, an almost 4-fold increase, which was significant at the p = 0.016,618 + 0.003,561 + 0.000,457 + 0.000,025 = 0.020,663 probability level;

c) Even had there been no "histological findings" such as glomerulosclerosis in the kidneys of those male mice, this would not make the increase in the relative weight of the kidney to be "not considered significant". An increase in relative weight of any organ is a lesion or a manifestation of toxicity in its own right and in no way dependent on or linked to the presence of other findings. For a Ph.D. toxicologist to have swallowed without blinking this kind of argument advanced by the registrants and, moreover, to adopt it as his own, is in itself an eloquent

manifestation of the kind of "expertise" and independent or critical judgment that we seem to have here.

As a matter of fact, the weight of the kidney relative to the body-weight in the male animals of this study manifested a dose-response slope of 0.003 016 with standard error of only 0.001,117, yielding a t value with 132 degrees of freedom as high as 2.701 whose one-sided probability is only 0.003,915 and which was consistent with linearity (F value with 2 and 130 degrees of freedom as low as 0.981 whose probability is as high as 0.38) and the chi square with two degrees of freedom for the goodness-of-fit was as low as 0.003 whose two-sided probability is as high as 0.998.

In sum, this represents the third aspect listed here which indicates the absence of a demonstrable NOEL in this particular work.

Another example:-

The "absolute (as distinct from the "relative") weight of the kidney for the male mice in this study was even more spectacularly and significantly increased in a dose-related manner, yet this is being glossed over in the review originating from the Hazard Evaluation Division: this is because the registrants elected not to highlight this in the first 14 pages of their report and, the EPA reviewer in turn, chose to ignore everything else in that report. Had he not elected to do so, he could have determined what I did:- a dose-response slope of 0.000 752 with standard error of only 0.000,109, yielding a t value with 132 degrees of freedom as extremely high as 6.891 whose one-sided probability is as extremely low as 0.000,000,000,5 and where the goodness-of-fit chi square with two degrees of freedom is as low asa 0.002,8 with a two-sided probability as high as 0.999.

This would constitute the fourth aspect listed here which indicates the absence of a demonstrable NOEL in this particular study.

Still another example:-

Yet another feature not addressed in the review originating from the Hazard Evaluation Division (again, probably because it was not addressed by the registrants in the initial pages of their report) is the highly significant slope of the dose-response function pertaining to the relative weight of the liver of the male animals. I found this to be as steep as 0.015,441 with standard error of only 0.007,776 yielding a t value with 132 degrees of freedom of 1.986 whose one-sided probability is as low as 0.024,6 (0.049,2 two-sided) with insignificant departure from linearity (F value with 2 and 130 degrees of freedom of only 0.735 whose probability is as high as 0.481) and very good goodness-of-fit (chi square with two degrees of freedom of 0.054 whose two-sided probability is as high as 0.973).

This would be the fifth aspect listed here which indicates the absence of a demonstrable NOEL in this particular work.

Although the few hours at my disposal to audit the data presented in this particular study did not allow me to make an exhaustive evaluation of all aspects of toxicity for oxamyl manifested here, nevertheless, what is presented above is sufficient to demonstrate that the Hazard Evaluation Division had in fact misled Mr. Campt into stating in the Federal Register proposal appended here as Attachment 2 that the (lowest) NOEL to be established for oxamyl can be derived from the rat study and estimated to be as high as 50 parts per million (ppm).

To appreciate the worth of other estimates given in that same document, I am presenting below the results of a formal risk assessment made on the basis of the data presented in item (c) or second paragraph on page 12 here.

For additional details on this, I have used two separate extrapolating procedures:- the Mantel-Bryan approach (also known as the log-probit method) and the "one-hit" procedure. In each case the maximal estimates of the "virtually safe" dosage or concentration of oxamyl were provided by the results obtained at the middle level of exposure, and these are the ones tabulated below; for conversion of parts per million in the diet to mgm per kgm body-weight per day, I have used the factors given by the Association of Food and Drug Officials of the United States, as well as the body-surface correction necessary for extrapolating from small laboratory rodents to humans; also used here was the Abbott Correction as well as a two-sided confidence interval of 90%. The estimates are given for a wide variety of choices for the upper limits on the risk in the table following immediately here on the next page:-

RESULTS OF THE FORMAL RISK ANALYSIS.

Upper limit on risk:	"Virtually safe" levels of oxamyl expressed in ppm		expressed in mgm/kgm/day	
	log-probit:	one-hit	log-probit	one-hit
1/100,000,000	0.000,501	0.000,001,59	0.000,005,2	0.000,000,016,5
5/100,000,000	0.000,966	0.000,007,94	0.000,010,0	0.000,000,082,6
1/ 10,000,000	0.001,29	0.000,015,9	0.000,013,5	0.000,000,165
5/ 10,000,000	0.002,63	0.000,079,4	0.000,027,3	0.000,000,826
1/ 1,000,000	0.003,61	0.000,159	0.000,037,6	0,000,001,65
5/ 1,000,000	0.007,84	0.000,794	0.000,081,5	0.000,008,26
1/ 100,000	0.011,1	0.001,59-	0.000,116	0.000,016,5
5/ 100,000	0.026,3	0.007,94	0.000,274	0.000,082,6
1/ 10,000	0.039,1	0.015,9	0.000,406	0.000,165
5/ 10,000	0.105	0.079,4	0.001,09	0.000,826
1/ 1,000	0.166	0.159	0.001,73	0.001,65
5/ 1,000	0.543	0.796	0.005,65	0.008,28
1/ 100	0.965	1.60	0.010,0	0.016,6
5/ 100	4.63	8.15	0.048,2	0.084,7
1/ 10	10.7	16.7		

Comparing in the table above the estimates expressed in ppm with those expressed im mgm/kgm/day, we may note that the latter are smaller than the former by a factor slightly less than 100; as to the comparability of the estimates generated by each of the two extrapolating procedures, we may note that the one-hit estimates are smaller than the comparable ones generated by the log-probit approach for the lower upper limits on the risk:- thus for an upper limit on the risk of 1/100,000,000, they are smaller by a factor in excess of 300; at the very high upper limits, the converse situation is true:- the estimates deriving from the one-hit method are larger than those originating from the log-probit method; the two kinds of estimates are virtually identical in the neighborhood of an upper limit on the risk of circa 1/1,000.

If we now focus on the new tolerance of oxamyl that had been increased for bananas imported from Costa Rica from 0.1 ppm to 0.3 ppm, (see the proposal published in the Federal Register and signed by Mr. Campt as given in Attachment 2 here) and assuming further that the pesticide could permeate the entire edible part of the fruit and thus could be found there at a concentration of 0.3 ppm, we have the following:-

Assuming that merely one middle-size banana weighing approximately 150 grams is included in the daily diet of an adult human, such diet having an average weight of approximately 1,500 grams, this would represent the ingestion of 1/10-th of 0.3 ppm, i.e., 0.03 ppm. If we look up this value in the table presented on the previous page here, we note that it is associable with an upper limit on the risk between 5/100,000 and 1/10,000 (log-probit) and between 1/10,000 and 5/10,000 (one-hit). Exact interpolation would yield estimates of the upper limit on the risk ranging from 6.3/100,000 (log-probit) to 1.9/10,000 (one-hit). Inasmuch as this would not represent an unreasonably high daily consumption rate of bananas, I should think that this kind of risk is perhaps unacceptably high; for those whose proportion of the daily diet comprised of bananas is higher, and perhaps for some infants, the risks would be correspondingly larger.

If we now address Mr. Campt's statement that the ADI for humans is calculated to be 0.025 mg/kg of body weight (bw)/day" and look up this value in the table on the preceding page here, we note that this relates to upper limits on the risk between 1/100 and 5/100 for both the log-probit and the one-hit extrapolating procedures. More exact interpolation yields a value between 1.5/100 (one-hit) and 2.6/100 (log-probit).

Overview and General Discussion.

Although it is amply evident from the foregoing text that in the first 14 pages of their report the registrants did not properly evaluate the significance of the findings in this two-year mouse study with oxamyl, I hasten to add that the Law, as I understand it, does not require them to do so.

What the Federal statutes do require of registrants for pesticide or other products is that the circumstances of the conduct of each study and the actual observational findings emerging from it, i.e., "the facts", be fully and adequately presented to the Government. As a result of our audit of this work at the site where its original records are stored, I can state that we found no evidence whatsoever that this was not the case here.

As to the process of the evaluation of such facts or observational findings, the people of this country depend on their Federal Government, in this particular case, on the Environmental Protection Agency. It is, I believe, the function of this Agency to determine from reports submitted to it by the regulated industry what is the safety of such products and to regulate them in view of their potential benefits and risks. This is

basically the job that is entrusted to us and we are all being paid very well to do it.

It is also evident that in this particular case, as in other similar ones cited earlier here, such reliance and trust conferred on this Agency may have been in fact misplaced. To "cut-and-paste" parts of the evaluation attempted by the registrants and to represent this as constituting an independent and searching assessment of the technical facts simply so as to avoid doing the work one gets paid to do and, additionally, to circumvent secondary review by supervisors who could have discovered such practices, strikes me as representing not only a form of serious negligence on the part of both the reviewer and on the part of his supervisors, but also an abuse of that trust and a total disregard or perhaps downright contempt for the health of the American people exposed to potentially toxic products.

Disconcerting or disappointing as this might be, it is also clear that the situation in the particular case discussed here was compounded much further:- in actuality, what happened here with this specific study had been brought to light some time ago through the investigation carried out by the Battelle Corporation Their findings, however, as with their findings on many other similar reviews in the Hazard Evaluation Division, were referred to a "Review Group" numbering amongst ts members some from the very unit which was implicated in such shoddy conduct.

The supervisor of that unit, Mr. Burnam, in a view concurred with by his own immediate supervisor, Mr. Malone, the Director of that Division, apparently chose not only to ignore those revelations of Battelle's but to actually deceive others in this Agency on what had happened here and this was done with the aid of bold and utter lies. I would assume that such "cover-up" effort was made by them out of a desire to deflect from themselves any possible criticisms on their own responsibilities and their own negligence in this entire sordid matter.

The net effect of such actions was that the Agency published in the Federal Register only a few months ago a proposal that, contrary to the explicit statement contained in t, is in fact not "protective of the public health" of the citizens of this country. It has been shown here in some detail that the risk of cancer associated with the new tolerance established for bananas imported from Costa Rica may be unacceptably high (up to 6.3/100,000 - 1.9/10,000) and that the same kind of risk emanating from what the Agency states is an "acceptable" consumption rate for this pesticide product (0.025 mgm/kgm/day) s as high as 1.5 2.6/100, clearly a rate that can be easily perceived to be nothing short of catastrophic.

Perhaps as a result of such "calculations as listed in that Federal Register proposal of last Decemeber, the EPA Report from OPP dated as late as March the 8th, 1985, indicates that a Section 18 exemption from tolerance had been approved for oxamyl for another food commodity only last month and that the proposed tolerance on bananas published last December had in the meantime become "final".

Entirely apart from such regulatory considerations as discussed above, there is here yet an additional dimension, another indication on the philosophy or overall policy apparently in effect in the Hazard Evaluation Division on the assessment of risks posed by potentially toxic pesticide products.

Appended here as Attachments 3 and 4 are copies of two memoranda issued in a single day there as recently as a couple of months ago. Each of those communications clearly indicates that whenever a carcinogenic (oncogenic risk s initially perceived for a certain product, an elaborately complex machinery s set in motion; amongst its elements there are described in those instructions "tripartite reviews", a statistician and a pathologist expected to spring into action, a "preliminary potency assessment", an "ad hoc peer review an "exposure assessment", etc. It seems as if the purpose of all this intense scrutiny and activity is to minimize the possibility that any product nitially or presumptively tagged as bad news will finally emerge as such in an undeserved manner.

Laudable as such efforts might be (and one ought not view them as simply a pretext to delay action on such agents), unfortunately, they do not seem to be balanced on the other side by the converse possibility or the alternate type of error:- whenever the initial reviewer forms an opinion that some pesticide product s "safe", .e., it does not appear to be a carcinogen, oncogen mutagen, cataractogen, teratogen or some other kind of ...gen meaning toxic in some other kind of way, not only are there no pathologists, no statisticians, no peer-reviewers, etc., scurrying about to verify such first impressions, which may also be false, but the supervisors of that reviewer at the first, second, and n-th level (as we have seen n the case of oxamyl here) apparently make no effort whatsoever to assure themselves or others that such first impressions are in fact justifiable. It seems as f once a toxicology report submitted by some registrant is initially assessed as presenting "no problems", no one else in this Agency takes the trouble to verify the soundness of the initial review by a secondary review of that original report submitted to the EPA.

Clearly, this alternate type of possible error cannot adversely affect the welfare of any registrant but merely that of the consumer exposed to potentially toxic residues of that pesticide product. Would this be the reason for situations such as this not being given even a modicum of the attention and time expended on the others ? Would this kind of outlook or policy in the Hazard Evaluation Division not denote the lack of an even-handed regulatory approach, an inbalance between our concern with the "health" of the industry we are supposed to regulate and that of the people we are supposed to protect ? Does this not constitute a rather peculiar form of aberration in thinking ?

This kind of odd dichotomy can be illustrated by yet another customary practice there:- often when a reviewer thinks that there may be a carcinogenic or other toxic risk manifested by some statistically significant result in the data, one of two (and sometimes both) "strategies" are resorted to:- a request is made that an additional pathologist re-examine

the specific tissue sections that had led to that particular significant result. Note that such request essentially denotes a certain lack of confidence on our part on the reliability of the results obtained by the original examining pathologist. Yet, even though these kinds of re-examinations of the pathology material can be quite expensive, their cost has not been invariably borne by the registrants, as they ought to be; on several such occasions the Hazard Evaluation Division had contracted for such additional re-examinations out of public funds.

It is interesting, however, that when such re-examinations are requested, as mentioned, out of a desire to have certain aspects of pathology "verified" as it were, such requests for re-examination can be limited strictly to the kind of data initially perceived as having yielded "significant" results. In other words, what is happening here is that if a change is to take place as a consequence of such re-examination, this can only "undo" so-to-speak an initial conclusion of lack of safety and never a converse one; I know of no instance where a pathology re-examination of material had been requested by the Hazard Evaluation Division where they may have felt the original pathologist's characterizations may be suspect n that he/she may have improperly determined that some product or other does not elicit certain kinds of lesions. This has all the earmarks of the situation described above here.

The other kind of "strategy" employed almost always when someone initially perceives a carcinogenic or oncogenic risk s to attempt to derail such impression with the aid of the so-called "historical control" data. Again, I know of no instance where the Hazard Evaluation Division had seen fit to request such data and utilize them in an attempt to establish the flip side of this situation - a certain contrast being just short of statistical significance and yet where consideration of the "historical control" data may render that same contrast more highly significant than would be the case where merely the local or contemporaneous control animals are considered. It is again that very same inbalance that described earlier we seem to spare no effort aimed at classifying pesticide agents as more "safe" than first appreciated, yet we pay only scant if any attention to the reverse situation.

This situation with the "historical control" data in reality is even worse than appreciated at first glance. All too frequently we seem to be satisfied with what I can denote as merely "anecdotal" such "historical control data:- no serious effort is made to secure for such data the kind of detai we expect for the contemporaneous control data, no specific requests are made by the Hazard Evaluation Division to have those kinds of data "audited" for their reliability, etc. additionally, such data are often used in an improper way in that Division:- little if any consideration is given to the rate of mortality of those "historical" animals and, therefore, whether they were at a risk to manifest tumors truly comparable to those in the study under consideration, the examining pathologists for those animals may be entirely different (and therefore, with possibly different "orientations" in the classification of lesions) than those who examined the tissues in the study of primary concern, and the actual

such "historical control" data are evaluated in a totally inappropriate fashion.

With reference to this last point, yet another laboratory audit in which I participated only last month had disclosed still another objectionable feature:- a draft of a communication containing certain serious misconceptions on this particular subject and originating in the Hazard Evaluation Division had been released to a certain registrant in what I believe was an unauthorized fashion; this was done perhaps out of a desire to "help" that particular registrant with his own "evaluation" (?) of the data originating in some specific long-term study; you may have already guessed what happened next:- that same registrant saw fit to turn around and include that particular "draft" with all its faults in his own official report on that study which was submitted to the Environmental Protection Agency for regulatory purposes. Perhaps the underlying hope here was that certain reviewers in that very same Division would be influenced by the contents of that flawed original draft originally issued there.

If you are interested in still other examples of this sort through which there seems to run a common thread, much like Ariadne's mythological one, let me know and I shall be willing to provide these for you.

Cheers,

Encl.:- Attachments 1 through 4
MAGROSS:mag - 3/20/85.

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5. Animal Assignment

Three hundred and twenty mice of each sex were selected for study on the basis of body weight gain and findings observed during the quarantine period. The animals were randomized into four treatment groups according to body weight. The randomization process was done separately for males and females.

mice were housed individually

Fresh water and Purina Laboratory Meal were provided ad libitum throughout the study.

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groups
follows

The dose levels in the groups were set based upon findings in an k range finding study run at WIL, report dated 9/27/77. Four sisting of 80 males and 80 females were established and were as

Treatment Group	Dose Level (ppm)	Animal Numbers Male	Animal Numbers Female
1	0	1-80	81-160
2	25	161-240	241-320
3	50	321-400	401-480
4	100/75*	481-560	561-640

VIL-77033
. L. du Pont de Nemours
louse Oncogenicity Study

*Due to unexpected high mortality rates in the mid- and high-dose groups during the first few weeks, the 100 ppm group was decreased to 75 ppm on week 6.

Also 22 extra mice, not previously selected for the study but from the same shipment were added 11/28-12/9/77 to provide additional mice for long term evaluation: 721 added to group 2 female 11/28/77; 722 added to group 3 male 11/28/77; 7233, 724, 725, 726 added to group 3 female 11/28/77; 727, 728, 729 added to group 4 male 11/28/77; 730, 731, 732 added to group 4 female 11/28/77; 733, 734, 735, 736, 737 added to group 4 male 12/6/77; 738 added to group 4 female 12/6/77; 741 added to group 4 female 12/6/77; 742 added to group 4 female 12/9/77. These animal additions were made at the request of the sponsor after consultation with the study director.

During the study, all mice were observed twice daily for signs of mortality, toxicity and behavioral changes.

b. Palpations

All mice were palpated once weekly for the presence of masses. Any positive findings were recorded as to size, location and appearance.

c. Mortality

A record was kept on all mice that died or were killed in extremis during the study. Mice which became moribund or had a sudden large weight loss were sacrificed by CO_2 asphyxiation and necropsied according to the original protocol. Tissues from animals dying before the end of the study or sacrificed in extremis were preserved for histopathologic examination. A gross pathological examination was performed and the tissues saved in 10% buffered neutral formalin on all animals that died within the first weeks of dosing. Most of these latter tissues were not evaluated histopathologically as per instructions from the sponsor, since no alterations of a carcinogenic nature were anticipated from such a short exposure to the test diet. A weekly cumulative record of mortality was maintained.

4 y Weights

five dy weights were measured for all mice once weekly during the first : months (weeks 1 through 29), once every other week during the cond half of the fir . year (weeks 31 through 53), and then once a onth until study termination (weeks 57 through 105).

- od Consumption, Food Efficiency and Diet Concentration

ach time the mice were weighed, the amount of diet consumed by each sex of each group was measured. From these data, food efficiency and average intake of oxamyl per group was calculated.

M rements for Hematology

Te male and ten female mice randomly selected from each group were bled from the orbital sinus after 1, 3, 6, 12, 18 months of dosing and prior to termination of the study. Parameters evaluated were: white blood cell count, red blood cell count, hemoglobin concentration, hematocrit, mean cell volume, mean corpuscular hemoglobin, mean corpuscular hemoglobin concentration, complete differential WBC

All surviving mice were weighed, sacrificed with CO_2 asphyxiation and necropsied on November 14, 15, 16 and 17, 1979 under the supervision of Dr. Fred W. Sigler, a Board eligible veterinary pathologist.

1. Organs Weighed

Liver	Testes	Heart
Kidneys	Brain and stem	

Brain (Forebrain, midbrain and hindbrain)	Prostate
Eyes with contiguous Harderian glands	Ovaries
Pituitary	Corpus and cervix uteri
Salivary glands	Spleen
Heart	Lymph nodes
Thymus	Skin
Thyroid (Parathyroid)	Sciatic nerve
Lungs (2 coronal sections with mainstem bronchi)	Mammary gland
	Bone, bone marrow, or tibio-femoral joint
Trachea	Muscle
Esophagus	Aorta
Stomach	Uterus
Intestine, small and large	*Nasal cavity and paranasal sinuses
Adrenal glands	*Spinal cord (2 levels)
Pancreas	*Head (3 coronal sections) nasopharynx, middle ear, tongue and oral cavity
Liver, 2 lobes	
Gall bladder	
Kidneys	*Seminal vesicle
Urinary bladder	Gross lesions (with normal tissue)
Testes, epididymides	

Prior to the issuance of the proposed regulations tissue specimens were collected from animals found dead and sacrificed moribund throughout the study according to the above list except for the tissues marked with *.

ERS

Sc als died early in the first few weeks of the study and only a gross nc was performed, no tissues were histologically examined (see M section). These mice were 210, group 2 male; 346, group 3 male; 4', 495, 514, 503, 510, 500, 481, 547, 492 group 4 male; 269, 308, gr female; 438, 409, 436, 410, 443 group 3 female; 570, 606, 624, 626, 61 0, 738, 592 group 4 female. Also, several mice were judged to be in suc an advanced state of autolysis as to preclude histopathologic evaluation. These mice were 540, group 4 male; 111, group 1 female; 308, group 2 female; and 564, 583 group 4 female. Many other mice were found to have advenced postmortem autolysis, but it was not extensive enough to preclude a histopathological evaluation.

One mouse (71, group 1 male) was cannibalized (cages used in the study had center dividers and one mouse penetrated the divider and was cannibalized) and one (800, group 4 female) was not necropsied (technician oversight).

All other mice placed on the study were examined histologically.

G. Clinical Observations

There was no apparent test material-related effect on any clinical observations.

H. Palpation of Masses

Tissue masses observed and palpated throughout the study and at termination were evaluated histopathologically. No apparent consistent test material-related effect was noted.

Group 4 males mean food consumption was significantly less than ($p < 0.05$ or $p < 0.01$) that of the control, group 1, males for weeks 11 through 84 with the exception of weeks 12, 19, 26 and 44. From week 88 through the end of the study there was no significant difference. No pattern was shown throughout the study for the other test groups 2 and 3 males and 2, 3 and 4 females.

R of p ven

ights

an bo ghts for group 3 males were significantly less than those ontrc weeks 1 - 81. The mean body weights for group 4 males ignific less than those of the controls from weeks 2 - 43 and variable eafter to the end of the study. There was no significant rence tre nout the remainder of the study. The mean body weights group 3 or 4 females were variably significantly different during the st 21 weeks of the study, but were only sporadically significantly different after week 21. No other consistent pattern was noted in any of the treated groups compared to the controls throughout the remainder of the study.

No consistent test material related effects were noted in the body weight of the treatment groups compared to that of the controls after the first 81 weeks of the study.

VII. Summary

A. Mortality

The cumulative life graph data reflected the early mortalities. These deaths appeared to be related to the acute toxic effect of the test material in the diet mixture. Subsequently, life table analysis indicated no further increased mortality due to oxamyl occurred during the remainder of the study.

C. Hematology

Sporadic significant differences in hematology parameters were noted throughout the study. These changes are suggestive of a compound related effect upon red cell mass in group 4 males early in tha study week 4 but this did not persist.

D. Organ Weights and Organ/Final Body Weight Ratios

There was a slight decrease in absolute weight of the liver in group 3 males and a slight increase of the organ to body weight ratios of the kidney for group 4 males. Based on the absence of histological findings, these effects are not considered significant.

E. Gross and Histopathology

No significant histopathological changes were noted for the test groups when compared to those of the controls except that the chronic interstitial nephritis of the kidney was significantly less for the test groups (group 2, 3 and 4), males, compared to that of the controls. Oxamyl was not carcinogenic at any level tested.

page 13

Attachment 1

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

FEB 3 1984

MEMORANDUM

TO: Douglas D. Campt, Director
Registration Division (TS-767)

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

THRU: John W. Melone, Director
Hazard Evaluation Division (TS-769)

SUBJECT: Oxamyl Oncogenicity Study in Mice

The purpose of this memo is the following:

1. To state the Battelle position regarding a study reported to be the subject of a "cut and paste" review.

2. To state the position of the Review Group.

3. To provide my opinion of the regulatory significance of the Review Group's finding.

Battelle's Comments (verbatim)

Considerable duplication of text from the registrant's report is included in the EPA review. The only original component of the EPA review is the conclusion statement on page 5 that Oxamyl was not oncogenic at dietary levels up to 75 ppm. No independent evaluation of the registrant's data was performed to support this conclusion.

Review Group's Comments

The Review Group noted that the initial TOX Branch review included an analysis of the lung tumor data and noted no pesticide-related effects. This seems to be evidence of an independent evaluation.

Regulatory Opinion

Based on this Battelle review there seems to be no reason to alter our present regulatory position regarding Oxamyl and the review stating that Oxamyl showed no oncogenic potential in the mouse should stand.

William L. Burnam, Chief
Toxicology Branch
Hazard Evaluation Division

Attachment 2
(page 1 of 5)

6560-50

ENVIRONMENTAL PROTECTION AGENCY

[40 CFR PART 180]

[PP 3E2833/]

OXAMYL

PROPOSED TOLERANCE

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed Rule.

SUMMARY: This document proposes that a tolerance be established for residues of the insecticide/nematicide oxamyl in or on the raw agricultural commodity bananas. This proposed regulation to establish a maximum permissible level for residues of oxamyl in or on the commodity was requested, pursuant to a petition, by E. I. duPont de Nemours and Company.

DATE: Comments must be received on or before (insert date 30 days after publication in the FEDERAL REGISTER).

ADDRESS: Submit written comments by mail to:

Program Management and Support Division (TS-757C)
Office of Pesticide Programs,
Environmental Protection Agency,
401 M Street, SW.,
Washington, DC 20460.

In person bring comments to:

Room 236, CM#2,
1921 Jefferson Davis Highway,
Arlington, VA 22202

Attachment 2
(page 2 of 5)

FOR FURTHER INFORMATION CONTACT:

Jay Ellenberger,
Product Manager (PM) 12,
Registration Division (TS-767C),
Office of Pesticide Programs,
Environmental Protection Agency,
Room 202, CM#2,
1921 Jefferson Davis Highway,
Arlington, VA 22202,
(703-557-2386).

SUPPLEMENTARY INFORMATION: E. I. duPont de Nemours and Company, Wilmington, DE 19898, has submitted pesticide petition 3F2833 to the EPA proposing to amend 40 CFR 180.303 by establishing a tolerance for residues of the insecticide/nematicide oxamyl (methyl N'N'dimethyl-N-[(methylcarbamoyl)oxy]-1-thiooxamimidate) in or on the raw agricultural commodity bananas imported from Costa Rica at 0.3 part per million (ppm).

The data submitted in the petition and all other relevant material have been evaluated. The toxicological data considered in support of the tolerance included: a 2-year rat feeding/oncogenicity study and a 2-year dog feeding study, both which were negitive under the conditions of the studies, with no-observed-effect levels (NOEL) of 50 ppm and 100 ppm, respectively; a mouse oncogenicity study which was negative under the conditions of the study at dietary levels up to 75 ppm for 2 years; a three-generation rat reproduction study with a NOEL of 50 ppm; a rat teratogenicity study which was negative; and a rabbit teratogenicity study which

Attachment 2 (page 3 of 3)

was negative at up to 4 milligrams (mg)/kilogram (kg)/day with a NOEL of 2 mg/kg/day for fetotoxicity. Based on the 2-year chronic rat feeding/oncogenicity study with a NOEL of 50.0 ppm and using a safety factor of 100, the acceptable daily intake (ADI) for humans is calculated to be 0.025 mg/kg of body weight (bw)/day. The theoretical maximum residue contribution (TMRC) resulting in the human diet from this and previously established tolerances utilizes 42.67 per cent of the ADI.

The metabolism of oxamyl is adequately understood, and an adequate analytical method (gas chromatography using a flame photometric detector) is available for enforcement purposes. No regulatory actions are currently pending against continued registration of oxamyl nor are there any relevant considerations involved in the establishment of these tolerances. Because there are no livestock or poultry feed items involved, there will be no secondary residues in meat, milk, poultry, and eggs as a result of this use.

Based on the above information considered by the Agency, the tolerance established by amending 40 CFR 180.303 would protect the public health. It is proposed, therefore, that the tolerance be established as set forth below.

Interested persons are invited to submit written comments on the proposed regulation. Comments must bear a notation indicating the document control number, [PP 3E2833/]. All written comments filed in response to this petition will be available in the Product Manager's (PM-12) office, Registration Division, at the address given above from 8:00 a.m. to 4:00 p.m., Monday through Friday, except legal holidays.

Attachment 2 (page 4 of 5)

The Office of Management and Budget has exempted this rule from the requirements of section 3 of Executive Order 12291.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the FEDERAL REGISTER of May 4, 1981 (46 FR 24950).

Attachment 2 (page 5 of 5)

LIST OF SUBJECTS IN 40 CFR PART 180

Administrative practice and procedure

Agricultural commodities

Pesticides and pests

Dated: DEC 04 1984

Director, Registration Division,
Office of Pesticide Programs.

Therefore, it is proposed that 40 CFR 180.303 is amended by adding, and alphabetically inserting, the raw agricultural commodity bananas to read as follows:

§ 180.303 Oxamyl; tolerances for residues.

* * * * *

Commodities	Parts per million
* * * * *	
Bananas	0.3
* * * * *	

Attachment 3

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JAN 23 1985

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: "Risk Assessment" for Baygon

TO: Robert P. Zendzian, Ph.D.
Acting Section Head
Section II
Toxicology Branch

FROM: Reto Engler, Ph.D.
Chief, Scientific Mission Support Staff
Toxicology Branch

By memo of January 17, 1984, you transmitted a comprehensive review of a Baygon Rat Study to me for a "statistical analysis and risk assessment."

As you know, we are presently intending to restructure the risk assessment process to a degree. One of the changes involves a consulting review evaluation of the facts by a team consisting of the primary reviewer (toxicologist), a statistician and the pathologist. The other change in evaluating oncogenic effects involves the referral of the findings to an ad hoc peer review panel, before a risk characterization is carried out (the latter will always require an exposure assessment).

At first glance, Mr. Backus' review appears to be very good and thorough and it might be, in fact, sufficient for ad hoc peer review. Nontheless, it seems appropriate that the material be evaluated and scrutinized and possibly be improved by the input of the statistician and pathologist.

Once this is completed and a preliminary assessment of the chemical's potency is available the package will be referred to the ad hoc ocmmittee. I believe that it is in the best interest of a timely completion of this interdisciplinary review that the toxicologist manage it's completion. Would you, therefore, provide an expected completion date.

cc: T. Farber
B. Backus
B. Litt (reviews and data)
L. Kasza (reviews)
Tox Branch Section Heads

A. Kocialski
Attachment 4
FYI

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JAN 23 1985

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: "Risk Assessment" Bromoxynil

TO: R. Bruce Jaeger, Section Head
Section I, Toxicology Branch

FROM: Reto Engler, Ph.D.
Chief, Scientific Mission Support Staff
Toxicology Branch

By copy of a memo dated January 17, 1985, you referenced Bromoxynil for a "risk assessment".

As you know, we intend to change to some degree the process of risk assessment. First, studies showing an oncogenic effect should undergo a consulting (tripartite) review by the toxicologist, the statistician and the pathologist. Second, the toxicologist should prepare a comprehensive summary review of the chemical in question, consisting of the oncogenic (trigger) study and other relevant studies. This summary review package also must contain a preliminary potency assessment of the chemical. The evaluation of the chemical is then referred to the Ad hoc Peer Review Committee for further action.

Following this general procedure, we are referring this chemical back to your section and Dr. Robinson. Dr. Robinson should manage the "tripartite" review, providing further information as necessary for evaluation. In order to manage the process reasonably efficaciously, we would appreciate an approximate time frame for completion.

cc: T. Farber
L. Kasza
B. Litt
G. Robinson
Section Heads

MEMORANDUM - date :- March, the 22nd, 1985.

to :- A.E. Conroy II, Director,
Office of Compliance Monitoring
Pesticides and Toxic Substances, EN-342.

from :- M. Adrian Gross, BUD, OPP, TS-768/C.

subject :- Findings emerging from a laboratory inspection and data audit.

I am appending here for your information a communication made internally within the Office of Pesticide Programs. Although the findings discussed there arose during a laboratory inspection and data audit assigned by your Office, it seems unlikely to me that you would be directly informed of this matter; this could happen since I was told that, because of its sensitivity, it should not be discussed in the official report of that inspection and audit.

Due to your experience, there are two aspects here on which I would welcome your views:-

a) what in your opinion could your program of inspections of and audits of studies by laboratories in the regulated industry uncover that would be even remotely equivalent or comparable in effect to what we seem to have here ?

b) do you believe that what happened with this particular study of oxamyl in mice (and, more specifically, with the "cover-up" aspects of it) may contain elements of malfeasance and, if so, do you think this should be referred to the Office of the Inspector General of the EPA for an investigation ?

ORAL STATEMENT OF

DR. JACK D. EARLY, PRESIDENT

NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION

BEFORE THE

SUBCOMMITTEE ON DEPARTMENT OPERATIONS,

RESEARCH AND FOREIGN AGRICULTURE

OF THE

COMMITTEE ON AGRICULTURE

UNITED STATES HOUSE OF REPRESENTATIVES

May 21, 1985

Good morning Mr. Chairman and Members of the Subcommittee.

I am Jack D. Early, President of the National Agricultural Chemicals Association. I am accompanied today by Mr. Carl J. Kensil, Vice Chairman of our Board of Directors and President of Ciba-Geigy Corporation's Agricultural Division, and by W. Scott Ferguson, our General Counsel.

You, Mr. Chairman, and others on your Subcommittee have called upon all of us --- industry, agriculture, government, and special interests --- to be part of a process to address some of the nagging concerns in pesticide regulation. We are ready to help.

In giving our pledge to help, we add one observation: We believe, as we think many here do, that any amendments to FIFRA should reflect

the testimony given before the Subcommittee last month by EPA's Dr. John A. Moore, that FIFRA is a "fundamentally sound environmental law." This statement reinforces comments made last year before this Subcommittee by EPA's then Administrator, William D. Ruckelshaus, who testified that FIFRA is "basically a sound and workable statute which gives [EPA] authority to act on several fronts without waiting for changes in legislation." We agree with these EPA views and urge the Subcommittee not to make the extensive revisions to FIFRA suggested in H.R. 2482, 1416, 1910, and other bills that we believe may be yet introduced.

We understand that H.R. 2482 has been introduced in a bipartisan effort to encourage constructive dialogue on FIFRA. While this bill may achieve this laudable objective, enactment of the bill and the Heftel and Seiberling bills would cause severe injury to our industry and, perhaps, to our agricultural customers.

FIFRA currently strikes a careful balance among many legitimate concerns and interests. Changes proposed in bills before this Subcommittee would upset this important balance. Let me give some examples: Scrapping the present cancellation procedures in favor of rule-making would speed removal of products from the market, but at the cost of procedures that ensure due process, where literally millions of dollars of investment, crops, health, and the livelihood of thousands of members of the public ride on a product's registration. Wholesale data disclosures to foreign governments would make EPA's administration of FIFRA easier, but may cause data owners to lose their intellectual property rights and their investment in the data. Abolishing indemnification to those injured by federal suspension-cancellation

actions and imposing fees on the registration of pesticides may appeal to federal budget watchers, but would expose pesticide manufacturers and distributors to potentially catastrophic financial risks and operating costs. These are just a few examples of the highly objectional modifications proposed in H.R. 2482, 1416, and 1910. The proposals simply go too far. Some modest changes to FIFRA are worth considering, however, but we submit that major amendments are not only unnecessary, but also potentially dangerous.

I would like to turn now, briefly, to an assessment of EPA's implementation of the current law and how it relates to a decision on the scope of FIFRA amendments. As EPA has previously testified, the Agency has embarked on a vigorous program to address administratively the long-standing concerns in pesticide regulation. This effort has gone a long way in restoring EPA's credibility and the timeliness and scientific quality of its regulatory decisions. I will not repeat now the specifics of what progress EPA has made, other than to observe that this painful administrative process has relieved Congress of the need for making many statutory changes. But, some modest legislative work remains that will still retain the carefully crafted balance in FIFRA that has served well.

I would like now, in my remaining minutes, to discuss areas for constructive FIFRA amendments. We are not asking for a so-called "wish list" of improvements, solutions to remote problems, or ways to make our life easier. Instead, in the spirit of compromise, we offer ideas on

FIFRA changes that are not in our special interest and may assist you in preparing an acceptable bill.

The suggestions which follow are prepared on our firm conviction that FIFRA should not be opened to substantial changes, in whatever form. If our understanding is mistaken and FIFRA is to be overhauled, we too have ideas to amend FIFRA in the public interest and to maintain proper balance. For example: There are ambiguous FIFRA provisions affecting the use of data supporting registrations, compensation for data, and responsiveness of competing registrants to data call-ins. There are local jurisdictions and communities which supersede this Congress' judgment in FIFRA and EPA's scientific and regulatory assessments with their own. While such communities may be closest to local concerns, they are not technically capable of assessing risks and benefits and do not have the national perspective on assuring food, health, and commerce for us all. There are potential conflicts and gaps among the Federal statutes affecting our industry, especially in the areas of research and development, groundwater protection, community right-to-know, and worker exposure. There are increasing reports from our members of inflexible EPA regulation evidencing an apparent indifference or lack of understanding of the agricultural and commercial impact of certain regulatory approaches. Finally, there are increasing efforts in some sectors to frustrate EPA's registration of products and the Federal use of pesticides through the use of the National Environmental Policy Act.

We plan not to pursue these and other issues now. We believe that FIFRA can function well, with few changes, if the balance is maintained.

To further satisfy public concerns with the validity and completeness of data supporting pesticide registrations, however, we suggest that the Subcommittee consider the following:

1. Imposing stiff penalties on those who would willingly falsify any data in support of a pesticide registration.

2. Immediate suspension of pesticide registrations if the EPA learns that the registrations were obtained on the basis of deliberately falsified data.

3. Mandatory time-tables for identifying and filling data gaps.

4. EPA inspection authority for laboratories developing data in support of registrations.

5. Congressional authorization of increased funds for EPA to responsibily administer FIFRA.

We have legislative language on these 5 points that we will provide the Subcommittee in our written testimony. We will also address in our written testimony a number of other issues raised by proposed legislation being considered by the Subcommittee and by others' testimony.

Mr. Chairman and members of the Subcommittee, in concluding my testimony this morning, let me assure you that the agricultural

chemicals industry stands ready to help you and others formulate constructive amendments to FIFRA in a spirit of cooperation. Our desire is to address now in legislation, to the extent we can, those few unresolved concerns about the regulation of agricultural pesticides, and to avoid re-visiting FIFRA amendments again for the foreseeable future.

(Attachment follows:)

NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION
THE MADISON BUILDING
1155 Fifteenth Street, N.W., Washington, D. C. 20005
202 • 296-1585 Cable: NAGRCHEM

Dr. Jack D. Early
President

May 30, 1985

Honorable Berkley Bedell
Chairman
Subcommittee on Department Operations,
Research and Foreign Agriculture
House of Representatives
Washington, D.C. 20515

Dear Congressman Bedell:

As I promised in my appearance before the Subcommittee on May 21, 1985, I am happy to provide you proposed legislation on the five issues mentioned in NACA's testimony. (Attachment 1) As always, we stand ready to discuss these thoughts with you and to answer questions.

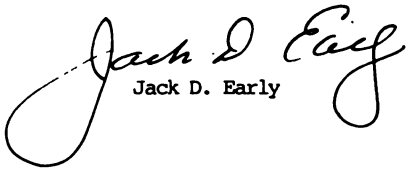
I would also like to take this opportunity to supply you and the Subcommittee NACA's views on a number of other issues raised in the proposed legislation to amend FIFRA. (Attachment 2) Given the number and complexity of the issues, and the fact H.R. 2580 had not yet been introduced, we thought it would be better to provide our views in this form and time, rather than in oral testimony at the hearing. Hopefully these views can be incorporated into the published record.

In closing, I would like to touch upon a further thought that perhaps should have been more strongly emphasized in our testimony. NACA is firmly opposed to opening FIFRA to substantial changes, even those that may be viewed as favorable to our industry or so called "business" issues. We believe that EPA has adequate statutory tools now to do its job right and that most deficiencies in its performance that some see can be attributed more to a different assessment of priorities or to the lack of adequate resources than to weakness in FIFRA. Adding more responsibilities and demands on the Agency, as do most of the amendments proposed, will only make matters worse.

We believe that efforts should be directed not to a major re-write of the law and a correspondingly major EPA funding increase, but to those few adjustments necessary to deal with the public's concerns. This course of action is both reasonable, in light of the real needs, and fiscally responsible.

We hope the attached material is helpful to you and the Subcommittee. If we may be of further assistance, please let me know.

Sincerely,



Jack D. Early

Attachments

WSF:kab

cc: All DORFA Subcommittee members

Attachment 1

PROPOSED LEGISLATIVE LANGUAGE ON 5 AMENDMENTS PROPOSED IN DR. JACK EARLY'S TESTIMONY ON MAY 21, 1985

1. Authorize cancellation of pesticide registrations based on false health and safety data.

Amend FIFRA Section 6(b) by adding the following new paragraph after the first paragraph:

"If the Administrator determines that a registrant willfully submitted data that he knew were false in support of a registration and such data are significant to the Administrator's determination under either subsections (b) or (c) of this section, the Administrator may, by order, cancel the registration of the pesticide immediately pursuant to this subsection."

2. Impose civil and criminal penalties for false health and safety data.

Amend Section 12(a)(2) by adding the following new sub-paragraph:

(2) It shall be unlawful for any person —

"(Q) to willfully falsify all or part of any data in support of a registration or application for experimental use permit, or to willfully submit such false data in support of a registration or application." (Underlines indicate new language.)

3. Require complete health and safety data on all pesticides by a certain date.

Amend Section 3(c)(2)(B) by adding the following new subparagraphs:

"(vi) Notwithstanding any other provision of this Act, each registrant of a pesticide for use on or in food or feed, registered prior to August 1, 1984, shall provide the Administrator within 6 months after the effective date of this Act a list of data and information submitted by the registrant in support of its registration and shall identify such additional data and information that may be required under the guidelines established under (c)(2)(a) of this section. Registrants of pesticides for non-food uses, registered prior to August 1, 1984, shall provide such lists and identification within 9 months after the effective date of this Act. The identification of such additional data shall not be construed by any court or in any other proceeding as indicating that the pesticide for which the information is provided may cause unreasonable adverse effects on the environment or may

cause an imminent hazard. The Administrator shall identify those registered pesticides in subparagraphs (vii)(I), and (vii)(II) on or in food or feed, as determined by the quantity of each such pesticide used for such purposes, and those registered pesticides in subparagraph (vii)(III) no later than 6 months after the effective date of this Act.

"(vii) The Administrator shall review the information provided by registrants pursuant to subparagraph (vi) and shall act in accordance with subparagraphs (i) through (v) --

I. for all pesticides in major use on or in food or feed no later than 18 months after the effective date of this Act,

II. for all other pesticides used on or in food or feed no later than 24 months after the effective date of this Act, and

III. for pesticides not used on or in food or feed no later than 36 months after the effective date of this Act.

Each notice issued under subparagraph (i) shall require the additional data to be submitted by a date certain no more than 5 years after the issuance of the notice.

"(viii) The Administrator shall review the additional data submitted by a registrant pursuant to a notice issued under subparagraph (i) and may within one year --

I. reregister the pesticide or initiate an interim administrative review, under sections 3(c) and 3(g), or

II. issue a notice of intent to cancel under sections 6(b)(1) or 6(b)(2), or

III. issue a notice of intent to suspend under section 6(c).

"If the Administrator issues a notice of intent to suspend the registration pursuant to this subparagraph, he shall hold a hearing as described in section 3(c)(2)(B)(iv) of this Act. The Administrator shall report annually to the Senate Committee on Agriculture, Nutrition and Forestry and the House Committee on Agriculture the data submitted that have not been reviewed by the Administrator within such 1 year period and the reasons therefor. Information submitted to the Administrator, the Administrator's notification of data required, and the data submitted in response to such notification pursuant to this section shall be made public consistent with section 10 of this Act."

In addition, amend FIFRA section 3(c)(2)(B) as follows:

> "(iv) Notwithstanding any other provision of this Act, if the Administrator determines that a registrant, within the time required by the Administrator, has failed to take appropriate steps to secure the data required under this subparagraph, to

submit information and data within the times required under subparagraphs (B)(vi) and (vii) other than for causes beyond a registrant's control, to participate in a procedure for reaching agreement..., the Administrator may issue a notice of intent to suspend such registrant's registration of the pesticide for which additional data is required."

4. Allow EPA inspection of laboratories.

Amend Section 9(a) by adding the following new paragraph after the first paragraph:

"For purposes of verifying the accuracy of data submitted in support of an experimental use permit or registration, officers or employees duly designated by the Administrator are authorized, after the submission of an application for an experimental use permit under section 5 or an application for a registration under section 3, to enter at reasonable times any laboratory to inspect relevant parts of such laboratory, related books and records, and data that have been or are being developed to support such application."

5. Increase EPA revenues.

Support the following authorization:

"There is authorized $_____ to carry out these amendments to the Federal Insecticide, Fungicide, and Rodenticide Act and to improve and expedite the registration and reregistration of pesticides under such Act for the fiscal years 1986-1990.

Attachment 2

NACA ISSUES ANALYSIS OF H.R. 2482 (BEDELL-ROBERTS), 2580 (BROWN), 1416 (HEFTEL), and 1910 (SEIBERLING)

During the 13 years since the revised Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was enacted, it has become increasingly clear that the Federal law has responded effectively to the technically complex and politically charged subject of pesticide regulation. Anxiety among certain individuals and groups, however, has caused Congress to look again at FIFRA amendments. The following discussion presents NACA's position on the major issues raised in those amendments.

H.R. 2482 (BEDELL-ROBERTS)

Certified Applicators

H.R. 2482 proposes to delete FIFRA Section 2(e)(4), defining the concept "under the direct supervision of a certified applicator," and, through companion changes, allow EPA to specify the extent of supervision which must be exercised by certified applicators over the application of restricted-use pesticides by uncertified applicators.

We share the view of many -- including agricultural users of pesticides -- that restricted use pesticides should be applied only by those adequately supervised and trained in their proper use. The amendment, however, does not address the basic problem of training and supervision. The change only addresses increased EPA discretionary authority over the terms of registrations. While attractive to EPA perhaps, the amendment will lead only to a more complex registration process (in which application management must be debated and possibly regulated), patchwork regulation, and confusion -- all without addressing the key element: adequate training and supervision in the field.

Disclosure of Inert Ingredients

Current law allows EPA to disclose the identity and percentage of deliberately added inert ingredients when such disclosure is necessary to protect against unreasonable risk to health or the environment. H.R. 2482 proposes to amend FIFRA to require the listing and percentage of inerts on pesticide labels if the inert ingredients are determined by EPA to be hazardous.

Our industry does not object to the disclosure of inerts if it is clearly in the public interest, but believes that there is significant anti-competitive impact in the virtually unrestrained disclosure allowed by the amendments. The confidentiality of deliberately added inerts is the "formulation edge" in one product's competition with another. The purpose of maintaining the formula in confidence, except when pressing health or environmental factors conflict, is to protect the research and development, marketing and other investments that a company has made in its product. The proposed FIFRA changes go too far in eliminating the current balance between the need for disclosure and confidentiality.

Definition of "Distribute or Sell"

H.R. 2482 would define the term "distribute or sell" to include "hold for distribution" and "hold for shipment" in addition to other activities described in FIFRA section 3(a). Current FIFRA is limited to those activities which may expose the public and environment to a pesticide. Manufacturing and related warehousing activities are covered by other laws applicable to the workplace. The amendment inserts EPA earlier into the manufacturing and distribution process when there is no showing that this is necessary. FIFRA should remain unchanged.

Definition of "Pesticide Testing Facility"

Section 3 of H.R. 2482 proposes a new provision that would define the term "pesticide testing facility" to include virtually any person or location that conducts any research activity on pesticides, including tests, studies, and surveys. The operation of this definition, through the other suggested modifications to FIFRA in H.R. 2482, would establish a national regulatory program for laboratories and other research facilities. If this needs to be done, it should be done in separate legislation and not by "housekeeping" amendments to FIFRA. While some degree of EPA inspection of laboratories developing data for registration may be appropriate, the proposed amendment is excessive.

Judicial Review of Arbitrations

Section 4 of H.R. 2482 would provide judicial review of arbitration decisions involving compensation for use of pesticide research data. This amendment is evidently designed to remedy possible constitutional problems with the existing arbitration provision, which, if decided adversely to the government, may affect EPA's registration process.

The question of the constitutionality of FIFRA's arbitration system presently is before the Supreme Court of the United States in the case of Thomas v. Union Carbide Agricultural Products Co. The issues in that case are complicated and could be decided in several different ways.

We are not in a position to recommend a particular course of action to the Subcommittee at this time.

Some companies have taken the view that Congress should defer on efforts to devise a cure for potential constitutional problems until the Supreme Court decides what the problems are, if any. We understand that the Supreme Court is expected to rule in this case before July.

On the other hand, there are some in our industry and elsewhere who believe that Congress should not wait for the Supreme Court to act, but rather should resolve any potential problems with the arbitration system now.

Suspension - Cancellation Procedures

FIFRA currently permits EPA to cancel the registration of pesticides that "generally cause unreasonable adverse effects on the

environment" when used "in accordance with widespread and commonly recognized practice." In addition, the Administrator may suspend registrations if he determines that the action is necessary to prevent an imminent hazard. H.R. 2482 proposes that this process be "improved" to make it more efficient and quicker. In fact, the proposal to change the procedure to an informal hearing will turn the entire process on its head, and unreasonably curtail the rights of the public, farmers, and industry to explore the factual and legal basis for withdrawing or amending the registration of a valued product.

Presently, cancellation and suspension decisions and underlying question of "unreasonable adverse effects" are based on sound scientific and economic evidence directed to what would serve the public interest. H.R. 2482 would place the decision-making on far less scientific grounds, where evidence of risks and benefits would not be tested or examined, in informal "hearings" conducted by agency officials who would be considerably less objective than administrative law judges in deciding the appropriate regulatory action. Speed and efficiency of cancellation and suspension proceedings are a legitimate concern, but there are less extreme ways of expediting the process, including internal administrative controls that would lead to more prompt, scientific, and responsible decisions. Using impartial scientists, together in a panel with an administrative law judge, would speed scientific review, especially if the panel's judgment was presumptively correct in later administrative review.

Re-Registration Delays

The current pace of EPA's re-registration of pesticides is intolerable. Our customers in agriculture and the public are entitled to the assurance from EPA, which they finance through their taxes, that pesticide products are safe and effective. Twenty years to wait for that assurance, on the 600 active ingredients presently registered, is too long.

We support most of EPA's administrative efforts to speed up the re-registration process. Unfortunately, legislative suggestions on speeding up re-registration have fallen far short of a real solution to the problem. We vigorously oppose the proposal in H.R. 2482 that informal rulemaking serve to determine whether a use or a proposed use of a pesticide or class of pesticides "causes or will cause unreasonable adverse effects on the environment." This is essentially the standard and function of section 3 registrations that the proposal would virtually eliminate, leading only to more delay, confusion and frustration.

Burden of Proof in Cancellation Proceedings

Proposed section 5(d) of H.R. 2482 provides that the burden of persuasion in a cancellation hearing rests with the party or parties contending that the use of a pesticide does not cause unreasonable adverse effects. The proposal significantly amends the current law in allowing the EPA to escape its obligation of showing that credible evidence raises prudent concerns of unreasonable adverse risks to man or

the environment. With the investment the EPA, the registrant and the public have made in the registration process, it is essential that EPA meet a reasonable threshold in cancellation proceedings before the burden of defending a product is shifted to the registrant and others who wish to have the product registration continue.

Initiation of Cancellation Proceedings

H.R. 2482 adds section 6(h)(4), allowing any person, regardless of their interest in the outcome, to petition EPA to cancel or suspend a pesticide registration. The evident reason for the amendment is that certain special interest groups want to be able to demand a hearing to challenge EPA's discretion that additional restrictions imposed on registrants, as a condition for continued registration, do not go far enough. In EDF v. Costle, these groups unsuccessfully contended that, under section 6(b) as currently written, they have a right to such a hearing.

There are substantial public policy reasons why FIFRA should remain unchanged:

(a) EPA must have discretion to decide how much restriction on a certain product is enough to protect the public interest. The Agency will be unable to function effectively if EPA managers and scientists are required continually to endure second-guessing through lengthy administrative proceedings whenever a special interest believes the Agency should have gone further in restricting a pesticide's uses.

(b) FIFRA already affords the public the right to challenge EPA decisions to retain rather than cancel a pesticide. Section 16(a) clearly permits judicial review of Agency refusals to cancel or suspend registrations.

(c) Special interest groups have ample opportunity to comment and submit scientific data in the special review process and prior to a final EPA decision. The amendment would make current review procedures meaningless and shift the process into an adversarial and time-consuming confrontation.

Section 6(a)(2) Reports on Unreasonable Adverse Effects

Amendments to Section 6(a)(2) in H.R. 2482 would attempt to confirm EPA's proposed interpretation of the section and significantly expand the burden and cost on registrants for reporting adverse effects. In essence, the modification would require reporting of all information, from whatever source and validity, on all impacts of a pesticide, whether favorable or unfavorable. The amendment goes too far.

Our industry supports the current law which states that registrants must submit "additional factual information" on "unreasonable" adverse effects. Those 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. The amendment, however, attempts to confirm EPA's excessive expansion of Congress's clear expression in the present 6(a)(2). The amendment should be soundly rejected and a more reasonable amendment adopted, defining with more specificity and reason, the scope of the reporting requirement.

Expanded Inspection Authority

H.R. 2482 proposes to amend FIFRA section 9 to expand EPA's inspection authority to allow inspections virtually anywhere EPA believes that FIFRA may be violated. Given the pervasive use of pesticides in the United States, the proposed amendment effectively allows the Federal, state and local governments almost unlimited right to enter any area of commercial and private activity in the country to ferret out what they believe may be violations of the pesticide law, copy files and seize products. Is this necessary? We believe that there has been no showing that this expanded authority is needed, in addition to the inspection authority and penalty provisions already in FIFRA.

Data Disclosure

NACA has often stated its wish that the data disclosure issue could be finally resolved so the EPA, registrants, and the public could operate with more certainty under FIFRA. We thought this happened with the Monsanto decision in the Supreme Court, yet now, again, the issue surfaces in H.R. 2482 -- this time in the expressed desire to give registration data to foreign competitors, foreign governments, states, and anyone else who wants it. Why? The answer is EPA's administrative convenience. The Agency simply finds the responsibility of protecting this kind of confidential data too bothersome.

It is not the position of our industry to block the disclosure of health and safety data to the U.S. public, or to inhibit scientific scrutiny of such data under appropriate safeguards. We think FIFRA permits adequate disclosure and appropriate review by the public and should not be changed. Disclosure of valuable registration data to our foreign competitors and others, however, is a bizarre extension of the U.S. public's legitimate and presently realized right to know. Our desire to protect the confidentiality of our technology and to prevent the disclosure of our data to foreign countries and competitors springs from the essential need to preserve our investment in creating, registering, and marketing U.S. pesticides. If this nation wants an industry willing to invest in developing and producing these essential products, we must continue to protect these intellectual property rights from foreign expropriation and exploitation.

Violation of FIFRA Regulations as an Unlawful Act

FIFRA Section 12 identifies over 20 separate activities as unlawful acts for which civil and criminal penalties may be imposed. H.R. 2482 proposes to expand this list to provide that a violation of any regulation under FIFRA is an unlawful act. While superficially appealing, the amendment goes too far. Most statutes, including the

Toxic Substances Control Act and other statutes implemented by EPA, limit unlawful acts subject to civil and criminal penalties to violation of regulations issued under clearly identified sections of those laws. FIFRA follows the same pattern by identifying actions under certain statutory sections as unlawful acts. To expand EPA's authority without restriction would permit EPA free reign to regulate in areas not presently contemplated by Congress. Enforcement of "good laboratory practices" through this means, for example, would convert FIFRA into a vehicle for EPA to regulate the nation's laboratories. Certainly, this is not what Congress would intend without special legislation considering all aspects of such federal oversight.

Registration Cancellation for False, Misleading, or Inaccurate Data

FIFRA section 12 currently states that it is an unlawful act to knowingly falsify an application for registration or other submissions to EPA. H.R. 2482 proposes to add authority for EPA to cancel registrations based on false, misleading, or inaccurate data.

While attractive in general concept, the proposal raises a number of difficult questions that may pose problems in its implementation. Data which may be accurate when submitted, may appear false, inaccurate or misleading several years later when further information becomes available. The falsification of data by an initial registrant, moreover, may lead to the cancellation of subsequent registrations and significant economic losses by innocent follow-on registrants.

If a modification to FIFRA is necessary, the scope of the amendment should be limited to those instances where data are willfully falsified at the time of submission and are of continuing importance to the Agency in determining whether the pesticide presents an unreasonable human health or environmental concern.

Vicarious Liability for Civil and Criminal Penalties

Section 9(b) of H.R. 2482 is reported to be a technical change which redesignates current FIFRA section 14(b)(4) as section 12(c). Section 14(b)(4) should be deleted from FIFRA altogether or substantially amended. In its present form, section 14(b)(4) arbitrarily and unfairly extends civil and criminal penalties to registrants for violations that may have been committed by any employee, agent or any other person acting for or employed by the registrant, regardless of the registrant's lack of knowledge or actions to prevent the violations. This draconian measure goes far beyond any enforcement needs in FIFRA. The section should be sharply amended to limit the registrant's liability to actions of those officers and employees in positions of responsibility.

Civil and Criminal Penalties

Section 10 of H.R. 2482 significantly expands the amount of civil and criminal penalties, including increasing civil penalties five-fold, for most violators up to $25,000 per day, and increasing criminal penalties from misdemeanors to felonies. The justification for this

modification presumably is to provide a stronger incentive for compliance with FIFRA and to make FIFRA conform to other "environmental" statutes. Recognizing that FIFRA is a consumer statute, where individuals may be penalized for applying pesticides inconsistent with a pesticide label, the higher penalties and other increased sanctions are excessive. Further information on why FIFRA enforcement has been inadequate and why such a significant change of this kind is essential should be provided before Congress considers this amendment.

Indemnification Provision for Suspension/Cancellation

FIFRA Section 15 currently requires EPA to reimburse people who suffer losses when the Agency suspends and later cancels the registration of a pesticide they own. H.R. 2482 proposes to delete this section. The reason for the change has been stated that pesticide companies, which have profited from the sale of the pesticide, should absorb the losses of any such cancellation/suspension action. We disagree.

Indemnity acts as a strong incentive to remove from use those pesticides that are determined to be imminent hazards and to dispose of existing stocks properly. The pervasive use of pesticides, in many formulations, by different suppliers, makes private recall efforts virtually impossible. Indemnification, moreover, has been viewed historically as a Federal obligation to be fair to those people who innocently have pesticides on hand that cannot be sold or used. Having registered a pesticide after careful review and, by that action, assured the public that the pesticide was available for purchase and use, any sense of equity would dictate that an innocent owner of the product should be entitled to public compensation if the Federal government later decides that the product can no longer be used.

EPA/OSHA Overlapping Jurisdictions

Section 14 of H.R. 2482 adds a subsection to FIFRA to sanction EPA/OSHA overlapping authority to prescribe and enforce workplace standards affecting occupational safety and health. This amendment is an invitation to administrative confusion and less effective protection of workers. FIFRA currently allows EPA to regulate the application of pesticides and worker entry, sufficient to protect the safety and health of workers exposed to pesticides. OSHA covers manufacturing workplace exposure to pesticides. The amendment would serve only to confuse this separate authority and to raise other questions on the scope of EPA's and OSHA's jurisdiction.

H.R. 2580 (BROWN)

Community Right-to-Know

H.R. 2580 requires submission and disclosure of information on the production of pesticides, including the identity and amounts of pesticides produced, intermediate chemicals, summary of health and environmental risks, manufacturing locations, nature of surrounding neighborhoods, evacuation plans, and information on exported pesticides.

The rationale for this requirement has been stated to be increased public awareness of the risks of chemicals and proper local control and anticipation of emergencies.

As a part of the larger chemical manufacturing industry, our industry supports submission and disclosure of useful information to increase public knowledge about the hazards of certain chemicals. Much of this information is already available to the public under FIFRA and other statutes. Since the pesticide industry is not unique in using chemicals that may be toxic if mishandled in storage or manufacture, other, more generally applicable statutes are more appropriate vehicles than FIFRA to ensure adequate public awareness of chemical hazards in the workplace and community response to emergencies.

Public Participation in the Registration Process

NACA supports the principles of openness and public involvement in regulatory decision-making. We oppose, however, the proposed changes to FIFRA that would permit special interest groups to obtain a pervasive hold on the Agency and frustrate EPA's regulation of pesticides.

NACA believes that public involvement in government decision-making is a matter of balance and reason: the public should have a reasonable opportunity to participate constructively, but should not be permitted to encumber the administrative process of the experts in EPA and to prevent the Agency from effectively performing its statutory duties.

FIFRA presently strikes a proper balance between public involvement and Agency capability to function efficiently. H.R. 2580 would disrupt this balance and overload the administration of FIFRA with new layers of involvement with interest groups in a manner that would seriously impede the conduct of Agency business. The bill would lead to extensive, unwarranted delays in registrations that would not be in the public interest.

Public Access to Pesticide Health and Safety Data Prior to EPA's Registration Decision

H.R. 2580 requires disclosure of health and safety data prior to EPA's grant of registrations. This provision would impose a severe competitive disadvantage on innovative companies. Data submitted to EPA often contain state-of-the-art scientific techniques, developed through extensive and costly research, and complete chemical and biological profiles of the newly developed but not yet registered compound. Advance information on these subjects to competitors can be of enormous commercial value. It not only permits competitors to appropriate the proprietary techniques, but also gives them years of valuable lead time in which to develop imitations or to engage in predatory marketing practices and pricing to discourage further commercial development. The competitive disadvantage of such disclosure would be a strong disincentive to research and development of pesticides. For this reason, neither FIFRA nor the Food, Drug, and Cosmetic Act permits access to data until after a registration or tolerance is approved.

Grassley-Allen Amendment Repeal

H.R. 2580 repeals the Grassley-Allen Amendment, which was added to FIFRA in 1978 to prevent the loss of products through unfounded cancellation actions and invalid claims. The Grassley-Allen Amendment required EPA to have validated evidence to initiate an interim administrative review. H.R. 2580 would re-introduce the confusion and administrative abuses prior to 1978 by allowing cancellation and suspension proceedings to be initiated with little or no scientific basis. Only a sound, scientifically based concern should initiate a special review of a registration. If a product is in fact causing unreasonable adverse effects, its continued use should be re-evaluated. But action should be based only on well-substantiated claims and through scientific investigation of the risks and benefits of the product. FIFRA currently requires this and should remain unchanged.

Registration Cancellation for Pesticides in Groundwater

H.R. 2580 requires registrations of pesticides to be cancelled if the product is found in groundwater, unless preventative action is taken. FIFRA currently gives EPA sufficient authority to regulate pesticide registrations to eliminate unreasonable adverse effects on groundwater. Arbitrary cancellation of registrations, proposed by the amendment, merely removes EPA's legitimate discretion in assessing costs and benefits in continued registration.

Registration of Pesticides Which Have Been Cancelled, Suspended or Voluntarily Withdrawn Because of Health or Environmental Concerns

H.R. 2580 prohibits new registrations of pesticides that have been cancelled, suspended or voluntarily withdrawn because of health or environmental reasons. The issue is more properly addressed administratively under current FIFRA, without statutory changes. The amendment unreasonably limits EPA discretion to consider new information and conditions. If the concern has been satisfactorily resolved through new tests or interpretations of existing research, then the pesticide should be eligible for registration or conditional registration.

Restrictions on Conditional Registrations

H.R. 2580 eliminates use of conditional registrations for new uses of registered pesticides or registration of new chemicals, and otherwise restricts conditional registrations. We believe FIFRA adequately addresses this issue and that EPA has sufficient authority to deal with the scope of conditional registrations administratively. No FIFRA amendments are needed.

Citizens Suits

H.R. 2580 would create a new Federal cause of action for violations of FIFRA, notwithstanding adequate common law and other statutory remedies defining and protecting the rights of the public in instances of pesticide misuse. Apart from the request of special interests, there has been no convincing showing that the provision for citizen suits

would materially improve the enforcement of FIFRA. In fact, the amendment has the potential of adversely affecting government enforcement. Our industry supports the right of injured parties to seek judicial redress against those who may have caused their injury. In virtually all states, use of a pesticide in violation of government laws and regulations is negligence per se or, at least, strong evidence of negligence. Where an individual is entitled to equitable relief, virtually every state allows its citizens to obtain injunctions against such unlawful or negligent actions. There is no reason to amend FIFRA to permit special interests to frustrate and confuse EPA's enforcement efforts.

Registration Fees

EPA recently testified that FIFRA should be amended to permit EPA to assess fees on registrants to cover the cost of the Federal pesticide registration program. While we support Federal budget reduction efforts, we believe that shifting the cost of the Federal pesticide program to the pesticide registrants is inappropriate.

The reasons for our view are: First, a system of pesticide registration fees would dramatically increase product costs, resulting in increased consumer prices, and would have an unfair and disproportionate impact on small businesses. Second, a user fee is a revenue-raising measure that would require additional review, with attendant delays, by the appropriate House and Senate Committees. Third, such fees would impermissibly and inevitably move more decisions on funding, scope and direction of EPA's pesticide regulatory activities from Congress to the regulated community. It is in the public's and industry's interests to have an independently functioning and financed EPA. Finally, the cost of operating the pesticide program confers no direct benefit on pesticide applicants, but rather meets the responsibility of the Federal government to regulate pesticides in the public interest.

H.R. 1416 (HEFTEL)

Foreign Trade in Pesticides

Our industry fully supports and actively encourages establishment of effective pesticide registration and enforcement systems in nations where agrichemicals are used. We are continuing to expand this effort. The major problem with exported agrichemicals, however, especially in developing countries, is misuse. This problem cannot be corrected or controlled by the changes proposed in the Pesticide Import and Export Act of 1985 (H.R. 1416). The reason is simply that the need for agricultural pesticides -- those registered and unregistered in the United States -- will be met by foreign manufacturers if exports are prohibited here. Barring U.S. exports of unregistered, restricted, and banned pesticides will not solve the problem. It will only take responsible U.S. companies out of the limited foreign markets where we are now -- where U.S. companies can provide the kinds of products and training to avoid misuse, reduce employment available to U.S. workers,

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and remove products from countries that have a considered and legitimate need for the products.

These comments do not mean, however, that our government is or should be blind to exports of products suspended or cancelled in the U.S. FIFRA currently provides for responsible action by our government to notify other governments receiving such products. There may be areas of improvement in our notification procedures, but our country's current treatment of foreign trade in pesticides is correct.

Revocation of Tolerances

H.R. 1416 requires EPA to revoke tolerances of residues when pesticide registrations have been revoked, suspended or withdrawn. The proposed amendment attempts to control indirectly the sale and use of pesticides abroad by controlling what foods may be imported into the U.S., not on the basis of whether the residues on food may be safe, but whether a pesticide used on the food was registered in the United States. United States registration has little or no bearing on whether a pesticide is safe in foreign agricultural uses or on imported foods. Many pesticides are designed for non-U.S. crops, such as coffee or bananas, where no U.S. registration is needed. Whether a tolerance should be set or revoked should not depend on registration decisions that involve completely different considerations -- for example, pesticide efficacy, applicator exposure, or local environmental factors -- but whether the residue continues to present a risk after the foreign crop is treated, shipped, distributed, sold and used by the ultimate U.S. consumer.

H.R. 1910 (SEIBERLING)

Birth Defects Registration Bar

Proposed amendments in H.R. 1910 would prohibit registration of pesticides shown to cause birth defects or reproductive abnormalities. Our industry recognizes that potential adverse reproductive effects may be a legitimate consideration in whether and how to register a pesticide, given certain conditions and exposures, and that the potential for this toxic effect should be considered along with other potential toxic effects, such as cancer. We also believe that FIFRA is currently structured to deal responsibly with such concerns.

TESTIMONY

of

MAUREEN K. HINKLE
DIRECTOR
AGRICULTURAL POLICY
NATIONAL AUDUBON SOCIETY

Mr. Chairman and members of the subcommittee, the National Audubon Society appreciates this opportunity to testify before you. The National Audubon Society has been officially concerned with the use of pesticides since 1957, when chapters in the South objected to USDA programs to eradicate the imported fire ant with heptachlor and dieldrin before research could be conducted on unintended side effects of the pesticides on wildlife.

Throughout the 1960s Audubon focused on the chlorinated hydrocarbons and their adverse effects on human health as well as on wildlife, particularly birds. Audubon joined with the Environmental Defense Fund in bringing cancellation cases against the use of DDT, Aldrin/Dieldrin, and mirex, all chlorinated hydrocarbons that not only adversely affected birds, but bioaccumulated in the blood and fat tissues of humans as well. Audubon was a vital part of the legislative battle to enact the 1972 amendments to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), and has been involved in every legislative effort since 1975. Audubon has also participated in the rule-making opportunities provided by FIFRA for more than 12 years. Our interest in current congressional action on FIFRA is a continuation of these efforts.

It is the hope of our organization that long awaited reform of the Federal Insecticide, Fungicide and Rodenticide Act will take place this year. The need for legislation is clear and has been illustrated in recent years through hearings and reports generated not only by this subcommittee, but by

other congressional committees, the National Academy of Sciences, and the General Accounting Office. In his forthright testimony before this subcommittee in April, Dr. John A. Moore, EPA Assistant Administrator for Pesticides and Toxic Substances, explained how the Environmental Protection Agency has recently reversed the deregulatory direction of his predecessor. While the National Audubon Society agrees that great improvements have begun to be made in the administration of the Office of Pesticide Programs (OPP), we believe that certain legislative reforms still are necessary.

Groundwater protection

Of major concern to our members is the growing problem of groundwater contamination by pesticides. Since the discovery of Aldicarb (Temik) and EDB (ethylene dibromide) in groundwater supplies, public concern has mounted and government agencies and others have become aware of the threat to the nation's groundwater resources. Groundwater is a major source of supply for drinking, as well as for agriculture and industry, in this country. Almost half of all Americans get their drinking water from groundwater sources, and in rural areas, the number of those so supplied climbs to 95%. As population increases and agriculture and industry expand, withdrawals from groundwater supplies multiply. In the early 1950s, 34 billion gallons of groundwater were withdrawn every day. Estimates for 1985 put this figure at 100 billion gallons per day.

As use of groundwater grows, evidence of widespread toxic chemical contamination of this vital resource continues to mount. Studies by the

Environmental Protection Agency show that one-third of our public water systems contain detectable amounts of man-made chemicals. In Iowa, pesticides have been detected more often than industrial chemicals. Other farm states may well produce similar findings if monitoring were conducted. Private, public, and industrial wells are also affected: 4,000 of them have been closed, or are partially contaminated. Unlike surface water, underground aquifers cannot be cleaned up through natural processes. Groundwater purification is prohibitively expensive and, in many cases, technologically impossible. Various methods, such as installing physical barriers or altering groundwater flow, have been tried but are limited in their effectiveness. Even limited success is expensive. Average costs for containment and cleanup of even small portions of contaminated aquifers are estimated at $5 million to $10 million.

The Environmental Protection Agency is currently developing a National Groundwater Strategy which involves a "cross-media" approach, coordination of the various statutes which govern groundwater protection, and an improved monitoring and detection program. We believe that the Agency's program has merit but that it needs to be backed up by the development of a comprehensive preventive program in which regulatory action would be triggered whenever groundwater contamination was discovered.

We urge Congress to require the Environmental Protection Agency to establish, on a nationwide scale, groundwater protection standards similar to those recently adopted by the state of Wisconsin (Wisconsin Act 410, May 11, 1984). These standards create protection at two levels. For every substance

detected in groundwater, an "enforcement standard" and a "preventive action limit" (PAL) would be established. Depending on the properties of the substance, the PAL would be set at 10 percent, 20 percent, or 50 percent of the enforcement standard.

The PAL would serve two functions. First, it would be used in the development of management practices and pesticide regulation so that contamination could be avoided. Second, the PAL would serve as a trigger and, when reached, would indicate to appropriate regulatory agencies that a hazardous level of contamination was being approached. The PAL is intended to give regulatory agencies forewarning so that further groundwater contamination may be prevented.

If an enforcement level is reached, the activity or practice which led to the contamination is subject to immediate enforcement action. The appropriate agency would halt the activity until it could be shown that contamination levels from the activity could be kept below the PAL. If contamination cannot be prevented, and studies conducted on the pesticide indicate that chronic exposure to the substance poses a health or safety threat, EPA should be required to suspend the registration as a public health emergency.

Audubon agrees with EPA that states must take a lead role in protecting their groundwater resources, but if the establishment of a national strategy is discretionary, residents of some states will be left unprotected. We urge Congress to require EPA to establish basic non-discretionary groundwater standards and to mandate a comprehensive plan to help states develop the

resources and tools necessary to carry out a valid program to protect our nation's invaluable groundwater.

Without comprehensive groundwater legislation, groundwater contamination is being addressed in the context of existing statutes. For example, FIFRA is responsible for pesticides, TOSCA regulates for toxic substances, RCRA covers contamination of groundwater from disposal sites,leaking storage tanks, etc., and the Safe Drinking Water Act (SDWA) is responsible for contaminants coming out of the tap from public water systems.

EPA is developing a national groundwater strategy, a groundwater monitoring program, and the Agency has focused on pesticides found in groundwater. Nevertheless, as Dr. Moore stated in his testimony on April 18th, "These are but the first steps of a long march." It is Audubon's contention that protection of the groundwater resource should be encouraged in all areas of existing or potential groundwater use. In order to ensure that contamination from pesticides is appropriately regulated, we believe legislation is required in FIFRA.

Regulation of inert ingredients

Under FIFRA, an inert ingredient is defined as any ingredient in a pesticide product which is not pesticidally active. This definition includes all intentionally added inerts, such as solvents, surfactants, aerosol propellants, dyes, or stabilizers in the formulated product, and non-pesticidally active impurities in the technical grade of the active ingredient or formulation.

In May, 1984, Audubon asked EPA to require information on inert ingredients at the same time the agency focused on the reregistration program. Our letter read in part: "In view of the presence of inerts in all pesticides registrations, the toxic hazard a large number of these inerts pose for nontarget species including man, and the vagueness with which current regulatory requirements apply to ingredients designated by registrants as inert, an analysis of inerts is in order. As EPA develops accelerated and expanded data call-in packages, inert ingredients must be included if the primary objective of the reregistration process is to identify potential health or environmental problems created by the use of the registered product."

EPA responded positively and promptly to Audubon's request, and, encouraged by the the agency's Science Advisory Panel, developed a discussion paper for the Pesticide Advisory Committee (APAC) meeting of October 25, 1984. EPA reported to the committee, of which Audubon is a member, that new regulations promulgated by EPA require acute tests and complete chemistry characterization of all supposedly inert ingredients contained in a pesticide formulation.

Throughout the past ten years, however, the complexity of regulation of inerts has served as an excuse to delay agency action. In view of the December 4, 1984, vote by the APAC that regulation of so-called inerts be a legislative priority, a mandate from Congress is in order to require tests on inerts that may pose health concerns.

Congress should direct EPA to require chronic studies on those inert ingredients identified as either biologically or chemically active. Regis-

trants have objected to such testing on the grounds that disclosure of the identity and characterization of inert ingredients is confidential. If the claim of confidentiality is insisted on by registrants, studies may be duplicated by the several companies using the same toxic inert ingredients. Duplicating tests of toxic inerts is not the only option. Other possibilities have been identified by EPA: registrant commitment to develop data and to allow EPA to share data with others; change inert ingredients; refuse to conduct studies and request voluntary cancellation; and pool resources for conduct of required studies.

As Dr. Moore pointed out in his statement, there are several legal, scientific and economic aspects of the regulation of inerts that need to be resolved. A congressional amendment could speed the process. Such legislative language could include, in addition to the requirement for chronic studies, monitoring for residues of toxic inerts, identification of hazardous inerts on the label, and disclosure to the public of the identity and hazards posed by selected inerts. Without legislative redress, EPA is likely to procrastinate on this complicated problem until either a crisis involving inert ingredients, or court action.

Public participation and legitimate legal challenge

Regulation of pesticides has been inadvertently hampered by Sections 3, 6, and 15 of FIFRA. The prospect of administrative hearings to appeal a proposed restricted use classification under Section 3, cancellation hearings under Section 6, and the anticipated costs of indemnification for suspended

uses under Section 15 (discussed at greater length below) have all created pressure against EPA restricting a use, cancelling a registration, or suspending a pesticide it otherwise might wish to regulate. Congress needs to encourage appropriate regulation, rather than allowing current law to serve as a regulatory constraint. Specifying legitimate legal challenge when EPA fails to act, and striking the indemnification section would discourage the tendency for EPA to back away from necessary regulatory action in order to avoid resource-intensive litigation.

1972 amendments to Section 6 of the Federal Insecticide, Fungicide and Rodenticide Act provide that a person "adversely affected" by a notice of intent to cancel a registration or to change its classification can request a hearing. The Congressional intent of this amendment was made clear in the Senate report on the 1972 amendments:

> The Agriculture bill...permits any citizen to initiate cancellation proceedings, obtain judicial review of every action and inaction he disagrees with, and intervene in every proceeding... (S. Report No. 92-838, Part II, 92nd Congress, 2nd Session 39 (1972)

In 1979, EPA Administrator Douglas Costle ruled that FIFRA appeal rights apply only to those with a direct economic stake and who are adversely affected by agency decisions. The consequence of this ruling is the exclusion of environmental, consumer, and labor groups from meaningful and cost-effective challenges to EPA decisions. Because of this ruling, pesticide registrants are able to control what cases EPA initiates as well as what issues will be considered. Preferential treatment of the chemical industry prevents a full

review of risk/benefit issues and precludes effective public participation in the regulatory process.

The National Audubon Society does not believe that Congress intended to deny the public the right to a hearing, nor do we believe that participation in the Special Review process is an adequate substitute for this right. We ask that Section 6 of FIFRA explicitly give to members of the public with or without an economic interest in the continuation of the registration concerned the right to initiate an administrative cancellation hearing.

In addition, administrative hearings need to be streamlined in the interest of all parties. As participants in several cancellation hearings, environmental groups have expended considerable resources, time, and funds on lengthy proceedings. The resource-intensive nature of current hearings has prevented EPA from initiating cancellation unless a case is forced upon it. Even industry's resources are taxed beyond their means. The world was shocked when Dow Chemical Company pointed to attorney costs as the reason to halt 2,4,5-T cancellation hearings. Finally, protracted hearings confuse the public as to the safety or risk of the pesticide while cancellation hearings are under way. Congress needs to mandate EPA to streamline the administrative hearing process.

Indemnification for suspended pesticides

Section 15 of FIFRA, which provides for indemnity payments to registrants for products that have been suspended, provoked one of the stormiest debates in Congress in 1972. The Republican administration had two consistent and

strong objections to the legislative package moving through Congress in 1971. These objections centered on the 3(c)(1)(D) data compensation and indemnification provisions. It was argued by the Administration and by the Senate (which rejected the indemnification provision) that having existing stocks of a pesticide when cancelled or suspended should be considered an ordinary risk of doing business, and economic hardship, to the extent it exists, can be compensated with the pricing structure and, or private insurance. In conference, the House provision for indemnity payments was retained as quid pro quo for a voluntary suspension provision wanted by the Senate.

Until 1983 the indemnities provision was only invoked for a handful of minor cases amounting to less than $3 million.*/ In June, 1983, however, $12,880,842 was awarded to Chevron Chemical Company for existing stocks of silvex. At the time of EPA's 1979 suspension of silvex for home use, Chevron agreed not to contest the suspension in return for indemnities. The Court of Claims awarded the automatic appropriation of funds based on a finding of legal conditions met as required by Section 15 of FIFRA. In 1984 EDB indemnities paid to registrants totaled several million dollars.

EPA's fear of multimillion dollar indemnity payments if it bans a pesticide needs to be emphasized to this fiscally-minded Congress. It is no longer a matter of whether or not a registrant can be paid off, it is how much can he extract from the government.

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*/ Previous indemnities had been nominal: $535,771 to Ag Chemical in 1982; $224,932 to Old Fort Industries; $1 million to Andersons Arbor Valley Nursery; $500,000 to Ag Way, Inc. in 1981.

The taxpayers should not compensate companies for excess stocks of substances which have been profitably marketed for several decades, and whose risks have been well documented and known for years. If a product is suspended without advance warning, Congress can enact special legislation. Indeed, the tris-treated pajama compensation is a case in point.

The only rationale for indemnification is assurance that stocks of the suspended chemical will be collected and destroyed safely by the government. As an alternative, Congress should consider the establishment of an industry-funded pool that would cover the cost of the indemnification program in the future. If indemnification is to continue, the taxpayers should not bear the burden of the pesticide industry's business decisions.

In view of the prevailing philosophy of this Administration, as affirmed by Assistant Administrator John Moore in his April 18, 1985 testimony to strike Section 15, the time is ripe to remove the indemnification provision of FIFRA.

Registration fee system

One of EPA's largest program activities is the review and evaluation of applications for registration and reregistrations of pesticides. In 1978, Congress required EPA to conduct a study on the feasibility of charging fees for registering pesticides. The directive was enacted in recognition that pesticide registrants received benefits from registration and could achieve earlier market entry if EPA had greater resources to review applications. Currently, the public pays for EPA pesticide evaluation, and as congressional

appropriations have dwindled over the years, the number of registrations EPA can process suffered. By 1980, OMB told OPP that no increase in appropriations would be approved until registration fees were collected from pesticide registrants.

Because registration is required for every pesticide before it can be marketed, the manufacturers of these products are direct beneficiaries of the process. Since 1980, the Office of Management and Budget and the Environmental Protection Agency have been exploring the possibility of establishing fees so that pesticide manufacturers pay for the services provided for them at the Office of Pesticide Programs. In the current atmosphere of fiscal responsibility and budgetary restraint, the establishment of fees for services provided by the Environmental Protection Agency to the chemical industry is a logical step.

Although the chemical industry has opposed such a move, a 1982 EPA analysis of the implementation of fees showed that the costs of the services provided EPA would represent only five percent of the total amount spent by pesticide manufacturers on research and development. National Audubon urges Congress to legislate a registration fee system so that the financial burden of placing and keeping pesticides on the market will rest on those who stand to gain from this marketing.

Community right to know

In 1981, the Delaware Valley Toxics Coalition, headed by a member of the Wyncote Audubon Society, helped establish the country's first local right to know laws in Philadelphia. The laws required that industry officials reveal

to the Fire Department and Air Pollution Control Board a list of the chemicals manufactured and used in their plants. City departments keep the lists on file along with information about possible health hazards from the chemicals and instructions about what to do in case of accidents. The recent tragedy in Bhopal, India, demonstrated to the world that the industrial accidents are not impossible and that ready access to information such as that maintained by the city of Philidelphia can make the critical difference when such emergencies occur.

However, because the chemical industry has vehemently opposed the establishment of right to know provisions around the country, most cities and towns are unequipped to deal with such emergencies. For this reason, National Audubon Society supports amendments to Section 7 of the Federal Insecticide, Fungicide, and Rodenticide Act requiring pesticide manufacturers to submit to the Environmental Protection Agency details of all chemicals used in the manufacture, formulation and packaging; the identity and amount of pesticides produced annually for domestic use and export; environmental and health risks associated with exposure; the location of all pesticide manufacturing plants in the United States and abroad; information of the proximity of facilities to residential areas; and contingency, evacuation or fail-safe plans in case of a disaster. Only with this type of information available to appropriate officials can United States citizens have assurance of protection from potential industrial accidents. In addition, the public needs to know what chemicals are being produced in their vicinity and be able to comment on contingency or evacuation plans.

Section 24(c) - special local needs

As EPA's special review of toxaphene registrations was underway, state registrations of toxaphene for use against sicklepod in soybeans was discovered. Southern states registered toxaphene in 1960, but under Section 24(c) agency notification did not occur until 1980.

Section 24(c) needs to be tightened up by requiring immediate notification to EPA headquarters together with submission of data in support of the state registration. If immediate notification and submission of data are not made, the state should have its authority suspended. Section 24(c) is a most attractive loophole now that Section 18 emergency exemptions have been tightened up. Congress needs to act to prevent a dangerous proliferation of pesticide uses by states which result from local ties to formulators and users.

Cancellation of registrations because based on false, misleading, or inaccurate data

Hearings following the exposure of fraudulent tests conducted by Industrial Bio-Test Laboratories (IBT) revealed that EPA officials did not have authority under the Federal Insecticide, Fungicide, and Rodenticide Act to cancel or suspend registrations which were based on false, inaccurate, or fraudulent data. Since FIFRA provides for cancellation on the establishment of unreasonable adverse effects, evidence that data has been fabricated is not grounds for cancellation. To eliminate this problem, Audubon urges Congress to authorize the Administrator to cancel registrations under Section 6(a) and revoke tolerances if they rely on false, fraudulent, misleading, or inaccurate data.

Data sharing with states and foreign governments

Under current law, the Environmental Protection Agency's ability to share data with state governments is limited. The law does not distinguish between private individuals and state governments and therefore, EPA sharing with state analogues of health and safety data as well as confidential business information is severely restricted. Without this information, states cannot adequately enforce FIFRA or coordinate local activities with those on the federal level. We urge Congress to amend FIFRA to allow EPA to share data with states provided that the states have the authority to protect confidential business information.

A similar problem exists with respect to the sharing of data with foreign governments, especially close allies like Canada. We urge Congress to enact legislation which would allow data sharing if: 1) a bilateral treaty for data sharing exists; 2) the foreign goverment shows that it can protect the data; and 3) the sharing of data is in the national interest.

H.R. 2339 - integrated pest management and cosmetic use of pesticides

H.R. 2339 was introduced on May 2, 1985 by Barbara Kennelly (D-CN) to authorize and direct the Secretary of Agriculture and the Administrator of the Environmental Protection Agency to study methods to accelerate the use of integrated pest management and to decrease the use of pesticides to meet domestic cosmetic marketing standards. Audubon urges the Agricuture committee to include H.R. 2339 in FIFRA legislation.

Despite the comprehensive authorities given to EPA to regulate the use of pesticides, EPA's Office of Pesticide Programs essentially regards its mandate to be a licensing activity, and for four decades the sale and use of pesticides has continued to increase each year. At the same time our understanding of the environmental and health implications of these chemicals continues to be fearfully inadequate.

One result of this chemicalization of American agriculture is pesticide residues in groundwater, in rain, in food, fish, meat and poultry, and in the blood and fat tissue of nearly all Americans. This can be expected as agriculture accounts for between 60 and 90 percent of the use of all pesticides. Yet the acreage devoted to agriculture has not increased. On the modern farm, a given acre is treated with an increasing multitude and quantity of chemicals to perform a variety of tasks. Pesticides are used to control not just insects, weeds, or even pest birds and rodents, but also to accelerate maturity of fruit, promote early ripening, improve shape of fruit, and even assure uniformity of color.

Like an ancient Greek chorus, a broad spectrum of scientists and others are urging a decrease in our reliance on pesticides as anxiety mounts about pesticide residues in our drinking water and in our food. Congresswoman Kennelly's bill, H.R. 2339, would initiate positive steps towards <u>reducing unnecessary</u> use of pesticides, and therefore Audubon is extremely enthusiastic about incorporating it entirely in FIFRA legislation or attaching it as a directive to H.R. 2355. Congress could direct the $1.2 million authorization

to study the encouragement of integrated pest management and discouraging cosmetic use of pesticides out of the $11.9 million addition to EPA's budget for "related research activities."

Conservation tillage

Conservation tillage has emerged as the major cropland management technique in the United States. The basis for this increase and for projections of from 240 to 430 million acres of our cropland in conservation tillage is savings in fuel, and labor, and erosion control. These savings are possible because of fewer passes over the field. Essentially, conservation tillage is a term applied to a range of tillage methods that reduces disturbance of the soil by the moldboard plow. By substituting herbicides to control weeds, and employing a surface mulch to cover the bare earth, soil erosion and runoff of agricultural chemicals are reduced. In the short term, conservation tillage is extremely attractive as the most efficient technology for reducing soil erosion and runoff of chemicals.

Because of the use of soluble herbicides in conservation tillage, however, infiltration and leaching of these chemicals to groundwater and eventually to surface water in detectable concentrations has been increasing. Currently, the Soil Conservation Service and EPA are cooperating on studies by the Agricultural Research Service on pesticides in groundwater resulting from agricultural practices.

Research on long-term effects of pesticides in the soil biota is vital in view of the undisturbed condition of the soil under conservation tillage.

Understanding effects on water quality is even more essential in regard to chemical movement in and through the soil to ground and surface waters.

Some initiatives by EPA, SCS, and ARS have focused on conservation tillage. The National Audubon Society encourages this emphasis, and urges Congress to direct EPA to cooperate with appropriate other federal and state agencies in researching the environmental implications of conservation tillage. I have attached to our testimony a reprint of an article on conservation tillage.

Conclusion

After the backsliding of the Gorsuch/Burford regime, in the last two years, EPA has demonstrated progress in regulation of contamination of groundwater by pesticides as well as toxic inerts contained in pesticide formulations, but legislation is needed if these issues are to achieve the priority they deserve. The Agency has given support for the concepts of providing citizens' standing to initiate cancellation hearings, and to striking the indemnification provisions of FIFRA. This gives Congress every reason to act on these proposals discussed above. At the same time, Congress needs to give EPA a harder push to establish a registration fee collection system, to enact a community right to know provision, and to place a lid on special local registrations. Even industry accepts the need for Agency authority to cancel registrations based on false, misleading or fraudulent data, a provision that involves only a minor change in FIFRA. Data sharing with state and certain foreign governments is also necessary and

broadly supported. Finally, EPA research on integrated pest management, cosmetic use of pesticides, and conservation tillage offers a positive direction for FIFRA.

The National Audubon Society appreciates this opportunity to share our concerns about pesticide regulation and legislation. Audubon's views on international pesticide control will be presented by Edith Meacham, who directs international pesticides for the Society.

We will be glad to respond to any questions you may have on any aspect of our statements.

Thank you.

TESTIMONY

of

EDITH D. MEACHAM
AGRICULTURE POLICY ASSOCIATE
NATIONAL AUDUBON SOCIETY

Mr. Chairman and members of the subcommittee, National Audubon Society appreciates this opportunity to testify before you on the important issue of pesticide export controls. Our half million members have expressed great concern about United States pesticide export policies; their concern stems from the numerous examples of problems surrounding pesticide use in developing countries. Since many of the problems are the result of a lack of scientific knowledge and exportise, we urge Congress to direct its efforts toward improving information exchange on pesticides between industrial and developing nations. Of even more concern are reports that pesticide use in the Third World will quadruple in the next twenty years. As pesticide use expands, the establishment and maintenance of adequate controls becomes increasingly critical. It is the hope of our organization that changes can be made in the Federal Insecticide, Fungicide and Rodenticide Act this year to improve United States pesticide export policies so that American consumers will be better protected from banned or untested pesticides on imported goods, and pesticides will be used in a more beneficial way around the world.

On December 18, 1984, the United States was again the sole opponent in the United Nations General Assembly of the continued publication of a directory listing potentially dangerous products that are banned or otherwise restricted worldwide. This vote came 15 days after the tragic leak of methyl isocyanate in Bhopal, India. In subsequent hearings before the House Subcommittee on Human Rights and International Organizations, State Department Assistant Secretary Gregory Newell testified that while the Administration opposed continued publication of the list, it felt that information sharing was of

utmost importance. Since the Administration seems unwilling to provide this information through international channels, we urge Congress to adopt the following provisions that will improve the notification process by which foreign governments are informed about hazardous products, expand the information available to the Food and Drug Administration so that it can better protect American consumers from imported produce contaminated with illegal pesticide residues, and improve cooperation at the international level to encourage the development of appropriate pesticide use worldwide.

Improved Notification

The current export notification process can be easily circumvented. United States chemical companies can go through the notification system with their own subsidiaries in importing countries and have a shipment on its way before the importing country's government is informed. To tighten this loophole, National Audubon urges Congress to adopt a policy of "informed request" whereby the government of the importing country must submit a request to the Environmental Protection Agency before certain categories of pesticides can be exported. We advocate this change because it will give countries without adequate internal regulatory structures the ability to control what substances enter their country.

We also advocate an expansion and clarification of the categories ofpesticides requiring notification. We believe that restricted use, voluntarily cancelled or suspended, and acutely toxic pesticides should be included in the notification process. The benefits of extending the

notification requirements to these types of pesticides are numerous. Increased knowledge about acutely toxic and restricted pesticides will help foreign governments take steps to protect farm workers and applicators. The addition of voluntarily withdrawn chemicals is important because many companies remove chemicals from the U.S. market in order to avoid EPA proceedings that are likely to result in cancellation and attendant restrictions. A voluntary withdrawal often means that there are major problems with the chemical's health and safety data. For example, endrin, the most acutely toxic of the chlorinated hydrocarbons, was withdrawn from the U.S. market in August, 1984, one month before EPA was scheduled to complete a review of that controversial chemical's remaining uses. In 1979, EPA cancelled some and restricted other uses of endrin based on its conclusion that endrin caused birth defects, killed many non-target species, and was acutely toxic to wildlife. But even under restricted use, endrin continued to cause significant problems, contaminating several species of game birds in Montana and other western states in 1981. Because of these and other incidents, EPA reopened its review of endrin and would probably have cancelled the remaining uses last fall if Velsicol Chemical Company had not removed the chemical from the market.

In 1982, the Burmese Ministry of Agriculture and Forestry imported large quantities of endrin and promoted it widely throughout the country. Fishermen bought the chemical, dumped it into rivers, and collected the poisoned fish that floated to the surface. While the use of natural poisons to catch fish

is a common practice in Burma, their effects are temporary and limited. The results of the large-scale release of endrin were staggering. Many species of fish and wildlife, including otters, kingfishers and herons, disappeared from Burmese rivers. Under current law, endrin could still be exported without triggering the notification process. National Audubon Society believes that this loophole must be eliminated.

Improved Monitoring of Pesticides on Imported Food

One of the Food and Drug Administration's most important jobs is the monitoring of imported produce for pesticides cancelled or severely restricted in the United States. However, FDA's ability to carry out this duty is hampered by a lack of information about worldwide pesticide use patterns. We go to great lengths in the United States to protect consumers from food contaminated by pesticides, yet we have little accurate information about what other countries are doing in this area. National Audubon Society suggests that Congress include in the notification system provisions that require governments of importing countries to disclose to EPA the intended use of the chemical, the nature of the country's applicator training program, and, in the case of food use pesticides, any regulatory requirements that might affect residue levels. Further, we suggest that Congress require United States chemical companies to submit to EPA an annual report stating the amounts and destinations of exported pesticides, intermediates, or formulated products. EPA and FDA could use this information to identify overseas use patterns and improve the accuracy of our pesticide residue monitoring system.

National Audubon Society urges Congess to improve further the protection of American consumers by requiring EPA to revoke tolerances in food and feed for cancelled, suspended, or voluntarily withdrawn pesticides. In the case of highly persistent chemicals, there may be a need to phase down tolerances to allow residues to diminish with time. We recommend that Congress establish residue action levels for these highly persistent chemicals and require the revocation of all tolerances for food uses of cancelled or suspended pesticides. EPA has recently taken the initiative in this area by proposing to revoke tolerances for DDT, TDE, aldrin/dieldrin, schraden, strobane, DBCP, and mirex, but we believe that requirements for tolerance revocation and the setting of residue action levels should be clearly specified in FIFRA.

Permitting foods to contain cancelled or suspended pesticides at levels which exceed amounts attributable to their historical use encourages foreign farmers to use less expensive but more hazardous pesticides to reduce their production costs and gain a compatitive edge over American farmers. The enactment of requirements for tolerance revocation and the setting of residue action levels will protect American farmers as well as Americans' health.

Cooperation with International Initiatives on Hazardous Export Controls

The United States has been a leader in efforts to ensure that importing countries have the ability to make informed decisions about pest control. This leading role has been relinquished in recent years to the detriment of the international information exchange system. We possess technology, data, and the ability to share it, and it is our responsibility to enter into global

efforts on hazardous export controls wholeheartedly. Instead of arguing that the United States has done enough in this area, we should continue to work for improved and uniform pesticide research and regulatory programs, and provide technical assistance whenever possible. National Audubon Society urges Congress to adopt and define this policy clearly in the Federal Insecticide, Fungicide and Rodenticide Act so that United States leadership will have the support of a Congressional mandate.

Conclusion

The use of pesticides is expanding exponentially in developing countries and the United States must play a primary role in developing an international strategy to ensure that this expansion will not cause a comparable explosion of problems. In addition, we must take steps to protect American consumers from unsafe residues, and American farmers from unfair competion. National Audubon Society urges Congress to enact the above provisions and return the United States to its former position of leadership. With its wealth of resources and expertise, the U.S. can make a substantial contribution to ongoing efforts to solve international pesticide problems.

I would like to submit for the record an article on the subject which I wrote for Audubon Action, a bi-monthly newspaper which goes out to Audubon's half-million members. I think it will further demonstrate Audubon's interest in this issue.

Thank you for the opportunity to testify.

(Attachment follows:)

Endrin: Exporting the Danger, Relearning the Lessons

By Edith D. Meacham

Endrin, the pesticide that nearly wiped out brown pelicans in the Mississippi Delta 10 years ago and more recently contaminated game birds in the Central Flyway, has been withdrawn from the U.S. market by its manufacturer, Velsicol Chemical Company. The company canceled registrations for all uses of endrin in this country, but is continuing to manufacture the pesticide in Mexico and sell it worldwide.

Audubon and other environmental organizations have worked for a decade to outlaw endrin, which has been used in the United States since 1951 on crops such as cotton, rice, and sugarcane. Endrin is the most acutely toxic of the chlorinated hydrocarbons, a chemical family that includes DDT and dieldrin. One-quarter of an ounce of endrin is enough to kill an adult man. In the early 1960s, leaks from a Velsicol plant on the Mississippi coupled with high use of the chemical on cotton virtually wiped out brown pelican populations in Louisiana and Texas and killed as many as 10 million fish. In the early 1970s, as concern mounted, use of endrin on many crops, including corn, potatoes, sorghum, and sugar beets, was halted.

In 1975, heavy spring rains washed pesticides into the Mississippi River, killing most of the brown pelicans imported from Florida to replace those lost in the early 1960s. At the same time, evidence was beginning to suggest that endrin was carcinogenic. The Environmental Defense Fund and National Audubon Society petitioned the Environmental Protection Agency to cancel all uses of the pesticide. EPA thereupon initiated a four-year review of the product's risks and benefits.

In 1979, EPA canceled many major uses of endrin after finding that it caused birth defects, killed many nontarget species, and was acutely toxic to wildlife. But endrin use was still allowed on cotton in parts of Texas and states to the west, on small grains to control cutworms and grasshoppers, in apple orchards to control pine and meadow voles, and in assorted minor uses.

EPA officials reasoned that problems could be greatly reduced by restricting endrin use to these categories. Events in Montana and Washington proved them wrong.

In the spring of 1981, Montana farmers treated approximately 120,000 acres of grains with endrin to control the pale western cutworm. On March 28th, the first fish kill was reported, and by May, the director of Montana's Department of Agriculture had issued a temporary ban on endrin sales. Residues of endrin were found in several species of game birds in August. Seven percent of ducks and 33 percent of geese analyzed in September contained residues higher than the permitted level of 0.3 parts per million.

The Fish and Wildlife Service Endangered Species Division feared that migrating whooping cranes would feed in treated fields and be poisoned. Aircraft and ground teams were organized to keep cranes out of contaminated areas. The hunting season for waterfowl was delayed in several surrounding states, and people were advised to limit their consumption of game birds.

In September 1981, National Audubon Society, National Wildlife Federation, Izaak Walton League, and Environmental Defense Fund responded to these events by petitioning EPA to cancel the remaining uses of endrin.

In Washington State, where endrin was used at high rates to control meadow voles in orchards, significant numbers of birds, including raptors and a bald eagle, were killed by endrin. In the fall of 1982, after two Audubon chapters filed suit, the Washington Department of Agriculture placed stringent restrictions on the sale and use of endrin and adopted the same types of hunting restrictions as those used in Montana the previous year.

Finally, in November 1983, with evidence against the chemical mounting, EPA scheduled a review of the remaining uses of endrin. The review was to be completed last September, but in August, Velsicol, the only U.S. manufacturer of the technical ingredient of endrin products, voluntarily canceled its registration, thus ending the decade-long fight.

Significant numbers of birds, including raptors, were killed by endrin.

Maureen Hinkle, director of agricultural programs in National Audubon's Washington, D.C., office, welcomes the cancellation of endrin in the United States but is disturbed by the continued promotion of endrin in the rest of the world: "For the entire time it was on the market, endrin caused dramatic problems for wildlife. As endrin use expands to Third World countries, wildlife kills include rare and exotic species."

The effects on wildlife of endrin misuse in developing countries especially are clear in Burma. In 1982, the Burmese Ministry of Agriculture and Forestry purchased large quantities of endrin from Shell International in England. The chemical was promoted widely throughout the country and used extensively to catch river fish. Fishermen dumped endrin into the water and collected the fish that soon floated to the surface. While the use of natural poisons to catch fish is a common practice in Burma, the effects of these poisons are limited and temporary. Endrin, on the other hand, causes long-lasting damage to fish populations and to wildlife that rely on fish as a food source. Otters, kingfishers, and herons are among the species fast disappearing from Burmese rivers.

Prevention of such problems must come from countries such as the United States that have undertaken extensive studies of many hazardous chemicals. But this country seems unwilling to play a responsible role on this issue. In the December 1984 meeting of the United Nations General Assembly, the United States was again the only country to vote against the publication of a worldwide directory of hazardous products banned or restricted in 60 countries.

The recent tragedy in Bhopal, India, where 2,500 people died when a deadly gas leaked from a Union Carbide pesticide plant, graphically shows the danger of transferring technology without sufficient information and expertise. Pesticide exports should be regulated so that importing countries are supplied with adequate information to help them prevent unreasonable risks to humans and wildlife. Until these countries have this information, humans, wildlife, and the environment will suffer. □

Edie Meacham, an agriculture policy associate in National Audubon's Washington, D.C., office, is supported by a grant from the Jessie Smith Noyes Foundation.

Drawing by Tom Eyles.

NATIONAL WILDLIFE FEDERATION
1412 Sixteenth Street, N.W., Washington, D.C. 20036 202—797-6800

STATEMENT OF BARBARA J. BRAMBLE
ON BEHALF OF THE NATIONAL WILDLIFE FEDERATION
BEFORE THE HOUSE SUBCOMMITTEE ON
DEPARTMENT OPERATIONS, RESEARCH
AND FOREIGN AGRICULTURE
OF THE COMMITTEE ON AGRICULTURE

On behalf of the National Wildlife Federation, I am pleased to have this opportunity to appear before you today to clarify our concerns about pesticide use in this country and abroad. I am Barbara Bramble, Director of International Programs of the National Wildlife Federation. The Federation is the nation's largest conservation organization, with over 4.5 million members and supporters dedicated to the wise use and management of natural resources. The Federation's constituency has a longstanding awareness of the strong link between sustainable development and intelligent use of natural resources. We are dismayed by the proliferation of pesticide use that destroys fish and wildlife, poisons humans, and threatens the natural balance of predators and prey. We therefore support the pesticide reform bill sponsored by Rep. George Brown, H.R. 2580, which will strengthen the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) by increasing protection of developing countries against pesticide misuse, augmenting control of pesticides that endanger United States citizens, and assuring public participation in

important decisions concerning pesticides. While the bill will not solve all pesticide-related problems, it is a needed effort to address known inadequacies in the current FIFRA legislation.

The package of amendments constituting H.R. 2580 covers several different facets of pesticide regulation and use, and the Federation strongly supports the entire bill. But in the interest of brevity, my testimony will concentrate on three points: (1) Our principal area of concern centers on the unrestricted export of hazardous pesticides abroad and the subsequent exposure of U.S. citizens to many of these same chemicals as residues on imported food. Pesticides manufactured only for export should be registered in the U.S. Developing countries must be given a fair chance to make an "informed request" for canceled, suspended, restricted, or voluntarily withdrawn pesticides before they are shipped, and residues of canceled or suspended pesticides on food imports must be eliminated. (2) We are concerned at the slow pace of re-registration of the older pesticide chemicals which came onto the market with inadequate testing for health and environmental impacts or, in some cases, with falsified test data. A strict schedule for finishing this work must be set. And (3) we believe that many dangerous regulatory decisions that have been made about pesticides could have been avoided with adequate public review of health and safety data, and we therefore favor increased public participation in the regulatory process for pesticides.

I. REMOVE THE DOUBLE STANDARD BETWEEN REGULATION FOR DOMESTIC USE AND REGULATION FOR EXPORT

The National Wildlife Federation is concerned that the pesticides exported by the United States to developing nations may not promote health or sustainable agriculture in those countries. All too frequently, it is learned that pesticide use abroad causes illness and death, poisons food and water supplies, and contaminates fish and wildlife. Hundreds of thousands of people are affected by pesticides yearly in developing countries. At least twenty thousand die.[1] This constant and unspectacular tragedy equals several times the numbers killed or injured by the accident at Bhopal, and it happens every year.

Overuse of pesticides, particularly the persistent organochlorines, has resulted in the survival of the most resistant of pest species, many of which are the severest crop pests. The pesticides also destroy many of the species which prey on these pests. Thus, pesticide use has increased the reliance on harmful chemicals. In this country, these dangers led to the adoption of FIFRA in 1972. Unfortunately, many other countries have not yet reached the same level of understanding.

Registration of Exports and Record Keeping

Assuring safe pesticide use is hard enough in the U.S., as you have heard and will continue to hear from most of the other witnesses testifying during these two days. In developing countries, pesticide

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1. Estimate by U.N. Economic and Social Committee for Asia and the Pacific.

misuse is magnified by poverty, illiteracy, the high cost of protective gear, lack of water for washing after pesticide use, and inadequate (if any) training for applicators. To add to these enormous obstacles, the U.S. -- and other countries -- have adopted a double standard which specifically exempts pesticides made for export from important legal safety requirements which are imposed if the pesticide is to be used domestically. For example, under Section 3 of FIFRA, pesticides made only for export need not go through the registration process. This means that even if an importing country asks EPA for information about the health and safety effects or efficacy of certain products, EPA has no information to give. In addition, not all domestic pesticide container labeling requirements apply to exported products--manufacturers of pesticides destined for abroad need not label pesticides with instructions for proper use. The current provisions ease the financial burden on U.S. corporations at the expense of the health of pesticide users abroad. In contrast, the proposed amendments in H.R. 2580 remove the double standard by requiring registration of all pesticides manufactured in the United States, and requiring label instructions for use.

The amendments also strengthen Section 8(a) and (b) by clarifying that current record-keeping requirements apply to manufacturers of pesticides both for U.S. use and for export.

Export Notification

One of the worst features of the current law is that not all important information about pesticide regulatory action in the United States is desseminated to foreign governments. Under FIFRA, the U.S. need only notify recipient governments about cancellations or suspensions of pesticide registrations. No sharing of information about restricted-use pesticides is required. Yet, most hazardous pesticides are subject only to use restrictions; only a few have been canceled or suspended.

Moreover, restricted-use pesticides may be the most dangerous for developing nations. Training in safe methods of application is rare, and most applicators do not understand the dangers posed by these chemicals. Even if containers were labeled with use instructions in the appropriate language, specialized equipment and other precautions required for their safe application generally is unavailable to users in remote areas.

For example, in the United States parathion use is restricted to certified, trained applicators or individuals acting under their direct supervision. The use precautions required by EPA include wearing natural rubber gloves, protective clothing, a mask, goggles, and an approved respirator. Farmers are instructed to keep humans and livestock away from the sprayed field for forty-eight hours after application and to wash their hands, face, and arms after spraying and before drinking, eating, or smoking.

It is wholly unrealistic to expect farm workers in Third World countries to follow these instructions, especially the restriction

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to use by trained applicators. We must remember that in the U.S. failure to follow these label requirements is unlawful under FIFRA. 7 U.S.C. §136j(a)(2)(G). In other words, but for the assumption that the label instructions will be followed, parathion would not be legal for use in this country. Parathion is an extremely hazardous chemical, which some experts believe is responsible for as many as 80 percent of all pesticide poisonings in Central America. Yet it is one of the many pesticides for which FIFRA requires no warning when exported to developing countries.

Aside from the fact that restricted-use pesticides are not covered, the current statutory notification system is inadequate. Under the present scheme of §17, adopted in 1978, there are two types of notifications. Section 17(b) requires EPA to notify foreign countries when it acts to cancel or suspend a pesticide registration. Only if a foreign country asks for further information does §17(b) require EPA to explain why it took the regulatory action.

The second part of the notification scheme involves shipment-related notices (§17(a)) which tell a country that a canceled, suspended, or otherwise unregistered pesticide is being shipped to a destination within that country. This type of notice is complicated and unhelpful. First, the importing company must acknowledge to the exporting company that it knows the pesticide is unregistered--which would presumably not be news to the importer (who is often a subsidiary of the exporter). A copy of this acknowledgment then goes to EPA, which prepares a notification document for transmittal

to the State Department, the U.S. Embassy, and eventually an official of the importing government. Meanwhile, however, the pesticide shipment is long gone. No acknowledgment is required that the appropriate authorities of the importing country ever received the information. While this is an improvement over no notification at all, the system needs to be improved.

H.R. 2580 strengthens the notification scheme in two important ways.

First, an amended Section 17(a)(1) expands the class of actions about which other countries must be informed. As noted above, FIFRA currently requires notification to an importing nation only when a pesticide registration is canceled or suspended. H.R. 2580 will enlarge the category of pesticides requiring notification to include those that are restricted to use by a certified applicator, voluntarily withdrawn or denied registration.

Second, the remaining portion of Section 17(a) improves the notification procedure. While the Act currently requires notification, it mandates neither confirmation of receipt of the notice nor an opportunity to request or refuse the pesticide. Frequently, the notification is received long after the pesticide shipment has been received and at that point it can be very difficult to refuse the shipment.

H.R. 2580 corrects this deficiency by requiring the information exchange to precede the shipment. Officials of the importing country must acknowledge receipt of information about the effects of the pesticide on human health and the environment. The officials must then request the shipment, as well as furnish a description of their own pesticide use and residue control measures.

This process will serve to warn the importing country and to promote regulatory improvements in developing countries over time. Although we cannot pretend that these measures will result immediately in reduced hazards to workers in the field or less contamination of the environment, the United States owes it to its customers abroad to improve the flow of timely information about pesticides.

A recent resolution proposed by the National Wildlife Federation and passed by the International Union for the Conservation of Nature and Natural Resources (IUCN), an international forum of citizen groups and government conservation agencies, adopted the "prior informed request" position. (Resolution attached.) A number of other countries and international organizations are considering adopting a similar position. It is important that, as a world leader, the United States also endorse "prior informed request" while other organizations are re-examining their policies.

Technical Assistance

The amendments suggested by Representative Brown enhance international cooperation by requiring the Administrator of EPA to provide foreign countries with technical assistance in safety training, regulatory programs, and alternative methods of pest control. This section could be a powerful tool to increase international awareness about safer pesticide use and methods to reduce reliance on hazardous chemicals.

* * *

H.R. 2580 will strengthen FIFRA by assuring similar standards for exported and domestic pesticides, increasing the availability of pesticide information to recipient countries, giving importing countries a fair chance to make an informed choice before the chemicals arrive at their docks, and providing developing countries with technical assistance to improve their own regulatory capabilities. EPA has drafted a version of FIFRA amendments which never emerged from OMB. While the EPA draft tinkers with some of the domestic provisions, it is strangely silent on these important international issues.

II. PROTECT U.S. CITIZENS FROM EXPOSURE TO INADEQUATELY TESTED PESTICIDES

In addition to improving policies regarding pesticide exports, the Brown-sponsored FIFRA amendments (H.R. 2580) also will reduce the threats now posed to U.S. citizens by exposure to hazardous pesticides.

There are several major areas of concern on the domestic front, but we will concentrate here on three: importation of foodstuffs with residues of pesticides for which registration has been canceled or suspended; re-registration of pesticides; and compulsory reporting of adverse health effects of pesticides to EPA.

Residues

Under current law, when a pesticide registration is canceled or suspended the tolerance levels (legal limits of pesticide

residues permitted on food products) corresponding to that pesticide are not automatically revoked. This means that a canceled or suspended pesticide can be used abroad on food destined for United States markets, and the FDA must accept the food for import unless the residues exceed the levels established before we knew of the pesticide's dangers. As a consequence, even after a pesticide is canceled in this country, we continue to consume it on imported produce. For example, a 1984 study of imported coffee beans by the Natural Resources Defense Council found residues of pesticides banned for use in the United States on 30% of the beans sampled.[2] We import nearly all our coffee.

This policy not only endangers our citizens by exposure to hazardous chemicals, but it also is economically unfair to U.S. producers who are prohibited from using the usually-cheaper banned pesticides. EPA justifies this procedure by stating that residues of some pesticides remain in the environment long after their application to crops has ceased. The current process could be improved while also taking into account EPA's objection, although the agency's draft bill fails even to try.

John Moore, EPA Assistant Administrator for Pesticides and Toxic Substances, testified before you on April 18 and said that EPA is "in the process of" revoking tolerances for fourteen pesticides canceled in the 1970s.[3] Surely we should expect EPA to act more quickly.

2. S. Hearne, Harvest of Unknowns: Pesticide Contamination in Imported Foods, 18 (Natural Resources Defense Council, 1984).

3. Statement of John A. Moore, Assistant Administrator for Pesticides and Toxic Substances, U.S. EPA, before the Subcommittee on Department Operations, Research and Foreign Agriculture of the House Committee on Agriculture, 7 (April 18, 1985).

H.R. 2580 addresses this problem in Section 17(d) by prohibiting import of agricultural commodities with detectable residues of a pesticide for which registration has been canceled, suspended, or voluntarily withdrawn. However, it allows an exception for situations where EPA has set a tolerance level specifically because the pesticide unavoidably persists in the environment. The bill also prohibits import of foodstuffs with residues of pesticides for which there is no tolerance established unless there is a special tolerance exemption.

Another potential solution to the residue problem which you have proposed, Mr. Chairman, is simply to forbid import of a food shipment from a country whose regulations permit use on that crop of a pesticide which the United States has canceled or suspended for use on the same (or similar) product. Such a provision would be an incentive for other countries quickly to develop significantly stricter regulations. We would welcome such a strong stand and support it. But because compliance with such regulations in many developing countries is not enforced, there still would be a need for FDA spot checks at the border.

Re-registration

Another major concern is the slow pace of the re-registration process now underway. Under the 1972 FIFRA Amendments, all old pesticides were to be re-registered using modern scientific testing protocols. The deadline for completion of re-registration has been changed twice, and in 1978 EPA was ordered to finish the project

"in the most expeditious manner practicable". John Moore's testimony last month indicated that of the at least 600 pesticides requiring re-registration, EPA has set the new registration standard for only 98. The complete data package has been received for only 6 out of the 600. At this pace, it will take decades to complete the re-registration process. The EPA draft bill does not even mention the problem.

We support Representative Brown's proposal in Section 3(g) to put EPA and pesticide manufacturers on a tight schedule for compliance with Congress' 1972 mandate. It is important to note that meeting the 1972 requirements is not overwhelmingly burdensome because EPA has a standard battery of tests for pesticide registration, and no test takes more than three years to perform. The bill requires EPA to identify data gaps for 300 top-priority pesticide active ingredients by July 1, 1986, and to publish a list of the remaining ingredients and their data gaps in the Federal Register by July 1, 1987. It allows registrants four years to supply the missing data. If registrants do not provide the information within the specified time period, then the Administrator must undertake to fill the data gaps at the registrants' expense.

A related area is the falsification of health and safety test data, a problem which was widely publicized in the wake of the 1977 Industrial Bio-Test (IBT) scandal. Today, eight years after the government learned of IBT's submittal of fraudulent test results, it remains difficult to cancel or suspend a pesticide registration even when the registration is based on faulty data. FIFRA allows cancellation only when there is evidence of adverse effects on man

and the environment. When registration data is incomplete or falsified, obviously there is no solid evidence of negative health effects. Even when there are indicators of health problems, the cancellation process includes four separate data-gathering and hearing processes which take years to complete. The EPA draft bill does propose some streamlining, which is an improvement. But the suggested changes do not simplify the process adequately. Moreover, the draft suggests an "informal rulemaking" procedure which would give OMB an important role in the cancellation proceedings. This could be disastrous because OMB has neither the expertise nor the incentive to evaluate the hazards of pesticides properly.

H.R. 2580 proposes a simplified procedure whereby the Administrator must act immediately to issue a Notice of Intent to cancel a registration or revoke a food tolerance if he believes that false, misleading, or inaccurate data has been supplied in support of an application and the information is material to EPA's registration or tolerance decision. The registrant may request a hearing concerning the accuracy of the data and may submit new data.

Compulsory Reporting of
Adverse Health Effects

We also support disclosure to EPA of all adverse health effects about which a pesticide registrant is apprised. At present, FIFRA requires registrants to submit information only about

"unreasonable" adverse health effects. The EPA draft bill improves this a bit by permitting the EPA Administrator to define "unreasonable". It therefore permits a broad reading of "unreasonable" if the Administrator exercises his discretionary opportunity to give an expansive definition to the word. H.R. 2580 goes further, though. It removes the word "unreasonable" entirely, thus requiring registrants to notify EPA about any adverse health effects caused by pesticides they manufacture. This change is appropriate, since it permits early warning to EPA about possible avenues for investigation. It does not trigger by itself any burden on, or penalty against, industry.

III. ENCOURAGE PUBLIC INVOLVEMENT

Right-to-Know

In the aftermath of the Bhopal disaster, U.S. citizens have begun to realize how little is known about dangers in our own communities, as well as how limited the opportunity is to be involved in decision-making processes that affect our well-being. NWF therefore supports several provisions of H.R. 2580 which will increase citizen knowledge about and participation in public policy concerning pesticides. Unfortunately, the EPA draft bill does not address these concerns.

FIFRA currently requires pesticide manufacturers to submit data to EPA concerning the amounts and types of pesticides produced. But most of this information is confidential and consequently is not available to the public. Intermediary chemicals, such as the methyl isocyanate (MIC) used in the Bhopal plant, are not covered. As a

result, like the residents of Bhopal, U.S. citizens have very little, if any, information about the poisons manufactured or used in chemical plants in their communities. Moreover, they are not aware of procedures which should be followed during an emergency.

Major pesticide companies, particularly Monsanto, are beginning to disclose this information voluntarily. This is a commendable action. But it underscores the need for such disclosure across-the-board.

Representive Brown's proposal would address this need. In Section 7(c)-(e) the bill requires manufacturers to submit additional information to EPA, including the names of all pesticides produced or intermediary chemicals used, the amounts produced and used, a summary of the health risks associated with the chemicals, the location of the plants using them, as well as "evacuation plans or documents for plant employees and residents of neighboring communities in the event of an emergency". It also requires this information to be submitted to state and local police, fire, and health officials and to chemical plant employees. The bill protects proprietary interests by maintaining confidentiality about the amounts of pesticides produced and intermediary chemicals used.

Public Review of Test Data

H.R. 2580 also facilitates public review of pesticide testing, by repealing §10(g) of FIFRA, which requires members of the public receiving industry health and safety test data to assure EPA that they "will not purposefully deliver or negligently cause the data to

be delivered" to foreign or multinational pesticide producers. This provision was designed to protect trade secrets by guaranteeing that foreign competitors will not use this data to register their own products in countries which are not parties to patent treaties with the United States. Section 10(g) has led to warnings of criminal prosecution and civil liability against groups that might publish or distribute these scientific studies for peer review. Because the benefits from wide review of pesticide health and safety studies are greater than proprietary interests of pesticide manufacturers, Section 10(g) should be repealed. At the same time, however, H.R. 2580 recognizes and protects commercial interests by adding Section 12(a), which creates civil and criminal penalties against any party using this type of health and safety data for licensing or registration in a country other than the United States. This provision places liability for misuse of the information on the appropriate parties--those who misuse it for financial advantage.

Disclosure of Test Data for Public Comment

A defect in the present law is its failure to provide disclosure of health and safety data during the public comment period on proposed registration and tolerances decisions. Instead, the test results are made available up to 30 days after the final decision has been made. This means that even if an error has been made and is pointed out by a competent public expert, the pesticide is registered and cannot be challenged except by the lengthy cancellation

process. To keep hazardous pesticides off the market, it is important that scientific data be available to the public before EPA final decisions are made. H.R. 2580 accomplishes this by amending Section 3(c)(2)(A) to provide disclosure of data submitted in support of an application for registration or for establishment of a tolerance prior to the end of the public comment period. However, dissemination of information would remain subject to the trade secret protections in Section 10.

Citizen Participation in Cancellation Proceedings

Equally important is citizen participation in pesticide cancellation hearings. FIFRA provides that "a person adversely affected" may request a hearing after a Notice of Intent to Cancel is issued. The courts have construed "adversely affected" to exclude environmental groups and other interested members of the public.[4] While citizens' groups rarely oppose a pesticide's cancellation, they sometimes assert that a proposed cancellation for certain pesticide uses does not go far enough. In such a case, the manufacturer would have no incentive to initiate a hearing and citizens' groups would be prohibited from doing so. We believe that citizens' right to initiate cancellation hearings is necessary to protect the public from possible "deals" between EPA and pesticide manufacturers. H.R. 2580 remedies the problem by specifying that pesticide users and members of the public

4. Environmental Defense Fund v. Costle, 15 E.R.C. 1218 (D.C. Cir. 1980).

without an economic interest in the registration may request a hearing concerning a pesticide's registration, cancellation, or change in classification.

Citizen Suits

Finally, we support addition of a citizen suit provision. EPA's resources are inadequate to monitor compliance with FIFRA's requirements effectively. Nearly all other environmental legislation includes a citizen-suit section. These provisions have been helpful both to encourage private conformity with statutes as well as to assure EPA's effective administration of the acts. The proposed amendment would create a civil right of action against parties alleged to be in violation of the Act. It probably would not create a massive increase in litigation, though, because it also prohibits lawsuits against private pesticide applicators unless the plaintiff notifies state and federal authorities of the claimed violation and those authorities have not commenced an action within sixty days after notification.

* * *

We commend you, Mr. Chairman, for holding hearings on these vital pesticide issues. We hope to work closely with you and your staff to ensure passage of a strengthened FIFRA this year.

NATIONAL WILDLIFE FEDERATION
1412 Sixteenth Street, N.W., Washington, D.C. 20036 202—797-6800

May 21, 1985

SUMMARY OF REMARKS

by Barbara J. Bramble

Director, International Program
National Wildlife Federation

- The National Wildlife Federation strongly supports the FIFRA reform package to be introduced this week by Rep. George Brown (D-CA), as well as the similar provisions in the Heftel Bill, H.R. 1416, regarding export and import of pesticides.
- NWF is particularly concerned about the export of hazardous pesticides to developing countries where they are often misused, causing acute poisonings, as well as long-term health effects and environmental contamination.
- Cancelled and suspended pesticides are allowed to be exported from the United States. The current export notification provision does not give developing countries sufficient or timely warning of the hazards of pesticides they are receiving.
- Cancelled or suspended pesticides tend to be persistent in the environment. If used on a food crop, they may remain as residues on food products.
- FIFRA does not now require automatic revocation of food tolerances (legally permitted amounts of pesticide residues in food) when a pesticide is cancelled or suspended.

- Thus a shipment of imported food may legally contain as much residue of a cancelled pesticide as was permitted when that pesticide was used in the U.S., prior to cancellation.
- Even more dangerous is the fact that no notification must be sent regarding restricted use pesticides. These must be used with extreme care, and in the U.S. can only be used by a certified applicator or one under his supervision.
- Restricted use pesticides cause thousands of poisonings and deaths each year in developing countries. Parathion alone is estimated to cause 80 percent of the poisonings in Central America. Yet Parathion is not covered by the FIFRA notification provision.
- Amendments to FIFRA are needed which would:
  - require all pesticides exported from the United States to be registered here;
  - require automatic revocation of tolerances when a pesticide is cancelled or suspended;
  - strengthen the notification system for hazardous pesticide exports by requiring receipt of information by the importing country and request for the chemical, prior to export;
  - broaden the notification system to cover restricted use and voluntarily withdrawn pesticides;
  - require the compilation of information on the production hazards, destination and use of exported pesticides;
  - offer technical assistance to developing countries to assist them in establishing training and regulatory programs to

reduce pesticide misuse and develop less chemical intensive alternatives.

- Amendments to FIFRA are also needed on the domestic side, including:
  - a strict schedule for re-registration;
  - community right to know;
  - citizen participation in review of test data and cancellation proceedings;
  - citizen suits for enforcement.

WORLD RESOURCES INSTITUTE
A CENTER FOR POLICY RESEARCH

1735 New York Avenue, N.W., Washington, D.C. 20006, Telephone: 202-638-6300

May 21, 1985

Statement of Robert Wasserstrom
on behalf of World Resources Institute
before the
Subcommittee on Department Operations,
Research and Foreign Agriculture
of the House Agriculture Committee

Farmworker Safety and Pesticide Use in the United States

Mr. Chairman, my name is Robert Wasserstrom. I am a Senior Associate and Project Director at the World Resources Institute, a research center which focuses on policy issues concerning the environment, development, public health, population and natural resources. In collaboration with Richard Wiles, I have recently completed a study of pesticide regulation and farmworker safety in the United States, which will be published by WRI in the near future.

Before joining the Institute, I served on the faculty of Columbia University in the Schools of Public Health and International Affairs. Previously, I also worked as a field officer specializing in agriculture and rural development with the National Council for Science and Technology in Mexico, where I was directly involved in testing insect pest management systems. I appreciate this opportunity to offer my views to the Committee.

I. EPA and Farmworker Safety

Since FIFRA was enacted in 1947, American agriculture has become heavily dependent on synthetic pesticides, which now represent a $4.1 billion-a-year market for chemical manufacturers. Yet because EPA has been unable to codify appropriate uses for these chemicals, as the law requires, significant problems of human health and safety remain.

In part, such problems stem from the ambiguous nature of FIFRA itself and from the Agency's convoluted efforts to balance the price of pest control against the need to limit human exposure. This difficulty has recently been underscored by specialists at EPA's own economic analysis branch: "While pesticide producers, users, and consumers benefit from the use of pesticides," they wrote, "...costs are distributed disproportionately throughout the population (in terms of acute and chronic toxic effects such as cancer)."[1] Although conclusive proof is not available, ample evidence suggests that such costs are borne mainly by farmers, fieldhands and agricultural laborers.

Let me review some important facts about occupational exposure to pesticides. Late in 1963, 94 peach pickers near Hughson, California, suddenly fell ill after working in orchards that had been sprayed with a common insecticide, parathion. Public health authorities quickly determined that most of these workers had not been contaminated during or soon after application.[2]

Rather, the worst episodes took place in orchards which had been treated as much as five weeks before the outbreak began.

Upon closer examination, such episodes seemed to fit an emerging pattern of multiple poisonings involving laborers exposed to the "dislodgeable residues" of organophosphate pesticides, which were rapidly replacing older, less toxic chemicals like DDT. At least seven times since 1949, agricultural workers had become sick after reentering orchards that had been sprayed with these chemicals.[3] Responding to such conditions, in 1971, the California Department of Food and Agriculture (CDFA) issued a set of "reentry intervals" for specific crops and chemicals; three years later, the federal government adopted similar (though considerably less restrictive) standards (Table 1).[4]

Today, twenty years after the Hughson incident, specialists still disagree about the effectiveness of such measures or indeed about what the risks of pesticide exposure really are. According to one estimate, for example, between 8 and 9 million people are employed in agriculture and at least half of them come into direct contact with dangerous chemicals.[5] Such people fall into three distinct categories: farmers, who often conduct their own spraying operations; laborers who mix, load and apply pesticides; and fieldhands, who may come into contact with so-called dislodgeable residues as they weed, pick, and prune.

Using information from California, Dr. Molly Coye, formerly staff epidemiologist at the National Institute of Occupational Health and Safety in San Francisco, has calculated that perhaps

as many as 313,000 of these people may suffer the effects of pesticide related illness each year, including such acute symptoms as dizziness, vomitting, "pin-point pupils" and severe skin rashes.[7] Complicating such calculations, however, is the fact that regional differences in crop production and pesticide use rates almost certainly give rise to different patterns of human exposure. What these patterns might be remains a matter of conjecture because accurate figures on the frequency of poisonings--or even educated guesses--have not been compiled. And beyond such estimates, an unknown number of people endure various chronic disorders or prolonged depression of an essential enzyme called cholinesterase.

Moved in part by these considerations, Congress has amended FIFRA over the years and has vastly extended EPA's responsibilities under the law. As a result, the Agency must now classify all pesticides into "restricted" and "unrestricted" categories, and it oversees the efforts of state governments to certify private and commercial applicators.

Federal enforcement of FIFRA is essentially based upon the certification program: in general, state agencies must take care that farmers and professional fumigators adhere to legal prescriptions--usually involving protective clothing---printed on product labels. EPA inspectors rarely take the initiative; instead, they review the activities of local officers to determine whether the law has been observed.

How well this arrangement works has been a subject of con-

siderable controversy. According to GAO investigators, for example, state enforcement activities improved significantly from 1978 to 1980. But more recent evidence obtained from EPA by the World Resources Institute under the Freedom of Information Act suggests that this trend has not continued (Table 2).

If fiscal year 1981 is used as a benchmark, several facts emerge. Although the total number of "state inspections" has remained approximately unchanged since the Reagan administration began, enforcement patterns have shifted away from sterner measures like suspending or revoking applicator licenses. Civil actions have decreased from 89 to a yearly average of 43, criminal prosecutions from 49 to 28 and the frequency of cases referred to EPA for final disposition from 33 to 13. Even the number of warnings has declined by 17.5 percent. Recognizing this trend, former Administrator Ruckelshaus told his enforcement staff last year: "I am nervous about what I perceive to be an apparent lack of action and serious commitment to ensuring that these laws and regulations are enforced. While the states do have a larger responsibility...than they did in the past, if we are carrying out oversight responsibilities, these laws should be enforced."[7]

But even with better enforcement, significant difficulties must be overcome. One of the most important concerns the fact that EPA has largely been "flying blind" in its efforts to set farmworker safety standards. Without comprehensive data on poisoning rates and human exposure, for example, the Agency

has been unable to formulate appropriate reentry intervals--even when the political will to do so has been forthcoming. As a result, federal standards often lag behind the rules which have been adopted in California (and now Texas).

Although EPA argues that such differences arise naturally when states are allowed to set their own requirements, they also give rise to some curious ironies. A case in point involves Guthion, which is governed by a 30-day interval in California and two days in areas that follow federal rules--even though 88 percent of all the Guthion used in tree crops is applied outside of California. In this case, EPA's assertion that Guthion must therefore represent a greater problem in California than elsewhere may be true, but it is not based on scientific evidence of any sort.

In fact, this problem was recognized over ten years ago by the federal Task Group on Occupational Exposure to Pesticides, which urged the Agency to require exposure studies as part of the registration process. As the Task Group observed, "If it has been demonstrated experimentally that a 21-day reentry period is reasonably safe while 14 days is reasonably unsafe, no amount of debate can transmute the unsafe period into a safe one, or the converse."[8] And beyond the experimental determination, we might add, is the question of ascertaining "ground truth"--the need to monitor human exposure levels in the field.

Why have federal authorities shown little interest in protecting farmworkers? Until recently, EPA maintained the position that

stricter standards were not needed. Instead, Agency managers have generally focused on a more limited task--that of finding safer ways to use dangerous chemicals.

The most dramatic example of this approach involves EPA's policies concerning protective clothing--both for applicators and for farmworkers in general. Under current rules, the Agency allows farmers to overlook reentry intervals if their workers are provided with a hat, shoes, long pants, "tightly woven gloves" and a long-sleeve shirt. And yet, a detailed report prepared for EPA by Dynamac Corporation argues that such rules cannot easily be defended on scientific grounds.[9] Similarly, path-breaking experiments by Richard Fenske and his colleagues using special infrared dyes have demonstrated that even the most "impermeable" garments (such as rubber gloves) allow considerable residue deposition on human skin.[10] All of this evidence points to an unmistakable conclusion: such garments are far less reliable in protecting farmworkers than EPA has heretofore assumed.

II. Towards a New Regulatory Framework

Fortunately, since 1980, this picture has begun to change. Responding to public pressure, EPA at first created a small farmworker safety unit within the Office of Pesticide Programs to consolidate existing information and suggest appropriate remedies. Then in August, 1984, the Agency issued an Advanced Notice of Proposed Rulemaking (ANPR) entitled "Worker Protection Standards for Agricultural Pesticides."[11] Recognizing that current policies have largely failed to protect both laborers and fieldhands, the ANPR and subsequent testimony by EPA Assistant Administrator Dr. John Moore before this Subcommittee outline a course of action designed to strengthen existing regulatory procedures.

Of considerable importance, the Agency now proposes to establish a "generic 24-hour reentry interval" for all acutely toxic chemicals, supplemented where necessary by longer periods for specific compounds. Thus, for example, this rule would encompass virtually all of the compounds included in Table 1 which are regulated in California but not under federal standards. New pesticides would not be registered without studies of their field degradation rates that would enable the Agency to set appropriate requirements. For compounds which are already on the market, EPA would like to collect such information under its on-going reregistration program, initiated at the behest of Congress in 1974. Manufacturers who failed to undertake

these studies would eventually be forced to withdraw their products from commercial sale.

The ANPR also proposes to take specific steps concerning the problem of long-term exposure to pesticides: "One option the Agency is considering is to establish reentry intervals or other special requirements...for all pesticide products that EPA has found to pose risks of cancer, birth defects, adverse reproductive effects, or other adverse chronic effects....regardless of their acute toxicity."[12] When agricultural workers must resume their tasks in fields that have been sprayed, for example, the Agency would now require farm operators to post appropriate warnings indicating that these intervals are in effect.

A much more far-reaching proposal concerns the suggestion that farmworkers should be afforded the same kind of protection enjoyed by other members of the labor force under the Occupational Safety and Health Act (OSHA). Unlike FIFRA, OSHA directs federal authorities to set whatever standards are needed to assure that workers remain unharmed by chemicals or other hazards over the entire course of their working lives. Using this approach, EPA has outlined a nine-point safety program that stresses the following measures:

> setting quantitative levels of maximum exposure averaged over a working day; notifying workers of workplace chemicals to which they are exposed; monitoring workers' exposure to workplace chemicals on a routine basis;...medical surveillance over specified time intervals; worker information and training programs; and recordkeeping.[13]

Another question addressed by the proposed regulations

concerns each state's right to set the standards which fit its own particular geographic and climatic conditions. Politics aside, scientific evidence suggests that pesticide degradation rates are dramatically affected by various factors including ambient moisture, humidity, temperature and rainfall. In hot, dry areas like California, where crops may only be grown with extensive irrigation, residues remain on foliage for long periods, unwashed by dews or rains.[14] In other places, like Florida and much of Texas, frequent precipitation accelerates the dissipation process and reduces the danger to human beings.[15] Recognizing this fact, several specialists, most notably Dr. Herbert Nigg and his collaborators, have argued that degradation rates should be calculated separately for wet and dry regions using "weather modeling" techniques that would yield different standards for each.[16]

In the ANPR, these views are reflected in a provision to "establish a full range of worker protection standards that would be set as either nationwide or regional maximums."[17] In contrast to current policies, which are designed only to "protect farmworkers from the most common risks of pesticide use," such regulations would "take into account the need for more stringent standards in areas with certain climatic conditons."

A very similar approach was recently proposed by the Texas Department of Agriculture (TDA), which drafted its own rules on farmworker safety in 1984.[18] Rather than wait until all the relevant data might be assembled, TDA developed a strict set of reentry requirements while at the same time allowing

manufacturers to provide additional information where they felt that shorter intervals were justified. Although TDA subsequently modified this procedure, EPA has suggested that new federal rules should be based upon a "worst case" evaluation of the potential hazard; where scientific arguments can be mustered, however, individual states may apply for exemptions from the national or regional norms. In fact, the Agency has already taken a major step in this direction: last October, after a decade of deliberations, it published a detailed set of instructions for conducting field exposure studies and calculating "worst case" reentry intervals.[19]

If the proposed regulations are put into practice, they might well resolve many of the major problems which have plagued EPA's actions concerning farmworker safety from the beginning--or they might not. The fact is that concrete evidence to support either view is almost unavailable and inevitably gives rise to contradictory interpretations. Unless the Agency collects such evidence, its proposals will leave unanswered several of the fundamental questions that have arisen over the past 20 years.

Primary among these is the issue of whether occupational health and safety among farmworkers have been affected by the overuse and in some cases misuse of pesticides. Using partial information from California, for example, it is possible to argue that some chemicals become substantially less dangerous when reentry periods are lengthened or when protective clothing is required, while others (like parathion) cause a more or less

fixed number of illnesses in direct proportion to the quantity applied. And yet, even such preliminary and tentative conclusions are difficult to draw because we have no idea how many workers come into contact with each of the chemicals involved and cannot calculate the poisoning incidence rates (number of cases/thousand individuals exposed) associated with each compound. Without such data, it is difficult to know whether any of the measures outlined by EPA or discussed at these hearings will effectively reduce human exposure, or whether the frequency of poisonings simply reflects changes in the pattern of pesticide use. As a result, the same data presented to justify longer reentry standards may be used to argue that a decline in illness will occur only if farmers shift to less toxic chemicals or find ways to apply relatively dangerous compounds more effectively.

Such dilemmas are compounded by another shortcoming in EPA's procedures, what Agency officials often call the "old chemicals bias": pesticides which were licensed for sale before 1974 under less stringent testing requirements do not necessarily meet today's safety standards but nonetheless continue to enjoy a significant share of major markets. Given their popularity, these chemicals represent a formidable barrier that impedes the entry of less dangerous compounds, which may take ten years to develop and cost as much as $20 million. Yet the Agency continues to license each new pesticide without considering whether its more toxic competitors should be taken out of circulation.

In fact, this problem has recently been acknowledged by EPA's Assistant Administrator for Policy, Planning and Evaluation,

Milton Russell. In an article entitled "Incentives to strengthen regulation of pesticides: the uses of regulatory reform," Russell argues that the Agency must formulate new policies which "harness these market forces in ways that better promote continuous swift replacement of registered products with safer (though perhaps still risky) ones..."[20] Specifically, he suggests that EPA should judge whether new products are less hazardous than old ones and should then subsidize the cost of registering such compounds by taxing the chemicals which they are designed to replace. Thereafter, as safer pesticides move toward commercial sale, the Agency would gradually cancel or suspend the individual uses of existing competitors until it had, in effect, reopened the market to more advanced products.

Whatever the merits of this proposal, it represents only a limited response to the problem of protecting both farmworkers and applicators. If most chemicals may be made reasonably safe by imposing adequate reentry intervals or requiring training and protective clothing, then a tax to support "new entrant grants" merely adds to the conflicting and burdensome responsibilities which EPA must already discharge without significantly enhancing its capacity to carry out existing functions. It also promises to embroil the Agency in endless controversies with the chemical industry over who should qualify for a subsidy and which products should be cancelled to make way for new entrants. And if existing compounds <u>cannot</u> be made safer by subsidizing technological innovation, then perhaps the tax proposal should be directed toward reducing overall pesticide use, or reducing

the application rate of high-risk pesticides.

Under these circumstances, Congress might well reexamine an idea which it originally rejected in 1972, namely that EPA should institute a system of "use by prescription" for pesticides similar to the one which governs pharmaceutical products. In fact, this approach has recently been adopted in Brazil by the state of Rio Grande do Sul and is also under discussion at senior levels of the Mexican government. Within the U. S., the framework for such a system has already been laid in California, which since 1972 has required farmers to consult a licensed "pest control advisor" before applying so-called restricted pesticides.

But there is another motive for stressing what goes on at EPA. As developing countries devise their own pesticide requirements, they frequently look to the Agency for guidance, advice and even specific regulations which they might adopt. Few scientific institutions in these countries can muster the expertise and resources to independently test and verify each of the standards that EPA has set. Like it or not, the Agency thus enjoys a broad responsibility to the world community that is almost unique among domestic institutions. By assessing the gaps and shortcomings in our understanding of farmworker safety, therefore, we hope to stimulate discussion of these matters and better enable regulatory officials at all levels to carry out their complex responsibilities.

III. Conclusions and Recommendations

Both in Dr. Moore's testimony and in other public statements, EPA has outlined a series of steps which it hopes will enable regulatory officials to make more informed judgments. We would like to comment on these ideas and offer a few suggestions of our own.

Of primary importance, the Agency's proposal to set much more restrictive reentry standards while allowing state exemptions where justified on scientific grounds is certainly welcome and should be adopted without delay. So should its suggestion that fieldhands must be informed about the standards in effect where they have been ordered to work. And if EPA decides to follow the same procedures as OSHA, it will have gone a long way toward overcoming one of FIFRA's major shortcomings--that it singles out agricultural workers for less than equal protection against chemical hazards.

In other respects, however, the Agency has not gone far enough in addressing the problem of occupational safety. For instance, it still favors the idea of suspending reentry limitations when certain types of protective clothing are provided--despite the fact that this position remains unsupported by solid scientific evidence. Similarly, its proposal to enforce the new regulations by "making them a part of the product label" confuses legal formalities with substantive action. EPA must undertake a serious

review of its entire enforcement program and devise a comprehensive plan to assure that the law is being obeyed.

Although such steps are important, it must be recognized that they may well not resolve the basic problems of farmworker safety. If it turns out that better reentry standards and other measures cannot reduce poisoning rates to an acceptable level, both Congress and EPA must confront the fact that more comprehensive policies are in order. In particular, they must address the argument--raised by economists at EPA--that endemic overuse of pesticides occurs because manufacturers, growers and perhaps consumers do not pay the full cost of current crop protection practices.[21] The solution to this dilemma lies in drafting a national policy of pest management similar to the one outlined in 1972.

Such a policy would simultaneously curtail occupational exposure to pesticide residues while harmonizing overall use with demonstrated need. As many specialists have argued, technologies like integrated pest management have made current crop protection practices not only wasteful but obsolete. By sharing "externalities" among beneficiaries and non-beneficiaries alike, FIFRA discourages farmers from taking advantage of these alternatives and lowering their costs. A better strategy would entail specific incentives designed simultaneously to incorporate such expenses into the price of pest control and to reward manufacturers who explore less hazardous alternatives.

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In our view, the following recommendations would lead to a more effective national policy:

A. Research Needs and Data Requirements.

1. Epidemiological Monitoring. Perhaps the most glaring weakness in EPA's data collection system involves epidemiological surveillance and monitoring. In the past, the Agency has relied largely upon passive reporting mechanisms like the Pesticide Incident Monitoring System (PIMS). But hospital admission records give no sense of how widespread pesticide exposure actually is--particularly where chronic effects are concerned. Nor will this information be obtained from better toxicological studies. Although such studies are absolutely necessary for setting registration requirements, they should be supplemented and checked by actual field data from human subjects. In this way, for example, it will be possible to verify whether local or regional exemptions from national reentry standards are justified on the ground.

The only way to carry out such studies is to monitor pesticide residue levels in human blood and urine. This program should be administered by state health authorities following a standard research protocol and uniform sampling techniques. It should be independent of on-going efforts to verify workmen's compensation claims and should be supported by federal research grants. Similarly, EPA should conduct

accurate annual state-wide surveys of pesticide use and calculate corresponding application rates for each chemical and crop. Results should be compiled by the regional EPA offices and forwarded to Washington for review and publication. Such results will guide state officials in their own regulatory activities and will enable both Congress and the public to assess how effective current procedures really are.

2. Notification. Aside from monitoring human blood and urine levels, EPA and the U. S. Public Health Service should define exactly what constitutes an acute poisoning incident and require all hospitals, private physicians and clinics to report such incidents as a "notifiable disease." This system would avoid many of the inaccuracies that characterized PIMS and would clearly reveal how many cases come to the attention of medical authorities.

3. Field Degradation Studies. Implementation of EPA's guidelines on agricultural worker reentry standards (40 CFR 158 Subsection K) depends on obtaining accurate field degradation studies of dislodgeable residues. To date, the Agency has received less than ten of these studies---even though several hundred are required by the new regulations. To rectify this deficiency, EPA should demand such data for all pesticides used on labor-intensive crops. Priority should be given to those chemicals which are most widely applied and which meet either of the following condi-

tions:

a. registration has been granted without complete information concerning major acute or chronic effects;

b. registrations standards or special review notices have been issued.

Given the fact that field degradation studies may be carried out within a single growing season, these data should be provided within one year. Specific research should also be conducted for oil-based formulations, which have the same active ingredients as other compounds but which are designed to be more persistant. Products which do not meet this one-year data requirement should automatically be suspended until the relevant evidence is forthcoming.

4. Applicator Exposure. EPA's guidelines do not address the problem of measuring direct exposure among pesticide applicators. Instead, the Agency often relies upon what it calls the "surrogate chemical approach" by which it extrapolates from data on one set of compounds to set standards for another. As many specialists have pointed out, however, such procedures are flawed because they tell us little about the most essential factor: how effectively these chemicals penetrate the surfaces on which they land. Instead of relying on the surrogate approach, then, EPA should sponsor whatever research is necessary to develop

- a uniform methodology for assessing applicator exposure similar to its procedures for setting farmworker reentry standards.

B. Strengthening EPA's Regulatory Program

1. Health and Safety. EPA should calculate occupational exposure levels for all workers employed in agriculture. These standards should be at least as high as those developed by OSHA. Even better, EPA might use the so-called "will endanger" test taken from Section 211 of the Clean Air Act (as interpreted in Ethyl Corp. v. EPA, 541 F.2nd [D. C. Cir. 1976]). This test enables the Agency to act on the basis of risk alone without a strict assessment of economic benefits. To carry out its mandate, EPA should create a new occupational health and safety branch within the Office of Pesticide Programs, which would replace the existing one-person farmworker safety unit. Revised standards for both acute and chronic exposure must be set as soon as the relevant data are collected, and should assure that agricultural workers receive the same degree of protection as other workers enjoy under OSHA.

If such data are not forthcoming in a timely fashion, the Agency should adopt a procadure now used in California under the state's Birth Defects Prevention

Act (1984), which allows officials to carry out the necessary studies themselves at the manufacturer's expense. Meanwhile, EPA should set emergency regulations by undertaking a "worst case" analysis of existing evidence. Should the studies outlined above subsequently indicate that less stringent regulations might apply in particular cases or regions, EPA or state officials may then make the appropriate adjustments. Finally, responsibility for enforcing these regulations must be transferred from state agricultural officials to health authorities, who would adhere to strict federal guidelines.

2. Reclassification of Pesticides. Classification of pesticides should be tightened to reflect the new standards and additional resources should be allocated to accomplish this task expeditiously. All pesticides should be grouped into three major categories depending on their relative toxicity, the danger of human exposure and epidemiological evidence of intoxication. Thus, for example, chemicals which do not appear to be particularly harmful in laboratory studies may turn out to cause significant damage when actually used in the field. Such information should figure into EPA's calculation of how dangerous these chemicals are and who should be permitted to apply them. Furthermore, the Agency should require manufacturers to pay a "regis-

trant's fee" for each new compound placed on the market. Such fees would be higher for chemicals in Category 1 than for those in Categories 2 or 3, and would effectively share the burden of epidemiological surveillance and monitoring with the chemical industry.

3. Protective Clothing. The best scientific information currently available suggests that protective clothing does not shield either applicators or fieldhands who must return to treated areas before the corresponding reentry periods have expired. Until safer methods are developed, EPA should enforce reentry rules with no special allowances for protective clothing except where positive scientific evidence shows that it is effective. Since very few agricultural tasks must be performed immediately after pesticides are applied, this procedure is unlikely to represent a severe hardship for most farmers and would rectify one of the most glaring inconsistancies in existing regulations.

4. Supervision of Sprayers, Mixers and Loaders. Under current regulations, certified applicators exercise general responsiblity for supervising the laborers who mix, load and spray pesticides, but need not be present when treatments occur or even give detailed instructions. At the same time, laborers do not normally receive special training in pesticide safety and quite

often suffer the highest incidence of poisoning episodes. To solve this problem, EPA should immediately assure that everyone directly involved in handling such chemicals undergoes a degree of training at least equivalent to what certified applicators now receive.

5. Enforcement. Like OSHA and the Food, Drug and Cosmetic Act, FIFRA should be observed uniformly throughout the country. To this end, EPA should set higher enforcement standards and state authorities should apply appropriate penalties (including fines) for misuse of pesticides. Various gaps and loopholes (e. g., in Sections 18 and 24(c)) should be closed and waivers granted only under extreme circumstances. In general, emphasis should shift from drafting elaborate labels to changing attitudes and behavior--a task which cannot be served by haphazard training programs.

Together with USDA, EPA should design and coordinate a major public education campaign explaining the dangers of pesticide use and should dramatically expand its efforts to reach all segments of the agricultural community: farmers, laborers, fieldhands, migrant workers, packers, etc. The cost of this campaign should be shared equally by the Agency and state governments, which would lose a portion of their enforcement grants if they failed to meet national standards. Finally, EPA should evaluate such efforts at least every two

years to detect weaknesses in emphasis and approach, and to focus on specific problems where these occur.

6. International Collaboration. Given the paucity of information on farmworker poisonings in the United States, it is not surprising that developing countries have encountered great difficulties in formulating their own policies and procedures. Even so, several of these countries--including Brazil, Mexico and Malaysia--have enacted regulations to protect farmworkers or reduce human exposure. EPA and OSHA could play a major role in facilitating this process by convening an international conference on pesticide safety each year which would underscore their willingness to collaborate bilaterally with concerned governments. A conference of this sort would reinforce the efforts of such multilateral agencies as the United Nations Environmental Program (through its International Registry of Potentially Toxic Chemicals), WHO, FAO and UNDP. More important, it would draw together a network of farmworker safety specialists with direct access to their counterparts in the U. S. and would create a mechanism for the direct exchange of common experiences.

C. A Future Agenda for FIFRA Reform

1. Use by Prescription. If these measures afford only an incomplete or partial reduction in farmworker poisonings, Congress may want to consider more fundamental changes in policy. In this case, we would suggest that it consider the idea of rewriting FIFRA to lay the groundwork for a national system of use by prescription, similar to the one that governs pharmaceutical products. Within each state, this system would be administered by environmental authorities and carried out by independent licensed pest management consultants (PMCs) who would be certified according to standards set by EPA. Their written consent and a description of the control procedures in use would be required for all pesticide applications. PMCs would be required to advise their clients about alternative strategies like IPM; their recommendations would be subject to review by state officials, who would audit these recommendations periodically to assure that they met federal and state guidelines.

2. Permits and User Fees. Once the prescription system had been implemented, growers should be compelled to request from state environmental authorities a

permit covering their annual pest management plan. Such permits would be issued upon payment of a fee which would vary depending upon the kind of chemical and the number of applications involved. Pesticides in Category I would be taxed at a significantly higher rate than chemicals in Categories 2 or 3. In every case, however, fees would reflect the real costs of carrying out related surveillance and monitoring activities, and of administering the permit system itself. Estimates of how such fees might affect production costs are included in the Appendix.

Whether these measures succeed will depend largely on EPA's lingness to develop and implement a coherent national program. past experience with FIFRA has demonstrated, partial remedies not the answer: pesticide misuse cannot be corrected by nting more detailed instructions on product labels. Congress uld accept its responsibility to take the steps that an effective :ategy demands. Like medicines, pesticides are both a vital :t of modern life and a potential hazard. In neither case ı narrow interests be allowed to set the terms of public policy. one orchard worker put it, "Chemicals are here to stay; ey're a threat, but they're also a boon... If pressure could put on employers to not go with the cheapest but the safest, ıt will be to my kid's benefit."

Notes

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3. Robert C. Spear, David L. Jenkins, and Thomas H. Wilby, "Pesticide Residues and Field Workers," Environmental Science and Technology; James H. Stamper et at., "Growth and Dissipation of Pesticide Oxons," Bulletin of Environmental Contamination and Toxicology, 27 (1981): 512-517; California Department of Food and Agriculture, "Incidence of Multiple Case Systematic Illness of Agricultural Field Workers from Exposure to Residues of Organiphosphate Pesticides in California," (Sacramento: California Department of Food and Agriculture, 1983).

4. Gunter Zweig, James D. Adams and Jerome Blondell, "Minimizing Occupational Exposure to Pesticides: Federal Reentry Standards for Farm Workers (present and proposed)," Residue Reviews 75 (1980): 103-111.

5. Task Group on Occupational Exposure to Pesticides, Occupational Exposure to Pesticides, (Washington, D.C.: Federal Working Group on Pest Management, 1974), pp. 16-25; Patricia A. Porter, The Health Status of Migrant Farmworkers, (New York: The Field Foundation, 1980); Molly Coye, "Occupational Health and Safety of Agricultural Workers in the United States" in Lawrence Busch ed., Food Security in the United States, (Boulder CO: Westview Press, 1984).

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6. Molly Joel Coye, "The Health Effects of Agricultural Production," unpublished manuscript, Department of Medicine and Division of Family Practice, University of California School of Medicine (San Francisco, 1984).

7. "Transcript of William D. Ruckelshaus' Remarks. EPA National Compliance and Enforcement Conference," The Environmental Forum, April, 1984, pp. 14-17.

8. Task Group on Occupational Exposure to Pesticides, Occupational Exposure, p. 76.

9. Dynamac Corporation, Review and Evaluation of Pesticide Applicator Exposure, Application Efficienty and Efficacy, (Rockville, MD, 1983).

10. Douglas Baugher, "Exposure to Pesticides During Application: A Critical Review of the State of the Art," prepared for World Resources Institute, Washington, D. C., 1984.

11. Environmental Protection Agency, "40 CFR 170. Worker Protection Standards for Agricultural Pesticides," Federal Register, 49 (1984): 32605-32609.

12. "Worker Protection Standards for Agricultural Practices," p. 32607.

13. "Worker Protection Standards for Agricultural Practices," p. 32608.

14. James P. Knaak, "Minimizing Occupational Exposure to Pesticides: Techniques for Establishing Safe Levels of Foliar Residues" Residue Reviews, 75 (1980): 8 1 - 9 6 ; Yutaka Iwata, "Minimizing Occupational Exposure to Pesticides: Reentry Field Data--a Recapitulation," Residue Reviews, 74 (1980): 124-147.

15. H. N. Nigg, James A. Reinert, and G. E. Fitzpatrick, "Weather-Dependent Residue Behavior of Malathion in Florida Citrus Varieties," Bulletin of Environmental Contamination and Toxicology, 21 (1979): 697-702.

16. H. N. Nigg, J. C. Allen and R. F. Brooks, "Weather and Pesticide Residues," Proceedingsof the International Society of Citriculture, 2 (1977): 437-441; Herbert Nigg and John C. Allen, "A Comparison of Time and Time-Weather Models for Predicting Parathion Disappearance under California Conditions, Environmental Science and Technology, 13 (1979): 231-233.

17. "Worker Protection Standards for Agricultural Practices," p. 32607.

18. Texas Department of Agriculture, Pesticide Safety for Texas, (Austin, TX, 1984); TDA, "Final Pesticide Regulations," (Austin, TX, December 21, 1984).

19. A description of these rules, which amend 40 CFR 158, Subsection K, may be found in James D. Adams, "Pesticide Assessment Guidelines. Subdivision K. Exposure Data Require-

ments: Reentry Protection," (Washington, D. C.: Environmental Protection Agency, 1982). The rules themselves may be found in Federal Register, 50 (1985): 159.

20. Milton Russell, "Incentives to strengthen regulation of pesticides: the uses of regulatory reform," UNEP Industry and Environment, 7 (1984): 8-12.

21. Regulatory Impact Analysis, p. 26.

(Attachments follow:)

TABLE 1

A COMPARISON OF FEDERAL AND CALIFORNIA REENTRY INTERVALS

Pesticide	California[a] Citrus	Peaches	Grapes	Apples	Federal All crops
E. Parathion[f]	30 days[b] 45 days[c] 60 days[d]	21 days	21 days	14 days	48 hours
Azinophosmethyl (Guthion)	30 days	14 days	21 days	14 days	24 hours
Ethion*	30 days	14 days	14 days	-	24 hours
M. Parathion[f]	-	21 days	14 days[e]	14 days	48 hours
EPN[f]	14 days	14 days	14 days	14 days	24 hours
Carbophenothion* (Trithion)	14 days	14 days	14 days	14 days	48 hours
Phosalone	7 days	7 days	7 days	-	24 hours
Demeton*	5 days	7 days	7 days	-	48 hours
Endrin	48 hours on all crops				48 hours
Metasystox-R	48 hours on all crops				48 hours
Azodrin	48 hours on all crops				48 hours
Bidrin	48 hours on all crops				48 hours
Chloro-benzilate	14 days	--	--	--	none
Diazinon	5 days	5 days	5 days	--	none
Dimecron* (Phosphamidon)	14 days	--	--	--	none
Dimethoate	4 days	--	4 days	--	none
Dioxathion (Delnav)	30 days	30 days	30 days	--	none
Malathion	1 day	1 day	1 day	--	none
Methiocarb (Mesurol)	--	7 days	--	--	none
Methomyl (Lannate, Nudrin)	2 days	2 days	2 days	2 days	none

TABLE 1 (continued)

Pesticide	Citrus	Peaches	Grapes	Apples	Federal
Mevinphos* (Phosdrin)	4 days	4 days	4 days	--	none
Naled (Dibrom)	1 day	1 day	1 day	--	none
Omite	--	--	7 days	--	none
Imidan	--	5 days	5 days	--	none
Sulfur	1 day	1 day	1 day	--	none
TEPP*	4 days	4 days	--	--	none
Torak	--	--	75 days	--	none
Supracide*	30 days	--	--	--	none
Disulfoton (Di-Systox)	48 hours on all crops				none
Endosulfan (Thiodan)	48 hours on all crops				none
Phorate (Thimet)	48 hours on all crops				none

Sources: California Administrative Code, Title 3, Section 2479 (I).

Federal Register, Vol. 39, No. 92, May 10, 1974, p. 16890.

(a) A 24 hour safety interval applies after each application of a toxicity category one pesticide in the production of an agricultural commodity.

(b) For all applicaiton with spray mixtures containing 2 lbs or less of actual parathion per 100 gallons, with rates of 8 lbs or less actual parathion per acre, and a total of no more than 10 lbs per acre in the previous 12 months.

(c) For all application with spray mixtures containing 2 lbs or less of actual parathion per 100 gallons, with rates of more than 8 lbs actual parathion per acre, or more than 10 lbs per acre in the previous 12 months.

(d) For all applications with spray mixtures containing more than 2 lbs of actual parathion per 100 gallons.

TABLE 1 (continued)

(e) The safety interval for methly parathion on grapes in Monterey County is 6 days. If encapsulated methyl parathion is used on grapes, the safety interval shall be 21 days in all counties.

(#) When more than one pound per acre of actual parathion, methyl parathion or EPN is applied singly or in combination to any plant, a 14 day safety interval applies.

(*) A 48 hour safety interval applies after each application of this pesticide in the production of an agricultural commodity.

Table 2: Agricultural Pesticide Enforcement Actions, FY 1981-1983

	Type	1981	1982/83 Average	% Change
1.	Inspections	6,598	6,814.5	3.3
2.	Civil Actions	89	43	-51.7
3.	Criminal Actions	49	28	-42.9
4.	Suspension of license	34	28	-17.6
5.	Revocation of license	140	10.5	-92.5
6.	Warning	732	604	-17.5
7.	Referred to EPA	33	13	-60.6
8.	Administration hearing	92	102	10.9
9.	Other Action	43	84	95.3
10.	Total Actionable Inspections	1,268	958	-24.4
11.	% Resulting in Action	19.2	14.1	-26.6
12.	Number of Fines	71	35	-50.7

Source: EPA, "Enforcement Actions Resulting from Grant Inspections," 1981, 1982 1983

STATEMENT OF THE NATIONAL COTTON COUNCIL OF AMERICA
ON THE
FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT
BEFORE THE
SUBCOMMITTEE ON DEPARTMENT OPERATIONS, RESEARCH & FOREIGN AGRICULTURE OF THE
HOUSE COMMITTEE ON AGRICULTURE
BY
LLOYD CLINE, VICE PRESIDENT
MAY 21, 1985

Mr. Chairman and Members of the Subcommittee:

I am Lloyd Cline, Cotton Producer from Lamesa, Texas and Vice President of the National Cotton Council. I appear here as a concerned farmer and on behalf of the Council which represents producers, ginners, seed crushers, warehousemen, merchants, cooperatives, and textile manufacturers from the Carolinas to California.

The cotton industry strongly supports a clean environment and safe use of chemicals. However, we are gravely concerned about the continued availability of essential pesticides that are currently registered, and about the development and registration of new pesticides that are safer, more effective and less expensive.

We recognize the need for, and support, reasonable regulations for pesticides. However, we are concerned about imposition of unnecessary rules that would make many essential pesticides unavailable to farmers even though they are registered and in the marketplace.

At the Council's 1985 Annual Meeting, delegates representing all seven segments of the U. S. cotton industry unanimously adopted the following resolution on pesticides:

> Continue supporting legislation and other measures to facilitate sound development and use of essential agricultural chemicals, and, in particular:
>
> - Urge continued registration of vital cotton pesticides unless there is valid, scientific proof that their use presents an imminent hazard or that the risks outweigh the benefits;
>
> - Urge expeditious clearance of critically needed new pesticides, and support efforts to develop procedures for more efficient negotiation of state emergency exemptions of pesticide product use;
>
> - Urge that buffer zones, minimum dilutions, and other pesticide application restrictions be imposed only upon valid, scientific proof that they are necessary to prevent a physical health hazard to humans or animals; and,
>
> - Support reform of pesticide law to establish the clear policy of national uniformity in the establishment of tolerances for pesticide residues in food.

Mr. Chairman, we have not had an opportunity to review any specific new FIFRA legislation that may have been introduced. It is our understanding that what became known as the "Harper's Ferry Bill" in the last Congress has been reintroduced in the Senate as S-309 and may be reintroduced in the House. The Council testified on this Bill as H.R. 3818 before this Subcommittee during the last Congress on October 6, 1983.

Basically, we support a simple one- or two-year reauthorization of FIFRA. However, there are some serious concerns we would like to discuss as concepts that should be considered if the Act is opened for amendments.

Federal Preemption for Setting Tolerances -- We strongly support Federal preemption for setting pesticide residue tolerances. States should be prohibited from setting tolerances. Agricultural commodities and products must move across state lines. We know you can appreciate the mass confusion and problems encountered if we have 50 different tolerances for the same pesticide on the same commodity. States shouldn't even have authority to set the same tolerances as the Federal government because it would only add more costs and regulatory burdens without providing any benefits.

Federal and State Preemption for Overall FIFRA Authority -- When the major overhaul of FIFRA was made with the 1972 amendments, Congress gave authority to regulate pesticide only to the Federal

and State governments. Yet, there have been numerous incidents where city and county governments have embarked on efforts to regulate pesticides at the local levels. Having different local regulations will create unworkable situations for farmers and other pesticide users. Congress should make it clear that state pesticide regulatory authority does not extend to local jurisdictions.

Use of Restricted-Use Pesticides -- In 1972 Congress wisely provided under FIFRA that restricted-use pesticides may be applied by a certified applicator or by a person under the direct supervision of a certified applicator. We understand that EPA and possibly some others have suggested that FIFRA be amended to eliminate the provision that allows restricted-use pesticides to be used "under the direct supervision" of a certified applicator. The justification given is that under the present statutory language, the Agency's ability to limit use to competent applicators can (emphasis added) be easily thwarted.

No one has presented any factual evidence to show that there have been problems under the present statutory language. We contend that removing the phrase "under the direct supervision of a certified applicator" will create hardships on farmers whether or not it is the farmer himself or someone else such as a private agricultural consultant hired by the farmer who is the certified applicator that supervises the use.

Lack of Essentiality Should Not Be a Criteria Against Pesticides -- Under Section 3 of FIFRA, Congress provided that lack of essentiality should not be a criteria for denying registration of a pesticide. That is, just because a pesticide is already registered for the same use, another pesticide should not be denied registration for that use. EPA is thwarting Congressional intent by saying that the "lack of essentiality" provision in the law does not apply to conditional registrations. Practically all new products are being given conditional rather than full registration.

We believe that Congress' intent also was that EPA would not use lack of essentiality as a criteria for cancelling pesticides, yet the Agency continues to do so in connection with Special Reviews (formerly referred to as Rebuttable Presumption Against Registration).

Congress should make its intent in this regard clear to EPA.

Indemnification and Disposal -- When EPA suspends and later cancels registration of a pesticide, the Agency is required by law to indemnify owners of existing stocks and to pay for disposal of those stocks. We support keeping such statutory requirements. However, we think that farmers who have existing stocks on hand should have the option of using them for labeled uses unless it can be shown that the dangers in allowing such use are too great to risk allowing such an option.

Imported Agricultural Commodities -- U.S. farmers are in the worst financial shape since the great depression. It is bad enough for us to have to compete with foreign producers who receive production and export incentives. For our own government to create incentives for foreign imports of competing commodities into this country is a slap in the face to U.S. agriculture. We strongly favor requiring all imported agricultural commodities and processed products from those commodities to meet our residue tolerance standards.

Pesticide Residue Action Levels -- A recent decision by the U.S. Circuit Court of Appeals for the District of Columbia raises doubt about EPA's authority to set pesticide residue action levels. The Court said that FDA had no authority to set action levels for aflatoxin, a naturally occurring toxin, in corn and other commodities. It said that FDA is statutorily required to establish tolerances through the formal process.

We feel strongly that both FDA and EPA need authority to set action levels. There are several situations where pesticide tolerances are not appropriate and where the Agency has set needed action levels. FIFRA should be amended to make clear that the Agency has statutory authority to set pesticide action levels.

Private Right of Action -- We strongly oppose any amendment to insert a "private right-of-action" provision in FIFRA. This would

create a Pandora's box. Any person who felt aggrieved by supposed (emphasis added) misuse of a pesticide could bring suit against farmers and ranchers. Instead of enhancing protections under FIFRA, such a provision will encourage law suits. Congress has considered similar proposed amendments before and had the wisdom to reject them. The current remedies under FIFRA and other statutes are adequate.

Public Standing to Initiate Cancellation Hearings, Etc. -- We also strongly oppose any new provisions to give the public standing to initiate suspension or cancellation hearings. Our reasons are similar to those we have stated for our opposition to private right-of-action provisions.

Registration Guidelines -- Considerable progress has been made by EPA in developing guidelines so that potential pesticide registrants will know what the registration requirements are. Yet, we continue to hear of numerous incidents of chemical companies conducting all the tests and obtaining the data called for in the guidelines, and the Agency delaying registration by adding additional requirements not covered in the guidelines. In a few cases, it seems that EPA doesn't know what it wants. A specific example is the case of aquatic or pond studies. The Agency won't tell the potential registrant what type of pond study will satisfy the requirements for registration.

EPA vs. OSHA Jurisdiction -- FIFRA preempts pesticide exposure standards and regulations to EPA. Some anti-pesticide groups have advocated transfer of jurisdiction regarding pesticides in workplaces, including farm workplaces, from EPA to OSHA.

In the early 1970's, a jurisdictional squabble between EPA and OSHA arose with regard to pesticide-treated field reentry standards. The Council and other farm groups endorsed the obvious statutory authority of EPA. We thought this issue was settled for good.

EPA has recently suggested that FIFRA could be amended so that EPA actions do not preempt OSHA provided that OSHA's actions are not inconsistent.

We strongly oppose transferring any authority over the farm use of pesticides under FIFRA to OSHA from EPA. Even if the actions by both agencies are consistent, the result will be additonal unneeded regulatory burdens on farmers and increased overall Federal costs without upgrading the safety level of farmers and farmworkers.

Pesticide Application Standards -- The current Federal pesticide application standards are adequate and workable. We support them. We, of course, also support regulations which promote safe application and use of pesticides. Along the same line, we oppose careless and irresponsible pesticide use that could endanger the

health and property of persons in and around pesticide-treated fields.

We strongly oppose establishment of unnecessary buffer zones, unworkable notification requirements, and other application standards unless there is valid scientific proof that they are necessary to prevent a physical health hazard to humans or animals.

Pesticide Registration Fees -- Rather large fees are established for setting pesticide residue tolerances. These fees, in a sense, are registration fees since tolerances are required for registration in most cases. We don't believe that additional registration fees should be imposed on registrants. They would result in higher pesticide costs that would be passed on to farmers and ranchers who, historically, have not been able to pass on such costs to consumers of farm and ranch products. For minor uses (uses with low market potentials), imposition of additional fees for pesticide approval could actually be a major factor in a company's decision not to pursue registration.

Adjudicatory Hearings and Special Reviews -- EPA has let it be known that the Agency would like for FIFRA to be amended to eliminate adjudicatory hearings and to convert the current public notice and comment period into informal rulemaking. Because of the serious consequences of the outcome on farmers and ranchers, we do not think the current 2-stage process -- (1) public notice

and comment and (2) adjudicatory process -- is too long. Neither is it unfair. We have serious reservations about eliminating adjudicatory hearings.

Emergency Use of Pesticides -- Section 18 of FIFRA provides for exempting Federal and State agencies from provisions of the act in order to use pesticides under emergency conditions. EPA felt that the regulations promulgating Section 18 needed to be revised.

We want to commend the Agency for the new approach it took. Rather than developing new regulations internally and then proposing them, a 21-member Negotiating Committee was established to write new regulations which the Agency was committed to propose. The members of this Committee represented farm organizations and other user groups, environmental organizations, the agricultural chemicals industry, state pesticide and health agencies, USDA, and EPA.

We would like to see EPA take such an approach on more of the major pesticide regulatory issues.

Mr. Chairman and members of the Subcommittee, we appreciate having this opportunity to express our views on FIFRA legislation and related pesticide regulatory matters.

STATEMENT OF
HAROLD M. COLLINS
EXECUTIVE DIRECTOR
NATIONAL AGRICULTURAL AVIATION ASSOCIATION

BEFORE THE
SUBCOMMITTEE ON DEPARTMENT OPERATIONS,
RESEARCH AND FOREIGN AGRICULTURE
OF THE
COMMITTEE ON AGRICULTURE,
UNITED STATES HOUSE OF REPRESENTATIVES
May 21, 1985

Mr. Chairman:

My name is Harold Collins and I am employed as Executive Director of the National Agricultural Aviation Association (NAAA).

Headquartered in Washington, DC, NAAA is a federation of state and regional associations throughout the United States. Members of the association include individual agricultural aviation businesses, agricultural pilots, allied industries who supply the products and services used by the operators, and international persons and/or companies from 18 nations around the world.

Agricultural aviation in this country is comprised of nearly 3,000 operating businesses which own and operate approximately 10,000 aircraft, of which approximately 900 are helicopters. The remainder are fixed-wing aircraft. Flying approximately 2,600,000 hours annually, applying fertilizer, seed, and crop protection chemicals, the ag air

fleet treats 180,000,000 acres of land at least once each year. Considering repetitive applications to the same acre of land, total annual treatment could approach 380,000,000 acres. It has been estimated that agriclultural aviation is responsible for approximately 10% of this nation's $134 billion food and fiber production. We are proud of the fact that this work is accomplished with 90,000,000 gallons of aviation fuel per year, providing very efficient energy utilization.

With regard to this hearing the NAAA has not had sufficient time to communicate with its Board of Directors and Legislative Committee in order to adequately respond to H.R. 2482. As a consequence Mr. Chairman, we respectfully request that the association be permitted to provide additional comment in the future in a time frame consistant with the subcommittee's needs.

Based on the testimony of Rep. Seiberling yesterday I would like to relate to the subcommittee that EPA did not ban the aerial application of Lasso (alachlor). That was entirely a Monsanto decision according to Mr. Steve Shatzow, Director of EPA's Office of Pesicide Programs. I personally advised Mr. Seiberling on this matter immediately following his testimony. Indeed, Monsanto has provided the EPA with new data that may return the aerial method of application to the Lasso label.

In addition to future comment NAA would like to offer the following thoughts for committee consideration.

Earlier this year NAAA participated in and was one of numerous sponsors of a pesticide waste disposal conference in Denver, Colorado. Attendees included state, federal and public entities vitally concerned with pesticide waste disposal. NAAA's observations as a result of that conference are attached via copy from the association magazine.

Based on ideas generated at that conference, NAAA would like this subcommittee to consider requiring that pesticide waste disposal be regulated exclusively under Sec. 19 of the FIFRA rather than the Resource Conservation and Recovery Act (RCRA). We believe that private and commerical pesticide applicators alike are unable to comply with RCRA. If we use existing technology to create waste disposal regulations under FIFRA that are practical and attainable, I believe the agricultural community would welcome the opportunity to be able to comply with the law.

Mr. Chairman, it seems to NAAA that medical studies of long time pesticide users in the agricultural community could provide strong evidence of health consequences associated with pesticide exposure. Such a study could even reduce the conjecture associated with laboratory animal test data which we try to extrapolate into human

terms. We would certainly end up knowing more than we know today.

NAAA would like to suggest that EPA conduct a nationwide health study of pesticide users. We suggest this because agricultural pesticide users as a group are voluntarily and repetitively exposed to pesticides at levels greater than the general public. This dose response relationship should provide valuable knowledge to the medical world.

In 1978 the NAAA funded an epidemiological study of ag pilots, their spouses and children. A copy of that study is attached. The association funded the study because the EPA, USDA and FAA denied in writing any interest in such a study. The control group for the NAAA study was the siblings of the ag pilots, their spouses and children as long as they had no involvement with aerial application, pesticides or farming. The results, although not statistically significant, indicated that the ag pilot group was somewhat healthier. The survey concluded that the absence of a difference is important. A nearly identical study of wheat growers in the U.S. produced similar results. In this case however the better health of the wheat grower was statistically significant.

NAAA appreciates the work this committee has accomplished on pesticide legislation over many years. We commend and support your continued singular oversight on these issues.

(Attachments follow:)

Editorial

Nearly 400 people from industry, state and federal government, universities, and the pesticide user community attended the first National Workshop on Pesticide Wastes Disposal in Denver, Colorado on January 28–29, 1985. Widespread interest in the workshop's topic exceeded the planning committee's early estimate of 150 attendees.

The workshop did not solve the pesticide user's waste disposal problems, but it was a beginning. For the first time, we learned from experts where we are, what we need to accomplish, and the problems which need to be resolved along the route of compliance with the Resource Conservation and Recovery Act (RCRA). Workshop chairman, Roy Detweiler of DuPont is to be commended for his leadership in planning and conducting the meeting.

From this association's point of view, here are the major findings and suggestions generated by the workshop.

1. Commercial and private pesticide users are technologically unable to fully comply with RCRA at this time.
2. Instead of accumulating vast quantities of hazardous wastes in one site and hauling it over long distances to a limited number of disposal facilities, it might be more sensible to develop portable, economical, and durable disposal systems which service a local area.
3. RCRA itself is inhibiting needed research and innovation. The financial and legal consequences for disposal errors made in good faith are scaring off the private investor.
4. Pesticide wastes generated in the 1950s and up to the enactment of RCRA should be considered apart from wastes generated after RCRA. Perhaps a moritorium on all wastes site enforcement actions involving dollar penalties would be in order until science has a chance to address the problem.
5. Exemptions from hazardous wastes regulations need to be uniform. When two generators create equivalent quantities of waste and only one is regulated, something is wrong with the law.
6. Disposal techniques presented at the workshop should be given practical field trials during the 1985 growing season. Reports on the results of such work should be presented at the second National Workshop in 1986.
7. The cost of compliance with RCRA may require cost sharing over wide segments of the population.

One-Stop Shopping A Way to Help Pesticide Waste Generators

A highlight of the workshop was the one-stop-shopping concept introduced by O. R. Ehart, a pesticide regulatory official from Wisconsin. Simply put, the agricultural community already has a long-term, well-structured and effective system of communication between the Department of Agriculture, land grant universities, and state lead agencies.

Today, agricultural users of pesticides are being asked to expand this communication to Departments of Environmental Resources, Transportation, Health, Water, Air Pollution, etc. As a result, there is confusion and probable duplication of work. If all needs for information exchange were funneled in and back out through our existing agricultural communications network, a better understanding of the law would be accomplished along with a greater chance for compliance.

Harold Collins

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Spontaneous Abortions, Stillbirths, and Birth Defects in Families of Agricultural Pilots

C. C. ROAN, Ph.D.
G. E. MATANOSKI, M.D., Dr. P.H.
C. Q. McILNAY, M.S.
K. L. OLDS, M.A.
F. PYLANT
J. R. TROUT, Ph.D.
P. WHEELER, R.N., M.P.H.
D. P. MORGAN, M.D., Ph.D.
Hopes Consulting, Inc.
2415 Buena Vista
Manhattan, Kansas 66502

ABSTRACT. Families engaged in Agricultural Aviation (314) and cooperating sibling families, not occupationally exposed to pesticides (178) provided information, in response to a questionnaire, on their general health status and pregnancy outcomes. These two groups were comparable in age, height, weight, and years of education. Statistical evaluation confirmed the null hypothesis with respect to total pregnancies, number of male or female children, spontaneous abortions, and birth defects.

THE UBIQUITOUS NATURE of many pesticides, demonstrable via exceptionally sensitive analytic technology, assures some level of pesticide exposure for the general public. In the case of 2,2-di[*p*-chlorophenyl]-1,1,1-trichloroethane (DDT) and other persistent pesticides this status has been verified by numerous studies.[1-6]

Possible adverse health effects of both public and occupational exposures to DDT were explored in 1944.[7,8] An investigation of the storage and excretion of DDT and its metabolites in man was completed a decade later.[9] Studies of qualitative and quantitative occupational exposures to pesticides have been abundant since the 1960s.[10-11]

Because of the exceptional acute toxicity of some organic phosphorus and carbamate pesticides, they have been the subject of extensive research.[14-18] These studies substantiate that occupational exposures to pesticide applicators are significantly higher than the exposures experienced by the public.

Although there have been numerous investigations[19-26] of possible acute and chronic effects associated with occupational exposures to pesticides, few studies have involved reproductive effects.

Possible adverse reproductive effects must be considered in toxicology, and such effects are apparently among those most feared by the public. Unfortunately, reproductive studies in animals do not exclude the possibility that human beings may be more susceptible than test animals to certain compounds. One startling example of such susceptibility is the case of dibromochloropropane.[27] Another pesticidial fumigant chemical, ethylene dibromide, has also been the subject of investigation for its reproductive toxicity.[28] The

design and conduct of studies involving the hazards to reproduction of occupational chemical exposures are exceptionally complex.[29-31] The most easily obtained information that may have some significance to this subject is sex ratio, fertility, spontaneous abortions, and birth defects.[30] In addition to the impact of occupational chemical exposures on reproduction are the complications of alcohol, tobacco, over the counter and prescription drug use, anaesthesia, and radiation exposures. Increasing interest is being shown in the subject of reproductive hazards in the work place.

The present study was initiated in 1978 at the request of the National Agricultural Aviation Association after their request for such a study was rejected by the United States Department of Agriculture, the Environmental Protection Agency, and the Federal Aviation Association. Agricultural Pilots, the most stable employment group in this industry, were selected because previously cited investigations indicated that their exposures are sufficient to make such a study meaningful.

METHODS

The National Agricultural Aviation Association provided membership lists for 1978 as a source for the selection of a study group. Based on this membership list a target group of 75% of the estimated number of pilots was established. Questionnaires (780 sets) were provided to each state and regional association affiliated with the national association for distribution at local meetings or by other methods available. A "questionnaire set" included a questionnaire to be completed by an Agricultural Pilot and his spouse, and an identical questionnaire to be sent by the pilot volunteer to a sibling (and spouse) who had never been engaged in agricultural aviation. The sibling control group was chosen to assure a close demographic match and to control for genetic factors. Matched pair evaluations were employed only when the data warranted this approach. The numbers of spouses do not match because of divorce, death, etc. The responses to this approach appear in Table 1. Participation was voluntary, which resulted in "self-selection." Direct mailing to individuals selected randomly would have resulted in lower returns since the responses would still have been voluntary.

Spontaneous abortion and stillbirth information provided by the responses of females have been used since the sibling females had the higher response rate as compared with the males. Sex ratio data were provided by male respondents. Birth defect data were requested from male respondents only.

Table 1.—Number of Responses Received from the Various State and Regional Organizations of the National Agricultural Aviation Association

Group	Geographical Areas				Total	%*
	1	2	3	4		
Pilots	47	46	84	137	314	40
Control Males†	29	20	31	70	150	19
Pilots' Wives	32	34	70	108	244	31
Control Wives†	54	20	33	71	178	22

NOTES: Area 1: Maine, New Hampshire, Vermont, Connecticut, New York, Pennsylvania, Massachusetts, Maryland, New Jersey, Delaware, Virginia, West Virginia, Rhode Island, Ohio, Illinois, Indiana, Michigan, Wisconsin, Kentucky; Area 2: Tennessee, North Carolina, South Carolina, Georgia, Alabama, Florida, Mississippi; Area 3: California, Arizona, New Mexico, Texas, Arkansas, Louisiana, Oklahoma; Area 4: Minnesota, Iowa, Kansas, Nebraska, Missoun, North Dakota, South Dakota, Colorado, Montana, Idaho, Utah, Nevada, Oregan. Washington, Wyoming.

* Percent of target group responding.

† Control males are brothers and brothers-in-law. Control wives are sisters and sisters-in-law.

Table 2.—Years of Experience in Agricultural Aviation

Years	No. Pilots	%
1-5	33	11
6-10	74	24
11-15	55	18
16-20	22	7
>21	128	41

RESULTS

The data in Table 2 indicate the general agricultural experience of this group of pilots. The fact that the majority have more than 15 yr of agricultural aviation experience is not unexpected since such a highly skilled group might be expected to be stable in employment. Information concerning the number and frequency of pesticide intoxications resulting in lost work days in the pilot group have been summarized recently.[32]

Weight, height, age, and educational level are summarized in Table 3. Inspection of these data does not indicate any statistically significant differences with regard to the characteristics recorded.

The data for overall reproductive performance, based on data supplied by female respondents of these two study groups, appear in Table 4. Chi square analysis of the data does not reveal any statistically significant differences between these two study groups with regard to age distribution or the number of live births. Comparisons of the spontaneous abortions and stillbirths reported by these two study groups likewise fail to reveal any statistically significant differences.

The data on sex ratios, obtained from the male respondents, appear in Table 5 on the basis of the decade of the births reported. These data do not suggest any differences in the number of children or the sex ratios based on the group data for the period covered. Com-

Table 3.—Average Characteristics of the Study Groups

	Pilots	Control Males	Pilots' Wives	Control Females
No. in Group	314	150	244	178
Characteristic				
Age (yr)	44	43	42	42
Education (yr)	13	14	13	14
Height (in)	70	70	65	65
Weight (lb)	184	182	134	138

parison of these data with those reported by the spouses in Table 4 support the similarity of the two groups.

Since the predominate occupational pesticide exposures were experienced by the pilot group, information regarding birth defects was obtained from male respondents only. These data were obtained in the questionnaire in response to the following: "If any of your children were born with or later developed any of the following conditions, please write in the number of the child (from question 8) and his/her age when the condition developed." The respondent was provided with a tabular list of 33 possible defects and the usual "other" category. Using this information from unmatched samples, i.e., not every pilot had data from a brother's or sister's family, the data in Table 6 were obtained.

Grouping the reported defects, based on the data from the unequal population sizes in Table 6 into major, musculoskeletal, and other significant defects for statistical analysis did not reveal any significant differences using the chi square analysis.

The number of individuals in a group reporting any defects has a greater significance than the total number of defects reported from the group. The use of the epidemiological concept of case matching provides a more precise approach to phenomena of low frequency such as birth defects. The data in Table 7, therefore, provides an additional basis for not rejecting the null hypothesis in the case of the birth defects.

DISCUSSION

Despite the fact that responses were less than targeted, the data reported here shed some light on the reproductive hazards possibly associated with pesticide

Table 4.—Reproductive Performance* in the Two Study Groups

	Control Wives		Pilots' Wives	
Number of Respondents	178		244	
Number of Respondents Reporting any Pregnancies	133		221	
Age Range	Pregnancies	Spontaneous† Abortions	Pregnancies	Spontaneous Abortions
15–19	30	3	61	3
20–24	166	17	271	17
25–29	115	10	184	10
30–34	66	10	99	17
35–39	15	3	31	1
40–44	4	NR	5	NR
$\chi^2 = 17.8896$, $df = 15$, $P = .27$				
SUMMARY				
Live births	350		588	
Spontaneous abortions and stillbirths	43		60	
$\chi^2 = 0.7509$, $df = 1$, $P = .6094$				
Live births per respondent reporting any pregnancies	2.63		2.66	
Live births per pregnancy	0.89		0.91	

* Pregnancies include those before marriage to the respondent spouse.
† Includes stillbirths.

Table 5.—Decade of Children's Birth and Sex of Child*

Decade	Pilot		Control	
	Male	Female	Male	Female
1921-30	4	1	1	3
1931-40	1	4	2	2
1941-50	37	44	23	16
1951-60	124	98	36	37
1961-70	110	124	59	59
1971-80	95	88	41	33
$x^2 = 19.0528$, $df = 15$, $P = .2135$				
Ratio of male/female	1.03		1.08	

* Data reported by male respondents.

exposures. To the extent that weight, height, age, and educational level are valuable socioeconomic indicators, the concept of sibling control groups appears justified. Data cited on the acute intoxications causing lost work days[32] indicate that exposure potentials are considerable. Although the overall reproductive performance of the pilots and spouses are not in essence different than that reported by their siblings, the statement, "... in general it is unusual for reproductive toxic effects to be observed at otherwise non-toxic doses."[30] caused us to review the responses from those individuals reporting pesticide intoxications. We failed to find any relationship between pesticide intoxication, as reported, and reproductive performance.

The fact that spontaneous abortion rates—10.9% for control wives and 9.26% for pilot wives—were considerably lower than the commonly accepted 15%[29] may well be a reflection of the socioeconomic status of these groups. There was certainly no adverse effect on spontaneous abortion rates experienced by the pilot groups.

The size of the study groups makes it impossible to make meaningful comparisons with general population birth defect data. The internal comparisons between the two male study groups failed to reveal any significant differences. It would generally be remarkable to see differences in birth defects without rather parallel differences in the spontaneous abortion rates.

Although data on the use of tobacco, alcohol, a variety of prescription drugs, etc. were collected it is pointless to examine these data in detail in view of the lack of differences in sex ratios, spontaneous abortions, and birth defects. Data on general family health, particularly children's health, were also obtained. Our evaluation of these data have not revealed any remarkable differences. We were surprised to discover five female pilots employed in agricultural aviation. This group is too small at present to be evaluated separately.

Table 6.—Birth Defects Reported by Pilots and Control Males

Ever Married	Pilots 306	Control Males 138
Defects		
Hydrocephalus	1	0
Down's syndrome	1	0
Cerebral palsy	2	2
Deafness	1	1
Hare lip/cleft palate	1	0
Congenital heart defect	7	0
Pyloric stenosis	1	2
Occluded/duplicated intestine	3	1
Cystic fibrosis	1	0
Displaced kidney	2	1
Malformed reproductive organs	5	2
Defective hip	3	0
Bone cysts	1	1
Club foot	2	1
Severe bow legs	0	1
Congenital hernia	5	7
Other	7	2
Total defects	43	20
Parents reporting defects	47	17
$x^2 = 0.4505$, $df = 1$, $P = .5095$		
Defects per 100 live births	5.9	6.4

Table 7.—Evaluation of Pair-Matched Individuals Reporting Birth Defects

		Pilots	
		yes	no
Control males	yes	2	17
	no	19	77

$x^2 = 1.282$, $df = 1$, $P = .2567$; relative risk = 19/17 = 1.12.

CONCLUSIONS

Although it is not possible to document the specific pesticide exposures of the group of agricultural pilots providing data for this study, the fact that their overall exposures to pesticides are higher than those sustained by the general population is well established. Occupational data available from the sibling group did not indicate any occupational pesticide exposure.

There were no significant differences between the pilot families and their siblings' families regarding age, weight, height, education, children per couple, sex ratio, spontaneous abortions, ages of live births or other termination of pregnancy, or number of birth defects among their offspring. The group sizes were small and there is no certain basis for concluding that there is a complete absence of a pesticide effect in the reproductive data collected and evaluated.

Because of the increasing probability of female exposures in the work place we strongly recommend that, to the extent it is consistent with biological facts, identical data be obtained from both male and female respondents.

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Requests for reprints should be sent to: Clifford C. Roan, Hopes Consulting Inc., 2415 Buena Vista, Manhattan, Kansas 66502.

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TESTIMONY BY CONGRESSMAN CEC HEFTEL

before the

SUBCOMMITTEE ON DEPARTMENT OPERATIONS,
RESEARCH, AND FOREIGN OPERATIONS

MAY 23, 1985

Mr. Chairman and members of the committee, I am pleased to be here today to testify on an aspect of the Federal Insecticide, Fungicide, and Rodenticide Act that has gone too long without sufficient attention. Specifically, I am here today to focus on the international provisions of FIFRA, and to discuss legislation I introduced, H.R. 1416, which addresses these provisions.

The safe use of pesticides in the U.S. and abroad is an issue of increasing concern to us all. We read regularly about pesticide mishaps Some are in the form of pesticides turning up in groundwater consumed by humans or wildlife, some involve villages in foreign countries being wiped out because people misused a pesticide or did not dispose of it properly. It is increasingly clear that our technology to develop new chemical weapons against pests has far outpaced our knowledge of their longterm human and environmental effects.

The Environmental Protection Agency knows with some precision which pesticides are used in the United States. Pesticide labels are required to provide information that shows what crops the pesticides can be used on, in what quantities and under what conditions. The system is far from perfect yet it does provide government agencies with some guidance on what pesticide residues should be looked for when monitoring domestic food products.

Yet we have very little useful information on pesticide use abroad. The findings of routine testing on imported foods shows that many more pesticide products are routinely used overseas, including many previously cancelled or suspended in the U.S. We also know that these products are often used at greater concentrations per acre with less care and precision These facts all suggest that we should exercise extra diligence in monitoring imported foods. Yet we do far less with almost no accurate information to guide us.

Strict control over pesticide residues on food products serves two functions it protects American consumers from unsafe residues on food products; and it helps assure that our farmers do not have to compete with overseas growers who are able to apply a far more potent arsenal of chemical pest control agents. Without the the protection offered by aggressive, comprehensive pesticide residue testing we have a system that is unfair unwarranted, and unwise. Furthermore as the leader of the western world and as the world's largest importer of food commodities, we have an obligation to promote the safe use of pesticides.

I have drafted legislation, H.R.1416, that addresses some of these pesticide inconsistencies. In all honesty though, I am not satisfied that the bill is dramatic enough. Ideally we should ban the export of any pesticide that is not registered for use in this country and we should ban the import of any food commodity that has been treated with a pesticide not registered here. I recognize, however, that this would be politically unfeasible, and that many would accuse Congress of trying to create trade barriers. Certain pesticide manufacturers have already indicated that they would respond to such a mandate by simply moving their operations abroad.

No provision in H.R. 1416 would hamper American export of pesticides or make it difficult for American companies to compete in the worldwide pesticide market. Rather, the thrust of the bill is to increase the content and transfer of information to EPA about pesticides which are exported from our country, their ultimate destination and the food crops to which they will be applied.

A modified notification process would be triggered for pesticides that are banned, pesticides that are available only for restricted use in the U S because of acute mammalian toxicity, and pesticides that have never been registered for use in our country. The expanded notification process would require importing nations to acknowledge their understanding of the dangers of such pesticides and includes several new measures designed to heighten awareness in the importing nation regarding how to use and dispose of these pesticide products. H.R. 1416 would also direct our government agencies which are involved in pesticide regulation to share information among themselves, and would further authorize the EPA and other agencies to work on a cooperative basis with other nations who request assistance from the U.S. in evaluating pesticide safety issues.

These provisions are designed to assure more equal safety standards throughout the world a change that will in fact directly benefit U.S. pesticide companies which are already well-ahead of most competitors in developing nations. Adoption of the provisions in H.R. 1416 would assure the world that America is a good trading partner, and that we do not view and treat the rest of the world as a dumping ground.

H.R. 1416 is also a step toward assuring that we are not undermining the safety precautions and costs imposed on American farmers by tolerating a pesticide residue double-standard for food produced here and abroad. Our farmers are required to use safer, often more expensive pesticides, and it is unfair that they should have to compete on such an inequitable basis, especially when legitimate human health concerns are also involved.

Mr. Chairman, as pesticide use around the world continues to increase, so do the dangers involved. Evidence accumulated over the past few years documents the problems and potential for pesticide abuse abroad. There have already been several major disasters overseas involving pesticide misuse, and I hope we act on this matter so that our own citizens can rest assured that they are not also paying a heavy price for inadequate protection. If we act now to codify the types of information and environmental protection technology called for by this bill, we might head off a serious crisis in future years.

Thank you, Mr. Chairman and members of the committee, for your attention to this matter.

STATEMENT OF MILAN P. YAGER,

LEGISLATIVE DIRECTOR,

UNITED FRESH FRUIT AND VEGETABLE ASSOCIATION

BEFORE THE

SUBCOMMITTEE ON DEPARTMENT OPERATIONS,

RESEARCH AND FOREIGN AGRICULTURE,

COMMITTEE ON AGRICULTURE

UNITED STATES HOUSE OF REPRESENTATIVES

May 21, 1985

Mr. Chairman, I am Milan P. Yager, Legislative Director of United Fresh Fruit and Vegetable Association (United). It is a great honor for me to appear before your committee and to share with you the thoughts of United's membership.

The United Fresh Fruit and Vegetable Association is the national trade association for the fresh fruit and vegetable industry, representing 2,500 member companies and organizations throughout the United States and in 14 countries. The membership is involved in all facets of the fresh produce industry, including growing, packing, shipping, wholesaling, distributing, retailing and transporting fresh fruit and vegetables to American consumers. United's members handle over 80 percent of all fresh produce marketed commercially in the United States.

Our members take an active interest in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as users of federally registered pesticides, as consumers of food products--guaranteed safe by established tolerances, and as citizens interested in the protection of our environment from hazardous chemicals. We agree with the comment Assistant Administrator John Moore made before the committee on April 18, when he said the FIFRA was a fundamentally sound environmental statute. We believe, however, the FIFRA is also a sound agricultural statute. With advances in agricultural sciences, modern agricultural pesticides have helped American farmers produce the safest and most wholesome food in the world. Food that is abundant, available, affordable and appealing. However, this is not an easy task. Farmers are confronted with a never ending battle against 800,000 species of insects, 100,000 plant diseases, 30,000 species of weeds and 3,000 species of nematodes. It is estimated that we annually lose 30 percent of our U.S. agricultural production to this battle--a loss of over $35 billion of food and fiber for a hungry world. In the face of challenge, our members place great trust in the Environmental Protection Agency to administer the FIFRA.

Recently, a "chemophobia" toward pesticides in foods and a mistrust in EPA has spread across the country. This chemophobia has been fueled by ignorance and inflamed by alarming headlines. One such headline appeared in the New York Times and read, "Chemical Tie to Cancer Hinted." The story described the "tentative conclusions" of a group study where "some evidence" suggested a chemical caused cancer in male rats. The example

involved hair spray where "animals inhaled high levels of the chemical for 5 hours a day, 5 days a week, for 2 years." Now there is not doubt that when misused, chemicals can cause serious health problems for humans and hazardous environmental concerns. However, let us keep this concern in perspective and work together as farmers, public interest groups and lawmakers, to assure a sound FIFRA statute and an adequately funded and effective EPA to implement the responsibilities of the Act.

Mr. Chairman, let me now specifically address H.R. 2482, the Federal Insecticide, Fungicide and Rodenticide Act Amendments of 1985 which Congressman Roberts and you introduced May 14. Section 3 of H.R. 2482, deals with applicators under supervision. The FIFRA under Section 2(e)(4) defines "under supervision of a certified applicator" as:

> Unless otherwise prescribed by its labeling, a pesticide shall be considered to be applied under direct supervision of a certified applicator if it is applied by a competent person action under the instructions and control of a certified applicator who is available if and when needed, even through such certified applicator is not physically present at the time and place the pesticide is applied. (Emphasis added.)

The law acknowledges situations in which the certified applicator is not "on site." However, current EPA regulations clearly maintain the Administrator's control over these situations. The Administrator's control is in direct relationship to the probability of an adverse effect of the pesticide on man or the environment. Under 40 CFR 171.6(a), EPA has defined the availability of a certified applicator to those supervised:

> The availability of the certified applicator must be directly related to the hazard of the situation. In many situations, where the certified applicator is not required to be physically present, "direct supervision" shall include verifiable instructions to the competent person as follows: (1) detailed guidance for applying the pesticide properly, and (2) provisions for contacting the certified applicator in the event he is needed. In other situations and as required by the label the actual physical presence of a certified applicator may be required when application is made by a noncertified applicator.

Under the FIFRA Amendments of 1985, H.R. 2482, the words "by or under the direct supervision of a certified applicator" would be deleted from the FIFRA, Section 2(e)(4), and substituted with the words "by a certified applicator or under such degree of supervision by a certified applicator as the Administrator may specify." Furthermore, Sections 3(d)(1)(A) and 3(d)(1)(C)(ii) would also be amended with the same aforementioned language.

United members believe that existing law and regulations provided the needed protection to ensure the safety of farmers, farm workers and the environment and that this change is not needed. However, members of our association are currently reviewing this proposal and we will be happy to provide the committee our recommendations when our report is completed. Fortunately, serious accidental agricultural pesticide injuries throughout the United States are few. However, any accident which has an adverse effect on agricultural workers or the environment needs to be addressed and we urge the Administrator to use his current authority to take appropriate action.

Sections 11 and 13 of H.R. 2482 concern indemnity payments to owners of pesticide products whose registrations have been suspended and cancelled. Under the FIFRA, Section 6, the Administrator is authorized to take certain action to prohibit production, sale, and use of pesticide products that cause danger to human health or the environment. Depending on the situation, the Administrator may, to prevent an imminent hazard to human health, suspend a pesticide registration immediately, and at the same time issue a notice of intent to cancel the registration. A suspension order immediately halts all sale or distribution of the pesticide in both intrastate and interstate commerce. In these situations, farmers--interested only in producing quality and safe food products--are often awakened with the emergency order that the federally registered farm pesticides they legally purchased pose a hazard and must be destroyed.

Section 15 of the current statute requires EPA to make indemnity payments to any person who suffers economic loss by reason of suspension or cancellation of a pesticide registration and who satisfies other statutory requirements. It is important to note that conditions limit the federal financial exposure while providing economic protection to the injured party--(1) the registration must have been suspended to prevent an imminent hazard; (2) the registration was then cancelled; (3) the person owned the pesticide immediately before the suspension; and (4) the economic loss was by reason of the suspension or cancellation. Finally, Section 19 of the FIFRA requires the Administrator to accept those hazardous cancelled pesticides at convenient locations for safe disposal.

If all scientific and legal safeguards fail and the Administrator needs to take emergency action to protect human health and the environment, we support the Administrator's authority to immediately suspend use of all hazardous pesticides. However, farmers purchase those products knowing that they are federally registered and approved as safe at the time of purchase. We can not accept elimination of the indemnity payments or termination of Section 19, which deals with the safe and proper disposal of those hazardous pesticides. It is in the public's interest that the production, sale, and use of hazardous pesticides be immediately halted and that these products be safely disposed in order to protect the environment and public health. The current statute helps provide this protection by eliminating the economic loss suffered by persons in possession of these products. We urge the committee to strike Sections 11 and 13 of H.R. 2482 and maintain the indemnity payments and safe disposal program.

Finally, Mr. Chairman, let me comment on an area of great concern to the food industry which we suggest needs to be addressed in your amendments. The Administrator of EPA has responsibility for registering pesticides, establishing conditions for their use and application and also the authority and responsibility to establish tolerances for pesticides on raw agricultural commodities.

A tolerance is the maximum residue level that a crop may contain at the time it leaves the "farm gate" under the most strenuous conditions of pesticide use; i.e., at the maximum application rate, the maximum number of applicators, and as

close to harvest as the label permits. The tolerance thus represents a level of residue that provides consumers with the safest possible food products.

The establishment of a tolerance for a particular pesticide/commodity is a scientific and technical task that requires the funding, staffing and facilities of the quality that EPA and the federal government possess. Consumers throughout the United States rely upon EPA to guarantee the safety of raw agricultural products. Products safe to be sold in one market or region of the country should be safe throughout the country and likewise, raw agricultural products not safe in one area of the country should not be safe for residents of other markets. Wherever you shop, wherever you travel in the United States, you can be assured that the fresh produce is safe for consumption.

Clarifying language is needed to continue to assure consumers of uniform safe tolerances throughout the United States. Section 24 of the FIFRA should be amended to prevent multiple pesticide/commodity food tolerances in different areas of the country--a possibility that destroys consumer confidence in governmental regulatory food safety, hampers interstate commerce, artificially inflates food prices, and frustrates and disrupts agricultural marketing practices. To avoid this regulatory chaos, language needs to be adopted to Section 24 of FIFRA to assure consumers of safe, wholesome food under a national uniform food tolerance.

Mr. Chairman, all of us--government, industry, farming, and public interest groups--have a common responsibility to respect and protect our environment and provide consumers healthy and safe food. To this end, we pledge our cooperation.

PPA Pesticide Producers Association
Over a Decade — Serving the Industry
1200 17th Street, N.W., Washington, D.C. 20036 • (202) 429-8405

STATEMENT OF THE PESTICIDE PRODUCERS ASSOCIATION
BEFORE THE SUBCOMMITTEE ON
DEPARTMENT OPERATIONS, RESEARCH AND FOREIGN AGRICULTURE
COMMITTEE ON AGRICULTURE
U.S. HOUSE OF REPRESENTATIVES
WASHINGTON, D.C.

MAY 21, 1985

Good afternoon Mr. Chairman and members of the Subcommittee. My name is Bob Hasness of Riverside Terra Corporation of Souix City, Iowa, and I am the current President of the Pesticide Producers Association. Accompanying me is Mr. George Miller of Trans Chemic Industries who is the chairman of our legislative committee.

The Pesticide Producers Association (PPA) is a non-profit trade association made up primarily of small to medium sized businesses engaged in the formulation, manufacture and distribution of agricultural chemicals in the United States. For the majority of their business our members rely upon the production of "generic" pesticides, those products on which the patent has expired. Our membership provides a much needed service to the Agricultural community in securing and distributing those chemical tools necessary to allow all of us to enjoy an abundance of agricultural products at a fair and competive price.

We regret that we are unable to provide the committee with our written testimony today, but we only received a copy of H.R. 2482 last Friday. We do however, request that the record be held open for a reasonable period of time so that we may provide you with our detailed

written comments. We will briefly address those areas which we believe will be problem areas for us.

(1) We are opposed to the listing of inerts in the ingredients statements of pesticide labels. The original intent of the ingredients section of the label was to provide information to the consumer on the amount and type of active ingredients in a product in order to protect him from fraudulent manufacturers. The inclusion of inert ingredient information on the label will not provide the consumer any additional information of value in making an informed purchase, it will only add useless information to a label which is already confusing enough.

To include inert ingredient information on the label will however provide the competitors of a manufacturer with trade secret information and the opportunity to duplicate months of someone else's formulation development in only a short period of time.

Also, a variety of manufacturers produce, under various trade names, inerts which give similar results in formulations. Formulators often continually switch inerts based on pricing and availability. In addition, the ratio of inerts used often varies from day to day. Under these proposed amendments each pesticide producing establishment would need a full time printing operation just to handle the various labels which would be needed on a daily basis.

(2) The proposed changes to the Resticted Use classification system could require that anyone applying a restricted use pesticide be certified. This is not practical on today's farms which are large and operated by families in which not only the head of the farm applies the necessary pesticides to his crops but also uses the

assistance of other members of the family. Under the proposed changes, every working member of the farm family may be required to obtain certification for the application of restricted use pesticides in order to work in the production of their crops.

In situations where commercial applicators are involved, the required mandatory certification may be advisable and practical since these individuals are applying pesticides as their primary source of income. Proper certification of such individuals should be required much as we require the licensing of health care professionals.

(3) The proposed amendments to Section 6 of FIFRA may have inequities which can and would affect the formulator who relies upon data submitted by others for the registration of their products. Under the proposed language, a company who cites data submitted by another could lose his registration if he should rely upon a piece of data which, in the future, proved to be inadaquate or fraudulant even though he has never had direct access to the data. While we believe that there may be some merit to this amendment we would suggest that the language be carefully examined and modified to protect individuals who did not submit the original data from the possiable cancellation of their labels.

(4) We oppose the deletion of the indemnification and disposal sections of the law for those products which are suspended and cancelled by the Agency. Manufacturers do not in general benefit from such indemnification payments. Those who have purchased the products receive the majority of the benefit. By providing the encouragement to return and properly dispose of suspended and cancelled pesticides, we prevent the improper dumping of these products.

We were not aware that H.R. 1416 and H.R. 1910 were to be considered by the Subcommittee at this time and we have not prepared any comments. We will address both of these bills in our written testimony.

There are several areas which have not been addressed by H.R. 2482 which are affecting the operation of the pesticide industry and in many cases has reduced competition. It is important to have a healthy, competive market in order to provide a reasonably priced product to the public. When there is limited competition or even a monopoly, the public suffers through inflated prices. FIFRA is one of the few laws in America which presents barriers to entry beyond the 17 year patent period. We believe that the following items should be addressed by the committee in order to protect a viable competitive market place:

(1) Section 3(c)(2)(B) should be amended to provide for the formation of mandatory task forces to produce those data necessary to continue the registration of a pesticide product. Currently there is no such provision within FIFRA for such mandatory task forces. Without the support of the total industry in the production of new data required to continue the registration of a pesticide product, a registrant with a major portion of a market can freeze out a minor producer.

(2) We believe that Congress must once and for all address the problem of defining "reasonable compensation" under section 3(c)(1)(D) of FIFRA. For too long we have been groping in the dark trying to allow the settlement of a few cases to determine the definition of this term. To date we have had three (3) decissions handed down by either the Administrator or the Arbitrators with none of them the

same. PPA has developed a constructive definition of "Reasonable Compensation" for the use of data. We will provide the committee with complete details of this definition in our written testimony.

(3) PPA supports an amendment to Section 2(ee) of FIFRA to provide for the common industry practice of repackaging or re-formulation of a purchased registered end-use product into another registered end-use product.

(4) PPA also supports amendments to Section 3(c)(2)(D) of FIFRA to exempt the formulator from the submission of data for the registration of pesticide products. The current trend within the pesticide industry is for me-to registrants to enter the market only after the initial period of exclusive use or patent has expired. These registrants are not introducing new products to the market nor are they increasing the exposure to the pesticide, since the products they are producing and registering are for established use patterns. PPA supports amendments to FIFRA which would limit the need for me-to registrants of end use products to submit or cite data necessary for registration or reregistration of a pesticide product unless the formulation or use pattern is new and different.

Mr. Chairman we wish to thank the committee for this opportunity to present our views on the proposed amendments to FIFRA and look forward to working with the committee in the coming weeks to resolve many of the problems addressed during the past two days. At this time I will be glad to respond to any questions from the members.

(Attachments follow:)

PESTICIDE PRODUCERS ASSOCIATION'S POSITION ON THE NEED FOR A LEGISLATIVE DEFINITION OF REASONABLE COMPENSATION

The Pest cide Producers Association (PPA) is a non-profit trade association made up primarily of small to medium sized businesses engaged in the formulation, manufacture and distribution of agricultural chemicals in the United States For the majority of their business our members rely upon the production of "gener c" pesticides, those products on which the patent has expired. Our membership provides a much needed service to the Agricultural community in securing and distributing those chemical tools necessary to allow all of us to enjoy an abundance of agricultural products at a fair and competitive price.

PPA contends that FIFRA must have included within its framework a definition for "reasonab e compensation under section 3(c)(1)(D) of the law. We believe that due to recent court decisions and the decisions of arbitrators n data compensation cases that a disincentive has been establ shed for the entry nto the market of a second registrant of an agricultural chemical after the expiration of its patent.

FIFRA provides that if a registrant relies upon data submitted by another registrant he must offer to pay compensation to the original data submitter The aw does not provide a definition of "reasonable compensation If the parties involved cannot reach an agreement then either may request that the matter be submitted to binding arbitration before the Federal Mediation and Conciliation Board which is to determine "reasonable compensat on" on a case by case basis.

The Law provides that the decision of the arbitrators s binding and is not appealable to the Federal courts except n cases of fraud or misconduct on the part of the arbitrators. This provision of the Law was upheld on July , 985 by the United State Supreme Court in the Union Carbide case Therefore any decision of the arbitrators must be considered to be final and binding upon both parties.

To date, only one data compensation case has been decided by binding arbitration, Stauffer Chemical Company vs. PPG Industries, Inc. (Stauffer/PPG). The Stauffer/PPG case was heard before a panel of 3 arbitrators. The final decision against PPG provided for

- PPG to pay 50% of the cost of the data rel ed upon by the EPA to register their product which had been submitted by Stauffer and was in the Agencies f es. The data n question was valued at $2,930 000 and PPG was ordered to pay $1,465 000 to Stauffer within 30 days of the f nal decision. (NOTE: The data which Stauffer had submitted s not suff cient to ful y register the product under section 3 of FIFRA and will require PPG to possibly develop or replace several million dollars worth of data when the registration standard is finalized by the EPA.)

- The arbitrators ruled that PPG had gained a market advantage by not having to wait the 5 to 7 years necessary to develop the data themselves and obtain EPA registration. They also ruled that since PPG had gained valuable time by relying upon Stauffer's data and having the benefit of their registered labels to copy. To compensate Stauffer for the market advantage PPG gained by relying upon Stauffer's data and labels the arbitrators awarded them $0.15 per pound of technical produced or purchased by PPG during the 10 calendar years from 1983 through 992. The price per pound is to be adjusted annually based on the change n the Producer Price Index using November 1982 as the base year.

It is important to note that the $0.15 per pound awarded was determined by the arbitrators based upon a net profit by PPG of $0.60 per pound of technical This is equivalent to 25% of PPG's net profits. No allowance was made n the decision for a drop in the net profit to below the projected $0.60 per pound. If PPG's net prof t dropped to $0.30 per pound they would then be paying Stauffer 50% of their net profits.

The cost of the actual arbitration process must also be considered. The fees charged by the 3 arbitrators and the American Arbitration Association (AAA) in the Stauffer/PPG case were $96,000. Stauffer and PPG split this cost with each paying $48,000. It is estimate that the legal fees for PPG in this matter would have been approximately $300,000. The hearings lasted 20-22 days and the case was months in preparation. This estimate of PPG's costs in this matter does not include theri in house administrative costs.

Based upon the above figures and estimates for sales contained in the arbitration decision, PPG's nitial costs for data compensation and arbitration were $1,813,000 plus an additional $7 087,500 n royalty payments during the first f ve years of sales. If PPG's sales remained stable during the 10 year period in which royalty payments are to be made, the total cost to PPG for data compensation would be approximately $15 988,000 or 5.4 times the cost of the data involved.

As can be seen by the above case, it would be very difficult for a small company to decide to enter a market previously held by a major producer. The cost of such an arbitration award under the law would be be out of the reach of a small businessman. If he were successful n obtaining entry into a market, he could still be faced with future development of several million dollars worth of data when the registration standard for the product was issued and he was required to reregister his product.

We believe that a decision such as the Stauffer/PPG decision is totally outside of the original ntent of Congress when it passed the requirements for reasonable compensation n 972. That the intent of this section was to al ow two or more companies to share the cost of developing the data necessary to register a pesticide and further, that if a company relied upon the data submitted to the Agency by another registrant that the second registrant should share in the cost of the development of that original data and not reward the first

company for being the first to register a pesticide product. We contend that such reward is the purpose of the patent laws and not FIFRA.

In addition to the disincentive in the present system of determining data compensation, a recent decision by the United States Courts has brought into question the practice of developing the data necessary to support the registration of a "me-too" product prior to the expiration of a patent.

On April 23, 1984 the United States Court of Appeals for the Federal Circuit handed down a decision in Roche Products, Inc. vs. Bolar Pharmaceutical Co., Inc. ruling that the use of a patented product by a second party, to develop data for the purpose of obtaining a early market entry following the expiration of a patent was a violation of the "use" provisions of the law. The court held that while there was an exemption for the use of a product for "Scientific Purposes" the exemption stopped when the information gained was for commercial purposes. This decision has a direct impact on the ability of a second registrant to develop any data which would be necessary for the registration of a product prior to the expiration of its patent.

A certain core set of data may be required by the EPA in order to register a me-too product. This data consists of a minimum of the acute toxicity series and the product specific chemistry requirements under 40 CFR 158. The production of this data will require approximately 4-10 months. To prepare to enter a market on the day of patent expiration, the data would have to be prepared and submitted to the EPA at least 1 year prior to patent expiration date. The restrictions on "use" of a product such as presented in this decision, would in essence provide a patent holder at least 1.5 to 2 years of additional patent life in order for the second registrant to have time to develop the minimum data necessary to register his product.

If a company wished to do the entire set of data in order to obtain a registration due to the fear of an unreasonable data compensation determination the period of time which the original patent holder would enjoy the continued monopoly in the market would be approximately 5 to 7 years.

PPA believes that the time is ripe for Congress to define within the law what is a reasonable compensation for the use of another parties data. We believe that only if this is done now can Congress promote not only the development of new chemicals but also guarantee that a competitive market is established for pesticide products thereby, assuring the American farmer and rancher of an adequate and fairly priced supply of agricultural chemicals.

At times it is questionable if the original data developer should even receive compensation for his data when you consider that such cost are considered to be research and development expenditures and are provided with the status of most favored business cost under the Internal Revenue Codes. By applying the tax codes in the most

favorable way, a company can reduce its actual R&D costs by as much as 75%.

PPA believes however, that an original data developer should receive "reasonable compensation" for the use of his data by a second registrant. We contend that such "reasonable compensation" should be determined by a def nition which encompass the following points:

1. That data has a compensable life of 15 years from the date is first submitted to the EPA;
2. That compensation should be based upon the actual benefit the second registrant receives from the use of the data during its useful life; and
3. That the original data developer should receive compensation for the development of the market the second registrant is entering equal to 15% of the original data cost.

PPA proposes the following formula which takes in account each of these:

DATA COMPENSATION = [((ACD + (MDF X ACD))/CL](AMS)

Where:
ACD = Actual Cost of Data
MDF = Market Development Factor (15%)
CL = Compensable Life of Data (15 Years)
AMS = Annual Market Share of Second Registrant (Min. 5%)

EXAMPLE:
Original data submitted in 1980 at a cost of $1,500,000
Data would be compensable for 15 years until 1995.
Data relied upon in 1985 by second registrant
Annual Market Share of second registrant for compensable years of:

1985 = 3%	1989 = 12%	1993 = 20%
1986 = 5%	1990 = 15%	1994 = 20%
1987 = 8%	1991 = 17%	1995 = 20%
1988 = 10%	1992 = 20%	

DATA COMPENSATION FOR 1985 = [((1,500,00 + (.15 X 1,500,000))/15](.03)
DATA COMPENSATION FOR 1985 = $5,750 (5% min. rule applies)

DATA COMPENSATION FOR 1985 = [((1,500,00 + (.15 X 1,500,000))/15](.05)
DATA COMPENSATION FOR 1986 = $5,750

DATA COMPENSATION FOR 1985 = [((1,500,00 + (.15 X 1,500,000))/15](.08)
DATA COMPENSATION FOR 1987 = $9,200

DATA COMPENSATION FOR 1985 = [((1,500,00 + (.15 X 1,500,000))/15](.10)
DATA COMPENSATION FOR 1988 = $11,500

DATA COMPENSATION FOR EACH YEAR OF THE 11 YEARS

YEAR	COMPENSATION	YEAR	COMPENSATION
1985	$ 5,750	1991	$19,550
1986	5,750	1992	23,000
1987	9,200	1993	23,000
1988	11,500	1994	23,000
1989	13,800	1995	23,000
1990	17,250		

TOTAL COMPENSATION PAID BY SECOND REGISTRANT = $174,800

PPA contends that the original data submitter would have received "reasonable compensation" under the above example if you consider the following facts.

1. The major cost of the original data has already been written off under IRS Codes.
2. During the 11 year period the second registrant obtained an average market share of 13.64% and paid compensation of $174,800.
3. The original data submitter enjoyed exclusive use of the data for 4 years prior to the second registrant entering the market.
4. The original data submitter enjoyed a 90% market share over the entire 15 year life of the data and received 11.65% recovery of his data cost under data compensation.

Only in an open, competitive market can American agriculture be assured of a supply of agriculture chemicals which is reasonably priced and not subject to a single source of supply.

PESTICIDE PRODUCERS ASSOCIATION

July 11, 1985

POSITION ON

ADDITIONAL DATA TO SUPPORT EXISTING REGISTRATIONS

FIFRA 3(C)(2)(B)

In our oral testimony, we briefly discussed the fact that the Pesticide Producers Association membership had a problem with 3(C)(2)(B) of the FIFRA law and felt the need for a change.

Under the current provisions of FIFRA, two or more registrants may join together to produce the data necessary to support the continued registration of a pesticide product. The 1978 Bill does not address nor provide for the mandatory cooperation of various registrants in the production of this required data nor does it provide for an equitable method to determine the costs by these participants associated with the production of this data.

The membership of the Pesticide Producers Association support an amendment to FIFRA similar to the 3(C)(2)(B) amendment in HR 5203. The amendment in HR 5203 took long hard deliberation and provides for:

1. The mandatory formation of industry task forces to develop the data required under a Section 3(C)(2)(B) data call-in notice. Such task forces to be open to any registrant effected by said data call-in notice. This part of the amendment would free up research facilities that would otherwise have done duplicative testing, would use less manhours of agency time because only one set of data would be reviewed and would enable every registrant who desires, to participate in the production and ownership of said data.
2. The immediate suspension of the registration of any registrant who refuses to join a task force. After the 180 day waiting period, the Agency will know which registrants have complied and immediately letters of "Intent to Suspend" could be sent out, thus making certain everyone is in compliance.

3. The allocation of the cost associated with the development of Section 3(C)(2)(B) data should be divided among the participating registrants based on the following:

   a) The first 25% of the estimated cost for the development of the data to be divided equally among the participants with a maximum initial contribution from any one registrant of $100,000.

   b) The balance of the cost to be shared based upon the market share of each participant as determined by an independent auditor or an annual basis during the lifetime of the task force. Each member of the task force shall be considered to have no less than a 5% market share for any given year.

4. Data developed by the Task Force shall be made available to subsequent registrants under the provisions of Section 3(C)(1)(D).
   This enables any company to make use of the data and therefore would not hold anyone from producing a product because they cannot obtain the data. Again, competitiveness in the marketplace would be retained.
   This approach is reasonable and will not keep any registrant from participating because of outlandish costs. In the past a freeze out, because of upfront costs, has stopped some registrants from participating and thereby hurting competition in an industry where, because of laws and regulations, registrants already have an anti-competitive environment. This joint venture testing will also meet the mandates of the 1972 FIFRA to conserve financial and testing resources.

Attached is a copy of 3(C)(2)(B) from the December 14, 1981 Bill, HR 5203 which can be used as a guide for what the Pesticide Producers Association believes is a necessary amendment to FIFRA.

PESTICIDE PRODUCERS ASSOCIATION

July 11, 1985

POSITION ON

FORMULATORS EXEMPTION

SECTION 3(C)(2)(D)

In our testimony, the Pesticide Producers Association supported amendments to Section 3(C)(2)(D) which is called Formulators Exemption. Our amendment would exempt the formulator from the submission of any data for the registration of pesticide products provided he does not have a unique formulation and desires to submit said data and that the formulator purchases a registered technical product from a registered establishment.

The current trend within the pesticide industry is for generic registrants to enter the market only after the initial period of exclusive use or patent has expired. These registrants are not introducing new products to the market nor are they increasing the exposure to the pesticide since the products they are producing and registering are for established use patterns. PPA supports amendments to FIFRA which would limit the need of generic registrants of end use products to submit or cite data necessary for registration or reregistration of a pesticide product unless the formulation or use pattern is new and different.

We all already know that overregulation profits no one, but the large and powerful companies and is probably the greatest problem that the small company has today. Small companies are unable to bear the massive costs of regulation. They have neither the staff to handle the compliance nor the volume and production to spread out the increased capital and operating outlays. The pesticide industry is the most regulated industry in the world today.

This is also true of data production and the pesticide formulator today. A small formulator may have between 50 and 200 labels for formulation that he either makes or sell. Each label may only generate a small portion of his income, but all are important to the eventual profit of his company. Under the present law, the formulator is responsible for what is called the "below the line" data, the acute toxicology studies.

The cost of these data is between $10,000 and $20,000 per label. For an average of fifty (50) labels, the cost would be between $500,000 and $1 million. Very few small companies can continue operating with an overhead

as large as this. The Pesticide Producers Association believes the production of these data should be with the producers of the technical product and not lie with the formulator.

Another aspect of Formulators Exemption we would like to address and see added as an amendment.....to exempt the formulator from revealing the source of his raw materials (technical pesticides) except to EPA on the Confidential Statement of Formula or on the Alternate Source of Supply Registraton Form.

In the past, the Agency suggested that each end use label have the registration number of the producer of the active ingredient indicated on the end use label. PPA was against this type of regulation in the past and is against any type of regulation or law now or in the future. The reasons are as follows:

1. Government regulation would then force an anti-competitive aspect where there was none before. The formulator could not use any alternate source of supply.
2. The regulation is fostering restraint of trade by not allowing the formulator a choice of suppliers due to labeling.
3. The formulators competition would know his source of supply.

We would be very willing to cooperate with the Staff on the writing of this language.

y 11, 1985

PESTICIDE PRODUCERS ASSOCIATION

POSITION ON LISTING OF INERTS

In our oral testimony, we stated that we were opposed to the listing of inerts on the registered label. We believe that the listing of inerts can only hurt the small formulator and provide competitors with trade secret information and the opportunity to duplicate months and even years of someone else's formulation development in a short period of time.

The argument against this could be made that any analytical chemist could break down the components of a formulation and duplicate the formulation with minimum information. The state of the art does not permit this chemist that duplication. The perfect example is Coca Cola. Until COKE changed their formula, no one duplicated the product though many tried.

It is the same with pesticide formulations. You may be able to find out that a specific emulsifier group was used, but you would find it very difficult to tell the exact emulsifier used. It is the last little pinch of something that would make a formulation unique and unless you were told to look for that little pinch of something, you would not come up with the same formulation.

A variety of manufacturers produce under various tradenames, inerts which give similar results in formulations. Formulators often switch inerts based on the best price and availability during the formulating season.

Under the amendments proposed, each pesticide producing establishment would need a full time printing operation just to handle the label changes needed for inerts on a daily basis. If not the formulator would have one label and be tied to one producer of the inerts. This again would limit competition in a field where competition is necessary for our national good health.

July 12, 1985 PESTICIDE PRODUCERS ASSOCIATION

POSITION ON REGISTRATION FEES

The subject of EPA imposing registration and reregistration fees continually comes up and the Pesticide Producers Association believes that it is now time for Congress to take some action regarding these fees and the fears being generated by rumors.

The Pesticide Producers Association is against EPA charging registration or reregistration fees or fees to change a label. The Pesticide industry is the most regulated industry in the United States. Being the most regulated industry, the pesticide industry therefore is an expensive industry in which to have a business. The average gross sales of pesticide formulators are $2,750,000* and any regulation or law enacted should take into consideration small business and the end cost to this small business.

An added burden of a registration fee for an end use formulation could put some of the smaller firms (below the $2,750,000 average) out of business. The PPA does not believe that it is the intent of Congress to put people out of business by law or allow Agencies to do so through regulation. We therefore urge this sub-committee and the full committee to take positive action against registration fees now and in the future. The pesticide industry pays its dues with being such a regulated industry.

PPA would be more than willing to help write any language necessary so that you can take positive action against registration fees.

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* FIFRA: Impact on the Industry; EPA Office of Pesticide Programs; March 7, 1977; pages 6-7.

PESTICIDE PRODUCERS ASSOCIATION

July 12, 1985

POSITION ON USE INCONSISTENT

WITH LABELING

On December 3, 1980, Mr. Edwin L. Johnson, Deputy Assistant Administrator for Pesticide Programs, wrote a letter to the major trade associations advising them that, according to their (EPA) interpretation, FIFRA, Section 12(a)(2)(G) provides that use of a pesticide in a manner inconsistent with its label is a misuse violation that the act of reformulating or repackaging an end use product would be defined as a misuse.

Prior to this letter from Mr. Johnson, it was a standard practice within the pesticide industry, especially at the small formulator level, to use end use products for formulation or repackaging purposes since many of the small pesticide producers dealt in very limited quantities of materials and could not afford to purchase large quantities of technical grade materials to produce their products. To be denied the ability to use end use products for formulation or repackaging purposes will severely handicap the small producer from being able to compete in their regional markets.

PPA is proposing that Section 2(ee) be amended to read as follows:

SECTION 2. DEFINITIONS

(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 (1) applying a pesticide at any dosage, concentration, or frequency less than that specified on the labeling, (2) applying a pesticide against any target pest not specified on the labeling if the application is to the crop, animal, or site specified on the labeling, unless the Administrator has required that the labeling specifically state that the pesticide may be used only for the pests specified on the labeling after the Administrator has determined that the use of the pesticide against other pests would cause an unreasonable adverse

effect on the environment, (3) employing any method of application not prohibited by the labeling, (4) mixing a pesticide or pesticides with a fertilizer when such mixture is not prohibited by the labeling, or (5) use a registered pesticide for manufacturing purposes unless such use is prohibited by the labeling: Provided further, that the term also shall not include any use of a pesticide in conformance with Section 5, 18, or 24 of this Act, or any use of a pesticide in a manner that the Administrator determines to be consistent with the purposes of this Act: and provided further, that after March 31, 1979, 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.

This change in the current law would permit the continued practice of formulating or repackaging pesticides from the end use products and would allow the small regional producer and manufacturer to continue to be competitive in a market from which he is rapidly being forced due to excessive regulations.

STATEMENT OF
KENNETH W. WEINSTEIN
ON BEHALF OF ABBOTT LABORATORIES,
CIBA-GEIGY CORPORATION,
E.I. du PONT de NEMOURS & COMPANY,
ELANCO PRODUCTS COMPANY, FMC CORPORATION,
MONSANTO COMPANY, RHONE POULENC INC.,
ROHM AND HAAS COMPANY, STAUFFER CHEMICAL COMPANY,
UNIROYAL, INC., VELSICOL CHEMICAL CORPORATION
AND ZOECON CORPORATION
HEARING ON H.R. 2482
BEFORE THE SUBCOMMITTEE ON
DEPARTMENT OPERATIONS, RESEARCH
AND FOREIGN AGRICULTURE
COMMITTEE ON AGRICULTURE
HOUSE OF REPRESENTATIVES
MAY 21, 1985

This testimony presents the views of several companies who are presently parties to an action in the Supreme Court of the United States, Thomas v. Union Carbide Agricultural Products Co., No. 84-497, or who have been parties in related litigation. The only issue we address is the provision of H.R. 2482 which would amend FIFRA to provide for judicial review of arbitration decisions awarding compensation for the use of pesticide research data. Because the Supreme Court is expected to resolve questions that have been raised concerning the constitutionality of FIFRA's arbitration system within the next few weeks, we suggest that it would not be advisable for the Subcommittee to adopt amendments to the arbitration provision until after the Supreme Court has acted.

I. JUDICIAL REVIEW OF ARBITRATION DECISIONS MAY NOT BE ADEQUATE TO RECTIFY THE CONSTITUTIONAL PROBLEMS

In Thomas v. Union Carbide Agricultural Products Co., the Supreme Court will decide whether FIFRA's arbitration system for resolving compensation disputes is unconstitutional. The constitutional problems with the arbitration system are similar to the problems that arose under the Bankruptcy Act because of the employment of bankruptcy court judges who were not appointed pursuant to Article III of the Constitution.

The Supreme Court, in the case of Northern Pipeline Construction Co. v. Marathon Pipe Line Co., 458 U.S. 50 (1982), found that the Bankruptcy Act was unconstitutional because it permitted monetary claims to be decided by bankruptcy court judges who did not have the full protections accorded by Article III. Very importantly, the Supreme Court stated that the mere appellate review of bankruptcy judges' decisions by the federal courts was not sufficient to cure the constitutional problem. The entire adjudication, according to the Supreme Court, had to be under the control of a federal court judge.

If the Supreme Court were to reach the same result in Thomas v. Union Carbide, the amendment in H.R. 2482 that provides for judicial review of arbitrations would not cure the constitutional problem. We would still be left with an unconstitutional arbitration system.

There is an additional problem with the arbitration system that is not addressed by H.R. 2482. FIFRA does not provide a standard for determining how much compensation to award, or what factors should be considered in an award. For example, former EPA Administrator Douglas Costle testified before the Committee on Agriculture that the lack of a compensation standard required registrants to sign a "blank check" for the use of data. He pointed out that "an offer to pay reasonable compensation without knowing what that means in terms of dollars and cents is unpalatable from a business point of view." H.R. Rep. No. 663, 95th Cong., 1st Sess. 59 (1977). As the Administrator observed, "It would thus be helpful to applicants if the Congress would make more explicit what factors it feels are pertinent in determining reasonable compensation." Ibid.

Because of the absence of a compensation standard, the arbitrator does not know how much to award, registrants do not know how much compensation they will have to pay, or can expect to receive, and there is a lack of continuity and consistency in the implementation of the compensation provision.

In Thomas v. Union Carbide Agricultural Products Co., the Supreme Court presently is considering whether the lack of a compensation standard renders the arbitration system unconstitutional. If so, it will be necessary for Congress to adopt a compensation standard in order to repair the statute. In that

eventuality, a mere provision for judicial review of arbitration awards would not cure the problem.

In summary, it is very possible that the amendment to the arbitration system proposed in H.R. 2482 will not be adequate to address the legal problems with the statute. We believe that it would make more sense for the Subcommittee to permit the Supreme Court to render its ruling before an amendment is adopted. In this manner, the Subcommittee will be able to determine what if any constitutional problems exist and how they can best be addressed. The Supreme Court's ruling in the Union Carbide case is expected by the end of this term in July 1985.

II. JUDICIAL REVIEW WILL NOT RESOLVE THE UNDERLYING POLICY PROBLEMS WITH THE ARBITRATION SYSTEM.

Wholly aside from the potential constitutional infirmities of the arbitration provision, the Subcommittee should recognize there is widespread dissatisfaction with the entire system.

FIFRA's compensation and arbitration system has been the subject of litigation since its enactment in 1978. This system was intended to fairly compensate companies who perform innovative research -- which brings safer, more effective and less expensive pesticides to the farmer and public -- for the inequity they suffer in bearing the full brunt of federal regulation. Unfortunately, the compensation system has not fulfilled this purpose. There has been but one arbitration since the system was adopted in 1978. The system has been criticized because of its

high cost and lack of predictability. Due to these problems, the compensation system has been unsatisfactory both to the innovative companies who generate research data, and to the "me-too" registrants who desire to use the research data to support their own registrations. As one commentor stated during the 1982 FIFRA Oversight Hearings, "The thing that we all agree on absolutely is that we have to phase out and get rid of compensation." H.R. Rep. No. 97-566, 97th Cong., 2d Sess. 77 (1982). The House of Representatives proposed to do just that in 1982. It adopted a bill that phased out compensation, and substituted in its place 15 years of exclusive data rights.

The judicial review amendment in H.R. 2482 does not address these underlying problems with the arbitration system. Until the root causes of dissatisfaction with the compensation and arbitration scheme are resolved, the congressional purposes of the system will continue to go unfulfilled and the potential for further legal problems and litigation will continue to plague its operation.

The only effect of the judicial review amendment in H.R. 2482 will be to increase the cost and delay involved in obtaining a final compensation award. For this reason, the amendment should not be adopted. The Subcommittee should instead give consideration to an alternative mechanism that will achieve Congress' purposes in a manner that is satisfactory to the regulated community.

TESTIMONY OF RALPH ENGEL
PRESIDENT
CHEMICAL SPECIALTIES MANUFACTURERS ASSOCIATION
BEFORE THE
SUBCOMMITTEE ON
DEPARTMENT OPERATIONS, RESEARCH & FOREIGN AGRICULTURE
COMMITTEE ON AGRICULTURE
UNITED STATES HOUSE OF REPRESENTATIVES
MAY 21, 1985

My name is Ralph Engel; I am president of the Chemical Specialties Manufacturers Association (CSMA) located at 1001 Connecticut Avenue, N. W., Washington, D. C. I am accompanied today by Warren Stickle (Director of Legislative Affairs), CSMA.

CSMA has a membership of nearly 400 firms engaged in the manufacture, formulation, distribution, and sale of aerosols; antimicrobial products; automotive chemicals; detergents and cleaning compounds; pesticides; and waxes, polishes and floor finishes for household, institutional and industrial use. 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 (FIFRA), as amended.

Specifically, CSMA represents the non-agricultural pesticide industry, including disinfectants and sanitizers; home, lawn and garden pesticides; and a wide variety of other pesticides for home, industrial and institutional use.

I would like to take this opportunity to commend you, Mr. Chairman, for holding these hearings on the reauthorization of FIFRA, and to applaud the subcommittee's continued interest and concern about this legislation. We are here today to review some

of the areas raised in H.R. 2482 and to address, as well, some of the concerns we have with the existing statute.

I. CSMA'S REVIEW OF H.R. 2482

1) Data Sharing: We fully support the concept that EPA should be able to share data with State governments, but only if the state or state agencies adopt "security precautions" for this information.

The Administrator should require as a condition to the disclosure of information under section 10 that the state or state agencies receiving data adopt the necessary authority and procedures for the protection of such information equivalant to that provided under FIFRA and should take such security precautions and confidentiality protection respecting the information as the Administrator should prescribe by regulation.

We also believe that the state ought to adopt, as a minimum, identical civil penalties for disclosure by state employees and state contractors similar to the section 10(f) provisions for federal employees and in section 10(e) for federal contractors.

We do, however, oppose sharing confidential business data with foreign governments, especially governments that do not have a bilateral or multilateral defense treaty with the USA, do not have a bilateral data sharing agreemant with the USA, or do not provide for the protection of the data equivalent to FIFRA.

We also believe that the inclusion of provisions dealing with foreign governmants could invite a sequential referral to the House Foreign Affairs Committee. To avoid this problem, the 1985 FIFRA amendments should be crafted to prevent other commit-

tees, besides the House Agriculture Committee, from exercising their rights for a sequential referral of these amendments.

2) Indemnification and Disposal: Whenever as a result of an imminent hazard the EPA suspends and/or later cancels the registration of a pesticide, the Agency is required by FIFRA to indemnify owners of existing stocks that can no longer be sold or used and to pay for the disposal of those stocks. We support the present statute's handling of the problem.

Such a proposal, as contained in H.R. 2482, would have a disproportionate impact on small manufacturers, marketers, processors, and distributors, as well as the basic manufacturers or suppliers. Severe dislocation could occur at each level.

In weighing the risks and benefits and the economic impact of regulatory decisions, the Agency ought to take into consideration the economic dislocation that might occur as a result of its decision. In addition, the EPA should consider alternatives to ban a product or to immediately remove the existing stocks from the marketplace.

Also, there is an important seasonal impact on the marketplace. For many home, lawn and garden products, marketers and distributors may stockpile supplies and ingredients over the summer and winter for heavy spring usage. Consequently, the timing of an agency action is critically important to everyone.

Although we share the Agency's concern about the impact that indemnification might have on its operating budget, we would recommend that: 1) the Agency establish a line item in its annual budget for potential indemnification cases, and let it

accumulate funds from year to year; or 2) provisions be made to obtain the funds from general revenues. Under these options, there would be little adverse impact on the Agency or the owners of existing stocks.

3) Cancellation Due to False, Misleading or Inaccurate Data: The EPA would like to more easily cancel a product registration when the Agency discovers that a portion of the data supporting a registration is based on false, misleading or inaccurate data. The Agency, however, already has sufficient existing authority to start a cancellation proceeding if the data, for any reason, are not sufficient to support a determination that the pesticide is safe to use.

CSMA in no way countenances the intentional submission of false or misleading data and would sanction a quick response by the Agency.

On the other hand, when the Agency determines that data submitted is inaccurate and concludes that it does not make a significant impact on the overall data submitted for a registration, then the Agency should seek to fill the gaps with new studies, rather than immediately beginning a cancellation proceeding. In short, a reasoned judgment should prevail.

4) Special Review: Since EPA considers the present RPAR process too long, it is seeking authority to eliminate the adjudicatory hearing, and to convert the current public notice and comment period into informal rulemaking. We strongly disapprove of eliminating the cancellation hearings.

We would like to offer three comments on this process. First, the adjudicatory hearing is an important safeguard in the

administrative process. It provides a fair and equitable forum in order to develop a solid hearing record.

Second, many of the legislative changes suggested in H.R. 2482 are presently being implemented by the Agency in the form of proposed regulation (please see Federal Register Vol 50, No. 59 (March 27, 1985), 12195-12196. This notice concludes that "the Agency has developed procedures intended to provide opportunity for public participation in the Special Review process."

As a result of the settlement agreement between the parties in NRDC and AFL-CIO v. EPA et al., Civil Action No. 83-1509, U. S. District Court for the District of Columbia, and the Federal Register notice mentioned above, the Agency is proposing to adopt the following steps: a) public notification of Agency decisions concerning Special Reviews; b) opportunities for public comment concerning issuance of a Special Review, a proposed Special Review decision, and a decision following pre-Special Review not to initiate a Special Review; c) procedures employed in determining whether to issue a Special Review notice; d) optional procedures which the Agency may utilize to expedite the Special Review process; e) maintenance of dockets for each pesticide in pre-Special Review or Special Review containing written communications and descriptions of meetings with persons or parties outside of Government; f) preparation and public distribution of docket indices; and g) general principles governing public participation in pesticide decision making and meetings with persons or parties outside of Government.

Since the Agency has proposed regulations governing Special

Review of Pesticides and is still receiving comments, the legislative language in H.R. 2482 is unwarranted.

Third, the above-mentioned proposed regulations advocating increased public participation are to occur during the decision making process, and are designed to allow for full participation by all groups in that process. Once this regulatory decision, however, has been made by the Agency, the registrants, environmentalists and other parties adversely affected, can seek judicial review under FIFRA Section 16(a). Other parties should not be given the opportunity to become involved in the administrative process once the Agency has made its decision.

5) Inerts: Under FIFRA as presently written, an inert ingredient is any component of a pesticide other than the active ingredient added to be ective on a specific pest or pests. Under current law, pesticides are generally required to be labeled with only their active ingredients. We support the present statutory provisions for active ingredients and do not believe that FIFRA should be amended to include specific inerts on the label.

Under the provisions of H.R. 2482, FIFRA would be amended to require the listing of inerts on the label, if the inert is determined by EPA to be of toxicological concern. EPA is given the flexibility and discretion to determine which inerts need to be listed based on their toxicological properties.

We have several concerns with this proposal:

First, we believe that many inerts and intermediates could be regulated under sections 4 and 5 of the Toxic Substances Control Act (TSCA), rather than under FIFRA because they are not pesticides, and in many cases, the potential pesticidal use is

only a small fraction of its total use. The EPA has the authority to request toxicological data if the Agency feels it needs it. In addition, under section 4(c) of TSCA, there is in place an existing system for "fair and equitable reimbursement" for test data submitted on a chemical substance. Under FIFRA, there is no agreed upon formula for reimbursement of "defensive" data requested by the Administrator.

Second, disclosure of inert ingredients on the label seriously compromises the confidentiality of the final product. Consumer products for the home, lawn and garden are directly affected.

In many cases, the essential differences between one consumer product and another is the inert ingredient. The use of a particular surfactant, for example, may determine the performance of the product, and give the product a competitive advantage in the marketplace. Disclosure of the name of the inert on the label would, in fact, alert the competition to the key difference in the product formulation.

The present law only requires that the total percentage of inerts be placed on the label and does not require the disclosure of specific inerts. When the Congress originally enacted FIFRA, it correctly stipulated that inerts needed to be treated confidentially and most certainly did not require that they be specifically named on a label.

Third, although the amendment to section 2(n) deals only with labeling provisions for inerts, it also raises a fundamental concern about testing of inerts. What information does the

Administrator need to determine if a "hazard" exists? Who should provide the requested data, test studies or information -- the basic manufacturers or the marketers or distributors of the finished products? Who should pay for such data, test studies or information, and how would it be apportioned? What statutory language needs to be created to put in place an appropriate system for compensation for data? In essence, many questions about testing and compensation are raised by this language in H.R. 2482, but none are answered.

Fourth, if the Administrator has some concern about a potentially troublesome inert, his determination to require label identification should be based on data demonstrating that the inert has an unreasonable adverse effect on man and the environment. An administrator's request for data on a particular inert should be prompted by evidence similar to that which is required by the Grassley-Allen amendment to the cancellation process. This amendment requires that there should be "a validated test or other significant evidence raising prudent concerns of unreasonable adverse risk to man or the environment."

Fifth, if the Administrator feels he has a concern over a potentially troublesome inert, he has the existing authority to request that information be placed on the label. In at least three cases, the Administrator requested that products containing chlorofluorocarbons (CFCs) be so identified on the label, that certain products containing petroleum distillates carry a warning on the label, and that all products containing sodium nitrate stabilizers be identified on the label. In essence, the Administrator has the authority to act quickly if he sees an emergency,

or if he feels that a troublesome inert poses an unreasonable risk to man and the environment. Consequently, there is no apparent need to rewrite the statute.

Sixth, the Agency is presently burdened with several high priority projects, including: 1) on-going registration; 2) re-registration program; 3) labeling program, and others. Each of these programs requires significant resources. To comprehensively review inerts with a limited budget and reduced staff would add new burdens to the Agency's already heavy agenda. Rather than starting this new program, the Agency might conduct a study to resolve many of the unanswered questions and deal with such controversial areas as confidentiality and compensation for data as it pertains to the testing of inerts.

Although we have serious problems with any number of the provisions of H.R. 2482, we welcome an opportunity to work with members of the subcommittee regarding this proposed legislation in the hope that we can resolve some of our difficulties.

II. CSMA'S REVIEW OF THE FIFRA STATUTE

We are equally concerned, however, that the present and potential legislative discussions have not addressed several other pressing problems with FIFRA. We would like to take a few moments to touch on some of our concerns.

1. State Political Subdivisions Under Section 24(a). We would like to focus on whether or not political subdivisions of a state, such as a county or township, should be able to exercise the same pesticide jurisdiction as a state.

In passing the 1972 amendments to the Federal Insecticide, Fungicide and Rodenticide Act, Congress granted limited pesticide regulatory authority to the states. The legislative history indicates that in amending FIFRA, Congress intended to share its authority with the states, but not with local jurisdictions.

If the language of a statutory provision is open to conflicting interpretations, the intent of Congress in passing it will determine how that provision is to be construed and applied. The legislative history of the 1972 FIFRA amendments confirms Congress' intent.

Section 24(a) was added to FIFRA by the Federal Environmental Pesticide Control Act of 1972, Public Law 92-516 (FEPCA). In passing FEPCA, Congress made clear that it was extending limited regulatory authority to the states, but not to local jurisdictions. In March of 1972, the Senate Agriculture Committee considered the bill passed by the House of Representatives. On June 7, 1972, the Senate Committee reported out the bill. Regarding the preemption of local government regulation of pesticides, the accompanying report states (Senate Report No. 92-838, 92d Cong., 2d Sess.):

> The Senate Agriculture Committee considered the decision of the House Committee to deprive political subdivisions of States and other local authorities of any authority or jurisdiction over pesticides and concurs with the decision of the House of Representatives. Clearly, the fifty States and the Federal Government provide sufficient jurisdictions

> to properly regulate pesticides. Moreover, few, if any, local authorities whether towns, counties, villages, or municipalities have the financial wherewithal to provide necessary expert regulation comparable with that provided by the State and Federal Governments. On this basis and on the basis that permitting such regulation would be an extreme burden on interstate commerce, it is the intent that Section 24, by not providing any authority to political subdivisions and other local authorities of or in the States, should be understood as depriving such local authorities and political subdivisions of any and all jurisdiction and authority over pesticides and the regulation of pesticides. 3 U.S. Code Cong. & Ad. News, p. 4008 (1972).

The summary of the Senate committee report bears repeating: "it is the intent of Section 24 ... [to deprive] local authorities and political subdivisions of any and all jurisdiction and authority over pesticides and the regulation of pesticides."

If any more insight into Congressional intent is needed, it is provided by what occured thereafter, when the Senate Commerce Committee offered an amendment to the bill specifically to allow local jurisdictions to regulate pesticides. The Senate rejected that amendment by a vote of 71-0. 118 Cong. Rec. 32251, 32263

During the 1980s, there have been attempts by various political subdivisions of thirteen states, such as cities and townships, to get involved in the process of regulating the sale or use of pesticides or requesting generation of data. Local jurisdictions are enacting restrictions that create considerable hardships for farmers, foresters, and homeowners.

Not only do local regulations place burdens on pesticide users, but local regulations are unnecessary in light of the extensive system of state and federal regulation. Additionally, local jurisdictions are not equipped to make the scientific decisions needed to regulate pesticide use properly.

To solve the growing problem of local pesticide regulation, an amendment is proposed to Section 24(a) of FIFRA, which grants limited pesticide regulatory authority to the states. With the amendment, that Section would read: "A State, but no political subdivision of a State, may regulate the sale and use of any federally registered pesticide ...."

We believe that the statute ought to reflect the Congressional intent that political subdivisions below the state level should not regulate the sale or use of pesticides.

2. Distinction Between Agricultural and Nonagricultural Pesticides. Congress added a new requirement to FIFRA in 1978 to the effect that regulations prescribed by the Administrator to carry out the Act must 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. This amendment extended the provision in the

existing law which required the Administrator to take into account the differences in concept and usage between various classes of pesticides, by mandating the Administrator to apply such distinction in prescribing and evaluating data for nonagricultural pesticides.

The Agency has not, in fact, yet fully implemented this congressional directive. We respectfully urge this subcommittee to provide specific language directing the EPA to separate out and utilize current administrative staff to specifically administer any regulations and guidelines which pertain to the nonagricultural portion of the pesticide industry.

We specifically recommend two changes in this area:

a) A new section 24(d) could be added to Section 24 to mandate that states take into consideration the differences between agricultural and nonagricultural pesticides.

In promulgating any regulations, policies, or protocols pertaining to the sale or use of peticides within a State, the State shall take into account the difference in concept and usage between various classes of pesticides and the differences in environmental risk and the appropriate data for evaluating such risk between agricultural and nonagricultural pesticides.

b) A new subsection 3(f) is needed to deal with data in support of a state registration.

In making a request for data submitted in support of a Federal registration, the State should take into account the difference in concept and usage between agricultural and nonagricultural pesticides.

3. To Use Any Registered Pesticide in a Manner Inconsistent With Its Labeling. A new section 2(ee)(5) could be added to permit use of one pesticide in the formulation of another registered end-use product or to allow repacking of a registered product into another end-use product unless prohibited specifically by the labeling (similar language was included in H.R. 5203, 97th Congress).

Another new section 2(ee)(6) should be added to specify that a misuse statement is not required on the label of all pesticides as is required by regulation. Household disinfectants and sanitizers that are required to use the statement "It is a violation of federal law to use this product in a manner inconsistent with its labeling" make such statements unbelievable. The users will simply refuse to believe they may be prosecuted if they do something other than that listed on the label.

Under section 2(ee), there should be an exemption for those "applying a household cleaning product containing a disinfectant or sanitizer active ingredient, in household or institutional cleaning uses."

4. Section 10. Protection of Trade Secrets and Other Information. We would like to specifically recommend three potential changes in section 10.

a) FOIA Procedures. Under FOIA procedures, the EPA routinely releases the label of a product and internal EPA memos on the review of data submitted as soon as registration is granted. The EPA does not recognize that such notification to a competitor before sales begin can be a disclosure of highly confidential marketing information, i.e., that a company intends

to enter a specific market with a specific product. The time lag between registration and sales can be quite lengthy.

Disclosures of any information on the intent to market a pesticide should commence at the start of sales, unless such disclosure is specifically necessary to protect against a suspected unreasonable risk to health or the environment.

b) Notification About Information Requested. Although the Administrator shall notify the submitter of his intent to disclose trade secrets under Section 10(d)(3), disclosure of other data and information is not covered under FIFRA. A submitter should have the right to be advised that its data has been requested and that the agency plans to release it.

c) A New Section (f) Concerning Disclosure to States and State Agencies. This amendment would allow disclosure of information to states or state agencies if the state or state agencies adopt "security precautions" for this information. Information otherwise protected from disclosure to the public, under subsection (b) of this section, may be disclosed to states or state agencies or state employees for registration at the state level, and under such conditions as the Administrator may by regulation specify. The Administrator shall require as a condition to the disclosure of information under this subsection that the state or state agencies receiving it adopt the necessary authority and procedures for the protection of such information equivalent to that provided under this Act and shall take such security precautions respecting the information as the Administrator shall by regulation prescribe.

We support the EPA efforts to also address this important area.

5. Section 3. Registration of Pesticides. We would like to comment very briefly on some potential changes to section 3.

a) Development of FIFRA Registration Data Guidelines. CSMA has in the past expressed serious concern over the development and implementation of guidelines which are intended by Congress to set forth the kinds of data which would be requried to support a registration.

The Congressional intent behind Section 3(c)(2) of FIFRA is to specify generally the kinds of basic data or information which may be required to support a registration, but at the same time permit latitude and flexibility on the part of scientists in developing their data.

During the 97th Congress, CSMA worked with EPA, members of Congress, and other interested parties to achieve some legislative changes to FIFRA, Section 3, to correct the guidelines problems. Legislative language providing for publication of flexible guidelines and modifications in the Federal Register and for submission of public comment for agency guidance was adopted by the House when it passed H.R. 5203 on August 11, 1982.

While the EPA has moved a long way in addressing this problem, we still believe that the FIFRA statute should appropriately address this issue, so as to reflect Congressional intent.

b) Section 3(c)(3). Time for Acting With Respect to Application. This section should be amended to include a time

period in which an application should be reviewed and approved, or, reviewed and a determination made as to any shortcomings. A 90-day period is suggested in which the EPA must notify the registrant of approval or 30 days to notify the registrant of a deficiency of the application.

c) Section 3(d)(1)(C). Restructuring of Classification System For "Restricted Use." This classification should be "as determined by the Administrator" rather than automatic if certain arbitrary scores on eye irritation, etc., are found. Administrator's determination should be based on hazards which cannot be adequately dealt with by labeling (warnings, etc.).

6. Section 7(d). Confidential Records and Information. This section covers keeping records submitted under Section 7(c) confidential. EPA, despite having such data in its files (updated annually), periodically seems to separately request such data for other purposes because it does not have the data catalogued in a way that allows it to retrieve them. For example, if it wants to know how many products are using sodium hypochlorite in what amounts, it asks the registrants to duplicate data already in EPA's files. Section 7(d) should be amended to force EPA to use these data in its files for these purposes instead of asking registrants to continually duplicate them.

III. CSMA'S CONCERNS ABOUT OTHER POTENTIAL FIFRA AMENDMENTS

Finally, we understand that a revised version of H.R. 3818 (98th Congress), and perhaps other amendments, are likely to be introduced in the near future.

We request that additional hearings be held to examine these amendments in some depth before they are considered by the subcommittee. This policy would be consistent with the long-standing tradition of the subcommittee.

CONCLUSION

We would like to generally associate ourselves with the testimony offered by other members of the FIFRA Coalition. This broad-based coalition of organizations representing urban and rural pesticide user groups, agricultural user groups, farm groups, and commodity producers as well as manufacturers reflects many different concerns about FIFRA. (Please see attached list of the FIFRA Coalition membership.)

In addition, we would like to commend this subcommittee and the full House Agriculture Committee for its long-standing commitment to reasonable and rational FIFRA legislation.

In conclusion, we share a common concern that all pesticides are safe and effective for their intended uses and that they do not pose unreasonable risks to man and his environment. Many of the concerns we have noted in our full text today impose an unnecessary economic burden upon our industry and will deprive consumers of safe and effective pesticides needed to control pests which disrupt our economy and reduce the quality of our lives. CSMA is committed to work with this subcommittee to help resolve these important concerns.

(Attachment follows:)

FIFRA COALITION

American Association of Nurserymen
1250 Eye Street, NW, Suite 500
Washington, D. C. 20036
John Satagaj
(202) 789-2900

American Pulpwood Association
1619 Massachusetts Avenue, NW
Washington, D. C. 20036
Kenneth S. Rolston
(202 265-0670

American Seed Trade Association
1030 15th Street, NW, Suite 964
Washington, D. C. 20005
David Lambert
(202) 223-4080

American Soybean Association
600 Maryland Avenue, SW, Suite 510
Washington, D. C. 20024
John Baize
(202) 554-7804

American Wood Preservers Institute
1945 Gallows Road, Room 405
Vienna, VA 22180
Walt Talarek
(703) 893-4005

Chamber of Commerce of the USA
1615 H Street, NW
Washington, D. C. 20062
Stu Hardy
(202) 463-5533

Farm and Industrial Equipment Institute
410 N. Michigan Avenue, Room 680
Chicago, IL 60611
L. James Nelson
(312) 321-1470

Florida Sugar Cane League
918 16th Street, NW, Suite 501
Washington, D. C. 20006
Mike Morton
(202) 785-4070

Interior Plantscape Association
11800 Sunrise Valley Drive
Reston, VA 22091
Jane Dockery
(703) 476-8550

International Apple Institute
P.O. Box 1137
McLean, VA 22102
Derl Derr
(703) 442-8850

International Sanitary Supply Association
5330 N. Ellston Avenue
Chicago, IL 60630
Jack D. Ramaley
-800-225-4772

National Agricultural Aviation Association
115 D Street, SE
Washington, D. C. 20003
Harold M. Collins
(202) 546-5722

National Agricultural Chemicals Association
1155 15th Street, NW, Suite 514
Washington, D. C. 20005
Luther Shaw
(202) 296-1585

National Arborist Association
3537 Stratford Road
Wantagh, NY 11793
Robert Felix
(516) 221-3082

National Association of Wheat Growers
415 2nd Street, NE, Suite 300
Washington, D. C. 20002
Margie Williams
(202) 547-7800

National Cattlemen's Association
425 13th Street, NW, Suite 1032
Washington, D. C. 20004
Ronald Michieli
(202) 347-0228

National Club Association
1625 Eye Street, NW, Suite 609
Washington, D. C. 20006
Gerald F. Hurley
(202) 466-8424

National Corn Growers Association
c/o Mike Hall Associates
1015 15th Street, NW, Suite 201
Washington, D. C. 20005
Michael Hall
(202) 371-1450

National Cotton Council of America
1030 15th Street, NW, Suite 700
Washington, D. C. 20005
LaVerne Still
(202) 833-2943

National Council of Agricultural Employers
1435 H Street, NW, Suite 435
Washington, D. C. 20005
Pat Quinn
(202) 628-8650

National Council of Farmer Cooperatives
1800 Massachusetts Avenue, NW, Suite 604
Washington, D. C. 20036
Tom Van Arsdall
202 659-1525

National Fertilizer Solutions Association
9923 N. Industrial Road
Peoria, IL 61615
Bob Wanzell
(309) 691-2870

National Food Processors Association
1401 New York Avenue, NW, Suite 400
Washington, D. C. 20005
Claudia Fuquay
(202) 639-5942

National Forest Products Association
1619 Massachusetts Avenue, NW
Washington D. C. 20036
Robert Kirshner
(202) 797-5863

National Golf Association
200 Castlewood Drive
North Palm Beach, FL 22408
Sheridan "Joe" Much
(305) 844-2500

National Pest Control Association
8100 Oak Street
Dunn Loring, VA 22027
Harvey S. Gold
Jack Grimes
(703) 573-8330

National Peach Council
P.O. Box 1085
Martinsburg, WV 25401
Lillie E. Hoover
(304) 267-6024

National Sprayer & Duster Association
c/o H. D. Hudson Manufacturing Company
1625 Eye Street, NW, Suite 819
Washington, D. C. 20036
Gustav "Gus" Blackett
(202) 331-1245

Pesticide Producers Association
c/o Bishop, Liberman, Cook, Purcell,
& Reynolds
1200 17th Street, NW
Washington, D. C. 20036
Graham Purcell
Denny Larr
(202) 857-9800

Pesticide Public Policy Foundation
1511 K Street, NW, Suite 623
Washington, D. C. 20005
Steve Sember
(202)
1270 Chemeketa Street, NE
Salem, OR 97301
David Dietz
(800) 438-7773

Professional Ground Management Society
c/o Moltz Environmental Maintenance
4612 Kellogg Avenue
Cincinnati, OH 45226
Joe Moltz
(513) 871-3992

Professional Lawn Care Assn. of America
1225 Johnson Ferry Road, NE, Suite B220
Marietta, GA 30067
James R. Brooks
(404) 977-5222

Rio Grande Valley Sugar Cane Growers Cooperative
918 16th Street, NW, Suite 501
Washington, D. C. 20006
Horace D. Godfrey
(202) 785-4070

Society of American Wood Preservers, Inc.
1401 Wilson Boulevard, Suite 205
Arlington, VA 22209
E. David Lewis
(703) 841-1500

Southern Agricultural Chemical Association
P.O. Box 686
Dawson, GA 31742
Ed Duskin
(912) 995-2125

United Fresh Fruit & Vegetable Association
727 N. Washington Street, 4th floor
Alexandria, VA 22314
Hilan Yager
(703) 836-3410

U. S. Beet Sugar Association
1156 15th Street, NW
Washington, D. C. 20005
David Carter
(202) 296-4820

Western Agricultural Chemicals Association
6650 Belleau Wood Lane
Sacramento, CA
John Browning
(916) 393-4050

Center for Commercial Floriculture
1601 Duke Street
Alexandria, VA 22314
(703) 836-8700
Elaine Acevedo

Chemical Specialties Manufacturers Association, Inc.
1001 Connecticut Avenue, NW, Suite 1120
Washington, D. C. 20036
Ralph Engel
Warren Stickle
(202) 872-8110

SUBMITTED BY RICHARD D. KELLEY:

Agricultural Chemicals and Groundwater Quality in Iowa

George Hallberg

In the past year or two, there has been much discussion in the news media about drinking water supplies being contaminated with agricultural chemicals. Interest peaked in the spring of 1984 when more than 40 public water supplies in Iowa went on notice for exceeding the drinking water standard of 45 mg/l nitrate (10 mg/l as nitrate-N). This included Des Moines, which is the largest municipality in the country ever to exceed this standard. Reports of increasing problems with nitrates in drinking water has been the trend over the last two decades.

During the same time, the primary concern related to agricultural chemicals and water was on the "nonpoint" source contamination of surface water or streams related to runoff and soil erosion from row crop areas. Nonpoint source problems involve the delivery of sediment, nutrients, and other chemicals (particularly pesticides) into surface waters from the extensive areas of cultivated and chemically treated land.

Only recently has attention been turned to groundwater. Groundwater is a major component of our hydrologic system, and most Iowans depend on groundwater for their drinking water supplies, either directly (through wells) or indirectly (groundwater sustains the base flow of Iowa's streams).

For the past 4 years, the Iowa Geological Survey (IGS), in cooperation with other state, federal, and local agencies, and workers from Iowa State University, has been conducting extensive research on groundwater quality related to surface-applied chemicals. This work has been carried out primarily in northeastern Iowa for two principal reasons: (1) in northeastern Iowa there are extensive areas where important, regional limestone aquifers (rock or soil units that can supply water to wells) occur very near the land surface; and (2) over the past decade in particular, well drillers and individuals in this area have reported increasing difficulty in finishing wells of reasonable depth (and cost) without nitrate (NO_3) problems, and many dairy operators have had to drill new wells or find new water supplies because of nitrate and bacteria problems.

All these events have transpired at the same time that Iowa and the Corn Belt have undergone great expansion in total corn acreage and, more important, a dramatic increase in the rate of nitrogen fertilization. Between 1960 and 1976, the amount of nitrogen applied in Iowa increased from about 100,000 tons to over 1,000,000 tons (Harmon and Duncan, 1978).

Experimental Farm Studies

In conjunction with corn yield and N-fertilizer response research, several midwestern experimental farm studies also have collected data on the relationship between chemical N-fertilizer application rate and the amount of NO_3-N stored in the soil profile after harvest and/or the amount of NO_3-N lost in subsurface tile drainage water.

In order to provide a background for this discussion, a few typical examples of the results are shown graphically in figures 1 through 3. Figures 1 and 2 show data from south-central Minnesota and north-

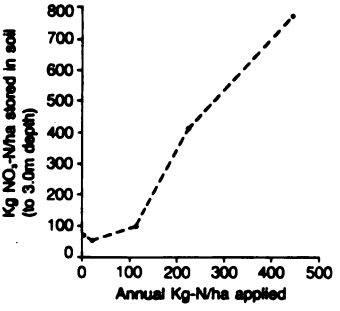

Figure 1. Minnesota experimental farm data showing relationship between N-fertilization rate and the amount of NO_3-N stored in the soil to about 10 feet depth. Soil type—Webster CL; 3 years of treatment (from Gast et al., 1978).

To convert Kg/ha to lb/A, multiply by 0.9.

George Hallberg is chief, Geological Studies, Iowa Geological Survey, Iowa City. This paper is a summary of his presentation at Iowa's 37th Annual Fertilizer and Ag Chemical Dealers Conference, January 8-9, 1985, Veterans Memorial Auditorium, Des Moines.

Cooperative Extension Service
Iowa State University
Ames, Iowa 50011

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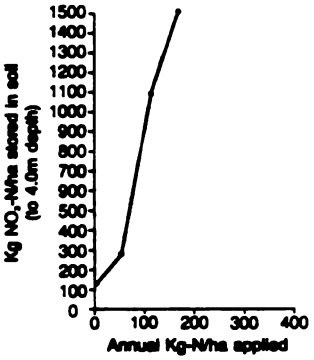

Figure 2. Iowa experimental farm data showing relationship between N-fertilization rate and the amount of NO_3-N stored in the soil to about 13 feet depth. Soil type—Moody SiCL; 17 years of treatment; (from Jolley, 1974).

To convert kg/ha to lb/A, multiply by 0.9.

western Iowa experimental farms. The bottom (horizontal) axis of the graph shows the rate of chemical-N applied, and the left (vertical) axis shows the amount of NO_3-N per hectare (ha) remaining in the soil. The scale of the left axis differs because of differences in the depth of measurement in the soil and in the length of time of treatment.

Figure 3 shows the relationship between rate of N-application and the amount of NO_3-N/ha lost in tile drainage water. Tile drainage water is shallow groundwater, and the response in tiles can provide a proxy view of infiltrating groundwater, although at a very shallow depth.

The important point of the graphs is not the absolute numbers shown, but rather the overall trend. From these and other studies, it is apparent that the amount of NO_3-N that accumulates in the soil and the amount that may be lost in tile drainage water (groundwater) increases in a direct and nearly linear fashion with N-fertilizer application rates above about 50 lb N/A.

This occurs because the amount of N available is in excess of the amount being taken up and utilized by the corn crop. For example, figure 4 shows the "N-balance sheet" for 17 years of continuous corn from the northwestern Iowa study. These data are corrected from plots, with no N-fertilizer applied and are expressed in terms of the percentage of fertilizer-N recovered.

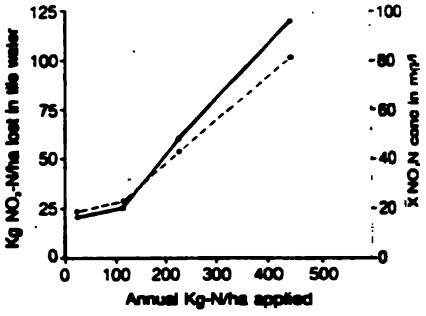

Figure 3. Minnesota experimental farm data showing relationship between N-fertilization rate and amount of NO_3-N lost in tile-drainage water (solid line) and flow-weighted mean NO_3-N concentration in water (dashed line). Soil type—Webster CL; 3 years treatment; (from Gast et al., 1978).

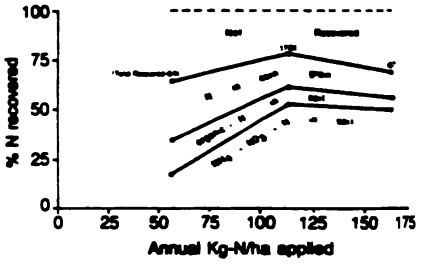

Figure 4. Percentage of fertilizer-N recovered in soil and grain (corrected from no-fertilizer-N check plot) (from Iowa experimental farm study, as figure 2, from Jolley, 1974).

Note that at application rates of 100 and 150 lb N/A only about 15 percent of the fertilizer-N was removed with the corn; over 50 percent remained stored in the soil. Another 20 to 30 percent was not recovered and was lost in runoff water, groundwater and/or in gaseous losses. Many published studies would suggest that average N-fertilizer recovery for corn is in the range of about 35 percent. Recent studies using isotopically labeled fertilizers also suggest that large amounts of fertilizer-N may be leached below the root zone before the corn is even capable of using it. Such losses have been "built-in" to N-fertilizer yield-response models without fully understanding the inefficiencies and losses involved.

A different picture emerges if these data are extrapolated to areas where aquifers occur at shallow depths below the land surface, or where the aquifers and soils promote rapid, deep infiltration. In such settings, the excess NO_3-N is no longer simply stored in the soil or discharged in tile drainage water, but some of this NO_3-N is delivered into the groundwater that is used for drinking. Such settings occur over broad areas of northeastern Iowa and in alluvial aquifer settings along stream valleys throughout the state.

Temporal Changes in Groundwater Quality in Northeastern Iowa

As part of the IGS studies in northeastern Iowa, a variety of detailed information has been compiled for the Big Spring basin in northern Clayton County. Various data indicate that the natural, or background, concentrations of nitrate in the aquifers in northeastern Iowa were very low, generally <5mg/l (<1mg/l NO_3-N). At Big Spring, the nitrate concentration in the groundwater averaged about 12 to 14 mg/l NO_3 (3mg/l NO_3-N) during the 1950s up through about 1968. In 1981-82, when IGS began detailed monitoring, the NO_3 concentration averaged 40mg/l (9 NO_3-N), and 45mg/l (10 NO_3-N) in 1983. Data from over 50 wells sampled in surrounding counties during 1975 and 1983 show the same rate of increase.

Data compiled by the Crop and Livestock Reporting Service was used to evaluate changes in land use and chemical use that took place in the basin during this time frame. From the late 1960s until around 1980 the livestock population increased about 30 percent, the corn acreage increased about 40 percent, and the N-fertilizer application rate increased about 80 percent. These data can be converted to the amount of N applied in the basin from the various sources.

Using standard assumptions, the amount of manure-N is a direct function of the livestock population. Thus, manure-N increased about 30 percent. The corn acreage increase and the N-fertilizer rate increase are additive factors and, thus, the amount of fertilizer-N applied in the basin increased about 250 percent over the same time frame that the NO_3 concentration in the groundwater increased about 230 percent. The maximum amount of N harvested with the corn can also be estimated from standard formulas; this estimate is a maximum because the data cannot be corrected for zero-N treatments. All these data are shown graphically on figure 5.

The increase in NO_3 concentration in groundwater directly parallels the increase in the amount of

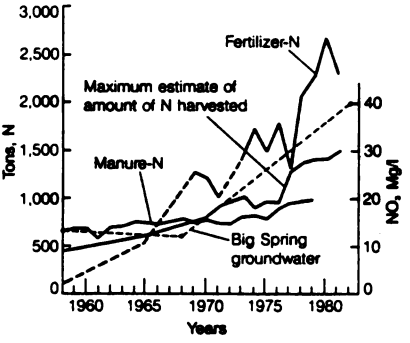

Figure 5. Estimated tons of fertilizer-N and manure-N applied in the Big Spring basin; estimated tons of N removed by corn harvest (gray line) and average NO_3 concentration (dashed line, right axis for scale) in groundwater at Big Spring (from Hallberg et al., 1983, 1984).

fertilizer-N applied in the basin. This is the same direct, linear response shown by the experimental farm studies, and this is the response that should be predicted in areas with shallow aquifers, such as in the Big Spring basin. Also, there are no industries, landfills, municipalities, or large feedlot operations in this basin to complicate the interpretation.

Delivery of Agricultural Chemicals to Groundwater in Carbonate Aquifers in Northeastern Iowa

In some areas of northeastern Iowa "karst-topography" has developed on the carbonate aquifers. Over long periods of time, portions of the limestone, or carbonate rocks, are dissolved away by the percolating groundwater. This dissolution eventually may form caves or conduits in the rock and widen vertical fractures. As these features enlarge, the overlying soil may collapse into the widened fracture, or soil and rock may collapse into an underlying cavern. This process creates a sinkhole at the land surface, which may range in size from a few feet in diameter to sinkholes large enough to swallow sizable streams.

When sinkholes collapse around buildings, under machinery, or in livestock areas they can be a physical hazard to farmers. Sinkholes are also detrimental to groundwater quality because they allow surface runoff water, and the contaminants it may carry, to enter the groundwater system directly.

Thus, there are two basic components of recharge that deliver surficially-applied chemicals into the groundwater in these karst-carbonate aquifers: (1) infiltration, diffuse percolation through the soil; and (2) direct runin of surface runoff water into sinkholes. Too often in the past, we have attributed the water quality problems in northeastern Iowa to sinkholes. Recent, detailed studies show that nitrates, pesticides, bacteria, and suspended sediment and organics are the groundwater contaminants of primary concern at the regional level in northeastern Iowa.

These studies also show that: (1) the infiltration component delivers to groundwater the largest mass and the highest concentrations of nitrates (and other soluble, mobile chemicals) and the largest mass of soluble pesticides but generally in low concentrations; (2) the runin component delivers to groundwater high concentrations and large loads of pesticides and relatively insoluble chemicals for short periods, peak turbidity and sediment loads, and other peak loads of organics and pathogenic organisms.

Detailed monitoring during rainfall runin events at Big Spring shows that the high surface water concentrations of parameters, such as suspended sediment and pesticides, move as a "slug" through the groundwater system, discharging from the groundwater in essentially the same concentration that they entered. These events also introduce bacteria and potentially pathogenic organisms into the groundwater.

Various quantitative methods provide estimates (greater than 10 percent) of the relative contributions of these components. Over the duration of a water year the infiltration component contributes about 90 percent of the water, about 95 percent of the nitrate-N, and 50 to 85 percent of the more soluble pesticides (e.g., atrazine). The runin component delivers about 10 percent of the water, only about 5 percent of the nitrate, but from 15 to 50 percent of the pesticides. While the runin component delivers contaminants to the groundwater, which is of concern for public health on the local level, the infiltration component is responsible for regional aquifer contamination. Also, infiltration is the recharge mechanism common to all aquifers, which gives these data much broader implications.

Additional studies in Floyd and Mitchell counties show that the greatest concentrations of nitrate and pesticides in groundwater occur in an area that has no open sinkholes. This is an intensive row-crop area of corn and soybeans where the aquifer occurs at 3 to 15 feet. The land is relatively flat and marked by high rates of infiltration. The quality of drinking water from the groundwater in this area is very similar to that in tile lines from other row-cropped areas.

Statistical review of water quality data from across Iowa shows that shallow wells (less than 50 feet deep in particular) exhibit elevated concentrations of nitrate. In some alluvial aquifer settings, denitrification is removing the nitrates but pesticides are still infiltrating to (and persisting in) the groundwater.

Also, these surface-applied chemicals are stored in the soil until infiltrating water carries them downward into the groundwater. Because infiltration is the principal component of recharge, the timing of nitrate fluctuations in water supplies is related to seasonal recharge periods and not to the timing of seasonal agricultural practices. This is why nitrate concentrations in wells and streams may increase during spring recharge, often many weeks before N-fertilizers are applied.

Pesticides in Groundwater

One of the unexpected findings of recent IGS studies has been that the most commonly used herbicides in Iowa are occurring in groundwater, and also that they persist in groundwater year round (This only includes monitoring in areas of routine use. In isolated instances, from spills or siphoning accidents other pesticides or higher concentrations have been noted.)

Table 1 shows the pesticides that have been detected in groundwater and the maximum concentrations detected to date (in micrograms/liter or parts per billion). Only one insecticide has been detected. Fonofos was detected in low concentrations in a few samples in a karst area, and these samples were related to the runin water component To date, however, the analyses have been only for

Table 1. Pesticides and their maximum concentrations detected in groundwater in northeastern Iowa, 1981-83. (From Hallberg et al., 1983, 1984; Libra et al., 1984.)

Common name—Active ingredient	Typical trade name	Maximum concentration ug/l (ppb)
Herbicides*		
Alachlor	Lasso	16.6
Atrazine	Atrazine, AAtrex	10.0
Cyanazine	Bladex	1.2
Metolachlor	Dual	0.6
Metribuzon	Sencor, Lexone	4.4
Insecticides		
Fonofos	Dyfonate	0.1

*All herbicides have been found in winter or "pre-application" groundwater samples

parent compounds, and it is not known if metabolites, or breakdown products, of these or other pesticides are occurring.

From the IGS studies in northeastern Iowa 70 to 80 percent of the wells and springs sampled in karst, shallow-bedrock, and alluvial settings (in the latter two categories only infiltration recharge occurs) have shown detectable concentrations of some pesticides over the course of a water year. The maximum concentrations noted in table 1 are associated with either runin-recharge in karst areas, or very shallow bedrock-high infiltration conditions. The typical year round or winter concentrations of these pesticides are generally 0.1-1.0 ug/l.

If NO_3 concentrations greater than 10mg/l occur in well water samples, there is a very good liklihood that the groundwater will contain detectable pesticides. However, the concentration of nitrate is not a very good predictor of the absolute concentration of the pesticides. Also, as noted in some alluvial settings, denitrification is removing the NO_3, but pesticides may still occur.

Magnitude of Chemical Losses in Waters

The monitoring of water discharge, water chemistry, land management, and chemical use in the Big Spring basin allows some mass-balance calculations to be made. For two complete water years of monitoring, the amount of NO_3-N discharged with groundwater and surface water from the Big Spring basin totaled about 1.8 and 2.8 million pounds during a near-normal and wet year, respectively. This equals about 50 and 75 lb N/A for the long-term row-cropped area of the basin. These losses are equivalent to about 33 to 55 percent of the average amount of fertilizer-N applied during the preceding years (table 2). As with the experimental farm studies, this does not imply that all of this NO_3-N is derived directly from the fertilizer-N. However, the large losses occur in response to the large amounts applied.

These are minimum figures for the amount of N lost, because only the NO_3-N losses are computed. Other forms of N are also discharged with the water and losses by denitrification cannot be estimated. Comparison with other regional data and other local studies suggest that these losses are probably typical for Iowa under current management practices.

Beyond the environmental impact, the magnitude of the N-losses are of economic concern as well. When crops (corn) are not utilizing 50 to 70 percent of the nitrogen applied there is obvious room for improved efficiency and economic gain. As noted, these concerns reach much further than northwestern Iowa and southcentral Minnesota where the leaching of chemicals probably has not directly affected drinking water supplies from groundwater, but the same chemical inefficiencies are apparent.

In contrast to the nitrate losses, the total pesticide losses are quite small. The total amount of atrazine discharged in groundwater at Big Spring, during the 2 water years, was about 14 and 32 lb. Total pesticide losses in groundwater were less than 1 percent; total losses in surface water and groundwater are estimated at between 1 and 5 percent.

Environmental Concerns

There are legitimate concerns for public health over the long term, if these groundwater, drinking water quality problems continue or increase. At the present time, only relatively shallow aquifers are affected. This, however, may simply be a function of time. Over time, if such chemicals persist in groundwater, they will be transmitted to deeper aquifers.

The pesticide concentrations, which are being routinely detected, are far below toxic levels and generally well below levels thought to contribute to long term, chronic problems such as cancer. However, there are many uncertainties involved with the combinations of pesticides, and possibly other metabolites, that occur in groundwater in relation to other environmental factors.

Concerns for nitrate have generally been centered around drinking water for infants and the problems of methemoglobinemia. However, recent research suggests that high-nitrate drinking water may contribute to other long-term health problems in children and adults. One recent epidemiological study suggests

Table 2. NO_3-N losses in groundwater and surface water from the Big Spring basin for 2 water years (Hallberg, et al., 1984).

Water year	Millions lb NO_3-N discharged/water	Equivalent lb/A, total basin	Equivalent lb/A, long-term corn acreage	Equivalent avg. fertilizer-N applied, percent **
1982	1.8	27	50	33
1983	2.8	43	75	55

*Over 5-year rotation.
**1979-1982

that nitrate concentrations below current standards may contribute to congenital (fetal) malformations. These studies are not definitive, but point out that there are many unknowns that need further research.

Future Needs

Results from the ongoing research described in this report and other parallel research at Iowa State University are providing a definition of the problem between land application of chemicals and groundwater quality. The next step is to look for solutions. A consortium of state, federal, and local agencies and university researchers and extension personnel are already at work on the design of needed research and demonstration projects. Agribusiness and industry also must play a role. A coordinated effort is needed to define cost-effective management alternatives, new technology, and education programs that can be applied to these problems.

The groundwater quality problems related to agricultural chemical use that are described here can only be resolved through a more holistic approach to agricultural management. We must couple our standard concerns for soil conservation and surface water quality with the need to also protect groundwater. Many standard approaches used to treat soil erosion can increase the infiltration of chemicals. New combinations of many current practices may be needed, and undoubtedly better chemical and nutrient management must play a part.

The magnitude of nitrogen losses, in particular, suggests that economic gains may be made from better N management, even if the costs of the impact on the environment are ignored. These problems will require a concerted effort by all segments of agriculture to gain the experience and data necessary to effect a satisfactory balance between efficient agricultural production and the protection of our water supplies.

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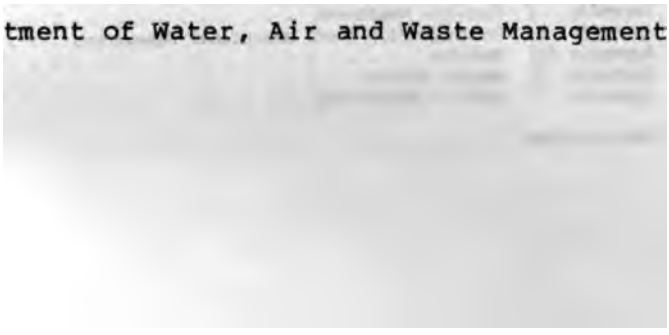
SYNTHETIC ORGANIC COMPOUND SAMPLING SURVEY OF PUBLIC WATER SUPPLIES

Richard D. Kelley

Iowa Department of Water, Air and Waste Management



April 1985

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ABSTRACT

The Department of Water, Air and Waste Management conducted a sampling survey of public drinking water supplies for the purpose of determining the presence of commonly detected synthetic organic compounds (SOC's) and commonly used pesticides. A total of 128 wells from 58 public water supplies were sampled between May, 1984, and March, 1985. Samples collected from 127 wells were analyzed for the presence of SOC's and analyses for pesticides were made on samples from 70 wells. Public water supplies monitored in this survey were selected because of the high probability that one or more of the contaminants would be present. Fifty-seven (57) wells serving 33 supplies were found to have one or more contaminants present in low concentrations. The herbicide, Atrazine, was the most commonly detected contaminant.

This survey was funded by the U.S. Environmental Protection Agency with additional support for analyses provided by the University Hygienic Laboratory. Technical support was provided by the Iowa Geological Survey.

INTRODUCTION

In 1979, the U.S. Environmental Protection Agency (EPA) conducted a nationwide monitoring program for the detection of synthetic organic compounds (SOC's). As a result of this monitoring effort, a number of public water supplies were identified as being contaminated with SOC's; some of these supplies were in Iowa. In 1981/1982, the EPA Region VII again monitored drinking water supplies in an effort to identify those systems contaminated by SOC's. The 1981/1982 monitoring was not conducted in Iowa, however, as the State did not have a drinking water program at that time. In 1984, with the State again operating a drinking water program, the EPA found it possible to support a sampling survey for the detection of SOC's in drinking water supplies in Iowa.

Based upon the findings of the Iowa Geological Survey in research conducted over the previous three years in northeast and north-central Iowa, the Department of Water, Air and Waste Management requested that the analytical parameters be expanded to include commonly used pesticides. Originally, the sampling was to have covered a six week period. However, the lab was not in a position to analyze the large number of samples in such a short period of time, and thus, the sampling was extended over a longer period.

Sampling began in May of 1984 and continued through March of 1985. Early in the course of the survey, it was decided that recheck samples would be collected from any supply where the initial sample indicated the presence of a contaminant in that supply's source of water. When supplies were rechecked, samples were collected from the wells originally monitored, additional sources of water in some cases, and the supply's finished water.

METHODOLOGY

The regional staff of the Department of Water, Air and Waste Management sampled 128 wells providing water to 58 public water supplies across the State of Iowa (Figure 1). The sampling locations were selected by the staff of the Department's regional offices. Sites were chosen on the basis of their proximity to industrial areas, hazardous waste sites, spills or abandoned dumps; the detection of SOC's in previous sampling programs; or, elevated levels of nitrate. Elevated nitrate levels are believed to be a good indicator of the ground water's susceptibility to the leaching of agricultural chemicals. Thus, locations with elevated nitrates would be likely locations for the detection of pesticide movement into ground water.

Sample collection containers were distributed to the regional offices by the University Hygienic Laboratory (UHL) intermittently to control the flow of samples for analysis. Upon receipt of the collection containers, samples were collected from the raw water source at or near the well head and returned to UHL.

Samples were analyzed for 31 synthetic organic compounds and, in some cases, 34 pesticides. The SOC parameters were chosen because they were previously identified by the EPA as those chemicals most commonly detected in ground water. The pesticide parameters represented those compounds which are commonly used in the state and have characteristics conducive to their appearance in ground water or that had been detected in ground water in the course of other studies. The University Hygienic Laboratory is certified by the EPA and followed accepted standard analytical procedures in conducting the analyses of the samples.

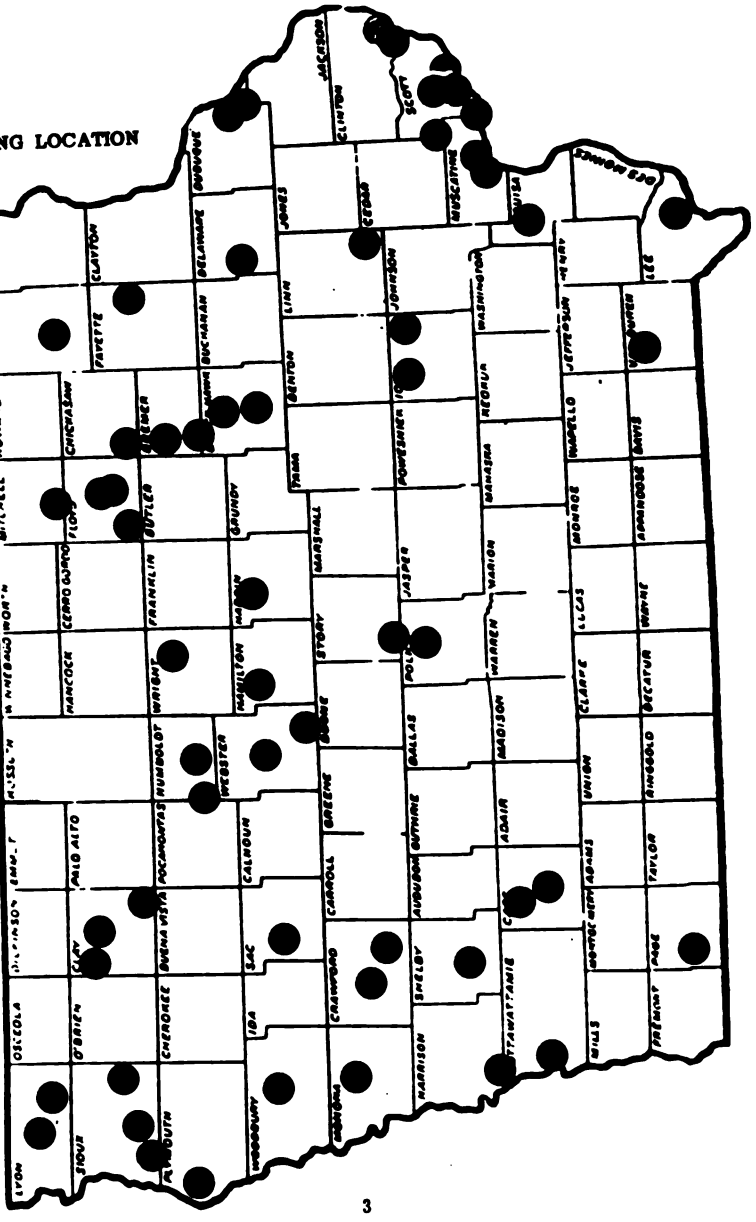
When contaminants were detected in the samples at quantifiable levels, containers for the collection of recheck samples were forwarded to the regional office. Recheck samples were then collected and returned to the lab for analysis.

Analytical results were reported directly to the Department of Water, Air and Waste Management. The Department of Water, Air and Waste Management notified the supplier of water of the analytical results and, when necessary, the significance of the level of a contaminant. In some cases, additional follow-up field activities were initiated.

The results of the sampling survey were assessed with respect to the frequency of occurrence of various contaminants, the range of concentrations and the geologic setting within which the contaminant occurred. The Iowa Geological Survey provided information on the wells monitored with regard to the well's depth, casing information and the geologic formation from which water was obtained.

Figure 1

SAMPLING LOCATION



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RESULTS AND DISCUSSION

A. Geographic/Geologic Distribution of Sample Collection. One hundred and twenty-eight (128) wells from 58 public water supplies were included in the monitoring. The distribution of the 58 supplies is shown in Figure 1. Sampling was for the most part equally distributed across the state with a noticeable absence of monitored supplies in south-central Iowa. Most of south-central Iowa is served by rural water systems, the largest of which relies upon surface water for its source. The majority of the remaining public water supplies of the region obtain their water from either surface supplies or deep aquifer systems. Given the criteria for selection of systems to monitor, the regional staff felt that very few acceptable sites existed in south-central Iowa.

A review of the geologic information on the wells sampled showed that the majority were shallow alluvial wells, although deeper pleistocene sands and gravels, buried channels and bedrock formations also served as sources of water for some of the supplies. The wells can be placed into one of four categories. These four categories represent the generalized description of the geologic setting within which the wells are located. Table 1 shows the number of wells within each category that were monitored for SOC's and for pesticides, and the percent of the total number of wells each represents.

Of the 128 wells that were monitored, 127 were sampled for the presence of SOC's and 70 were sampled for pesticides. Sixty-one (61) of the 128 wells were completed into alluvial groundwater systems. Twenty (20) of the wells were finished to deep alluvial, pleistocene sand and gravel or a mix of these two. Five of the wells were completed in bedrock aquifers but were either not cased or the casing was open to the overlying alluvial system. Forty-one (41) wells were completed and cased into the bedrock and information was not available on one well. The 46 bedrock wells represented two Cambrian wells; seven Ordovician, three of which were open to the overlying alluvium; 16 Silurian, two of which were open to the overlying alluvium; 12 Devonian; six Mississippian; and three Dakota wells. Figure 2 shows the distribution of well types and reflects the typical distribution of wells across the State.

TABLE 1

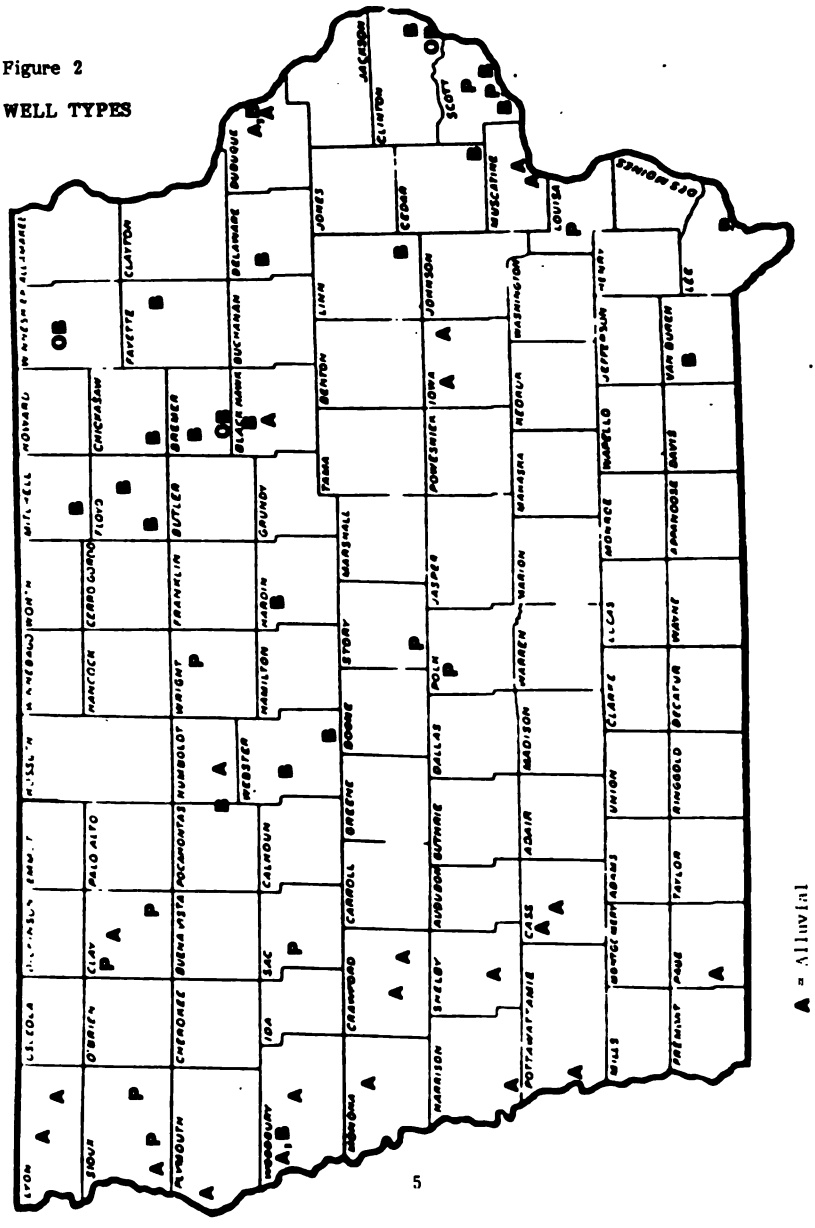
Number and Percent of Wells Sampled for Each Geologic Classification

	SOC		PEST	
	N	%	N	%
Alluvial	60	47.3	41	58.6
Pleistocene	20	15.7	9	12.9
Open Bedrock	5	3.9	4	5.7
Bedrock	41	32.3	16	22.8
Unknown	1	.8	0	0.0
TOTAL	127	100.0	70	100.0

57-556 O—86——24

Figure 2

WELL TYPES



B. Distribution of Contaminants. One or more SOC's and/or pesticides were detected at some quantifiable level in 57 wells serving 33 supplies. These 33 supplies were distributed fairly evenly across the State with the exception of north-central Iowa (Figure 3). The absence of contaminants in the supplies monitored in this region appears to be related to the fact that six out of eight supplies monitored in the region used wells finished into the bedrock. However, a review of the geologic setting of the 57 wells does not show a clear relationship between the geologic setting and the overall occurrence of a contaminant until individual groups of contaminants are considered. Individual groups of contaminants are discussed later in this report.

The most commonly detected contaminant was the herbicide Atrazine appearing in 24 wells from 14 supplies. The next most commonly detected contaminant was chloroform which was found in measurable levels in 11 wells serving 10 supplies. Tetrachloroethene, dibromochloromethane and the herbicide Bladex appeared in six supplies, and bromoform, bromodichloromethane and trichloroethene each were found in five supplies. Each of these will be discussed further below.

Sixteen (16) of the 31 organics for which analyses were made were detected in at least one supply at some measurable level. Six of the 34 pesticides analyzed for were detected at a measurable level in at least one supply. Although collection and analyses of recheck samples has not been completed yet, 22 of the 24 rechecks collected to date have confirmed the presence of contaminants either in the source or in the finished water.

The 22 contaminants that were detected in the survey can be divided in three groups: trihalomethanes, pesticides and other common synthetic organic compounds.

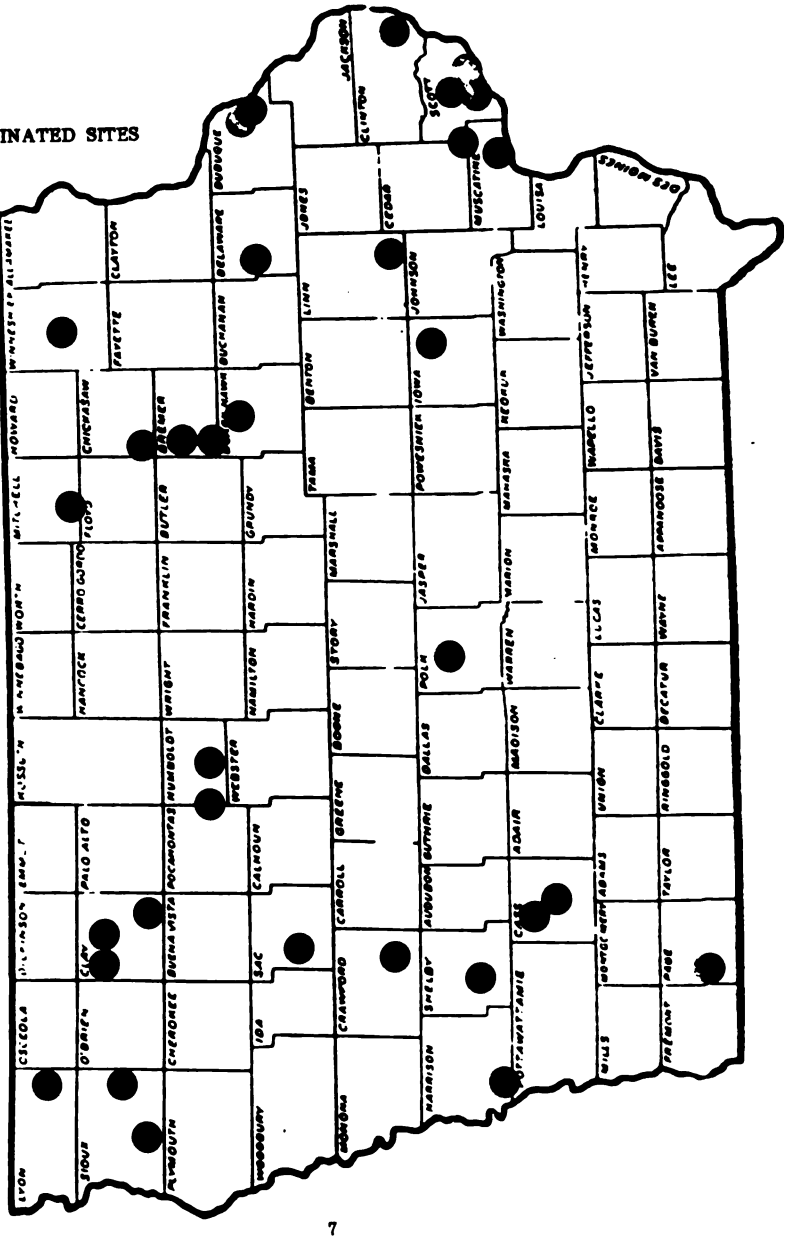
C. Trihalomethanes. Trihalomethanes (THMs) are members of a group of organic chemicals that form when organic compounds, primarily humic and fulvic acids, combine with chlorine, bromine and/or iodine. Synthetic or man-made organics usually will not combine with chlorine, bromine or iodine to form THMs, and raw water seldom contains THMs in significant concentrations.

Trihalomethanes are important in that at least one, chloroform, is a potential human carcinogen. The U.S. EPA also considers three other THMs to be potential carcinogens. Public water supplies serving at least 10,000 people are required to monitor for four THMs. Analysis for these same four trihalomethanes (chloroform, bromoform, bormodichloromethane, dibromochloromethane) was included in this survey.

The trihalomethanes, as a group, were the most commonly occurring contaminants, being detected at measurable levels in 18 supplies. At the same time, however, their appearance is the most difficult to explain. One would not expect THMs to be found in raw water samples; however, in 13 wells of 11 supplies, they were found. Recheck sampling found THMs in the finished water of 11 supplies, seven of which had no THMs present in their wells. At the same time, seven of the supplies which had THMs in measurable quantities in their wells had no measurable THMs in their finished water. All but five of the 18 supplies in which THMs were

Figure 3

CONTAMINATED SITES



found had at least one other organic and/or pesticide present in measurable concentrations. There was clearly no relationship between the geologic formation from which a well obtained water and the appearance of THMs.

Concentrations in the finished water of total trihalomethanes (TTHMs) ranged from 1 ug/l to 108 ug/l, with one-half the values below 13 ug/l. The maximum contaminant level for TTHMs is 100 ug/l but is only applied to public water supplies with a population of at least 10,000. Therefore, generally the concentrations found would not seem to pose a threat to human health by themselves. However, as has been noted, 13 of the 18 supplies had some other organic compound present in measurable concentrations. The implications to human health from exposure to low concentrations of numerous compounds over extended periods of time is unknown.

Individually, chloroform was the most commonly occurring THM, being detected in measurable concentrations in 10 supplies. Dibromochloromethane was detected in six supplies and, bromoform and bromodichoromethane were each detected in five supplies. The range of concentrations for each THM is shown in Table 2.

TABLE 2

Range of Values for THMs in ug/l

	Chloroform	*Bromoform*	*Bromodichloromethane*	*Dibromochloromethane*
LOW	*1.0*	*1.0*	*2.0*	*1.0*
HIGH	*100.0*	*10.0*	*21.0*	*28.0*

D. Other Common Synthetic Organic Compounds. Twelve (12) other commonly detected synthetic organic compounds were found in 25 wells serving 17 supplies. Four other compounds were detected below measurable concentrations in three additional supplies. Of the 17 supplies with measurable concentrations in their raw water source, seven had two contaminants, three had three contaminants, and one had four contaminants detected. No supply had more than four contaminants from this group present.

Four of the contaminants from this group; benzene, styrene, toluene and ethylbenzene are aromatic compounds commonly associated with petroleum products. Their presence strongly suggest the spill or leakage of petroleum products in the vicinity. Aromatics were detected in the wells of six supplies and, toluene and benzene in the finished water of one supply each (Table 3). One well contained benzene in a concentration of 540 ug/l; the next hightest concentration was 4 ug/l. The well is located near a spill and has been taken off line.

The most often detected of the common synthetic organics was tetrachloroethene which appeared in eight wells of six supplies. A concentration of 260 ug/l was

reported in one well; the next highest concentration was 13 ug/l. Table 4 shows the number of wells and supplies from which low concentrations of organics were detected.

The compounds represented in this group are all organics one would generally associate with a spill or a waste disposal site. Clearly, shallow ground-water systems are more susceptible to pollutants from these types of sources and the geologic information on the wells indicates that the vast majority of wells with problems are finished into alluvial formations (Tables 3 and 4).

In three supplies, the concentration of the contaminant in the source water was high enough to be of some concern with respect to human health. In all three cases, the well has been taken off line (or closed) and the supply is continuing to monitor for the contaminant. Concentrations in the finished water are all low. However, as with THMs, the affects upon human health from long term exposure to low concentrations of a number of organic compounds are unknown.

TABLE 3

Aromatics

Contaminant	*Benzene*	*Styrene*	*Toluene*	*Ethylbenzene*
# of Supplies Contaminated	*2*	*2*	*1*	*1*
# of Supplies w/Positive Values in Finished Water	*1*	*0*	*1*	*0*
# of Wells Contaminated	*2*	*2*	*0*	*1*
# of Alluvial Wells	*2*	*0*	*0*	*0*
Low Value (ug/l)	*2.0*	*1.0*	-	-
High Value (ug/l)	*540.0*	*1.0*	*5.0*	*1.0*

Table 4
Other Organics

Contaminant	Tetra-chloro-ethene	Tri-chloro-ethene	1,1,1-Tri-chloro-ethane	1,1-Di-chloro-ethane	Methylene Chloride	Carbon Tetra-chloride	1,2-Di-chloro-ethane	1,1,2-Tri-chloro-ethane
# of Supplies Contaminated	**6**	**5**	**4**	**4**	**3**	**2**	**3**	**1**
# of Supplies w/Postive Values in Finished Water	1	0	2	1	0	2	0	0
# of Wells Contaminated	8	7	5	7	4	3	3	1
# of Alluvial Wells	7	5	4	6	2	3	2	0
Low Value (ug/l)	1.0	2.0	1.0	1.0	1.0	0.1	4.0	-
High Value (ug/l)	260.0	10.0	24.0	3.0	5.0	66.0	19.0	1.0

E. Pesticides. Twenty-eight of the 70 wells monitored for pesticides were found to have a measurable concentration. The 28 wells represent 18 supplies. Of the 34 pesticides analyzed, only Atrazine, Bladex, Lasso, Dual, Sencor, and Dyfonate were found. Of these six pesticides, Dyfonate is the only insecticide, the rest are herbicides.

Table 5 summarizes the pesticide information with respect to the frequency of occurrence and range of concentrations. The high concentrations in parenthesis are values associated with one unique situation. The city involved has now closed the wells which produced these values. However, the water taken from these wells does represent the water quality of the alluvial aquifer at that location.

TABLE 5
Summary of Frequency and Range of Concentrations Information for Various Pesticides

		Atrazine	Bladex	Lasso	Dual	Sencor	Dyfonate
# of Supplies Contaminated		14	6	3	2	2	3
# Reported in Finished Water		5	0	0	0	0	0
Range ug/l	Low	.1	.1	.09	.32	.29	.11
	High	3.0(13.0)	1.4	.32(11.0)	.32(7.8)	.29(1.1)	.9

Atrazine was the most commonly detected pesticide being found in 24 wells in 14 supplies. Bladex was the second most commonly detected pesticide found in seven wells in six supplies. Lasso and Dyfonate were each detected in three supplies. Only Atrazine was found in the finished water of any supplies and it was present in five of them.

There is a clear relationship between the depth of the well and the appearance of pesticides. Nineteen (19) of the wells with Atrazine were alluvial and the other five were bedrock. However, three of the five bedrock wells were open to the surface (i.e., the wells were not cased, the casing was perforated, the well was located in a karst setting or the overlying alluvium was screened). Further, 14 of the alluvial wells were less than 50 feet deep.

Neither the occurrences of these six particular pesticides, nor the relationship between their appearance and well depth is surprising. Work conducted by the Iowa

Geological Survey (IGS) has shown that the most commonly used herbicides are occurring in ground water. Further, the work conducted by the IGS suggest that the largest percentage of the pesticide concentration is being delivered to the ground water through infiltration. The pesticides detected in this survey are identical to those found in other studies and the concentrations are all within the range of values found in other studies (Table 6). Concentrations resulting from spills would be expected to be much higher.

TABLE 6
Pesticides and their Maximum Concentrations
Detected in Groundwater in Northeastern Iowa, 1981 - 1983
(From Hallberg, et al., 1983, 1984; Libra el al., 1984.)

Common Name - Active Ingredient	*Typical Trade Name*	*Maximum Concentration ug/l (ppb)*
Herbicides		
Alachlor	*Lasso*	*16.6*
Atrazine	*Atrazine, Atrex*	*10.0*
Cyanazine	*Bladex*	*1.2*
Metolachlor	*Dual*	*0.6*
Metribuzin	*Sencor, Lexone*	*4.4*
Insecticides		
Fonofos	*Dyfonate*	*0.1*

From the IGS studies in northeastern Iowa, 70 to 80 percent of the wells and springs sampled in karst, shallow-bedrock, and alluvial settings (in the latter two categories, only infiltration recharge occurs) have shown detectable concentrations of some pesticides over the course of a year. The percentage of wells sampled containing pesticides in this survey is somewhat less than the percentage found by IGS (Table 7). The discrepancy is not great considering that the sampling of wells in this survey represents one or two samples per well which may or may not have been collected at the appropriate time for the detection of pesticides. The monitoring conducted in this survey does suggest, however, that Atrazine is likely to be present throughout the year (Table 8). The work of IGS also tends to support this finding.

While concentrations appear to increase in mid-summer, the sample size is too small to determine conclusively. Overall, the concentrations are low and below any known acute or chronic toxicity. The highest combined concentration from any one well was 4.19 ug/l. However, it should be pointed out that very little is known

about the chronic toxicity of the majority of pesticides. Far less is known about the health implications of chronic exposures to combinations of whole pesticides or their metabolites.

TABLE 7
Number and Percent of Contaminated Wells by Geologic Class

Well Class	N	% of Wells Sampled in Class
Alluvial	20	48.8
Pleistocene	3	33.3
Open Bedrock	3	75.0
Bedrock	2	12.5

TABLE 8
Month in Which Pesticide was Detected in Public Water Supply

	MONTH											
PESTICIDE	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC
Atrazine	X	X	X		X	X	X	X	X	X		X
Bladex						X	X					
Lasso							X			X		
Dual						X						
Sencor						X						
Dyfonate							X					

CONCLUSION

One hundred twenty-eight (128) wells serving 58 supplies were monitored for 31 SOC's, and 70 of the wells were monitored for 34 pesticides over a one year period. The sites were selected on the belief that contaminants were likely to be present in the wells. Contaminants were detected in 57 of the wells (44.5%) serving 33 public water supplies (56.9%).

A review of the geologic data on the wells sampled indicates that 61 (47.6%) were alluvial wells. Thirty-one (31) of the alluvial wells (50.8%) were found to have at least one contaminant present in a measurable concentration. Twenty (20) wells (15.6%) were finished to the pliestocene or deep alluvial formations. Eight (40.0%) of the pliestocene wells were found to be contaminated. In the case of the five wells (3.9%) finished to the bedrock but open to the surface because of a lack of casing or perforated casing, all five were found to have one or more contaminants present. Forty-one (41) wells (32.0%) were finished and cased to deep bedrock formations. Thirteen (13) of the bedrock wells (31.7%) were found to be contaminated. The survey suggests that shallow ground-water systems are more likely to be contaminated and that no ground-water system is safe from contamination.

Three major groups of contaminants were detected in the course of the study: trihalomethanes, pesticides and other common synthetic organic compounds. Trihalomethanes (THMs) were found in 13 wells (10.2% of wells monitored) and the finished water of 11 supplies. In total, 18 supplies (31.0% of those supplies monitored) were found to have THMs in either their wells or their finished water. One supply exceeded the 100 ug/l standard for total trihalomethanes in the finished water. However, the standard applies only to cities with a population greater than 10,000. Trihalomethanes may be expected to form in the finished water of any supply, but are not expected to be found in raw water. However, 13 wells did have measurable concentrations of THMs; yet, seven of the supplies served by these wells had no THMs detected in the finished water. The survey clearly shows that THMs are present in ground-water although no explanation can be offered for their presence.

The second major group of contaminants was composed of 12 commonly detected synthetic organic compounds. The presence of these contaminants suggest a waste disposal or spill site may be impacting the ground water. Four of the compounds were aromatics commonly associated with petroleum products. This group of contaminants was detected in 25 wells (19.7%) of 17 supplies (29.3%). No single compound from this group affected a large number of supplies. Tetrachloroethene was the most commonly detected organic of the group, being found in eight wells of six supplies (10.5%). Most of the wells in which one or more of the organics from this group were found were shallow. The survey indicated that a small but limited number of supplies primarily drawing water from shallow alluvial systems are being contaminated.

The third group of contaminants was made up of commonly used pesticides. Of the 34 pesticides that were looked for, only six were detected. However, Atrazine was

the most commonly detected contaminant found in the survey. Atrazine was detected in measurable concentrations in 24 wells (34.2%) of 14 supplies (35.9%). The five other pesticides detected were Bladex, Lasso, Dual, Sencor, and the insecticide Dyfonate. Research conducted by the Iowa Geological Survey over the past four years has shown that most of the pesticide concentrations in ground water are derived through infiltration. Further, they have shown that the source of the contaminants is nonpoint in nature arriving in the ground water as a result of widespread application to overlying fields. The results of this survey tend to support the findings of IGS in terms of the widespread nature of the problem, the concentration and distribution of pesticides in ground water over time and the apparent systematic deterioration of shallow ground-water systems resulting from infiltration of commonly used pesticides.

All concentrations observed in the survey were below any level currently thought to pose an immediate threat to human health and all supplies, from which positive samples were collected, have been advised to continue to monitor. In several cases, the Department of Water, Air and Waste Management has initiated additional field work to attempt to identify and resolve the problem. While concentrations of contaminants detected in ground water are below known acute and chronic toxic levels, there is a legitimate concern for public health. There is a general lack of information regarding the health effects related to human exposure for many of the contaminants found in this survey.

At the present time relatively unprotected aquifers are being affected by the contaminants found in this survey. However, if such chemicals persist in ground water they will likely be transmitted to deeper, generally more protected, aquifers and thus expose larger populations over longer periods of time. Therefore, it is important that activities be undertaken to identify and eliminate the sources of the contamination and ensure the adequate detection of contaminants in the future.

RECOMMENDATIONS

1) A study should be undertaken to scientifically assess the extent and significance of ground-water contamination statewide.

2) An investigation should be undertaken to identify the source of THMs in raw water.

3) Site specific investigations should be undertaken at locations where common synthetic organic compounds were detected to identify and eliminate the source.

4) Supplies using ground water drawn from relatively unprotected formations, or found to have contaminants present as a result of this survey, should monitor regularly for those contaminants commonly detected in ground water.

5) Ongoing and proposed research to assess environmentally sound and safe agricultural chemical use should be encouraged.

6) The EPA should be informed of the need and importance of adequate public health information and be encouraged to update and develop usable health advisories.

7) A ground-water monitoring network should be established to monitor trends in ground-water quality.

APPENDIX I

SUPPLIES MONITORED

Region 1

Manchester
Decorah
Dubuque
Waterloo
Elgin
John Deere Dubuque Works (Dubuque)
Nashua
Plainfield
Waverly
Janesville
Mount Vernon

Region 2

Marble Rock
Frit Industries (Humboldt)
Dayton
Osage
Georgia Pacific Corp. (Ft. Dodge)
Triggs Manufacturing (Belmond)
Salsbury Laboratory (Charles City)
American Cynamid Co. (Alden)
Charles City *
Webster City *

Region 3

Akron
Early
Hospers
Spencer
Pierson
Everly
George
Rock Rapids *
Orange City
South Sioux RWA
Sioux City
Gilmore City

Region 4

Atlantic
Marne
Westside
Denison
Mapleton
Missouri Valley
Council Bluffs
Shennandoah
Harlan

Region 5

Polk City
Cambridge

Region 6

Muscatine
Durant
Eldridge
Marengo
Douds
Umthun Trucking (Buffalo)
Middle Amana
Columbus Junction
Chemplex (Clinton)
Hawkeye Chemical Co. (Clinton)
Red Jacket Pump (Davenport)
Chevron Chemical (Ft. Madison)
LeClaire
Monsanto Co. (Muscatine) *

* Analyses not completed

APPENDIX II

PESTICIDE COMPOUND STUDY ANALYTICAL PARAMETERS

Aldrin (HHDN)
alpha-BHC (A Benzene Hexachloride)
beta-BHC (B Benzene Hexachloride)
delta-BHC (Benzene Hexachloride)
gamma-BHC (Lindane)
Chlordane
DDD (TDE)
DDE
DDT (Dichlorodiphenyltrichloroethane)
Dieldrin (HEOD)
Endosulfan I (Thiodan I)
Endosulfan II (Thiodan II)
Endosulfan sulfate
Endrin (Endrex)
Endrin aldehyde
Heptachlor
Heptachlor epoxide
Toxaphene (polychlorocamphene)
Dyfonate (Fonofos)
Counter (Terbufos)
Lorsban (Chlorpyrifos)
Thimet (Phorate)
MoCap (Ethoprop)
Atrazine (Atrex)
Bladex (Cyanazine)
Lasso (Alaclor)
Treflan (Trifluralin)
Sencor (Metribuzin)
Dual (Metolachlor)
Prowl (Pendimethalin)
Amiben (Chloramben)
Banvel (Dicamba)
2,4-D
Silvex

SYNTHETIC ORGANIC COMPOUND STUDY ANALYTICAL PARAMETERS

acrolein
acrylonitrile
benzene
bis(chloromethyl)ether
bromoform
bromodichloromethane
carbon tetrachloride
chlorobenzene
chloroethane
2-chloroethylvinyl ether
chloroform
dibromochloromethane
dichlorodifluoromethane
1,1-dichloroethane
1,2-dichloroethane
1,1-dichloroethene
1,2-dichloropropane
1,3-dichloropropylene
ethylbenzene
methyl bromide
methyl chloride
methylene chloride
1,1,2,2-tetrachloroethane
tetrachloroethene
toluene
1,2-trans dichloroethene
1,1,1-trichloroethane
1,1,2-trichloroethane
trichloroethene
trichlorofluoromethane
vinyl chloride

APPENDIX III
RESULTS

Trihalomethanes

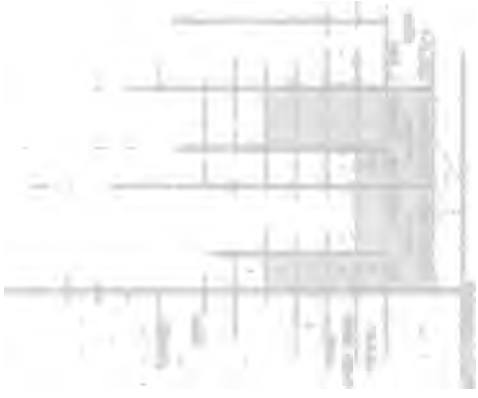
City	Contaminant							
	Chloroform		Bromoform		Dibromochloromethane		Bromodichoromethane	
	raw	finish	raw	finish	raw	finish	raw	finish
Atlantic		X		X		X		X
Decorah	X	X		X		X	X	X
John Deere Dubuque		X				X		
Early	X		X		X		X	
Eldridge	X	X						X
George	X		X	X	X	X	X	
Gilmore City			X	X	X	X		X
Harlan	X							
Frit Indust. Humboldt	X							
LeClaire	X							
Marne	X	X	X	X	X	X	X	X
Missouri Valley		X		X		X		X
Muscatine		X		X				X
Spencer		X		X		X		X
Waverly				X				X
Westside *	X		X		X		X	
Janesville			X			X		
Hospers	X							

* Well off-line

X indicates a measurable concentration present.

Aromatics

City	Contaminant							
	Benzene		Ethylbenzene		Toluene		Styrene	
	raw	finish	raw	finish	raw	finish	raw	finish
Missouri Valley	X	X						
Muscatine						X		
Osage							X	
Westside *	X							
Waverly			X					
Polk City							X	



Other Organics

City	Contaminant																	
	Tetrachloro-ethene		Trichloro-ethene		1,1,1-Trichlor-ethane		Methylene Chloride		Carbon Tetra-chloride		1,2-dichloro-ethane		1,2,2-trichloro-ethane		1,1-dichloro-ethane	
	raw	finish	raw	finish	raw	finish	raw	finish	raw	finish	raw	finish	raw	finish	raw	finish
Atlantic	X*		X*												X	
John Deere Dubuque	X		X		X	X									X	X
Muscatine	X				X											
Mt. Vernon	X		X													
Osage	X	X						X								
Shenandoah	X															
Red Jacket Pump Davenport			X		X											
Plainfield			X										X			
Waupara **									X	X	X					
Middle Amana					X	X										
Durant							X									
Missouri Valley									X	X						
Spencer							X								X	
Nashua											X				X	
Westside											X					

* Well off-line
** Well closed

Pesticides

City	Contaminant											
	Atrazine		Bladex		Lasso		Dual		Sencor		Dyfonate	
	raw	finish	raw	finish	raw	finish	raw	finish	raw	finish	raw	finish
Middle Amana	X	X										
Atlantic	X											
Chemplex Clinton	X											
Decorah	X	X										
Dubuque	X											
Everly	X	X	X		X							
George	X		X									
Gillett Grove											X	
Harlan	X	X	X									
Manchester	X											
Marne	X											
Muscatine	X				X							
Orange City	X		X				X		X			
Osage											X	
Spencer											X	
Waverly	X		X									
Hospers *	X	X	X		X	X	X	X	X	X		

* Well Closed

APPENDIX IV
HEALTH EFFECTS

Contaminant: BENZENE

Acute Exposure: Benzene is acutely toxic at very high concentrations. One human death has been attributed to an exposure of 20,000 ppm. Exposure to high concentrations may lead to nausea, headache, unconsciousness, convulsions or paralysis. Acute toxicity is generally associated with inhalation of benzene.

Chronic Exposure: Benzene has been reported to produce thrombocylopenia, leukopenia, myelocytic anemia and leukemia. The recommended occupational exposure to benzene is 10 ppm. However, current literature does not provide a clear dose-response relationship in chronic exposure of humans to benzene. Data on the toxic effects of ingestion are not complete.

Acceptable Short-Term Exposure Level ---------- 230 ug/l

Acceptable Long-Term Exposure Level ---------- 70 ug/l

	ug/l	Excess Cancers of 1 in
Cancer Risk Assessment ----------	6.8	10^5
	.68	10^6
	.068	10^7

Contaminant: TOLUENE

Acute Exposure: All of the information available on acute human exposure to toluene suggest that it has a narcotic effect. The major metabolites of toluene are relatively innocuous. In fact, one of these metabolites, benzoic acid, has been approved as an antimicrobial food additive in concentrations up to 1,000 ppm.

Chronic Exposure: Reports on long term exposure to toluene suggest that concentrations below 200 ppm have no effect upon humans. Data indicates that some effects of narcosis are evident at around 200 ppm. Exposure is generally associated with inhalation. Data on the toxic effects of ingestion are not complete.

Acceptable Short-Term Exposure Level ---------- 21,500 ug/l

Acceptable Long-Term Exposure Level ---------- 340 ug/l

Cancer Risk Assessment ---------- None

Contaminant: ***TETRACHLOROETHENE***

Acute Exposure: *A single exposure at 200 ppm in man has been shown to effect the central nervous system. Similar effects in humans were not seen in concentrations of 100 ppm. The oral LD_{50} in dogs and rabbits is 4,000 mg/kg and 5,000 mg/kg, respectively.*

Chronic Exposure: *Chronic exposure studies have been conducted on rats, rabbits, guinea pigs and monkeys at various concentrations (100-2,500 ppm) over various periods of time (18-250 days). No adverse effects were observed at 100 ppm. However, a lack of data on mutagenicity and carcinogenicity prevents any confident estimates of the effects of chronic oral exposure.*

Acceptable Short-Term Exposure Level ---------- *2,300 ug/l*

Acceptable Long-Term Exposure Level ---------- *20 ug/l*

	ug/l	Excess Cancers of 1 in
Cancer Risk Assessment ----------	*35*	10^5
	3.5	10^6

Contaminant: ***TRICHLOROETHENE***

Acute Exposure: *Trichloroethene depresses the central nervous system and exposure, through inhalation, will lead to incoordination and unconsciousness. Acute toxicity from ingestion may be evident at extremely high rates of exposure.*

Chronic Exposure: *Long term exposure to trichloroethene has been shown to have carcinogenic effects on animal populations. Trichloroethene has been demonstrated to be mutagenic in microorganisms and caused transformation in cultured mammalian cells.*

Acceptable Short-Term Exposure Level ---------- *200 ug/l*

Acceptable Long-Term Exposure Level ---------- *4.5 ug/l*

Cancer Risk Assessment ---------- *None*

Contaminant: 1,1,1-TRICHLOROETHANE

Acute Exposure: High dosage of 1,1,1-Trichloroethane will cause depression of the central nervious system, loss of manual dexterity, coordination and preception. Inhalation is the major route of exposure.

Chronic Exposure: There is no data to suggest any adverse health effects from long term exposure. Further, there is no evidence to suggest that 1,1,1-Trichloroethane is carcinogenic. However, there is some data to support the teratogenicity of the compound, albeit inconclusive.

Acceptable Short-Term Exposure Level ---------- 300-500 ug/l

Acceptable Long-Term Exposure Level ---------- .001 ug/l

Cancer Risk Assessment ---------- None

Contaminant: METHYLENE CHLORIDE

..Acute Exposure: There are no known effects upon human health from exposure to methylene chloride at concentrations between 50-100 ppm. Primary exposure is through inhalation. Therefore, the recommended occupational exposure level is 75 ppm. However, the oral LD_{50} values for various animals are .95 - 2.3 mg/kg.

Chronic Exposure: No adverse health effects have been shown from low level chronic exposure studies at concentrations below 5,000 ppm.

No Acceptable Exposure Levels are available.

No Cancer Risk Assessment is available.

Contaminant: *CARBON TETRACHLORIDE*

Acute Exposure: *Carbon Tetrachloride was once used as a treatment for hookworms. Thousands of patients have been given single doses of 2.5-15 ml without adverse health effects. One case has been reported as having safely ingested 40 ml of the chemical. However, a small adult population has died after receiving concentrations of 1.5 mg/l, and doses of .18-.92 ml have been reported to be fatal to children. Alcohol consumption enhances toxicity.*

Chronic Exposure: *No long-term toxicity data is available for carbon tetrachloride. However, animal carcinogenicity studies produced positive results and the chemical is considered to be a suspected human carcinogen.*

Acceptable Short-Term Exposure Level ---------- *200 ug/l*

Acceptable Long-Term Exposure Level ---------- *20 ug/l*

	ug/l	Excess Cancers of 1 in
Cancer Risk Assessment ----------	*45*	10^5
	4.5	10^6
	.45	10^7

Contaminant: *1,2-DICHLOROETHANE*

Acute Exposure: *Exposure to 1,2-Dichloroethane at both acute and chronic levels results in liver and kidney dysfunction accompanied by circulatory damage. Human ingestion of 1,2-Dichloroethane has been documented. Most of the case reports describe fatal consequences. However, no satisfactory dose response data is available presently.*

Chronic Exposure: *No satisfactory data is available on toxicity; however, data does indicate that 1,2-Dichloroethane is a carcinogen.*

No Acceptable Exposure Levels are available.

	ug/l	Excess Cancers of 1 in
Cancer risk Assessment ----------	*70*	10^4
	7.0	10^5
	.7	10^6

Contaminant: *1,1,2-TRICHLOROETHANE*

Acute Exposure: *No toxic effects have been observed in humans. LD_{50}'s in test animals have been calculated at .58-.35-3.73 for rats, mice and rabbits, respectively.*

Chronic Exposure: *No available data.*

No Acceptable Exposure Levels are available.

No Cancer Risk Assessment is available.

Contaminant: *PESTICIDES*

Not surprisingly, pesticides generally exhibit relatively low acute toxicity characteristics. However, the carcinogenicity of these compounds are often of greater concern. In the past, the National Academy of Sciences has established recommended acceptable daily intake (ADI) values for a number of pesticides. The ADI value was based upon chronic feeding studies with considerations being made for data (or a lack of) on mutagenicity, teratogenicity and information on sex and strain. The acceptable daily intake value reflects the no observed effects level (NOEL) over some factor of uncertainty or safety factor. The safety factor represents the level of confidence that was determined to be justified on the basis of animal and human toxicity data.

Standard Safety Factors for Toxicological Effects

Effect	*Safety Factor**
cholinesterase inhibition based on two-year rodent or dog studies	*10*
cholinesterase inhibition based on human NOEL	*10*
general toxicity based on chronic studies	*100*
cholinesterase inhibition based on subchronic studies	*200*
teratogenic effects	*at least 100*
general toxicity based on subchronic studies	*2,000*

**These are minimal safety factors and actual margins of safety are likely to be higher.*

If the data indicated a NOEL of 25 mg/kg/day and a safety factor of 1,000 was used, the acceptable level would be 25/1,000 or .025 mg/kg. This value is then used to establish a suggested level or concentration of the pollutant in drinking water. In calculating the value for drinking water, it was assumed that the average weight of a human was 70 kg; the average daily intake of water for that human was two liters; and that 20% of those two liters was taken in directly as drinking water. Therefore, from the example above, one could derive the maximum level on the pollutant allowable in drinking water to be considered safe to be .7 mg/l (25/1,000 = .025 x 70 x 0.4 = .7 mg/l).

The following is a summary of the toxicity data base for the four remaining pesticides detected in this survey and their associated NOEL.

COMPOUND	DATA SUMMARY	BASIS FOR ACCEPTABLE INTAKE CALCULATIONS AND THE NOEL
Atrazine	- Rat teratology, NOEL = 100 mg/kg - Negative mutagenicity (1 study) The other Pivotal data are not adequate (CORE supplementary) to regulate this chemical: - 2-Year dog feeding, NOEL = 150 ppm (LDT) - 3-Generation rat reproduction, NOEL = 100 ppm (HDT) using the 80W formulation	2-Year dog feeding, Core supplementary:* NOEL = 150 ppm

*The Core classification system was developed by the Office of Pesticide Programs in 1977 to assess the adequacy of toxicology studies.

COMPOUND	DATA SUMMARY	BASIS FOR ACCEPTABLE INTAKE CALCULATIONS AND THE NOEL
Metolachlor (Dual)	- 6-month dog feeding, NOEL = 100 ppm - 2-Year supplementary (IBT) onco. in rate: weak oncogen, i.e. liver tumors; - 2-Year chronic in rat (repeat study): weak oncogen - liver tumors, NOEL = 30 ppm (testicular atrophy) - 2-Year oncogen in mouse negative at 3,000 ppm Highest Dose Tested (HDT) Industrial Bio-Test, validated) - 3-generation rat reproduction - 300 ppm - Teratology rat NOEL = 360 mg/kg (HDT) - Teratology rabbit NOEL = 360 mg/kg - Mutagenicity: negative (2 tests) - Positive skin sensitizer - 2-Year oncogen in mouse: negative at 3,000 ppm (HDT)	6-month dog feeding NOEL = 100 ppm weak
Cyanazine (Bladex)	- Teratology in Fisher rat: a potent al weak teratogen, (NOEL for study not yet determined: m10 mg/kg for microophthalia/ anophthalmia, and pending additional studies, the NOEL may be lower than 1 mg/kg (LDT) for liver induced hernia) - Teratology in SD rat: negative at 30 mg/kg (HDT), (however, MTD not tested) - Teratology in rabbit: negative at 4 mg/kg HDT , NOEL = 1 mg/kg/day - 2-year oncogen in mice: negative at 1,000 ppm (HDT)	2-Year rat feeding, Core supplementary: NOEL = 12 ppm

COMPOUND	DATA SUMMARY	BASIS FOR ACCEPTABLE INTAKE CALCULATIONS AND THE NOEL
Metribuzin (Sencor)	- Rabbit teratology; NOEL = 15 mg/kg (HDT) - Mutagenicity: negative (three tests). All the other Pivotal data were not CORE classified - 2-Year dog feeding NOEL = 100 ppm - 2-Year rat feeding/oncogen, negative for onocogencity; NOEL = 300 ppm - 2-Year mouse oncogen, negative at 3,200 ppm HDT - 3-Gen. reproduction, NOEL = 300 ppm - Rat teratology, NOEL = 100 mg/kg HDT)	2-Year dog feeding not Core classified: NOEL = 100 ppm

In the case of alachlor Lasso the greatest concern is the carcinogenicity of the pesticide. The EPA has made the following assessment of the risk of increased cancer as a result of ingestion of Lasso in the drinking water:

Exposure Level (ppb)	Upper Limit Estimate of Lifetime Cancer Risk	
	10 Kg Child	60 Kg Adult
0.15	10^{6}	10^{7} to 10^{6}
1.5	10^{5}	10^{6} to 10^{5}
15.0	10^{4}	10^{5} to 10^{4}

Sufficient toxicity and carcinogencity data are unavailable for the following chemicals:

Styrene
Ethylbenzene
1,1-dichloroethane
Dyfonate

APPENDIX V

SPECIAL MONITORING

In the course of conducting the original sampling, common synthetic organics were detected in supplies downstream of the LaBounty waste disposal site in Charles City. In an effort to establish whether or not the LaBounty site could be a possible source of the contaminants, additional special monitoring was conducted at several locations downstream of Charles City. All wells sampled in this special monitoring were known to be taking water from the Cedar Valley aquifer.

Results and evaluation of the data from this sampling will be completed in the near future. Analytical results have not been reported from the lab.

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