EPA'S IMPLEMENTATION OF THE PESTICIDES CONTROL ACT

HEARINGS

BEFORE A

SUBCOMMITTEE OF THE COMMITTEE ON GOVERNMENT OPERATIONS HOUSE OF REPRESENTATIVES

NINETY-FOURTH CONGRESS

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EPA'S IMPLEMENTATION OF THE PESTICIDES CONTROL ACT

WEDNESDAY, FEBRUARY 11, 1976

HOUSE OF REPRESENTATIVES,
CONSERVATION, ENERGY,
AND NATURAL RESOURCES SUBCOMMITTEE
OF THE COMMITTEE ON GOVERNMENT OPERATIONS,
Washington, D.C.

The subcommittee met, pursuant to notice, at 10 a.m., in room 2203, Rayburn House Office Building, Hon. William S. Moorhead (chairman of the subcommittee) presiding.

Present: Representatives William S. Moorhead, L. H. Fountain, and Gilbert Gude.

Also present: Norman G. Cornish, staff director; Edwin W. Webber, assistant for energy; David A. Schuenke, counsel; Robert K. Lane, assistant for environment; Ronald J. Tipton, assistant counsel; and Stephen M. Daniels, minority professional staff, Committee on Government Operations.

Mr. MOORHEAD. The Subcommittee on Conservation, Energy, and Natural Resources will please come to order.

This morning the subcommittee will examine whether the Environmental Protection Agency is meeting its responsibilities to enforce pesticides and other toxic and hazardous substances controls with which it is charged by law.

National awareness and concern over the hazards to human health and to the environment caused by the use and discharge of numerous toxic and hazardous materials mounts virtually every day.

Scientific evidence that the threat to human health from environmental pollution may be far greater than was previously suspected is rapidly accumulating.

As the links between cancer and environmental pollution emerge, it is profoundly disturbing to hear that the agency charged by law with the enforcement of our laws to protect our health and the environment from cancer-causing toxic materials has failed and refused to enforce those laws vigorously.

The Congress has enacted a series of laws intended to protect human health and the environment from pollution and degradation. We directed that the protection be the best that modern science and technology can provide. We authorized billions of dollars for this effort, and we provided a system of legal enforcement, complete with administrative and judicial remedies, and civil and criminal penalties to assure compliance with those requirements.

Today we will hear the sworn testimony of three former officials of the Environmental Protection Agency, who have resigned from that Agency in protest of the repeated failure of that Agency to meet its full responsibilities to enforce the environmental protection laws.

These three, formerly the Associate General Counsel of the Agency, his Deputy, and the Senior Trial Attorney, are well qualified to speak to the Agency's record. They were recently described by the Agency as dedicated and brilliant professionals, who served in the forefront of several recent Agency battles to control some cancer-causing pesticides.

I believe we have here not merely an issue of individuals frustrated with the cumbersome workings of bureaucracy, but very serious allegations of agency failure or reluctance to carry out legal responsibilities charged by experienced and responsible agency officials.

I have indicated to Administrator Train that we hope to have an Agency response to these allegations in the very near future.

To speak out in the face of governmental failure or abuse is a thing we can only welcome and applaud. It's occurrence in a number of situations in recent days speaks well for the conviction and dedication of many of our public servants.

The resignations of the three individuals here today was an action taken because of principle. Theirs was a resignation of honor, and we welcome their statements.

These witnesses are Mr. Jeffrey H. Howard, former Associate General Counsel for Pesticides and Toxic Substances of the Environmental Protection Agency; Mr. Frank J. Sizemore III, former Deputy Associate General Counsel for Pesticides and Toxic Substances of the Environmental Protection Agency; and Mr. William E. Reukauf, former Senior Trial Attorney for Pesticides and Toxic Substances of the Environmental Protection Agency.

Mr. Gude, do you have a statement?

Mr. GUDE. No statement, Mr. Chairman.

Mr. MOORHEAD. Will you gentlemen rise while I administer the oath?

Do you solemnly swear that the testimony you are about to give to the subcommittee is the truth, the whole truth, and nothing but the truth, so help you God?

Mr. HOWARD. I do.

Mr. SIZEMORE. I do.

Mr. REUKAUF. I do.

Mr. MOORHEAD. I understand that you have a joint statement that Mr. Howard will start with.

You may proceed, Mr. Howard.

STATEMENT OF JEFFREY H. HOWARD, FORMER ASSOCIATE GENERAL COUNSEL FOR PESTICIDES AND TOXIC SUBSTANCES, ENVIRONMENTAL PROTECTION AGENCY; ACCOMPANIED BY FRANK J. SIZEMORE III, FORMER DEPUTY ASSOCIATE GENERAL COUNSEL FOR PESTICIDES AND TOXIC SUBSTANCES; AND WILLIAM E. REUKAUF, FORMER SENIOR TRIAL ATTORNEY FOR PESTICIDES AND TOXIC SUBSTANCES

Mr. HOWARD. Mr. Chairman and members of the subcommittee, we thank you for inviting us to appear today to discuss the problem of EPA regulation of toxic chemicals.

We have already been introduced.

My name is Jeffrey Howard, and for 1 year and until February 5, 1976, I served as Associate General Counsel for Pesticides and Toxic Substances of the Environmental Protection Agency.

To my immediate right is Frank J. Sizemore III, who served as Deputy Associate General Counsel for Pesticides and Toxic Substances during that period, and to his right is William E. Reukauf, who served as Senior Trial Attorney for Pesticides and Toxic Substances.

Mr. Sizemore and I have been with the Environmental Protection Agency for approximately 2 years and Mr. Reukauf has been with EPA for approximately 2½ years.

As you know, on February 5, 1976, we announced our resignations from the U.S. Environmental Protection Agency. We have represented EPA in proceedings to ban the cancer-causing pesticides aldrin/dieldrin and heptachlor/chlordane.

We have resigned because of the continued failure of EPA to take effective action under its existing authority to regulate toxic chemicals in water, in air, in human and animal foods, as well as in drinking water. It is clear from recent actions that the Agency intends to refrain from vigorous enforcement of available toxic substances controls and to retrench from the few legal precedents which it has set for evaluating the cancer hazards posed by chemicals.

We wish to point out at the beginning of our testimony that our charges against EPA are not made lightly or without considerable thought and we resigned only after we had repeatedly advised EPA of our concerns.

EPA has authority under existing laws: (1) To set toxic pretreatment standards for discharges into municipal treatment systems; (2) to set toxic effluent standards for discharges into rivers and streams; (3) to regulate and respond to hazardous chemical discharges; (4) to issue emergency orders to stop imminent and substantial endangerment to human health for water pollutants; (5) to set standards for toxic emissions into the air; and (6) to set limits on toxic chemicals in drinking water supplies.

As an example we would like to refer to the Safe Drinking Water Act. Under that act, EPA is required to publish "national interim primary drinking water regulations" within 90 days of enactment. That is section 1412 (a) (1).

The law requires that these interim regulations "shall protect health to the extent feasible, using technology, treatment techniques, and other means, which the Administrator determines are generally available—taking into account costs." That is section 1412(a) (2) of the act.

Within 2 years of enactment the National Academy of Sciences, under contract with the Administrator, is required to report to Congress "recommended maximum contaminant levels" for drinking water—section 1412(e) of the act.

The Administrator is then required to publish final regulations under which "no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety." Thas is section 1412(b) (1) (B).

The Safe Drinking Water Act was enacted by Congress in December 1974 in response to serious public concern over the safety of drinking water throughout the country.

This concern has been aroused by alarming reports of widespread contamination of drinking water with organic chemicals. EPA's "interim primary" regulations—which are the first step in this regulatory system—were not published until December 1975.

These standards were many months overdue. A much more serious deficiency, however, is the failure of the interim standards to impose any limitation on many cancer-causing chemicals which are known to be in drinking water. A case in point is aldrin and dieldrin.

Aldrin and dieldrin are pesticides which are highly persistent, bioaccumulative, and mobile in the environment. On October 1, 1974, the Administrator of EPA, after extended hearings, suspended most registrations of pesticides containing aldrin and dieldrin on the grounds that their continued use and ingestion through contaminated food and water posed an imminent cancer hazard to man.

Notwithstanding this serious cancer risk and EPA's awareness that aldrin/dieldrin are in the water. EPA failed to set any limitation on their continued daily ingestion through our drinking water.

Of course, aldrin and dieldrin are merely examples. The Administrator has recently banned many uses of heptachlor and chlordane because they pose an imminent cancer hazard to man. No primary limitation on residues of heptachlor or chlordane has been proposed as yet.

The same can be said about DDT—which was banned in 1972 in part on the same basis. The list of suspected carcinogens in drinking water which EPA has chosen not to limit in drinking water supplies is, of course, much longer. No interim limitations have been set for vinyl chloride, asbestos, chloroform, carbon tetrachloride, benzene, and trichloroethelene.

EPA's position with respect to these chemicals appears to be that the Agency is not sure of the health effects and that the Agency is also unsure whether there is any effective treatment system.

As to the first point, surely EPA now has an idea of the health risks of daily ingestion of DDT, aldrin, dieldrin, heptachlor and chlordane since after all it was EPA that found that all of these chemicals pose a serious cancer risk to man.

As to the second point, although carbon filtration has not been tested for every chemical under the sun, EPA knows that it works for chemicals like chloroform and dieldrin.

EPA is now using carbon filtration to clean up Kepone waste waters in Hopewell, Va. Perhaps the most telling point about carbon filtration was offered by Dr. Robert Harris of the Environmental Defense Fund, who has testified previously that EPA scientists who test drinking water in EPA's Cincinnati laboratory have installed makeshift carbon filters in their own homes.

The legislative history of the Safe Drinking Water Act and the public concerns surrounding its passage demand that EPA take action now to make the water safe to drink.

The inaction of EPA in setting drinking water standards has importance for two other broader purposes, however.

First: It serves as a shocking example of administrative inaction in the face of overwhelming public and congressional concern.

Second: It serves as a foundation from which to view the broader problem of toxic chemical control. Obviously, the water we drink

continues to contain scores of organic chemicals because EPA has not only failed to regulate their presence in drinking water, but EPA has not taken action to prevent their introduction into the environment through toxic effluents, through toxic emissions, and through the continued use of EPA-licensed toxic pesticides.

EPA has identified approximately 100 cancer-causing pesticides and has the authority under existing law and indeed public responsibility, to regulate these materials immediately.

EPA officials, as reported in the Wall Street Journal, recently admitted that EPA does have a list of 100 pesticides suspected of producing cancer. The identification of the 100 pesticides, surprisingly enough, is based on data in Agency files which were submitted to establish the safety of the pesticides in question.

These same EPA officials were also reported as having admitted that EPA has not acted on these pesticides because the Agency has not yet been able to prove a cancer hazard to men, which, they charge, would be required for the EPA to ban the substances.

These statements we believe demonstrate the contemplated retrenchment to which we have referred.

First: The burden of proof is not on the Agency to show a cancer risk to man—the statute, the regulations and the court decisions provide specifically "the burden of establishing the safety of a product requisite for compliance with the labeling requirements of the pesticide law at all times rests on the applicant and registrant."

Second: Under Agency regulations, which have been published in final form at 40 F.R. 28242, the Agency is required to issue a notice of presumption against continued registration to the manufacturer whenever a pesticide induces tumors "in experimental mammalian species or in man."

If the manufacturer is unable to rebut the presumption, the Agency is required to issue a notice convening a public hearing.

This notice initiates the formal public process and insures that decisions weighing the risks and benefits of use of a potential carcinogen are carried out in the public forum.

The U.S. Court of Appeals has recognized the necessity for forcing public health decisions to be made in the open, and we quote:

> For when Congress creates a procedure that gives the public a role in deciding important questions of public policy, that procedure may not lightly be sidestepped by administrators. The statutory scheme contemplates that these questions will be explored in the full light of a public hearing and not resolved behind the closed doors of the Secretary.
>
> There may well be countervailing factors that would justify an administrative decision, after committee consideration and a public hearing, to continue a registration despite a substantial degree of risk, but those factors cannot justify a refusal to issue the notices that trigger the administrative process. [Public hearings bring the public into the decisionmaking process, and create a record that facilitates judicial review.] If hearings are held only after the Secretary and now Administrator is convinced beyond a doubt that cancellation is necessary, then they will be held too seldom and too late in the process to serve either of these functions effectively.

Let me say at this point although it's not in my prepared remarks that the Agency has identified these chemicals for some time. We do not take the radical position of saying that the Agency must now remove these chemicals from the market immediately. Our position is that we have known about them for some time and no action is

being taken to explore in the public forum the risks and benefits of their continued use. And that is the action that we feel is compelled by the facts and the public's right to know.

We also say that part of the process that caused this was that we were unable within the Agency even to see the list of a hundred chemicals, much less to review the data upon which their cancer-causing properties are based.

The legal precedents at stake represent a public health decision that toxic chemicals which cause tumors in laboratory animals and are widespread in the environment present a significant risk that some of the exposed people will get cancer.

Such chemicals should be banned from further use or limited to those uses which are absolutely essential—after a thorough weighing of the risks and benefits.

We believe this position represents sound public policy for the protection of human health, especially since where exposure to a chemical is widespread and it has been shown to cause cancer in animals, the burden must be on the manufacturer to prove that there is no threat to human health.

This policy has been severely attacked by certain Members of Congress and by industry scientists and industry lawyers who take the position that until human beings have died of cancer from exposure to such chemicals, their uses should be continued.

Mr. SIZEMORE. Mr. Chairman, recent hearings by the Senate Health Subcommittee only scratched the surface of an even more insidious problem:

Inaccurate, sloppy, and even fraudulent data submitted by industry to support the safety of chemicals licensed by EPA and FDA. We feel confident in stating that the data underlying the registrations of a substantial number of widely used pesticides do not support their safety as required by law. Although EPA has publicly committed itself to review these data, no priority authorization for review by more than a skeleton staff has been forthcoming.

Mr. Chairman, yesterday for the first time we had the opportunity to read a report which was prepared by the GAO and which was submitted to Congress on December 22, 1975.

We were not interviewed in connection with this report and had nothing to do with its preparation. This report exhaustively considers the adequacy of EPA's record in evaluating the hazards of pesticides that the Agency registers.

Although we have had little time to review the material, we believe the report supports the statements we have made.

Specifically, the report refers to the inadequacy or absence of data to support the safety of pesticides licensed by EPA.

The report and a supplemental report submitted to Congress on January 26, 1976, comment on the competency of laboratories which generate data on behalf of industry and also comment on the inability of EPA to carefully monitor the data submitted for quality and accuracy.

The result of these deficiencies in the regulatory system is that pesticides are registered without the safety evaluation required by law. Accordingly, the human population continues to serve as the testing ground for toxic chemicals, although the long-term effects, such as cancer, are not realized immediately.

In order to remove harmful pesticides that have been registered, the Agency must resort to cumbersome adjudicatory hearings, customarily utilizing as proof that the products are unsafe, the very data initially utilized by the manufacturer to register the product.

As an example, of the three major active ingredients canceled or suspended by the Agency, DDT, aldrin-dieldrin, and heptachlor-chlordane, all of the proceedings were initiated on the basis of data in the Agency files indicating that these pesticides were potential carcinogens.

Thus, the activity of the Agency to date has been in the area of cancellation of pesticides, not the initial review before granting a Government license.

Permit us to quote the ultimate conclusion of this GAO report I referred to, and I might say we agree with this conclusion of the GAO report:

> The American consumer has not been adequately protected from the potential hazards of pesticide use because of inadequate efforts to implement provisions of the Federal laws regulating pesticides.

Mr. Chairman, our collective experience confirms this conclusion. But this conclusion is not new. It was for these reasons that pesticide regulation was transferred from the Department of Agriculture to EPA in 1970. Furthermore, this is not the first but the third time that the GAO has reported to Congress on the inadequate regulation of pesticides.

The problem involves a vicious cycle, which can be illustrated by our experience during the past several months.

Heptachlor and chlordane, two widely used pesticides, were registered by the U.S. Department of Agriculture and registrations were maintained by EPA despite data in Agency files which indicated that the chemicals were potential carcinogens.

The bulk of the data submitted to support the registrations and tolerances for the chemicals was supplied by two contract laboratories.

EPA undertook to cancel these pesticides on the basis of the existing data in November 1974. When the data were subjected to review by independent experts, the review demonstrated that the contract labs had utilized testing procedures which were not scientifically sound and which masked the carcinogenic properties of the compounds.

Moreover, it came to our attention during the course of litigation that the manufacturer had additional data, not submitted to the Agency, which incriminated the products as carcinogens.

On the basis of these new data and evaluation which we brought to the attention of the Administrator, he announced his intention to ban most uses of the compounds pending completion of a hearing. The suspension action caused a major reaction in Congress and among chemical and agricultural lobby groups.

There was a threatened emasculation of the pesticide law and an eventual weakening of its provisions.

In response to intensive lobbying efforts by the National Agricultural Chemical Association, the Farm Bureau, and the National Pest Control Operators Association and continued pressure from the House Agriculture Committee, the Administrator began a series of

internal organizational changes designed to defuse the clamor of the agricultural and chemical interests.

These changes, incorporated into a memorandum from the Administrator, dated October 10, 1975, followed a report of a special investigating committee of the same date. Both these memorandums are attached to our statement.

Mr. Chairman, I would submit copies of them for the record.

Mr. MOORHEAD. Without objection, they will be made part of the record.

[The information follows:]

[MEMORANDUM]

U.S. ENVIRONMENTAL PROTECTION AGENCY,
OFFICE OF PLANNING AND MANAGEMENT,
Washington, D.C., October 10, 1975.

Subject: Pesticides: Cancellation and Suspension.
From: Walter Barber, Charles Elkins, and G. William Frick.
To: The Administrator.

Pursuant to your request, we have reviewed the Agency's procedures related to the cancellation and suspension of pesticides.

We have found that the implementation of this aspect of the pesticides program has resulted in disagreement within the Agency and substantial concern among the affected public concerning the Agency's motives and policies. The problems which have created this disagreement and concern are based, in part, on perceptions of EPA actions and intentions and, in part, on problems of internal management. We believe that these problems require immediate attention if we are to achieve an effective program of pesticide use control. This memorandum summarizes our observations which are based, in large part, on discussions with EPA personnel and with representatives of the Environmental Defense Fund, the Farm Bureau, the Pest Control Applicators, and the State Departments of Agriculture.

The focus of our investigation was the procedures used in making pesticide decisions. We did not inquire into the substance of past decisions. We should note, however, that these discussions gave us no reason to believe that these earlier actions were in any way incorrect or unjustified. Looking to the future, we find that the program requires increased management attention to improve the review and coordination of scientific and policy matters within the Agency.

The major problems which we have identified are discussed below; followed by our recommendations.

PROBLEMS

The Public perceives EPA's pesticide policy to be leading to a ban of all major pesticides

EPA does not have clear, well articulated goals and policies for the pesticides program. The Agency appears to be implementing programs to cancel and suspend pesticides which are much more aggressive than those to implement the other use control provisions of the law. Although this appearance is fostered in part by industry, it has been reinforced by a number of EPA actions—most significantly, the cancellation of several widely used pesticides.

In addition, the adversary nature of the cancellation/suspension process has inhibited participation in the decision process by some affected parties and other interested members of the public, leading some to question the Agency's objectivity and motives.

The Agency is perceived to have adopted a cancer policy for pesticides which is to minimize exposure to potential carcinogens regardless of costs

The absence of a formal Agency cancer policy has created the appearance that the policy is the "cancer principles" developed in the Aldrin/Dieldrin cancellation hearings. The principles appear to dominate EPA's pesticide policy and lead the public to believe that a pesticide which demonstrates any risk of human carcinogenicity by violating one or more of the principles will be cancelled. The perception that EPA is unwilling to accept any cancer risk from pesticides is reinforced by the failure to provide an open mechanism for evaluating and

comparing risks and benefits and by the belief of some people that the "middle of the road" scientific testimony on the subject does not get introduced at the hearings.

Management of the cancellation/suspension program including communications between Office of General Counsel and Office of Pesticide Programs has not been adequate

Top management interest in this aspect of the pesticides program has not been sufficient to insure its effective implementation. At the program level, Office of Pesticide Programs has accorded a lower priority to the problem of suspect chemicals than to the registration and certification programs, and as a result, adequate resources and attention have not been provided to the development and support of cancellation/suspension actions. In response, the Office of General Counsel staff has moved ahead independently, and in the process has excluded the program office from many important policy and scientific decisions.

The Office of General Counsel, having a dual role of counsel to the program and participant in policy formulation, has had a disproportionate impact on the program. In addition, the Office of General Counsel has not always followed normal bureaucratic procedures in the development of documents related to the program. As a result, significant policies have been decided by legal interpretation rather than policy debate.

The cancellation/suspension procedures have inhibited internal analysis of risks and benefits

The use of formal adversary proceedings as the principal mechanism for discussion and decision-making on pesticide cancellation/suspension issues, including consideration of benefits, makes it difficult for the staff to present a broad range of views and positions for consideration. Although information-gathering hearings are provided for by Section 6(b)(2) of FIFRA, the hearing procedures under present EPA rules are essentially the same as for cancellation hearings, and similarly, result in adversary positions.

Recommendations

We believe that the solution to the major problems outlined above is to conduct a thorough, more open evaluation of both risks and benefits before a decision to register a suspect chemical or to issue a notice of cancellation or suspension. By involving interested parties and by soliciting external scientific and technical review of our data and analysis as appropriate, we can insure that the decisions are based on the objective evaluation of all available information. A more open process would also help to prevent any misunderstanding by the public. This recommendation would require, in addition to careful analyses of health effects, a more intensive review of the economic and agricultural implications of cancellation and substitute chemicals than has previously been conducted prior to the hearing process by the Agency. It would also shift the focus of EPA decision-making from the adversary hearing process to a less formal, open review of pertinent facts and opinion.

The conduct of these analyses would require careful management to insure timely completion and thorough review. The analyses would constitute the basis for the Agency's findings and policy decisions. If a decision were to be appealed, it would be subject to the hearing process.

We have a number of specific recommendations to make. However, we have phrased these in fairly general terms to allow the program managers who are more aware of their resources and constraints to work out the details. Consequently, our recommendations will not be "self executing", but will require both careful planning and vigorous monitoring if they are to be successfully implemented.

Specific recommendations for each organizational element include:

The Administrator

(a) Establish an ad hoc group under the direction of the Assistant Administrator for Water and Hazardous Materials to develop a coordinated, well articulated pesticide policy, including goals and objectives for the cancellation/suspension program.

(b) Adopt and make public an Agency cancer policy and procedures.

(c) Require that a fully coordinated, thorough analysis of cancellation/suspension actions be prepared before decisions are made to issue notices of cancellation or suspension.

(d) Insist that Office of Pesticide Program and Office of General Counsel reinstate and adhere to the normal decision-making processes of the Agency and that issues are discussed before they are brought to the Administrator for decision.

(e) Increase personal contacts with the affected parties, particularly the farm community.

OFFICE OF WATER AND HAZARDOUS MATERIALS AND OFFICE OF PESTICIDE PROGRAMS

(a) Develop a strategy for implementing the recommended revisions to the suspect chemical review program. The strategy should include integration with the Section 3 registration program, descriptions of analytical studies to be performed, the nature and timing of external participation, and a prioritized list of chemicals to be considered. In addition to external scientific reviews, the strategy should provide for full utilization of the knowledge and expertise of the Department of Agriculture in the development of benefit analyses.

(b) Develop specific plans and schedules for the review and analysis of each of the chemicals anticipated to require detailed study. Such plans should include the analyses to be performed, resource requirements, and alternative use control strategies which will be analyzed.

(c) Determine in consultation with the Office of General Counsel whether regulatory, statutory, or procedural changes are required to implement the recommendations and initiate appropriate action.

(d) Strengthen the hearing support program and take a more active role in the development of related policy documents, particularly hearing strategies and briefs.

(e) Improve technical capabilities in cancer-related fields and economic analysis through augmented staff or outside consultants.

OFFICE OF GENERAL COUNSEL

(a) Coordinate policy documents and actions related to hearings with the Office of Pesticide Programs.

(b) Distinguish policy advice from legal advice in dealings with the program office.

(c) Develop in cooperation with the Office of Pesticide Programs procedures for 6(b)(2) fact finding hearings which will provide a less adversary vehicle for gathering information and making decisions on issues when analyses are inconclusive.

OFFICE OF PLANNING AND MANAGEMENT

(a) Participate in the development of the goals, objectives, and strategies, including external participation for the suspect chemical program, and conduct periodic management reviews with the Office of Water and Hazardous Materials and the Office of General Counsel.

(b) Review resource requirements to implement the recommendations and take appropriate action.

[Memorandum]

U.S. ENVIRONMENTAL PROTECTION AGENCY,
Washington, D.C., October 10, 1975.

Subject: Pesticide programs.
From: Russell E. Train, Administrator.
To: Andrew W. Breidenbach, Assistant Administrator for Water and Hazardous Materials; Robert V. Zener, General Counsel; and Alvin L. Alm, Assistant Administrator for Planning and Management.

The purpose of this memorandum is to convey my conclusions on the Agency's program related to the cancellation and suspension of pesticides. These conclusions are based on our recent discussions and on the results of the ad hoc review which I requested. While I remain convinced that our pesticide decisions have been sound, I am concerned that we make every effort to insure that all available scientific and other pertinent information be identified and carefully

considered in future actions. I am also concerned by public perceptions and misapprehensions about our pesticide policies, specifically those related to cancer.

I will continue to make decisions involving pesticides suspected of being carcinogenic, giving full consideration to both the health risks and the social benefits associated with the chemical to be controlled. To insure that decisions are consistent and sound I will establish policies and procedures for the development and review of risk and benefit evaluations which will form the bases for all future regulatory actions involving carcinogens.

With regard to cancellation and suspension decisions, I believe that misconceptions by the public are attributable, in part, to our reliance on the adversary hearing process to insure that all pertinent facts are brought out. While these procedures have been effective, they have inhibited full participation by the Office of Pesticide Programs in the decision process and have restricted effective public involvement in this aspect of the program. I have determined that the Agency should carry out a more open evaluation of risks and benefits in advance of decisions to issue notices of intent to cancel or suspend. By involving interested parties and by soliciting external scientific and technical review of our data and analysis, as appropriate, we can insure that decisions continue to be based on the objective evaluation of all available data. After a decision to register, cancel or suspend a pesticide is made, interested parties will still have the opportunity to request a formal adjudicatory hearing to review that decision. I will look to the Assistant Administrator for Water and Hazardous Materials as the responsible policy official for pesticide registration, cancellation and suspension and to the General Counsel to manage the adjudicatory hearings.

I have adopted the attached recommendations of the ad hoc group which I directed to review the Agency's cancellation and suspension process. The implementation of these recommendations will require careful planning and a continuing management effort on your part. Please prepare a coordinated plan including details and schedules and report back to me within 30 days. The plan should provide for the smooth transition of day to day policy and management responsibility for the Office of Pesticide Programs from me to the Assistant Administrator for Water and Hazardous Materials. After such transition is accomplished, I will continue to pay close attention to the program, providing policy guidance and management oversight.

Attachment. (See p. 9.)

[MEMORANDUM]

U.S. ENVIRONMENTAL PROTECTION AGENCY,
Washington, D.C., October 10, 1975.

Subject: Agency approach to cancer policy.
From: Russell E. Train, Administrator.
To: Assistant administrators, regional administrators, and office directors.

I have reviewed alternative approaches the Agency might take with respect to carcinogens and have decided to proceed along the lines outlined in the attached memorandum. By this memo, I am asking Al Alm and Wilson Talley to begin to implement the procedures contained in the attachment by establishing a Cancer Assessment Group and by coordinating and pulling together the required health and benefit analyses methodologies.

It is important that there be substantial input from all offices both in formulating these methodologies and in beginning to implement this new approach to the treatment of carcinogenetic substances. I would like Al and Wilson to report back to me in about one month with the proposed methodologies. Also, I would like Al to provide me with a status report on the implementation of the other aspects of the plan.

Attachment.

U.S. GENERAL ACCOUNTING OFFICE,
RESOURCES AND ECONOMIC DEVELOPMENT DIVISION,
Washington, D.C., January 26, 1976.

Hon. RUSSELL E. TRAIN,
Administrator,
Environmental Protection Agency.

DEAR MR. TRAIN: GAO has reviewed EPA's basis for determining whether safety and efficacy data submitted by pesticide registrants is complete, accurate, and reliable for registering pesticides and establishing tolerances (the maximum pesticide residues allowed in food). EPA uses safety data to evaluate the hazards a pesticide poses and to determine whether the pesticide can be used without unreasonable adverse effects on man and the environment. It uses efficacy data to determine whether the pesticide, when used as directed, will effectively control the target pest.

EPA, in determining pesticide safety and efficacy, relies primarily on tests made by nongovernmental laboratories and paid for by pesticide registrants. EPA has no program to accredit and/or inspect these laboratories to insure that they have the requisite personnel and facilities to make accurate and reliable tests.

Other Government agencies which use data from nongovernmental laboratories have ongoing accreditation/inspection programs to provide such insurance. For example, the Food and Drug Administration (FDA), which has drug-testing requirements analogous to pesticide-testing requirements, has inspected some of the same laboratories that have made health studies supporting pesticide registration. FDA has questioned the validity of studies from these laboratories because of (1) inadequate supervision and internal control of tests, (2) questionable procedures, and (3) poor recordkeeping. Because FDA has found deficiencies in some of the same laboratories EPA used, we believe that EPA should consider establishing its own accreditation/inspection program.

We made our review in the Washington, D.C., area, primarily at EPA headquarters and at FDA. We also talked to officials of other Federal agencies which rely on test data prepared at nongovernmental laboratories. We examined pertinent legislation and EPA regulations, records, and files relating to the use of laboratory data and to the completeness, accuracy, and reliability of such data. We also talked to and obtained information from officials of selected laboratory accreditation organizations.

EPA'S USE OF LABORATORY DATA

Under the Federal Insecticide, Fungicide, and Rodenticide Act of 1947 (7 U.S.C. 135), as amended, and the Federal Food, Drug and Cosmetic Act of 1938 (21 U.S.C. 301), as amended, EPA registers pesticides and establishes their tolerances. Generally nongovernmental laboratories under contract to pesticide manufacturers do the pesticide safety and efficacy testing required for EPA registration and tolerance setting.

EPA's proposed registration guidelines[1] require that studies "be done under the direction of qualified personnel, who are responsible for utilizing sound scientific experimental procedures adequately to determine a pesticide's toxicological hazard." The guidelines further state that the "validity of information submitted . . . depends on the test procedures employed and the expertise of the individuals performing the tests." However, the proposed guidelines contain no procedures for EPA to enforce these requirements by inspecting, licensing, or accrediting the participating laboratories.

EPA officials told us that EPA did not keep either a list of laboratories which made studies supporting pesticide safety and efficacy or a list of laboratories which had submitted faulty studies. We reviewed the files for the 1,199 pesticides registered during the 6-month period ended February 28, 1975, and identified 77 laboratories which recently had made studies used as a basis for registration. There were 37 laboratories which had developed safety data and 50 laboratories which had developed efficacy data; 10 of the laboratories had developed both types of data.

EPA's review of safety and efficacy studies was generally restricted to reading test results and questioning (1) obvious shortcomings in the test methods, (2) conclusions which were at variance with the raw data, and (3) results markedly different from those generally expected of certain families of chemicals. EPA emphasized assessing the validity of reported results and identifying and questioning statistical variations.

EPA data reviewers expressed differing opinions of the reliability of nongovernmental laboratory data. Many believed, on the basis of personal experience, that nongovernmental labortory data was accurate and reliable. Other officials said that reports were oversummarized, attempted to lead reviewers to favorable conclusions, and could contain false data that EPA might accept. Some reviewers believed that the market system provided an incentive for accurate data in that consumers would not continue to buy products found to be ineffective; others pointed out that consumers cannot detect the ineffectiveness of such products as germ killers or the long-term health hazards, such as cancer or birth defects, of pesticide products.

In their review of data registrants submitted, EPA reviewers have occasionally found inconsistencies, failures to follow prescribed test methods, results lacking statistical validity, and conflicting data. Many reviewers also said that

[1] The 1972 amendments to the Federal Insecticide, Fungicide, and Rodenticide Act required that registration guidelines be completed by October 1974. As of December 1975 EPA had published proposed guidelines in the Federal Register and had received public comments thereon. An EPA official told us that the guidelines were being finalized and were to be completed in February 1976.

fabricated studies not supported by laboratory work could pass review without detection if the data was consistent with data on similar pesticides.

EPA's limited preregistration testing had disclosed that some EPA results varied from data submitted by registrants. For example, one registrant submitted data which indicated that a sanitizer was irritating to the eye but not to the skin. After testing the product, EPA concluded that "confirmatory testing of the submitted samples of * * * [the product] significantly differ from the test results which were submitted in support of this registration." EPA's tests showed that the product caused severe eye damage and primary skin irritation. As a result, EPA required the registrant to change the signal word on the label from "Caution" to "Danger" and to add other precautionary statements to the label. Similar variances might be found in such safety testing as chronic-feeding studies;[2] however, EPA does not replicate these studies because it lacks the facilities.

EPA officials told us that they agreed that greater assurance was needed regarding the adequacy and accuracy of studies submitted in support of pesticide registrations and that this concern was shown in a May 1974 strategy document of plans and policies for carrying out the 1972 amendments to the Federal Insecticide, Fungicide, and Rodenticide Act. The strategy document stated that "The possibility of requiring industry to use Government certified laboratories to perform testing will be investigated as a further means of ensuring objectivity and standardization in data submissions." EPA officials told us that EPA had not taken any action in this regard because EPA's efforts had been directed to higher priority requirements mandated by the act to be completed by certain dates.

INSPECTION AND ACCREDITATION PROGRAMS REQUIRED BY OTHER FEDERAL AGENCIES

Other Federal agencies also use nongovernmental laboratories to assess the hazards of drugs and manufacturing chemicals. In its human-drug registration program, FDA requires essentially the same type of toxicity testing as EPA requires for pesticide registration. Thus for certain drugs and pesticides, analogous testing is required to determine acute (one-dose exposure) and subacute (continuous exposure generally over a 90-day period) toxicity, as well as chronic (long-term) studies, to determine a product's potential to cause cancers (carcinogenicity) or birth defects (teratogenicity) or to affect reproduction. In many cases the same laboratories do both pesticide and drug testing.

The EPA and FDA programs differ in one major respect—FDA has a program to inspect laboratories to insure the reliability of data submitted for drug registration. The objectives of FDA's inspection program are to insure that laboratories: Have sufficient and properly maintained facilities and equipment; keep complete and accurate records which allow for verification of data submitted; have qualified staff; and follow valid test procedures.

FDA inspectors have found inadequate internal control, insufficient supervision, questionable procedures, and poor recordkeeping in several nongovernmental laboratories which test both pesticides and drugs. For example, at one drug-pesticide laboratory, FDA inspectors found that: The laboratory had purchased animals which were not accounted for; animals' identifying numbers were changed in a record book without explanation, initials, or date; data sheets and corrections thereon were not always initialed; recalculations of animals' food intake for a 2-week period were not adequately explained.

The lack of accountability of animals and/or the substitution of test animals during a test could affect the test's outcome to the extent that a harmful chemical could be declared safe.

In addition to EPA and FDA, many Federal, State, and local agencies rely on other types of data prepared by nongovernmental laboratories, many of which are regulated by accreditation or inspection programs. (A number of accreditation/inspection programs and their cost are discussed in enc. I.)

One major area where the Congress recognized the need to insure high-quality laboratory data was clinical tests—tests for the diagnosis, prevention, or treatment of human diseases or impairments. The Clinical Laboratory Improvement Act of 1967 requires the Center for Disease Control (CDC) of the Department of Health, Education, and Welfare (HEW) to license clinical laboratories which receive clinical specimens that cross State lines. CDC accepts accreditation by

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[2] Studies during the lifetime of test animals involving multiple exposure to substances in their food. The study is to find a maximum level which induces no toxicological effect and to determine the nature and degree of long-term effects.

the College of American Pathologists and the New York State Department of Health in lieu of a CDC site inspection. CDC, which charges a licensing fee, has licensed about 700 such laboratories. Additionally, numerous other State agencies also inspect and accredit clinical laboratories, primarily those not involved in interstate commerce. CDC said that its licensing program had improved laboratory-proficiency testing.

EPA, FDA, the Department of Agriculture, the American Industrial Hygiene Association, the American Association for the Accreditation of Laboratory Animal Care (AAALAC), and various State agencies accredit or inspect a variety of other types of testing laboratories. A 1974 contract study for EPA's Office of Research and Development on the feasibility of an environmental laboratory accreditation/inspection program credited these existing programs with (1) reducing the frequency of incorrect data, (2) correcting technical problems, (3) weeding out poorly qualified employees, (4) standardizing laboratory procedures, and (5) upgrading facilities and equipment.

As a result of this contract study, EPA is establishing an accreditation/inspection program for environmental-testing (water quality) laboratories. In addition, the Department of Commerce and the Occupational Safety and Health Administration are considering similar programs for laboratories whose data they use.

Another means of improving the accuracy and reliability of data is to require accreditation of laboratories by existing professional associations. As mentioned previously, CDC uses such an approach in licensing clinical laboratories accredited by the College of American Pathologists and by the New York State Department of Health.

We identified two organizations—one which had, and one which was considering, accreditation programs. These organizations' programs appeared to have applicability to pesticide testing. The first, the American Council of Independent Laboratories, is a voluntary association of independent laboratories in the field of physical or biological sciences. Council accreditation requires a site inspection, made by two persons selected from the membership, to insure that the laboratory is adequately equipped and organized to render reliable service in its chosen fields in accordance with the council's guidelines. An apparent shortcoming of the council's program is that periodic followup inspections are not required after membership has been obtained.

The second, the Society of Toxicology, has recognized that a program to accredit laboratory facilities and competency in making toxicological studies is needed, and the society is studying the matter. EPA input into development of such a program could insure that EPA needs will be considered.

The National Institutes of Health (NIH) also requires that the animal-care facilities of nongovernmental laboratories with which it contracts be accredited either by NIH or by a nationally recognized professional laboratory animal-accrediting body, such as AAALAC. Although AAALAC does not evaluate such aspects as test procedures and quality of test personnel and facilities, an NIH official told us that accreditation by AAALAC improves the quality of research by insuring that good animal-care procedures are followed during studies, which keeps variables at a minimum.

One additional factor that EPA should consider, if it determines that an EPA-operated inspection or accreditation program is warranted, is whether a fee should be charged for EPA's service. It appears that licensing or accrediting laboratories should comply with 31 U.S.C. 483a, enacted in 1951, which states that it is the sense of the Congress that an agency charge a fair and equitable fee for "any work, service publication, report, document, benefit, privilege, authority, use, franchise, license, permit, certificate, registration, or similar thing of value or utility performed, furnished, provided, granted, prepared or issued by any Federal agency * * *." CDC assesses such fees for licensing clinical laboratories, and its program might serve as a model for a similar EPA program.

ADDITIONAL CONTROL OF TEST DATA DESIRABLE

EPA's proposed registration guidelines state that "the pesticide used for toxicological [safety] testing must be the same chemically characterized product which is proposed to be or is commercially produced and used." EPA did not require chemical analysis of the pesticide being tested, and test reports submitted to EPA generally did not contain a verification by the performing laboratory of the chemical composition of the substances tested. Reports merely cite the receipt and testing of samples labeled by a number or product name.

Examples of material descriptions are "a red-colored liquid" and "a green powder labeled Sample No. 1548." Occasionally disclaimers are made by the performing laboratories that the reported results are not applicable to apparently similar or identical products. One report, for example, included the statement: "This report applies only to the sample, or samples, investigated and is not necessarily indicative of the quality or condition of apparently identical or similar products." Reports such as these provide EPA with no assurance that the product which was tested is the product being registered. We believe EPA should not accept reports containing such disclaimers and should consider requiring analysis of chemicals being tested.

CONCLUSIONS

EPA relies on safety and efficacy studies by nongovernmental laboratories as the basis for registering pesticides. EPA has no program to inspect, license, or accredit these laboratories to insure that the laboratories have appropriate facilities and equipment and qualified personnel and that proper test procedures are followed. Other Federal, State, and local agencies which use such data, some of which is analogous to data required for pesticides, have found the accuracy and reliability of data from some laboratories to be unsatisfactory and consequently have their own inspection of accreditation programs.

FDA and CDC have inspection/accreditation programs for drug registration and clinical testing, respectively. It appears that poor tests in these areas would be more readily identified than poor pesticide tests. Adverse drug reactions or incorrect specimen analyses would be readily attributable to the laboratory and should have an immediate economic impact on the laboratory because the drug company or doctor would not use such laboratories further. Nevertheless the data generated from these laboratories has not been adequate, and inspection and licensing programs have been implemented.

Pesticide exposure presents equally, if not more, serious health hazards, because adverse effects from low-level exposure may not be apparent for many years. The identification of problem pesticides is further complicated because of the dispersion of pesticides, along with a multitude of other chemicals, in the nation's food supply and the environment. Despite the seriousness of potential problems and the almost complete reliance of EPA's pesticide registration program on safety and efficacy studies by nongovernmental laboratories, EPA has not systematically reviewed the capabilities of such laboratories or their compliance with appropriate test procedures that will reasonably insure the accurancy and reliability of test data.

We believe that EPA's acceptance of safety and efficacy studies which contain laboratory disclaimers regarding test results and do not adequately identify the chemical composition of the compound being tested prevents EPA from insuring, as required by law, that only safe and effective pesticides are registered.

RECOMMENDATIONS

We recommend that EPA determine whether an accreditation or inspection program is necessary to insure that accurate, reliable, and objective safety and efficacy data is being provided by nongovernmental laboratories. Such a determination should consider the various alternative methods available for inspection or accreditation as a basis for selecting the most cost-effective program for EPA. EPA's needs may be satisfied by: A joint EPA-FDA program which would avoid duplication of visits to laboratories serving both agencies; accreditation by one or more private organizations; or a combination of the foregoing.

We also recommend that EPA not accept studies containing laboratory disclaimers and consider requiring the laboratory to make a chemical analysis of the product being tested.

We have discussed this report with officials of EPA's Office of Pesticide Programs. They told us that they agreed that EPA should review the adequacy of laboratory data submitted for pesticide registration as a basis for determining whether a laboratory accreditation or inspection program is warranted. They also said that such a study had not been done because of higher priority work, such as completing registration regulations and guidelines which were required by amendments to the Federal Insecticide, Fungicide, and Rodenticide Act to be completed by October 1974.

An EPA official said that pesticide studies should contain positive identification of the compound being tested and should not be qualified regarding study

replicability. He said that these areas would be reviewed to determine whether EPA's proposed registration guidelines needed to be revised.

We invite your attention to the fact that this report contains recommendations to you which are set forth on page 9. As you know, section 236 of the Legislative Reorganization Act of 1970 requires the head of a Federal agency to submit a written statement on actions taken on our recommendations to the House and Senate Committees on Government Operations not later than 60 days after the date of the report and to the House and Senate Committees on Appropriations with the agency's first request for appropriations made more than 60 days after the date of the report.

We shall appreciate being informed of any action you may take on matters discussed in this report. We appreciate the courtesies and cooperation extended to our representatives during the review.

Sincerely yours,

HENRY ESCHWEGE,
Director.

[Enclosure I]

DESCRIPTION OF SELECTED FEDERAL AND STATE LABORATORY ACCREDITATION AND INSPECTION PROGRAMS AND THEIR RELATED COSTS

Organization.—HEW, Food and Drug Administration, Bureau of Foods.

Program.—Approval of State milk-testing laboratories and personnel. Includes proficiency testing and inspection.

Objectives.—Conformity of laboratory procedures.

Benefits.—Improved precision and accuracy of data, standardization of procedures, and upgrading of facilities.

Costs.—3 staff-days for each inspection.

Number of participating laboratories.—65.

Organization.—HEW, Food and Drug Administration, Bureau of Drugs.

Program.—Inspection of drug studies in animals and humans at commercial laboratories.

Objectives.—Insure that laboratories (1) have sufficient and properly maintained facilities and equipment, (2) keep complete and accurate records which allow for verification of data submitted, (3) have qualified staff, and (4) follow valid test procedures.

Benefits.—Analyses of benefits not currently available.

Costs.—None currently available.

Number of participating laboratories.—No estimate.

Organization.—HEW, CDC.

Program.—Licensure of clinical laboratories engaged in interstate commerce. Includes proficiency testing and inspection. Accreditation by College of American Pathologists and New York State Department of Health is accepted.

Objectives.—Improvement of laboratory performance; conformity of laboratory procedures.

Benefits.—Decrease of 11.5 percent in proficiency-testing deficiencies and 19 percent in number of laboratories found unsatisfactory.

Costs.—Total funding $9 million; licensing activities, $2 million; cost to laboratories, $125 plus $25 for each section inspected.

Number of participating laboratories.—700.

Organization.—HEW, Social Security Administration, Bureau of Health Insurance.

Program.—Certification of independent clinical laboratories performing services under Medicare. Includes inspection. Regulations incorporate CDC standards.

Objectives.—Improvement of clinical laboratory performance.

Benefits.—Upgraded laboratory quality control and personnel.

Costs.—Total funding—$3 million a year.

Number of participating laboratories.—3,000.

Organization.—EPA, Water Quality Office, Water Supply Division.

Program.—Certification of State laboratories analyzing potable water on interstate carriers. Includes inspection.

Objectives.—Conformity of laboratory procedures to insure data quality.

Benefits.—Improved testing procedures.

Costs.—56 staff-hours for each inspection by GS-13 through GS-15 personnel.

Number of participating laboratories.—50.

Organization.—EPA, Methods Development and Quality Assurance Research Laboratory.

Program.—Studying feasibility of certifying environmental-monitoring laboratories (water, air, and pesticides), including proficiency testing and inspection.

Objectives.—Reliable data. Legal basis for refusal of data of uncertain quality and reliability.

Benefits.—Not obtained.

Costs.—Estimated at $750,000 a year.

Number of participating laboratories.—No estimate.

Organization.—Department of Labor, Occupational Safety and Health Administration.

Program.—Proposed accreditation of independent laboratories which test products and devices for safety. Includes proficiency testing and inspection.

Objectives.—Facilitate enforcement of occupational safety and health standards.

Benefits.—Proposal revoked pending resolution of questions regarding legal authority, resources required, and program standards.

Costs.—No estimate available.

Number of participating laboratories.—No estimate.

Organization.—Department of Commerce, National Bureau of Standards.

Program.—Proposed national voluntary laboratory accreditation for selected classes of technologies, initially construction materials.

Objectives.—Maintain acceptable level of competence of private and public laboratories that serve regulatory and nonregulatory product evaluation needs.

Costs.—No estimate available.

Number of participating laboratories.—No estimate.

Organization.—New York Department of Health, Division of Laboratories and Research.

Program.—Approval of laboratories that analyze potable water.

Objectives.—Reliability of laboratory data and conformance with minimum standards.

Benefits.—Increased uniformity of data among laboratories; weeding out of poorly qualified personnel.

Costs.—None currently available.

Number of participating laboratories.—100.

Organization.—Oklahoma Department of Health.

Program.—Certification of prenatal and premarital blood-sample-testing laboratories. Includes proficiency testing.

Objectives.—Maintenance of satisfactory level of performance in serological testing of blood samples.

Benefits.—Increase in average proficiency-testing scores of approved laboratories.

Costs.—Not obtained.

Number of participating laboratories.—200.

Organization.—California Department of Health.

Program.—Licensure of clinical laboratories, except those owned or operated by licensed physicians for work on their own patients. Includes inspection.

Objectives.—Insure capability and satisfactory level of performance of facilities and personnel.

Benefits.—Reduced frequency of poor (incorrect) data.

Costs.—In fiscal year 1974–75, $465,199 was budgeted for 37.8 positions.

Number of participating laboratories.—2,000.

Organization.—AAALAC.

Program.—Voluntary accreditation of laboratory-animal-care methods and facilities. Utilizes NIH's *Guide for the Care and Use of Laboratory Animals* and fulfills NIH requirements for grants. Participated in by the Veterans Administration. Includes inspection.

Objectives.—Improved welfare and health of laboratory animals. Facilitate scientific research and testing requiring laboratory animals.

Benefits.—Improvements in animal care through identification of deficiencies; 70 percent of the laboratories, initially unacceptable, improved their programs to an accreditable level.

Costs.—Fee to laboratory of $100 annually. Cost varies by facilities.

Number of participating laboratories.—Accredited: 275.

Organization.—American Industrial Hygiene Association.

Program.—Voluntary accreditation of laboratories which analyze samples of airborne contaminants collected in the workplace and biological specimens of workers exposed. Includes proficiency testing and inspection.
Objectives.—Improved performance and assurance of quality data.
Benefits.—Improved laboratory data, selectivity in personnel hiring, and objective look at techniques and procedures.
Costs.—Operated since inception under sponsorship of National Institute of Occupational Safety and Health. Annual site visit cost estimated at $350.
Number of participating laboratories.—60.
Organization.—College of American Pathologists.
Program.—Voluntary accreditation of independent and hospital clinical laboratories. Includes inspection and proficiency testing.
Objectives.—Development and implementation of high laboratory medicine standards.
Benefits.—Upgraded level of performance.
Costs.—Average site visit: $400.
Number of participating laboratories.—12,000.
Organization.—Society of Toxicology.
Program.—Planning to establish a working party of past presidents to prepare an outline of the goals, objectives, and means of implementing an accreditation program.
Objectives.—Not obtained.
Benefits.—Not obtained.
Costs.—Not obtained.
Number of participating laboratories.—Not obtained.
Organization.—American Council of Independent Laboratories, Inc.
Program.—Voluntary accreditation requiring only an initial inspection to insure adequate equipment, organization, personnel, and quality control.
Objectives.—Promotion of scientific inspection, sampling, analysis, testing, consultation, development, and research.
Benefits.—Not available.
Costs.—Not available.
Number of participating laboratories.—171.

Mr. SIZEMORE. Despite a history of emphasizing benefits of pesticidal use in relation to risk, the Administrator specifically provided in his memorandum for a more "open evaluation of risks and benefits" and criticized the adversary process, which had accounted for the Agency's only meaningful pesticide regulation.

The Administrator took this action despite the conclusion of the EPA investigating committee that the Office of Pesticide Programs had failed to take action against suspect chemicals, forcing the Office of General Counsel, of which we were members, to proceed to take these actions independently.

Thus, the cycle was completed and the message was clear. There would be no further enforcement of the pesticide law for at least the next 12 months.

Although the appearances were obvious enough, Mr. Chairman, this view was confirmed by us in discussions with our superiors during the past several weeks.

In addition, we attended meetings, chaired by top EPA officials, which were convened for the express purpose of considering changing past cancer decisions in response to comments from an agricultural trade group.

We might remind you, Mr. Chairman, although this is not in our remarks, that we believe these cancer decisions which were the subject of these meetings are on the cutting edge of toxic regulation, and that any retrenchment from these decisions produces additional evidence that the Agency does not intend to act vigorously in toxic substances regulation.

Thank you.

Mr. REUKAUF. Mr. Chairman, we hope in our remarks here today to go beyond criticism of the Environmental Protection Agency and address ourselves to the question of what steps can be taken to remedy some of the problems which we have raised.

In the first place we believe that there must be a radical reordering of priorities to remedy these problems. We do not presume to tell the Congress how to regulate the regulatory agencies, but recent events raise serious questions about the role of Congress in protecting the environment.

The recent events to which we refer deal with the amendments to the Federal Insecticide, Fungicide, and Rodenticide Act, the FIFRA. The chemical industry which FIFRA purports to regulate had a strong hand in the drafting of that law and the law provides extensive safeguards to protect the industry's rights.

The committee of the House which has legislative and oversight jurisdiction over this law is the House Agriculture Committee. When that committee disagreed with some of EPA's policies and actions, it proceeded to pass amendments which, among other things, required greater participation by the Secretary of Agriculture in EPA's public health decisions relating to pesticides.

After extensive investigations into the failure of the Department of Agriculture to protect the public health from dangerous pesticides, Congress wisely transferred administrative responsibility over pesticides to the newly formed EPA.

Why then did Congress not clean its own house and transfer legislative and oversight responsibility to a congressional committee whose interest was in protecting public health? Surely if there were sound reasons to take pesticide regulation out of the hands of pesticide promoters in the executive branch, those sound reasons also apply in the legislative branch.

It is clear also that EPA must reorder its priorities if it is to deal effectively with toxic pollutants. Although there are many other areas of environmental protection with which we must deal, EPA employs over 9,000 people, and it could deploy this work force in a way which could deal effectively with toxic pollutants under existing authority. Not to do so would, in our opinion, serve to continue a situation which we believe has become a public health crisis in America.

There is a committee which vigorously represents agricultural interests. There are committees which vigorously represent industrial interests. But there is no one committee which represents environmental health interests.

When we announced our resignations because of EPA's failure effectively to regulate toxic substances, we were contacted by three House subcommittees and two Senate subcommittees, all of whom claim some jurisdiction regarding toxic chemicals.

We believe that the Congress cannot effectively oversee the protection of environmental health until it centralizes its jurisdiction over all statutes designed to protect public health and the environment. At the very least there should be clear arrangement for overlapping jurisdiction by environmentally oriented committees over other committees.

Additionally, Congress must make clear in all statutes which regulate toxic chemicals that the burden of proof of safety must always remain with the manufacturer of the chemical.

Furthermore, Congress should exercise continuous oversight to insure that the requirement of this burden of proof is not diluted by Agency regulations or policies.

Mr. Chairman, in addition to these general remarks, we make the following specific recommendations:

One: Immediate priority and resources must be allocated to undertake an extensive review of EPA pesticide registration files by independent experts. Legislation should be proposed which would provide for immediate removal from the market, followed by an opportunity for a hearing, of any pesticide where the data submitted are inadequate to support its safety as required by law.

Two: A process for appropriate certification of independent testing laboratories and assurances of their independence in fact must be considered a primary subject for new legislation, in our opinion.

Three: Urgent attention should be given to passage of the toxic substances control bill subject to intensive congressional oversight. Despite EPA's inadequate efforts under existing toxic control authorities, there are many toxics which are presently unregulated altogether.

Four: With respect to EPA's administration of existing toxic control authorities, Congress must manifest its intention that these existing laws be implemented fully as soon as possible and must convene comprehensive oversight hearings to review EPA's entire toxic regulatory program.

Mr. Chairman, this completes our prepared statement. We will be happy to answer any questions from the committee.

Mr. MOORHEAD. Thank you, gentlemen, for an eloquent statement. I think you have made it clear, at least to the Chair, that your objective in resigning, and I might say somewhat reluctantly appearing before this subcommittee, in no way represents a vendetta. I believe you have made a sincere attempt, by your action and by your statement, to clear up dangerous situations which have been allowed to exist.

For this and for the sacrifice you have made, I commend you.

You referred in your statement several times to GAO reports which this subcommittee has received, and without objection the GAO reports will be made part of the record.

Before I get into some detailed questions, I want to clarify the procedural situation.

As I understand it—and I am dealing particularly with the burden of proof issue—your statement is that the law and procedures, so far as getting a new pesticide registered, are adequate. You believe that the regulations and the judicial precedents are adequate, but that they have not been adequately enforced. Do I understand that correctly?

Mr. HOWARD. In the case of pesticides, with respect we have the greatest familiarity, we believe that that, in essence, is correct, that the present law is adequate but the administration of the law is not adequate.

Mr. MOORHEAD. I'll limit mayself to pesticides with which you are most familiar. In the case of pesticides which were already registered under preexisting law which charged the Department of Agriculture with the registration, the deregistration process is cumbersome and

the burden of proof is on the Agency—is that correct? I wanted to draw those distinctions between already registered and not yet registered.

Mr. HOWARD. Mr. Chairman, under existing law, even under a deregistration proceeding, the burden of proving safety is on the private party who holds the Federal license, the manufacturer of a pesticide.

Mr. MOORHEAD. But at some point in your testimony you talked about cumbersome proceedings. Even though it isn't a burden-of-proof problem, it's——

Mr. SIZEMORE. It's not a burden-of-proof problem, Mr. Chairman, but it is the fact that so many thousands of pesticides have been registered not in accordance with the legal standards. Then, the statute provides so many procedural steps for the Agency to leap through, it's virtually impossible, except for a 1- or 2-year-long process, to get these products off the market.

In addition, while the present law is adequate to regulate initially, we might say—and we spoke to this in our statement—that recent amendments to the act, in our view, make it even more cumbersome to remove a hazardous pesticide from the market by requiring not only consultation with the House Agriculture Committee but also with the Secretary of Agriculture who has opposed our actions in every adjudicatory hearing we have been involved in.

Mr. HOWARD. In fact, the Secretary of Agriculture has sued the Administrator of EPA in Federal court, along with the chemical company, to try to overturn decisions which would have banned the use of cancer-causing pesticides.

Mr. MOORHEAD. It's my recollection—and correct me if I am wrong—that, when the FIFRA bill was before the Congress, an attempt was made to give the Secretary of Agriculture, in effect, veto power over EPA. But the Congress refused to do that and, in fact, as I understand the way we wrote the law, gave EPA the final voice, although requiring consultation with the Secretary of Agriculture. Am I correct in that?

Mr. HOWARD. Yes, sir; that is correct.

Mr. MOORHEAD. We are talking about a number of laws. Fortunately, or unfortunately, all of you are lawyers.

Would you describe the legal authorities which set toxic pretreatment standards for discharges into municipal treatment systems, with toxic effluent standards for discharges into rivers and streams, regulate response to hazardous chemical discharges, to issue emergency orders to halt imminent and substantial dangers to human health and water pollutants, and to set standards for hundreds of toxic emissions into the air that sets limits on toxic chemicals in drinking water supplies?

We would like to have this complete record of legal authorities for our record.

Mr. HOWARD. Yes, Mr. Chairman. Let me go through them one at a time.

Toxic pretreatment standards, under the Federal Water Pollution Control Act, which was amended substantially in 1972, the Environmental Protection Agency has the authority and responsibility to publish regulations setting pretreatment standards.

These are standards which set limits on what can be in the waste waters that are discharged in municipal sewers. EPA has published regulations setting pretreatment standards. In doing so, although it had the authority, it did not set the standards for toxic chemicals in those sewer discharges.

The second item is toxic effluent standards, also under the Federal Water Control Act of 1972, section 307 gives EPA the authority and responsibility to publish effluent standards specifically for toxic chemicals that are in the effluent.

As to today, EPA has never published final regulations implementing that section. There was an abortive effort about a year or so ago when EPA proposed nine chemicals. That effort was abandoned by EPA after an extensive hearing. Nothing has been forthcoming since then.

These effluent standards would regulate what can be in your discharges directly into the rivers and streams across the country.

Mr. MOORHEAD. In these cases where waste goes into a municipal system, that municipal system is not really able to clear toxic substances out of waters; isn't that correct?

Mr. HOWARD. The municipal systems are not set up to clear toxic substances out of the water.

Mr. MOORHEAD. So one of the ways we can protect our water from toxic substances is to prevent their discharge into the municipal system; is that correct?

Mr. HOWARD. The only way to effectively deal with toxic chemicals is to deal with them at the source, which is what I think you are getting at.

Mr. MOORHEAD. Yes, at the source——

Mr. HOWARD. By the man who makes them and who causes them to be discharged. In the case of drinking water, however, there are actions which EPA could take under existing law with money that EPA has been authorized by Congress to have States and municipalities install treatment facilities to clean the drinking water much more so than it is now, to remove organic chemicals.

Mr. MOORHEAD. So EPA has authority to control the source of the discharge and to require municipalities to take steps which are feasible to remove toxic substances once they are in the water, but EPA has done neither; is that true?

Mr. HOWARD. Correct.

Mr. MOORHEAD. I am sorry to interrupt. You may continue with the other legal authority.

Mr. HOWARD. The third item is to regulate and respond to hazardous chemical discharges. Under section 311 of the Federal Water Pollution Control Act, which was the same act substantially devised in 1972, EPA has had, since 1970, the authority to regulate oil discharges and we are all familiar with oil spill discharges and the EPA authority, in conjunction with the Coast Guard, provides for a Federal coordinated effort to clean up oil spills and Federal resources in the bank to be used in those cleanups.

Since 1970 EPA has been charged with promulgating a list of hazardous chemicals and when, in 1972, Congress amended the law, they said that when you published the list, everything on the list will be treated just like oil.

The Federal Government will have the manpower; the money is in the bank, and a coordinated system is set up to respond to hazardous chemical discharges. In fact, in the six ensuing years EPA never published a final list of hazardous chemicals and although they have recently at the end of last month published a proposed list, there is no final list today.

What's more, the proposed list, which was published only a few weeks ago, specifically excludes from the list hazardous chemicals that can cause cancer and the report of EPA says so.

The fourth item to issue emergency orders to stop imminent and substantial endangerment to human health. Here, Congress gave EPA extraordinary powers, both under the Federal Water Pollution Control Act and under the brand new Drinking Water Act, to issue emergency orders to stop imminent hazards to health. This can be done on a localized basis in response to a particular problem or it can be done on a broader regional or national basis when emergencies arise.

These authorities have not been exercised.

Fifth, EPA has the power, under the Clean Air Act of 1970, to set standards for toxic emissions into the air. To date, EPA has set standards for only three compounds in emissions. Those compounds are barillium, mercury, and asbestos, and there are hearings underway today to set emission standards for vinyl chloride.

It's common knowledge across the country that organic chemicals that are persistent and mobile are throughout the environment. They get there not only through water discharges but through emissions into the air. And these authorities to regulate the source have not been used.

Mr. MOORHEAD. You mentioned a list that was published in the Federal Register. You also mentioned earlier in your statement a list of 100 carcinogenic or potentially carcinogenic substances. Is that a different list?

Mr. HOWARD. Yes, sir; that is a different list.

Mr. MOORHEAD. That is the list that you have not seen?

Mr. HOWARD. That is correct.

Mr. MOORHEAD. Did any of you make any effort to obtain this list?

Mr. SIZEMORE. All of us did.

Mr. MOORHEAD. You attempted to obtain this list and none of you were able to obtain it?

Mr. HOWARD. That is correct.

Mr. MOORHEAD. Was any reason given for this?

Mr. HOWARD. There was no reason given for this.

Mr. MOORHEAD. I suggest that this subcommittee should attempt to obtain that list.

You've mentioned these various legal authorities. Do any of them have a deadline for action? I think you mentioned one statute that had a 90-day limitation which is not anywhere near being met. Are there other statutes that have deadlines that have or have not been met?

Mr. HOWARD. Yes, sir; there are other statutes that have deadlines that have not been met. In addition to that, there are statutes without deadlines that require EPA to respond to hazards by publishing

regulations that would limit the hazard. In our view that is the equivalent to a deadline. Once you know about the hazard you are required to act. Substantially all of these matters fall into one of those classifications.

Mr. MOORHEAD. What extent is EPA given discretion to act or not to act under the law?

Mr. HOWARD. As you are aware, Mr. Chairman, discretion under the law is a complicated and a very particularized process, and it means that Congress has simply given an administrative official broad leeway in deciding not to act or deciding to act. We have not at this time reviewed all of these legal authorities at that point, but it seems to me at this time I am unaware of any of these authorities which gives the Administrator the kind of broad discretion which we commonly think of as a legal term in meeting administrative discretion.

Mr. MOORHEAD. You have made various charges of commission or omission on the part of EPA. Take, for example, the Kepone example at Hopewell, Va. Could that have been avoided? I am not talking about within the plant, but discharge into the river—could that have been avoided by more rigorous enforcement of the type you are recommending by EPA?

Mr. REUKAUF. Mr. Chairman, there is no doubt that if the regulations and the laws about which we have spoken had been more vigorously enforced, there would have been a substantial likelihood that some of these problems could have been avoided or detected at an earlier point in time.

Mr. MOORHEAD. You have made some serious charges against EPA. Before your resignations did you have occasion to point out to those with authority what you thought to be deficiencies in the implementation of these statutes and regulations?

Mr. SIZEMORE. Mr. Chairman, we didn't have the occasion to go through in the detail we have in respect to every act that the Agency administered because we actually didn't have responsibilities in all of those areas.

We did, however, have the occasion repeatedly over the past several months to attend meetings at which all of the issues relating to toxic substances control including what is the Agency's policy on controlling carcinogens. We were at every meeting in which that was involved and we did speak out at every chance that there was to tell the Agency that we didn't think it was effectively controlling in this area.

Mr. HOWARD. Mr. Chairman, one other point on that.

It is an interesting point that you have raised because I think when the Agency comes forward before this committee, you will be able to ask them this question.

I think they will confirm the fact that indeed one of the reasons we resigned was because we were so severely criticized in the Agency for speaking out, both in meetings and informal groups, in writing and otherwise, and that immediately prior or leading up to our resignations as a result of some of the processes we have discussed, we were uninvited to meetings and uninvited to attend briefings and uninvited to participate in the matters we have spoken out about. So there can be no question that at every opportunity we took the forum that was available to express precisely these views.

Mr. MOORHEAD. Would that explain why you were not able to see the list of 100 cancer-causing pesticides? Would that also be one of the reasons why you were not given access to or permitted to participate in the GAO investigation and report on the inadequate accreditation and control over laboratories testing toxic substances?

Mr. SIZEMORE. Certainly it's a reason for why we didn't see the list of 100 pesticides. I have no doubt about that.

As to the GAO report we have little knowledge as to how that was conducted. We know it was conducted within the Office of Pesticide Program. We don't know why we were not contacted.

Mr. MOORHEAD. All three of you were in the counsel's office. Did you have an adequate staff of lawyers to enforce the laws as you were suggesting they should be enforced?

Mr. HOWARD. In the manner that we are suggesting they be enforced we think we do, although every Agency official, including ourselves when we were Agency officials, pleads for additional assistance.

There is a problem. The problem is so huge, the backlog, the failure to regulate cancer-causing chemicals, the pesticides, is huge. They have been registered for 30 years substantially without any review as to human health aspects. So there is a big backlog. That's why there is a list of 100 chemicals, and to be sure that all of those went into formal trial at this time it would exceed our limited resources, the limited resources of the Agency and the counsel's office.

But the processes that we have been describing do not require an immediate hearing on all of these things. There are elaborate regulatory procedures to deal with these compounds that have not been been utilized as yet.

Mr. MOORHEAD. Thank you.

Mr. Gude?

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

I know the chairman intends to have EPA appear in regard to the allegations that have been made. As near as I can ascertain in looking over this material, a great deal of this is not new. We have been concerned about these matters and I am certainly tagged by a lot of people as a card-carrying conservationist.

I know my votes and views on various pieces of legislation, particularly the FIFRA, which was just passed, have differed from some of my colleagues. My colleague, Mr. Fountain, I know, differs with me on these matters, and I respect his view, because I know he believes very ardently in the way he votes and the way he feels about these things.

I was contacted by Administrator Train during the consideration of FIFRA. Personally, he talked with me about his concern and asked me to try to work with other Members to try to keep that law the way it was.

Were you aware that the Administrator was lobbying and working hard to keep control of that law?

Mr. HOWARD. We were aware of it, yes, sir.

Mr. GUDE. Were you aware of it?

Mr. SIZEMORE. Yes, sir.

Mr. REUKAUF. Yes, sir.

Mr. GUDE. I know you have flailed at the EPA. You have flailed at Congress and you have flailed at the manufacturers and the agricultural lobby, and it seems to me you are flailing at our very system

of government here. When Mr. Fountain doesn't agree with me and votes differently, I respect his position and that's part of the political process.

Mr. FOUNTAIN. What are you talking about?

Mr. GUDE. I am talking about the FIFRA in regard to the registration of chemicals and the extent to which the Department of Agriculture would have cognizance over these materials. Maybe we voted alike.

Mr. FOUNTAIN. I don't know if we did on that subject. I think I voted for the requirement that there be consultation which I think is responsible in an agency like Agriculture—an agency with jurisdiction over a tremendous segment of the economy of the country. But I would never have voted to give Agriculture the power to veto.

As I understand it, the Environmental Protection Agency has the authority to make the final decision.

Mr. GUDE. Let me say, Mr. Fountain, that I apologize if I misconstrued what I hadn't researched, but there are other Members who didn't agree with you and me and I respect their positions in regard to their votes. But if they voted to put this in the Department of Agriculture to change the act, I respect their vote and they are reflecting the views of their constituents.

I believe very ardently in some type of gun control legislation. I happen to think that a gun that is not registered can fall into the hands of people who don't know what they are doing with a gun, who don't know which end the bullet comes out of, that a gun is a dangerous thing in society. I think this is just as bad as a carcinogen, and I guess you could have law enforcement officers say:

> We're going to resign. They are not registering guns; they are not doing anything with people who are running around in society carrying guns; Congress isn't doing anything about it. Congress should pass a law to do something about these guns and take them out of the hands of the criminals and people who don't know how to handle them.

But Congress hasn't seen fit to do that because there are more people who disagree with me than agree.

When you say why didn't Congress clean its own house and transfer legislative and oversight responsibility to a congressional committee whose interest was in protection of public health, it's because there are more Members of Congress who feel they want the House organized the way it is than would like to see it changed.

I think that we could protect public health better if we reorganized, but I don't think it would be successful in the present political context.

Mr. SIZEMORE. I think you may be right when you say that the process that resulted in the amendment of FIFRA is the process of Government by which we live. What we are saying is that we saw that process work, that we don't like the result and that we think the result is traceable not to an awareness of what the real issues are but rather to where the strength and the money lies, and that is in the center of industry and agricultural groups. There is no concentrated public health lobby that is present to offset the tremendous pressure that can be brought to bear by the other side of the issue, and every time, in our opinion, the public health suffers.

It doesn't suffer necessarily in whether a law is passed because, as we detailed, many laws have been passed in public health. But it

suffers all the way down the line from the time the law was passed to the method in which it is implemented and whether it is implemented fully. This is the nature of the process we are talking about and we may have to agree to disagree on whether or not that process is working in the public interest.

We don't believe the amendment of FIFRA was an example of legislation that worked in the public interest or in the interest of public health.

Mr. GUDE. You say you don't believe that that was working in the public interest?

Mr. SIZEMORE. We absolutely do not. We believe that it was a tradeoff against the interest of public health to delay implementation of effective enforcement against hazardous pesticides and it succeeded.

Mr. GUDE. In political considerations what would you say if those who were—let me ask you this—could there have been a more radical amendment of FIFRA that would have more adversely affected the public interest?

Mr. SIZEMORE. Certainly; the veto proposed by Representative Poage and Representative Wampler for the Secretary of Agriculture would clearly have presented a more odious block to pesticide enforcement.

Mr. GUDE. We hate to say that politics was involved, but do you think in order to keep some measure of control that a tradeoff was made?

Mr. SIZEMORE. I don't doubt that at all. I think that is perfectly clear that there was a tradeoff. What bothers me is the fact that we had to get to the point where a tradeoff on public health had to be made. That, we think, is traceable to the fact that there is no organized public health group to counterbalance the groups that forced the amendment of the pesticide law.

Mr. GUDE. You say there's no organized public health group.

Mr. SIZEMORE. Yes, sir, with the money or cohesion that the industry and agricultural groups have. That's very clear.

Mr. GUDE. I don't know whether this speaks to your point, but the amount of money that is appropriated by Congress for health research, and this includes environmental health research, has steadily diminished in the last few years, much to my distress and to the distress of others.

Here again, Congress is responsible; it has made a real ordering of priorities. My priority is in the other direction from what Congress is doing.

Mr. SIZEMORE. We appreciate that that is the case.

Mr. GUDE. You are telling us to reorder our priorities. I think that is what we are trying to do and we appreciate your words and your support, but I am wondering just what you are suggesting, some type of reapportionment or readjustment of political power in Congress? Do you feel that creating a new committee in this area would necessarily make a shift in the balance of power as far as these various public policy decisions are concerned?

Mr. SIZEMORE. Mr. Howard has some remarks about that which I would like to have him make. The only thing I would say is that I don't think we would say that any restructuring will be the final answer to these problems.

There is not going to be an easy or mechanical answer to the problems that we have raised. What we hope to do is to cause these issues to be brought to the forefront and cause the system itself to be analyzed so that all of us can understand, as we have come to understand through Government, exactly what pressures are being brought to bear that determine the decisions that are made in the areas of public health.

Mr. HOWARD. Specifically on the question you asked, Congressman Gude, at the time in the late 1960's when the so-called Fountain report came out speaking about the failure of the U.S. Department of Agriculture to regulate the chemicals which they were also charged to promote, there was a decision by Congress and the Executive to transfer the authority to someone who is not charged with promotion of the regulated chemicals.

When that happened, there was no collateral transfer of authority within the House of Representatives and indeed, perhaps that's impossible, but indeed, there was no assertion of competing jurisdiction by another committee or subcommittee which could have claimed jurisdiction over that law that regulated the safety of pesticides. We don't ask for the impossible, although many of these may be impossible.

For example, if there were a competing claim of jurisdiction by a committee that was environmentally oriented to oversee the administration of the pesticide law instead of allowing the House Agriculture Committee, who is charged with the promotion of growing food and fiber in the use of agricultural chemicals, that would provide some added balance of the kind that the Fountain report spoke of in the executive forum.

Mr. GUDE. So you think that what we should do is have an oversight committee or legislation committee in the area of the hazardous substances in society?

Mr. SIZEMORE. We do feel that that is the case, but we don't know whether it is possible, but the purse string turns out to be the key element and unless there is competing jurisdiction over appropriations, the agency can be held hostage when it takes courageous action and we think that that is another key element that is involved.

Who has control of agency appropriations and how is that money to flow?

Mr. REUKAUF. Congressman Gude, obviously there are competing interests here and you have agonized over the same kinds of things that we agonize over. As I said, we don't purport to tell the Congress how it should go about these matters. We are only private citizens who have been inside the Government and who have seen some problems and we are only speaking to what we think might be appropriate ways to deal with the problems. We are familiar with the congressional process. We don't know how Congress exactly can do it. But one thought that came to our minds was this suggestion that perhaps a centralization of committee jurisdiction could be one thing.

I think basically we have agonized over these things and we want to focus attention on them. If our action can serve to focus the attention of this committee or some other committee or someone on these problems, perhaps someone has the answer. We are not saying that we have the answer, but we are trying to do the best we can to make recommendations that we think might be helpful.

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Mr. GUDE. In regard to the EPA's regulatory inaction and contemplated retrenchment from established enforcement policies, you say that this attribute in part to industry pressure brought to bear through congressional committees and to election year politics, both in Congress and in EPA itself. Is that right?

Mr. SIZEMORE. Yes.

Mr. GUDE. Do you know of any violations of the law that were carried out or made in regard to these industry pressures that were brought to bear in EPA?

Mr. HOWARD. Congressman, if I may respond to that. We are not familiar with any violations of any laws in regard to the matters that you referred to.

It is true, of course, that Congress passed the Advisory Committee Act and one of the purposes of that act was to prevent executive agencies from meeting with one side of the issue or another in private to discuss their contemplated actions and to be subjected to influence without advising other people to provide the opportunity for the public to come in.

We do know that there have been meetings within EPA with industry officials, without notice to environmental groups and to the public at large, to allow them to participate.

Mr. GUDE. This type of meeting has occurred?

Mr. HOWARD. Yes, sir.

Mr. GUDE. Mr. Chairman, I am glad that EPA is going to have a chance to comment in regard to this matter.

In regard to my comment to Mr. Fountain I didn't mean to characterize any of his votes. I made some assumptions considering an agricultural district, so I hope he won't take offense that I mischaracterized any of his votes.

However, what I was trying to characterize is that there is a large group of Members of Congress who evidently don't agree with you and me in regard to these matters, and they are representing their interest and their constituents as best as they know how, and we represent ours as we see things the best that we know how.

Thank you, Mr. Chairman.

Mr. MOORHEAD. It would be appropriate to recognize Mr. Fountain.

Mr. FOUNTAIN. I am sorry I wasn't here earlier and I won't take a lot of time, but I have been preoccupied with chairing another subcommittee which deals with a very important subject affecting the general welfare of the cities and counties and States in regard to revenue sharing and I haven't been able to keep up with all that is going on in this subcommittee, which has been doing a very effective job. I commend the chairman for what he has been doing.

I would agree with the gentleman from Maryland that philosophically we may differ on a number of items and we may even vote differently on legislation, but sometimes I think our votes whether for or against are quite often misconstrued.

I don't recall how I voted on the particular bill in question, but I do know that I would agree because of the impact of almost everything on agriculture in the country, a segment of the economy wherein 5 percent of the people in America produce the food and fiber for the rest of the Nation and for many parts of the world, ought to be consulted—and I may have voted for an amendment requiring consul-

tation with the Secretary of Agriculture—but I certainly have no intention of giving the Secretary of Agriculture the authority to veto any action by the Environmental Protection Agency.

Of course, I am getting correspondence all sorts of ways. I am getting correspondence saying repeal EPA, repeal OSHA, and I'm getting some saying why don't you get those agencies to do something? They aren't doing anything. But I yield to no one in the Congress in aspirations to see that the proper thing is done in terms of pesticides, in terms of drugs.

As a matter of fact, for some 15 years or more the subcommittee I have the honor to chair, the Intergovernmental Relations and Human Resources Subcommittee, has exercised surveillance on the Food and Drug Administration and I have had to go before cattle farmers on a number of occasions to explain why we had hearings that demonstrated the carcinogenic effect of diethylstilbestrol and why even the morning after pill may be cancerous.

We had an abundance of evidence indicating the impact of that on children some 15 years after the mother had taken it in an effort to prevent miscarriage. I think your observation about followup of the pesticide report and how you handle this sort of thing is extremely worthwhile.

Without taking a position one way or the other, I want to commend you gentlemen. I don't know enough about the facts but I admire anyone who has the courage of his convictions and who, having exhausted resources, if that is true, to get accomplished what you think ought to be accomplished to come to the proper forum, and I think the committees of Congress are the proper forum to at least publicly air the problem in a proper way in the hope that whatever action ought to be taken is taken by the administrative agency involved.

One observation I wanted to make is this:

What facilities do you have within EPA to put on an educational campaign before you start issuing regulations and implementing the law and "harassing" as some people say? You know public opinion determines whether we pass a law, whether it is properly and adequately enforced.

I am wondering if EPA has a group or committee which goes out into the agricultural areas of the country to meet and to discuss with agricultural leaders some of these areas we are now dealing with to the end that when the question comes up for debate, their positions are taken on the basis of fact and not fear as is often the case.

Would you care to comment on that?

Mr. HOWARD. Thank you for asking that question. That is a very important question and it is a question that goes to the very heart of the administrative process since indeed, if an agency is charged to enforce the law, it is also charged to tell the people what it is doing and why.

I think what is behind your statement is correct perception, that is, that EPA has not been adequately telling the story of what it is doing and why, and therefore people do respond out of fear and apprehension more than they do about awareness of the fact.

That problem, the question of why EPA has not done this, is very complex and would probably take another hearing to go into it in full.

I can say, however, that we have strenuously urged the top officials of the Agency in June and July of last year when the hearings were

underway in the House Agriculture Committee, that the Agency must proceed to develop a coherent, understandable presentation to tell people what we are doing on these cancer-causing pesticides in particular.

We understood, at that time, that a motion picture was going to be developed which would explain these things. So far as we know, nothing has happened as of the time we left.

There are people within the Agency who are charged with the responsibility of visiting with farm groups and other regulated groups and to talk with them about what the Agency is doing. I am not privy to what they have been saying or not saying, but my judgment is that there has been a lack of support within EPA for some of the more courageous decisions of the Administrator of EPA and that the result of that has been a failure to go forward and tell the story of what the Administrator has done in these specific cases.

Mr. FOUNTAIN. I appreciate your observation. I think it is pertinent but I had in mind more of an educational campaign in which someone who can speak with authority about these pesticides goes before agricultural groups and explains the dangers involved so that their opinions are not formed on the basis of the impact it may have upon the commodity they produce or the quantity of it, but they will be properly advised as to the health hazards involved.

On the subject of DES, which was given primarily to expedite the fattening of cattle and other animals for sale or consumption, I had to go before them because it so happened that we were the committee that was investigating this. Food and Drug hadn't done anything. After I had made the talk I made before about 500 cattlemen in my own congressional district, I might say, I got an entirely different response.

It might be interesting to note, however, Mr. Chairman, that the veterinarian for the North Carolina State University quickly got up and said:

> Mr. Chairman, I appreciate what you have said, but I noticed in the morning paper that the Food and Drug Administration has just approved a pill with DES which is about 1,600 times as strong as what the farmers had been feeding the cattle. What is your explanation of that?

I said I had read the story in the newspaper and I was sorry that I couldn't give an answer but I said I could tell them one thing that when I got back to Washington I was going to find out. We did, and it wasn't quite as bad as it sounded. That's what I am talking about, so that when these groups come in, these lobby groups, the Agriculture lobby, a big interest although it's now smaller and smaller, they'll know why actions have been taken. We had one or two amendments yesterday in regard to funds going into the counties or the cities, and the cities won. Obviously, there are many more votes from people who come from metropolitan areas of the country where there is even greater concern about the environment, water, air, than out in the open, free spaces where I grew up. We don't have that concern. We have more concern with water than with air.

There needs to be someone to go out and let these people know what the facts are because they are conscientious in their opinions although they may be dead wrong in those opinions, just like Members of Congress vote based upon two things, ignorance and knowl-

edge. Sometimes the ignorance may be worse than the knowledge. We don't know all the answers. We do the best we can and we have passed a lot of crazy laws, I think. If we had some way of repealing half of them and starting all over again, I think the country would be in much better shape, because we have so much redtape.

As a matter of fact I am putting out a newsletter this week in which I say that if you count all the pages in the Federal Register you will find about 60,000 pages in all, each filled with small type and bureaucratic prose. Those 60,000 pages contain no less than 309 brand-new regulations, about 7,000 existing regulations and 3,000 other regulatory documents, and that's a lot of regulations.

I don't know how many people read these things. I don't know how many people take the Federal Register. It doesn't get into the hands of the general public. So it seems to me the Congress needs to take an inventory of the procedures that we have for getting information to the general public and that administrative agencies need to take an inventory of their operations in the past and the present with a view to getting out to the general public the kind of education which is needed and which will enable them when they contact their Congressmen to exercise a much more mature and responsible opinion either for or against legislation.

Thank you, Mr. Chairman.

Mr. MOORHEAD. Thank you, Mr. Fountain.

Mr. FOUNTAIN. Would you agree with that?

Mr. HOWARD. Yes, sir; we would agree with that and wholeheartedly support your expression and concern and need for action.

Mr. MOORHEAD. I would hope that this subcommittee would try to emulate the work of the sister subcommittee, the Fountain subcommittee in its very fine work with the FDA. I think you have set an example for all subcommittees and Mr. Gude and I commend you for the work you have done over the years. I think it takes a long time to do the job that you have done and I fear that it will also take a long time for this subcommittee to get done the things that we want to do. One of the things you mention in your recommendations, which does include Congress, is oversight. We have passed laws as you have listed them, sometimes over intense objection from others.

As I understand it, the jurisdiction for appropriations for EPA is in the Subcommittee on HUD and Independent Agencies. I know at least that the chairman of that subcommittee does not come from an agricultural area. I have not researched who the other members of that subcommittee are. The Congress, with the exception of the passage of a toxic substances control bill, has passed laws to protect health and the environment. So far as I know, the usual reluctance of the Appropriations Committee to appropriate necessary money has not been a problem for EPA. The oversight function, other than the oversight function of the legislative committee, is lodged with this subcommittee. One of the reasons we are holding this hearing today is to do just what you are suggesting—to see to it that EPA does carry out as effectively and efficiently and as much in accordance with the intent of Congress those responsibilities we have placed on them.

To get more specific, I am going to refer to your press release where you speak of "inaccurate, sloppy, and even fraudulent data submitted by industry to support the safety of chemicals licensed by EPA and FDA."

Can you give us some concrete examples of that?

Mr. SIZEMORE. Mr. Chairman, we can give you some very detailed examples which I think would be much more appropriate to submit for the record, which we would like to do. But what we mean there that when the law requires that safety testing be carried out, particularly speaking in the area of testing for cancer hazard, the studies that are required are long-term feeding studies of animals.

Now there are many, many procedures that can be utilized, are utilized, have been utilized in the past by contract laboratories that contract with the companies to perform this data, that serves to misstate the information.

For instance, if you don't test all the way to the end of the animal's life where the tumors are more likely to appear, you can give the impression of no induction of tumors.

The fact is that if you tested all the way out to the end of the animal's life, the tumors would start appearing. This is a problem across the long-term feeding study testing area.

There are also examples of removal of tumors early in the life of the animals, sewing them back up and letting them live. The examples are numerous. We also had occasions where data was not submitted to the Agency although it incriminated the chemical agent.

We have taken action to the extent that we became aware of these things to refer them to the Department of Justice. The point is that concrete attention must be drawn and more criminal actions must be forthcoming so that people realize that when they submit safety testing it's a serious matter, and people are going to take regulatory action based on the data submitted.

Mr. MOORHEAD. You were going to submit for the record specific cases.

[The information follows:]

HOWARD, SIZEMORE & REUKAUF,
ATTORNEYS AT LAW,
Washington, D.C. April 2, 1976.

Hon. WILLIAM S. MOORHEAD,
Chairman, Conservation, Energy and Natural Resources Subcommittee of the Committee on Government Operations, U.S. House of Representatives, Rayburn Office Building, Washington, D.C.

DEAR CHAIRMAN MOORHEAD: During our testimony on February 11, 1976 before the Subcommittee you asked us to provide examples of "inaccurate, sloppy, and even fraudulent data submitted by industry to support the safety of chemicals licensed by EPA and FDA." With respect to FDA we refer you to the recent hearings before the Subcommittee on Health of the Senate Labor and Public Welfare Committee, and especially to the testimony of Commissioner Schmidt regarding the Searles investigation. We understand that the Subcommittee is investigating similar problems within the Environmental Protection Agency.

The examples of inaccurate and sloppy data in EPA files are legion. In reviewing this issue, we would suggest that the Subcommittee keep in mind that in the three major regulatory actions taken by EPA against DDT, Aldrin/Dieldrin and Heptachlor/Chlordane, the evidence which proved the chemicals hazardous was based largely upon independent review by experts of data submitted by industry to support claims of safety.

The EPA hearings on the suspension of Heptachlor/Chlordane uncovered innumerable examples of sloppy and inaccurate data, in addition to abundant evidence that much of the pathology data as submitted by industry was based upon the diagnostic opinions of pathologists who were not highly qualified, or whose views were at best extremely conservative. With respect to the Heptachlor/Chlordane case we refer the Subcommittee to EPA Exhibit 8 of that proceeding, the prepared written testimony of Dr. Samuel S. Epstein, an expert

in chemical carcinogenesis, who provided the most comprehensive critical review of all the available bioassay data on Heptachlor/Chlordane. This exhibit is available at the Hearing Clerk's office of the Environmental Protection Agency. We refer specifically to pages 8, 20, 28, 39, 41, 47, 57, 61, 62, 65, 66–69, 73, 74, where Dr. Epstein details the limitations of the data which Velsicol Chemical Company was relying upon to demonstrate the safety of these compounds. Additionally, we would refer the Subcommittee to EPA's brief filed with the Administrative Law Judge, and specifically to pages 1–56. A copy of the Table of Contents, the Introduction and pages 1–56 of that brief is enclosed. [In Subcommittee's files.]

In the Aldrin/Dieldrin case the data upon which Shell Chemical Company relied was critically reviewed by many witnesses including Dr. Epstein and Dr. Umberto Saffiotti, Associate Director for Carcinogenesis, Division of Cancer Cause and Prevention, National Cancer Institute. (EDF Exhibit 33 and EPA Exhibit 40 of that proceeding respectively). We refer specifically to pages 23–34 of EPA Exhibit 40 and pages 39–94 of EDF Exhibit 33 where Drs. Saffiotti and Epstein detail their opinions regarding these data. As can be seen some of the inadequacies of these data are minor while some are, in the words of Dr. Saffiotti, "deplorable".

With respect to fraudulent data we refer to Velsicol Chemical Corporation's submission of bioassay studies performed for Velsicol by the International Research and Development Corporation (IRDC) (EPA Exhibits 32 and 33 from the Heptachlor/Chlordane proceeding). At the time that Velsicol submitted these studies to EPA in 1973, it failed to disclose that pathologists consulted by it to review selected tissue slides from these studies had sharply disagreed with the IRDC pathologists. Unlike the IRDC pathologists, the Velsicol consultants had diagnosed many cases of cancer in the slides which they reviewed. We uncovered this information during the 1975 litigation. In our view, by this action, Velsicol defrauded EPA and the American people and failed to comply with § 6(a)(2) of FEPCA, requiring disclosure of any information relating to the adverse effects of a registered product on human health or the environment. Velsicol's actions in this case were referred by the Office of General Counsel to the Department of Justice for criminal investigation in July, 1975.

We hope that these materials are helpful to the Subcommittee in its investigation. If we can be of further assistance please do not hesitate to have the Subcommittee staff contact us.

Very truly yours,

JEFFREY H. HOWARD,
FRANK J. SIZEMORE, III,
WILLIAM E. REUKAUF.

[The documents referred to in the letter above are in the subcommittee's file.]

Mr. SIZEMORE. We can fill in some specifics in that.

Mr. MOORHEAD. Do you know of any instance where EPA has reviewed the submissions and then returned them to the company involved for more complete and accurate data?

Mr. SIZEMORE. I am sure that that has been done on many occasions although I couldn't cite you specific examples. I think that there are more occasions in which it has not happened than in which it has. I would feel pretty safe in saying that, at least in terms of these long-term feeding studies.

Mr. HOWARD. If I could make one other point.

Mr. MOORHEAD. Yes, Mr. Howard.

Mr. HOWARD. You get into that question when the EPA is called before the subcommittee. I think it is important to note that it's not enough simply to establish that EPA sent it back and told someone to do something. You still have to look at what the ultimate result was. Why were they sending it back and did they pick out all the important points and was the data adequate that came back eventually?

The only purpose of sending it back is that you get good data at the end and if the data is still bad at the end then something fell down in the process.

Mr. MOORHEAD. But the GAO letter, which we showed you, indicates that though the EPA relies on data provided by pesticide registrants based on nongovernment laboratories, the Agency has no program to accredit or inspect those laboratories. Would you care to comment?

Mr. SIZEMORE. That is absolutely correct. There is no Government program.

Mr. REUKAUF. There is no governmentwide program to accredit these laboratories, and certainly within EPA there is no quality check on the data that is being submitted.

There are obvious dangers in such a situation. The laboratories that are contracted by industry to perform the tests must be candid with the regulatory agency and cannot in any way color their judgment because of their financial arrangement with the manufacturer and because of possible consequences of the results of their safety testing.

We think that it's essential that the laboratories that are generating the data are checked to determine that they are independent in fact, and that beyond that that there be greater efforts within the regulatory agency, especially EPA, to monitor the data as it comes into the agency for quality and adequacy of those data.

Mr. MOORHEAD. Do you know if EPA has made any attempt to set up such a program? Is there a problem of staffing to get a sufficient number of inspectors to check these laboratories?

Mr. REUKAUF. Clearly those kinds of problems would evolve within the last couple of months within the Agency that such procedures be initiated. There's no doubt that it will be difficult to staff and to do a good job in monitoring these data and in certifying these laboratories. But we think it is of such sufficient importance that it has to be done and it has to be done very quickly because there are chemicals that are being registered by regulatory agencies every day.

There are hundreds of chemicals that are registered every year and if people don't have confidence in the safety data that is being generated, that is being utilized to support the licensing of these chemicals, then obviously we are in a very serious situation.

Mr. MOORHEAD. The present situation, again according to GAO, is that the pesticide manufacturer hires the nongovernmental laboratory. He can pick anyone it wants to—can even shop around, if you will——

Mr. SIZEMORE. And do.

Mr. MOORHEAD [continuing]. And do. And yet EPA has no mechanism for checking up on the laboratories hired by the person that wants to promote the pesticide.

Mr. REUKAUF. That is correct, Mr. Chairman. I am not familiar with too many cases but I am familiar with cases where for 25 years there has been a relationship between the industry producing the chemicals and the laboratory testing the chemicals and submitting the data to the Government in order to support claims of safety.

Mr. MOORHEAD. I think we have established that at least the legal staff at EPA was adequate in numbers to do the job that you think

should be done. But in your statement you describe only a skeleton staff to review safety data underlying registrations.

How many professionals are assigned to this important work and how many would you say are needed to do the job?

Mr. REUKAUF. Mr. Chairman, only very recently, as the result of pressures that have been brought to bear in committee hearings in the Congress, has EPA undertaken to start such a project.

To our knowledge that project has been underway for only a few weeks and is staffed by only one professional who was chosen by the Agency at our recommendation. He was a scientist who had participated with us in our adjudicatory hearings as an expert witness in helping us prepare these hearings.

Obviously, there is a backlog of work to be done. There are tremendous numbers of files and there are masses of data that need to be checked by independent people. There need to be procedures set up when the data is inadequate or when it is falsified or when it is sloppy, where actions be taken and products perhaps be removed from the market pending adequate data supply and we think that one professional scientist as an independent person reviewing all of those data is inadequate. We think that the Environmental Protection Agency needs to have a full-time staff of several professionals who are performing what you call this very valuable function.

Mr. MOORHEAD. In your press release of last week you say: "It is clear from the recent actions that the Agency intends to refrain from vigorous enforcement of available toxic substances controls and to retrench from the few legal precedents which it has set for evaluating the cancer hazards posed by man."

Could you elaborate on this statement and provide any examples of how this lack of enforcement is taking place?

Mr. HOWARD. Mr. Chairman, in our statement this morning we attempted to elaborate substantially on that and give some examples. The regulatory areas of inaction are the ones that we discussed involving air and water pollution, and drinking water standards, and pesticides.

The retrenchment is a contemplated retrenchment by any agency from the policies and procedures that the Agency has established at great cost to evaluate cancer hazards and the evidence that that retrenchment is being contemplated is the evidence we have alluded to that there have been meetings with top level officials for the express purpose of considering changing and weakening the policies in order to accommodate the arguments of an agricultural trade group.

Mr. MOORHEAD. One of your recommendations is the passage of the toxic substances control bill and I have introduced similar legislation to support your concept.

Do you really believe that additional authority is needed, or would existing legal authority be sufficient if it were implemented and enforced vigorously?

Mr. SIZEMORE. We do believe that additional authority is clearly needed in the area of regulating toxic chemicals. All of the authorities which are existing and if they were enforced, would obviously help the problem tremendously, but getting back to the idea of regulating at the source, the Toxic Substances Control Act has as its purpose prescreening of hazardous chemicals before they are marketed.

If you keep a hazardous chemical off the market before it gets on the market that means it's not manufactured, that means it doesn't create an effluent problem, that means it doesn't create an air problem, that means it doesn't create a problem of public health from exposure of the chemical either to workers or to the public in general.

If you wipe out a chemical, so to speak, before it's even on the market you take away a lot of the problems that we have identified in the regulation of toxic chemicals because they are never out there in the environment in the first place.

Mr. MOORHEAD. Thank you. I just have one wind-up question. Do you have further questions, Mr. Gude?

Mr. GUDE. No.

Mr. MOORHEAD. Mr. Fountain?

Mr. FOUNTAIN. Thank you, Mr. Chairman.

I have just one or two observations.

You made reference to advisory committees. You may observe that the subcommittee I chair has put out a report on the subject of the advisory committees. We were very much concerned about FDA's obvious violation of the Advisory Committee Act which I believe was passed in 1972.

Obviously, we favor the active use of advisory committees to get competent outside independent judgment, but we found that they had some 66 advisory committees and it was costing a tremendous amount of money and the Advisory Committee Act was designed to eliminate unnecessary advisory committees and to encourage proper ones, but as the advisory committee rate was going down in other agencies, it was going up there, and we also noted the absence of public hearings and public information so that the people would know what was going on and could participate in the decisionmaking process.

I note then a memorandum from Mr. Barker, Mr. Elkins, and Mr. Frick, dated October 10, 1975, to the Administrator. On page 3 under recommendations:

> We believe that the solution to the major problems outlined above is to conduct a thorough, more open evaluation of both risks and benefits before a decision to register a suspect chemical or to issue a notice of cancellation or suspension. By involving interested parties and by soliciting external scientific and technical review of our data and analysis as appropriate, we can ensure that the decisions are based on the objective evaluation of all available information.
>
> A more open process would also help to prevent any misunderstanding by the public. This recommendation would require, in addition to careful analyses of health effects, a more intensive review of the economic and agricultural implications of cancellation and substitute chemicals than has previously been conducted prior to the hearing process by the Agency.
>
> It would also shift the focus of EPA decision-making from the adversary hearing process to a less formal open review of pertinent facts and opinion.

I notice in a part of one of the specific recommendations, increased personal contact with the affected party, particularly the farm community. I would think that these are appropriate recommendations which are somewhat in line with the thought that I had in mind.

I was astounded to hear you say that you have no scientific input within EPA upon which to base a decision, that you have to get all of your information from laboratories that are associated with the pesticide industry and the decisions of EPA are based upon that.

Mr. SIZEMORE. That is essentially correct, Congressman.

Let me first back up a second and address this recommendation that you alluded to. We attached this memorandum to our statement as an example of a process that in our view has resulted in a reduction in the Agency's emphasis on the risk of pesticides.

We believe that the recommendation contained in this memorandum evidences an intent to continue to emphasize the so-called economic and agricultural implications rather than their risks. We believe that that is the process which will continue to haunt regulation of pesticides.

The facts are that very few pesticides have been removed from the market and the reason for that is because the benefits and the overpromotion have been emphasized to the underemphasization of the risk. So we would not at all agree with this recommendation in the context of pesticide regulation.

Mr. FOUNTAIN. You may be right, but as to the total picture as I read it it sounded to me as though it was trying to be objective and I am not familiar with where the overemphasis may be. But I do know that where you have a tremendous segment of the economy, which is agriculture, contributing $23 billion in exports last year, without which our balance of payments would have been in terribly bad shape, that you can't overlook it and that these people who produce these things need to have a better understanding of the process by which they produce, because pesticides have been the means by which they have been able to produce more and more.

If they are using the wrong pesticide, they ought to know about it. They ought to be educated about it. But just to outlaw it and to pass a regulation to enforce something authoritatively without a farmer knowing—and he sees the results of this production—all you do is stir public opinion in opposition to what you have done rather than educate and influence people to better understand what you are doing and what ought to be done.

Mr. SIZEMORE. We would agree with that, I am sure.

Mr. HOWARD. Congressman, there is one point that you have referred to that I think we need to highlight a little bit. That is that not only do we need to discuss openly the risks of the hazardous chemicals—the chemicals were designed to kill living creatures—we are also in need of discussing openly the overuse and the problems of use.

We have a system now whereby the people who manufacture chemicals are selling them across the country. We all know the massive input that the chemical manufacturers have in the farmers' trade journals, agricultural universities. There is a tremendous emphasis placed on the use of chemicals. We don't say that all chemicals are bad by any means, but that there is tremendous amount of overuse of chemicals and a lack of the people who sell them to give a balanced presentation of what you really need.

As we begin to run out of our precious natural resources, the petroleum resources, hopefully there will be more emphasis on appreciating that aspect of the problem as well.

Mr. FOUNTAIN. I think you may be right there. In my own State we have North Carolina University which has a school of agriculture and the North Carolina Agricultural Extension Service. We have experts on chemicals and they themselves do a lot of analyzing and recommend whether or not to use certain chemicals.

You made reference to hundreds, maybe thousands of pesticides that are on the market, and of course, that creates a problem. Something that has been used for years and years and nobody seems to know anything about the serious consequences, it isn't easy.

I can appreciate the Food and Drug Administration problem in dealing with over-the-counter drugs. They have a massive responsibility of trying to determine whether those drugs are even good for the purpose for which they were intended, whether they are harmful or not, whether people are just paying for something because it's advertised to relieve a certain condition.

What bothers me, as we pointed out in the report which we just released, is that in this monograph approach which they have of classifying these over-the-counter drugs, and waiting maybe 3, 4, 5, 6, maybe 10 years before they come to a result, if a new drug comes on the market and no application is made for the approval of that drug, in accordance with the law they have declared a moratorium and that drug may be carcinogenic, and yet they do nothing about it to enforce it.

My feeling is that while they are engaged in this long-term process of looking at these things which have been on the market for a long time and about which you can't reach a quick conclusion, for a lot of reasons all of the political implications involved, the economic factors, it seems to me that for the new ones that are coming on they ought not to wait until these monograms or standards come in before they take action. Maybe the same thing is true so far as EPA is concerned. I don't know. I just thought I would make that observation.

Mr. SIZEMORE. It is, and we can't say it any better than that, really. That is exactly our point.

Mr. MOORHEAD. Thank you gentlemen, very much. I think that I should comment first on the tenor of your testimony. I don't believe that the name of any official at EPA has been uttered in this testimony. So this is not a blame-throwing situation, at least not a personal one.

You have tried to keep to the facts, giving them to us as best you see them. To say that all three of you have made a sacrifice by resigning and pointing out to the country and to the Congress and this committee where there have been faults of commission and omission, you have done it in a very dispassionate manner. I for one feel convinced that you have given testimony which will be of benefit to this subcommittee in its oversight of EPA whom we will have before us.

I think that in summary, while you do suggest the passage of one piece of legislation, the major thrust of your testimony is that EPA does have the authority, or a great deal of authority, and it is not exercising that authority in a way adequate to insure the protection of the health and actually the life of American citizens.

For this service I think all three of you are to be highly commended and we thank you very much.

Mr. HOWARD. Thank you, Mr. Chairman.

Mr. SIZEMORE. Thank you, Mr. Chairman.

Mr. REUKAUF. Thank you, Mr. Chairman.

Mr. MOORHEAD. The subcommittee now stands adjourned.

[Whereupon, at 11:55 a.m., the subcommittee adjourned, to reconvene subject to the call of the Chair.]

EPA'S IMPLEMENTATION OF THE PESTICIDES CONTROL ACT

FRIDAY, MARCH 5, 1976

HOUSE OF REPRESENTATIVES,
CONSERVATION, ENERGY,
AND NATURAL RESOURCES SUBCOMMITTEE
OF THE COMMITTEE ON GOVERNMENT OPERATIONS,
Washington, D.C.

The subcommittee met, pursuant to notice, at 10:30 a.m., in room 2203, Rayburn House Office Building, Hon. William S. Moorhead (chairman of the subcommittee) presiding.

Present: Representatives William S. Moorhead, L. H. Fountain, and Gilbert Gude.

Also present: Norman G. Cornish, staff director; David A. Schuenke, counsel; Robert K. Lane, assistant for environment; Ronald J. Tipton, assistant counsel; and Stephen M. Daniels, minority professional staff, Committee on Government Operations.

Mr. MOORHEAD. The Subcommittee on Conservation, Energy, and Natural Resources will please come to order.

This morning we will hear from a representative from the Environmental Protection Agency on the subject of that Agency's implementation of the Pesticides Control Act, the Federal Insecticide, Fungicide, and Rodenticide Act, FIFRA, and related matters.

Recently this subcommittee heard criticisms of the effectiveness of EPA's pesticide program. We heard that the Agency was not fully meeting its responsibilities under FIFRA and other authority.

We also have in hand recent reports from the General Accounting Office which indicate that the EPA has failed to comply with its own requirements under FIFRA, that it has granted waivers and deferrals of required testing data, and does not have the benefit of accurate and reliable data in many cases.

We want to hear the EPA answer and explanation not only because fairness demands it, but because we hope to find solutions to what are clearly problems.

We would like to find ways to better assure that the goals of the pesticide control law are achieved. These goals are the protection of human health from unreasonable risks and exposures. We now know that these risks are often subtle, but persistent hazards from which the harm may not appear for many years or only in successive generations.

We need only turn to the recent CEQ report to sense the magnitude of the health hazard posed by a polluted environment. The law also requires the protection of the environment. Clearly this is a goal

which is at the heart of EPA's mission, and one which cannot reasonably be deferred.

Nor can we defer or ignore the protection that the law intended to be provided to the American farmer. Pesticides have been most helpful servants to all of us. They have helped us achieve agricultural preeminence in the world.

The individual farmer and consumer who must necessarily rely on pesticides was to be protected under the law from risks to himself and also from worthless and inappropriate pesticide products.

We understand some of the problems and difficulties confronting the Agency in this program. I cannot state too strongly the need of the American people, the farmer, the consumer, and the Congress to have confidence that the law is faithfully executed.

Mr. Gude, do you have any opening remarks? If not, the subcommittee would like now to hear from Mr. Robert Zener, General Counsel of the Environmental Protection Agency.

Mr. Zener, without objection your full testimony will be made part of the record. You can highlight it or you can read the entire thing. Before you proceed, Mr. Zener, I would like to administer the oath to you.

Do you solemnly swear that the testimony you are about to give this subcommittee will be the truth, the whole truth, and nothing but the truth, so help you God?

Mr. ZENER. I do.

Mr. MOORHEAD. It's nice to have you with us, Mr. Zener.

STATEMENT OF ROBERT V. ZENER, GENERAL COUNSEL, ENVIRONMENTAL PROTECTION AGENCY

Mr. ZENER. I would like to read my statement with perhaps a few ad lib remarks as I go along.

I am here today at the request of the subcommittee chairman to discuss the actions taken by the Environmental Protection Agency with respect to the control of hazardous and toxic substances. This was the subject of a previous hearing of this subcommittee on February 11, and you have specifically asked us to address various issues regarding EPA's implementation of its statutory authority which have been questioned by former EPA employees.

My statement will address issues that have been raised in the area of the Drinking Water Act and the Pesticides Act, and I'm sure I will be able to answer questions in this area or other areas.

Of course, there is no overall comprehensive toxic substances control legislation. Our authority is spread among several acts, each with different regulatory schemes. Under the Federal Water Pollution Control Act, EPA has authority to set effluent standards for industrial categories of point sources. These standards under sections 301 and 304 are technology based and may limit the toxic pollutants included in the effluents of the industrial facilities involved.

Similar standards may be set for new sources under section 306 of the act and pretreatment standards for discharges into municipal systems under section 307(b).

The act also sets forth a specific section for effluent limitations on toxic pollutants in section 307(a). Except for the pretreatment re-

quirements, these standards are implemented through permits issued pursuant to section 402 of the act, the national pollutant discharge elimination system.

We also have the Clean Air Act which requires the Administrator to set ambient air quality standards for pollutants which are determined to cause adverse effects on the public health.

The States, and where necessary EPA, then set emission limitations designed to reduce ambient concentrations below those levels necessary to protect public health. Where there are no ambient standards but it is determined that emissions of certain pollutants unreasonably impact upon health, the Administrator may set hazardous emission standards under section 112. EPA has established three such standards and has proposed regulations for a fourth.

I might add that under the Clean Air Act we also have issued regulations limiting the amount of lead in gasoline and other action designed to protect the public against exposure to toxic substances. Those regulations are now tied up in litigation before the District of Columbia Circuit Court of Appeals.

The Safe Drinking Water Act, which was passed a little over a year ago, requires the Administrator to set maximum contaminant levels or treatment techniques for harmful substances in drinking water. The Administrator is to take cost and technological limitations into consideration when setting the levels.

This last point is important in the testimony you received on February 11. The statement was made that the contaminant level set for drinking water supplies was to be based solely on health considerations. That is not correct. The act requires the setting of recommended maximum contaminant levels based on health considerations. The standard itself then is to achieve those levels to the maximum extent feasible taking into account cost, and that is an important point.

EPA's role in implementing the drinking water standards is to be secondary to the States and localities. Interim standards for a number of contaminants have already been established and additional study is being made of others.

Finally, the Federal Insecticide, Fungicide, and Rodenticide Act requires the registration of chemicals which are used as pesticides. EPA reviews the pesticides to see if their use will cause unreasonable adverse effects on the environment and the statute defines the phrase unreasonable adverse effects on the environment to require a determination which balances the health risks of the pesticides against the benefits of the pesticide in terms of their usefulness to the agricultural community. Where a finding is made of unreasonable adverse effects on the environment, the EPA may refuse to register or may cancel a registration. Where there is imminent hazard, the Administrator may suspend an existing registration, an authority we have exercised quite recently.

In the testimony you received on February 11, there was substantial criticism of the Agency in connection with our standards under the Safe Drinking Water Act. Let me elaborate on this subject.

Under that act the interim standards established December 24, 1975, include limitations on a number of inorganic chemicals, such as ar-

senic, cadmium, and mercury, as well as organic chemicals such as lindane and toxaphene, which are two pesticides.

Microbiological contaminant levels were also established. From the beginning of the standard setting process, most attention has been directed toward the Agency's actions with respect to organic chemicals. As you are aware, I am sure, publicity over the presence of organic chemicals, including known carcinogens, in known drinking water supplies of some of our largest cities was a major impetus to the passage of the Safe Drinking Water Act.

One of the criticisms was that the final regulations do not include limitations on aldrin/dieldrin, DDT, heptachlor, or chlordane. We had proposed a maximum contaminant level for total concentration of organic chemicals, as determined by the carbon chloroform extract method—CCE— but that was not included in the final regulations.

Before discussing that, I would like to point out that in all of our public discussions of these standards, and particularly in the preambles and supporting documents of the proposed and final regulations, we have extensively documented our concerns, our problems and our reasons for our ultimate decisions. So the public and the Congress have been fully informed of the reasons of our actions. We are not engaging in any under-the-table actions here.

It should be apparent from reviewing all these documents that we in no way question the fact that these organic chemicals present serious health problems. All we are laboring over is the precise regulatory strategy which the Safe Drinking Water Act contemplates and which is feasible.

With respect to heptachlor and chlordane, the proposed standards were deleted from the final regulations simply because of the pending proceedings under the pesticides act.

It was clearly indicated at the time that that was the reason standards were not promulgated and that the regulations would be reconsidered after the final decision in the pesticide case, and that is being done now.

The proposed regulations also stated carefully why standards were not being proposed for aldrin/dieldrin and DDT. Our data indicated that the amount of those pesticides in drinking water supplies is negligible. Accordingly, we saw no basis for establishing maximum contaminant levels which must take into account cost and treatment technologies, which I previously noted, and which normally should not be adopted for contaminants which are very rarely found in drinking water.

We did begin an extensive monitoring program of over 300 water supplies to verify our original data and it is expected that within a few weeks we will have the necessary information to determine whether the initial decision should be changed.

Preliminary indications are that our decision was correct. Again, the absence of a standard does not result from any question of the toxicity of the materials.

In response to the proposed maximum contaminant level for organic chemicals based on the CCE test—I might interpose here that the attempt in that kind of test was to have one measurement covering a broad range of chemicals, so you weren't putting out 15, 25 standards, each of which would have to be subject to separate meas-

urement, separate monitoring expenses on the part of the community which might be extremely difficult. There is a lot of attraction in a single measurement and that was the reason for trying that CCE test—we received a large number of comments questioning the validity of that measurement method for determining with any meaningful precision the actual concentration of the harmful organic chemicals in water supplies, and in reviewing the comments and the problem we reached the conclusion that there was no known indicator of harmful organic chemicals which could be used to set a meaningful general standard.

Accordingly, we determined that it would be more efficient to take the time now to develop an appropriate testing mechanism and to monitor extensively to obtain more complete information on the types and quantities of organic pollutants in drinking water supplies.

With that information, rational standards consistent with the intent of the act can be established. These research and monitoring programs have been instituted with 1-year deadlines so that the resulting maximum contaminant levels can be effective at the same time as the other interim standards.

A point to note here is that under the act the standards cannot go into effect before June of 1977 in any case, and we expect that this monitoring program will be completed by that time so that we can revise the standards in time for these statutory effective dates.

I think each of these decisions on drinking water standards was made only after a great deal of thought within the Agency and after discussions with involved members of the public, including the environmental groups.

The decision with respect to the CCE test was made quite reluctantly. I know I engaged in a number of agonized discussions on the point. But for the ultimate success of any program I think it is important that correct decisions be made at the time the standards are established since subsequent modifications might delay compliance or might cause unnecessary expenditures of limited public funds.

That point is quite important. You are dealing with municipalities here who, of course, have limited funds. If on the basis of incomplete knowledge we start them down one road to learn only a year later that better treatment could have been obtained through some other technique, then that result I think would indeed be sad. I think it is much better to take the time to make the correct decision now.

I think, of course, there may be dispute over EPA's decisions in this area as in any other, but I think there can be no reasonable suggestion that EPA has backed off from its conviction that these chemicals should be removed from drinking water supplies to the maximum extent permitted under the act and as quickly as possible.

I think the same observations can be made about our pesticides program. We have a vigorous program in this area. A number of major and controversial cancellation actions have been taken. We are now embarking on a comprehensive and indeed unprecedented program under which every one of the thousands of registered pesticides will be reviewed to determine whether it should be canceled in light of adverse effects on health or the environment.

We have established a procedure that guarantees that these decisions will be made in light of all the factors that the law requires us

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to take into account—the risks the pesticide poses to man or the environment, balanced against the benefits of its use.

The Agency is totally committed to the successful implementation of this program, and we welcome this committee's inquiry into any aspect of the program.

Let me say a few words about the charge that the administration of this program has been politically motivated. I think the facts on this point speak for themselves. As I am sure the members of this committee will recall, last summer there was a great deal of criticism of EPA from the agricultural sector and from the House Agriculture Committee as to its administration of the program, and at that time legislation was introduced which would have given the Secretary of Agriculture a veto power over our cancellation decisions in the pesticides area.

At that time, while that legislation was pending, and when the political pressure was at its height, at a time when the course of political expediency would have been to lie low, at that time the Administrator instituted a suspension proceeding against heptachlor-chlordane which are two widely used pesticides. I think it is pretty clear that the Administrator at that point was not knuckling under to political pressure, he was calling the shot the way he saw it.

Similarly, the charge has been made that as a matter of election year politics EPA isn't going to do anything in the pesticide area. Again, I think the facts speak for themselves.

On December 24, 1975, the Administrator issued a final suspension order for heptachlor-chlordane, incidentally overruling the recommendation of his administrative law judge. It was a quite controversial decision and again he was calling it the way he saw it and was not submitting to any so-called election year politics.

More recently, on February 17, 1976, the Administrator issued a final cancellation order for most uses of mercury-based pesticides. Again, I think he was calling the shot the way he saw it and not submitting to any so-called election year politics.

Of course, as you noted in your opening statement, Mr. Chairman, the law requires us to take the interests of agriculture into account in administering the pesticides law. We do so. We don't apologize for doing so, for I think that is the way it should be. But, having done that, when the Administrator thinks a regulatory action should be taken, he takes it and politics has nothing to do with it.

That concludes my prepared remarks, Mr. Chairman. I will be pleased to answer any questions you may have.

Mr. MOORHEAD. Thank you very much for your statement, Mr. Zener.

First of all, let me state I have great admiration for Mr. Russell Train, Administrator of EPA. I believe that he calls the shots as he sees them. But we all recognize that there are political pressures, and quite frankly, one of the purposes of this hearing is to at least make the political pressure somewhat balanced so that he can call the shots as he sees them.

Mr. ZENER. We surely appreciate that, Mr. Chairman.

Mr. MOORHEAD. I think you will find that this committee is a friend of EPA and wants you to do a good job and carry out the law as it has been passed by the Congress.

In this connection, have you read the GAO report of December 4, 1975, entitled Federal Pesticide Registration Program. Is it protecting the public and the environment adequately from pesticide hazards?

Mr. ZENER. I have not read it recently, Mr. Chairman, so I might not be able to answer questions in detail.

Mr. MOORHEAD. But you have read it?

Mr. ZENER. Yes, sir.

Mr. MOORHEAD. The report indicates that of 100 randomly selected pesticides registered with EPA, manufacturers had not submitted safety studies for numerous ingredients as required by EPA's regulations. In fact, safety data was lacking for 36 chemicals. How can you explain that?

Mr. ZENER. Of course, I am not familiar with the files on the particular chemicals and I can only give you a general answer, Mr. Chairman.

Most of the presently registered pesticides—at least the ones I am familiar with, I had better not say most—I think were registered years ago back in the 1950's and 1960's when the program was with the Department of Agriculture and when, frankly, environmental concerns were not as well recognized as they are today. That has certainly been our experience in the office of General Counsel with respect to particular pesticides involved in the proceedings that we have conducted.

It is pretty clear that what has to happen is that all these pesticides have to be re-registered so that the inadequacies and the data supporting their present registration are reviewed and corrected. Indeed, the Federal Environmental Pesticide Control Act which was passed by the Congress in 1972 requires that process to be done and requires it to be completed by October 1977.

Before embarking on the actual work of going through the review of data connected with each pesticide one by one—in other words, the reregistration which the statute requires—we had to set up a system. You just can't go through 35,000 pesticides without a set of rules, specific numbers and tests that you are going to run.

The first task we had after passage of the 1972 act was to establish a system, specific tests, specific data requirements, that would be imposed in the re-registration process. That task of establishing the reregistration system was basically completed with the issuance of our regulations under section 3 of the act, which I believe took place last summer.

The complexity of the problem can be seen by looking at the regulations themselves issued July 3, last summer. They run an enormous number of pages in the Federal Register, full of tables and numbers and what have you. That system having been established, we can now turn to the task of reregistering or deciding whether to reregister every one of the presently registered pesticides and that task is commencing now.

I guess the brief answer is yes, that the problem that GAO reports is correct, and we are attacking it.

Mr. MOORHEAD. The GAO sample of 100 pesticides found that toxicity data was missing from 3 chemical ingredients and chronic toxicity data was missing on 18 ingredients contrary to EPA requirements.

You have had this problem since 1970. So while 35,000 is a large number, you have had almost 6 years to get at it.

Mr. ZENER. Well, we are getting at it now. It's not that simple. Until you have a set of rules, specific numbers, you can't get at it in any systematic way, and establishing that system is a very controversial and complicated task.

Mr. MOORHEAD. We have studied the report that you published in the Federal Register of February 17, in which you categorized 1,505 active ingredients, which when combined in various forms and with inert ingredients, make up these 35,000 registered pesticides. In only 181 cases was all the safety data there. In 442 cases safety data is missing for long-term testing, and in 28 cases short-term testing was missing. In 854 cases EPA has not determined whether the data is missing or not, which is not a very good record to present after having had this authority for 6 years, since 1970.

Mr. ZENER. Well, all I can say is we are attacking the problem.

Mr. MOORHEAD. You are attacking the problem for which I must say I congratulate you. This is what the GAO recommended, and I am glad you are attacking it. But it certainly shows the magnitude of the problem when you don't even know if the data is missing or not in 854 out of 1,505 ingredients.

Mr. ZENER. That's right.

Mr. MOORHEAD. And also, as I understand it, you have waived requiring data on mutagenicity data, on efficacy data and on environmental data. So that even if you get all of what we normally think of as safety data, you are not even making an attempt to comply completely with the act.

Mr. ZENER. I am not familiar with the facts regarding that waiver.

Mr. MOORHEAD. This is what the GAO says. We will discuss this letter in a little bit. The letter to Chairman Brooks of the Full Government Operations Committee from Alvin L. Alm agrees that the GAO report is generally accurate but it fails to address the recommendations of the GAO. Quite frankly the letter is not satisfactory to Chairman Brooks. It's not satisfactory to me. I don't know if you would care to look at it, Mr. Gude, but it seems to me that the letter is a perfect example of what is wrong with EPA's pesticide program. The letter is a month late; it refuses to take advice to correct failings that it admits it has, and it's frankly not responsive. So I am going to ask you on behalf of Chairman Brooks to return the letter to Mr. Alm with the statement that it is not responsive and should direct itself to the recommendations made rather than saying such things as, "We are making corrections." It should be specific.

Mr. ZENER. Mr. Chairman, I am advised that the report itself contained a detailed response on behalf of EPA. I will look into this.

Mr. MOORHEAD. The letter says: "As required under section 236 of the Legislative Reorganization Act of 1970, we are submitting this written statement of the actions taken by the agency on the recommendations made in the report." Then it fails to do that. So I think the letter should go back.

True, there are comments on the GAO report contained in the GAO report, but that's not the same as the response to the Government Operations Committee as required by law.

Mr. Gude?

Mr. GUDE. Thank you, Mr. Chairman.

In reference to reregistering approximately 35,000 pesticides which I believe the Agency was required, under the 1972 law——

Mr. ZENER. Yes, sir.

Mr. GUDE. Exactly what is involved in reregistering any one of those 35,000 pesticides?

[The information follows:]

As Mr. Train's letter of February 26 to Chairman Moorhead discussed, reregistration is a one-time process designed to bring previously registered products into compliance with the amended FIFRA requirements and the new regulations for the registration, reregistration, and classification of pesticides which became effective on August 4, 1975. Each pesticide product must be reviewed and a determination made whether or not to register it for a particular use, and whether this use should be classified as general or restricted.

The new regulations set forth systematic means for rapid and efficient reregistration of approximately 35,000 products, incorporating about 1,400 active ingredients. Specific plans and implementation schedules, developed to minimize problems and delays, and a summary of data requirements are described in the attached *Federal Register* notice of February 17, 1976. Briefly, pesticides not subject to rebuttable presumption (which I described earlier) will be called in by batches. A batch is a grouping of products done on the basis of similarity of pesticide formulations and broad use patterns. At the scheduled time indicated in the FR notice, all registrants of products in a particular batch will receive a Reregistration Guidance Package and be asked to submit reregistration applications for each product. The Guidance Package will include a schedule for submitting applications, guidance on data compensation provisions, proposed classification, wording of precautionary statements and storage and disposal statements, and guidance on data requirements.

These data requirements are set forth in the registration regulations and summarized in the FR notice. They include data on acute and subacute toxicity, teratogenicity, oncogenicity, chronic feeding studies, reproduction studies, foliar residue and exposure for cholinesterase-inhibiting ingredients, and information in support of safe disposal methods. Data need not be resubmitted if data previously submitted satisfy particular requirements.

We are examining our files to locate relevant data previously submitted which meet these requirements. Data which are sufficient will be cited in a bibliography included in the Guidance Package. In addition, active ingredients of registered products are being assigned to five categories based on our review of available data. These categories are: 1) those which do not trigger a rebuttable presumption and for which sufficient data are available for reregistration; 2) those which do not trigger rebuttable presumption but which must complete long-term testing requirements; 3) those which do not trigger a rebuttable presumption but which must complete short-term testing requirements; 4) those which do trigger a rebuttable presumption; and 5) those which have not yet been adequately reviewed for placement in one of the above categories. We are hopeful that these procedures will keep reregistration problems to a minimum, while enabling us to make an adequate assessment of the potential human and environmental impact of all currently registered pesticides.

Mr. ZENER. I am probably not the best person to answer that question since my connection has been with the—what I call the more controversial of the 35,000. A rather large amount of data has to be submitted under our July 3 registration regulations concerning acute toxicity, chronic toxicity, as well as the data concerning efficacy of the pesticide—whether the pesticide actually does what the label claims it does.

Mr. GUDE. Why do you have such detail?

Mr. ZENER. You have to make determinations as to whether this is acutely toxic or chronically toxic and those determinations are made on the basis of tests, so you have to tell the registrants what

kinds of tests you want, and what kind of criteria you use for determining whether this is acutely toxic or chronically toxic. Acute toxicity can be defined in terms of say, LC–50 tests. This involves specific numerical criteria which you test for.

Mr. GUDE. If the Administrator thinks that one of these 35,000 pesticides is indeed a problem, couldn't he just remove it from the market and not allow it to go back on until the manufacturer had drawn up regulations providing for tests and gone through the tests, and had then demonstrated it to be safe; the Administrator could accordingly allow the material to go back on the market?

Is he required under law or can he just under his own volition——

Mr. ZENER. Under the law, in order to cancel the registration on a pesticide there is a procedure that you issue a notice of cancellation which contains findings concerning whether a substantial question of safety exists with respect to that pesticide.

At that point the manufacturer or registrant has the right to an adjudicatory hearing which is a hearing under formal procedures—the Administrative Procedures Act—before an independent administrative law judge, and that judge makes findings which are then appealed to the Administrator.

That is a very cumbersome procedure. The hearings with respect to DDT took over a year, as I recall, and the hearings with respect to aldrin/dieldrin took over a year, and I think part of the problem with the program as I was familiar with it back in 1971 when I came to the Agency was that you had no specific rules or criteria. All you had was the general statutory test on unreasonable adverse effects on the environment. So every time you took a cancellation action that was at all controversial, you got into a hearing in which, in the absence of specific rules, an enormous amount of evidence came in which was relevant to hearings, and they dragged on forever, or it seemed like forever to those of us who were involved in it, and it became almost impossible to take a large number of actions because each action was so strenuously fought.

It is my hope that with a set of registration regulations that contain specific rules, specific numerical criteria, some of that problem will be alleviated and we will be able to administer this program somewhat more expeditiously than it has been in the past.

Mr. GUDE. In other words, what you have to do in drawing up these rules is develop a set of rules which you maintain if violated would bring about an unreasonable adverse effect on the environment.

Mr. ZENER. At least they are rules for starting the proceedings. In essence, they are what you might call rules for picking out which chemicals we are going to go after. You can't just dive into 35,000 chemicals without some specific criteria for which ones you are going to pick out and institute proceedings. That's basically what these rules do.

Mr. GUDE. Once you develop this set of rules, are the rules subject to challenge in these administrative proceedings?

Mr. ZENER. I expect they will be challenged, yes.

Mr. GUDE. So it isn't just a matter of developing harmful levels of the materials, but also of developing rules by which you measure them.

Mr. ZENER. Sort them out, yes.

Mr. GUDE. What I am trying to understand is why getting at all these 35,000 materials is such a cumbersome procedure.

Mr. ZENER. Well, in the past, Mr. Gude, all we had really was a statutory test, unreasonable adverse effect on the environment taking into account the risks and the benefits of the use of the pesticide. That's not really a viable formula for diving into 35,000 pesticides or 1,400 active ingredients, and deciding which ones we are going to go after.

The task, which we completed last summer, was to draw a more specific set of criteria for picking out which ones among those thousands of chemicals should be the object of more intensive scrutiny, looking towards possible cancellation.

Mr. GUDE. Is the test that you would put these active ingredients to one by which you could confront the industry with the situation that until they showed that one particular ingredient did not have an unreasonable adverse effect on the environment, the Administrator could keep it off the market?

Mr. ZENER. Surely. Once you decide to start a proceeding against a particular pesticide, the registrant has the burden of proof; but what happens in actual practice is you issue a notice of cancellation putting the registrant to his burden of proof; he comes in and requests a hearing, puts on witnesses, puts on evidence, and at that point you have to put on evidence too. As a practical matter you just can't sit back and not do anything if you are seriously going after this pesticide. So you have a rather protracted proceeding.

That has been the history to date in the efforts to cancel DDT, aldrin/dieldrin, heptachlor, or chlordane. So the existence of the rule that the registrant has a burden of proof is helpful, of course, but it doesn't eliminate the cumbersomeness of the procedure.

In the DDT case, for example, there was no doubt there that the registrant had the burden of proof, but that didn't make the hearing any shorter. It may have affected the ultimate decision, but in terms of the difficulty and the time-consuming nature of getting to the point of ultimate decision, you still had a tough road to hoe.

Mr. GUDE. In regard to setting levels of contaminants under the Safe Drinking Water Act, the levels have been set for heavy metals but not for organic pollutants. Is that generally correct?

Mr. ZENER. That is generally correct, sir.

Mr. GUDE. In setting levels for organic pollutants there has been a great deal of public concern and, of course, a lot of this manifested itself at the time the Safe Drinking Water Act passed. Could you explain to me in this instance why the Agency hasn't set levels for organic pollutants. The public is concerned, and these are known to be in water supplies all across the Nation.

Mr. ZENER. When talking to the technical people, Mr. Gude, I understand the problem——

Mr. GUDE. Let me say that any technical people here who might speak to some of this matter, we would——

Mr. ZENER. Let me speak to what I understand to be the situation from talking to a number of these people.

Basically you are talking about carbon filtration treatment technology. There are several different ways of using carbon filtration.

It's not just a single technology. At this point we don't know which mode of using it would be best to deal with the problem, probably because we don't fully understand the extent of the problem.

Part of the difficulty is that carbon filtration has generally been used in treating industrial effluents where the level of organic chemical concentration is very high. Here we are dealing with very low levels where the problem is different and where we know very little about the relative efficacy of different types of carbon filtration systems.

As I said before, we are dealing with municipalities where funds are short, and we want to be very sure that when we finally go out and require the use of a particular type of system or issue a standard that has the effect of using a particular type of treatment system, it's the right one.

Also, as I noted before, the effective date under the law, the earliest effective data of the drinking water standards, is June 1977, so I think we have some time—not very much time—for trying to learn more about the problem of what type of treatment technology is best before we commit ourselves, and by committing ourselves, commit thousands of municipalities in the country to spending their money in this particular manner.

Mr. GUDE. Are you a biochemist?

Mr. ZENER. No, sir.

Mr. GUDE. Are you a chemist?

Mr. ZENER. No, sir; I am a lawyer.

Mr. GUDE. It seems to me if this committee is to understand not only the manner in which the Agency is administering the Safe Drinking Water Act as well as FIFRA, that we really should have the testimony of people who are knowledgeable in the field of measuring the toxicity and carcinogenicity of these materials. It doesn't seem to me we can just talk about the rules and regulations; proving a person was killed with a gun by a criminal is a much simpler task than proving that somebody developed cancer from a heavy metal or carcinogen.

Mr. ZENER. I think you are absolutely right, sir. I think lawyers tend to feel that we can solve all these problems by discussing legal concepts but, in fact, when you get into them, these problems are basically technical and I think if you want to get into this program in any meaningful detail, we should line up some technical people for you.

Mr. GUDE. I think Congress is composed of more lawyers than any other profession, and maybe that's why Congress believes it can solve all these problems when we pass a statute.

It certainly seems to me, Mr. Chairman, that if we really are going to get into the Agency's handling of these laws that we really should go into it and get the technical people and the professional people in here to testify.

Mr. MOORHEAD. The staff has advised me, Mr. Gude, that the suggestion was made to Mr. Zener to bring technical people with him and that apparently he elected not to do so.

Mr. ZENER. Sir, that was a very last minute suggestion and the problem is that the technical people tend to get very, very specialized and you have to know the particular area of inquiry and get the particular specialist there. As soon as you get out of his area you

need somebody else. It's not just an overnight thing to define the particular inquiry and get the particular person who is right for that question. But we could certainly do it given time and the indication of the committee's particular area of interest.

Mr. GUDE. Several years ago, I took a great deal of interest in the water supply for the Washington area both because I was one of the consumers and because I felt I had some responsibility for the laws and the regulations that control the water supply. I began to look into the treatment of water and found out that our water supply was treated with chlorine. I talked with the people who operated the water treatment facilities and was assured over and over and over again that the water supply was absolutely adequate; it was potable; and there was nothing to be concerned about.

I did some research on this subject and found indeed that municipal water supply professionals and technicians all across the country indeed said that if you treated water with chlorine and properly filtered it through sand, that the water was perfectly safe to drink.

Some other professional people kept raising the question whether viruses were indeed going through the water system and were not being eliminated by chlorine. The professional municipal water people said this was a red herring that was being dragged through the water.

When subsequent revelations and material were brought to the attention of the public, more people began to question whether viruses were being taken care of. I think actually the research that was developed was by some Navy scientists who were trying to find out whether the water supply for submariners was adequately treated; they found that carcinogens were developed in water to which chlorine had been added. Eventually, there was a great outcry that something had to be done in a great hurry; I think that over 100 carcinogens were identified as being in the average water supply all across the United States.

We have passed laws here to provide for taking care of this problem here in a hurry, sort out these materials, find out which ones are deadly and take care of them. I think, if we are to understand this, we ought to get the professional people here. I was unaware of whether professional people were to accompany you today or not.

When was this request made to you to bring some professional people along?

Mr. ZENER. As I recall, yesterday afternoon or yesterday morning. As I say, I think that any testimony of this sort has to be rather carefully arranged because you have to be sure you have the right person.

For example, in the drinking water area, you are dealing with somebody who is knowledgeable concerning treatment techniques, monitoring techniques, or you may be interested in the toxicology aspect of it, which ones of these chemicals are dangerous and which ones are not. There's also the question of tracing them, which ones are naturally occurring, which ones come from industrial discharges, because there is a question of whether you should treat or whether you should go after the discharge where it is the case of a chemical that is traceable to an industrial discharge.

In all these matters, your area of inquiry has to be defined so you have the right person.

Mr. GUDE. Just taking organic materials in a water supply, for example, you really have three areas, I imagine, which a person can study all his life and really not know enough about.

An organic chemical can be a cancer-forming agent, it can have genetic effects, and it also can be lethal. It can be toxic in itself. Each one of these is a separate area of professional expertise; isn't it?

Mr. ZENER. Yes, and in addition there's the very important area of treatment technology.

Mr. GUDE. Once you have determined that one of these hundred organic compounds that are found in water supplies across the country is not desirable then you get to the question of how do you get rid of them.

Mr. ZENER. Yes, sir, and there are monitoring problems too. As I said before: Are you going to set separate levels for each one or can you find some overall indicator? In other areas of pollution control, you have overall indicators like biochemical oxygen demand. Is there an overall indicator you could use here? That is very important, because the monitoring for these can be extremely difficult and expensive. If you can have some technique that tells you with a single measurement generally whether you have a high level of harmful organics in there or not, this would be enormously helpful. That is one question we are looking into now. We thought the carbon chloroform extract method was it.

Well, it wasn't, so we have to look at this further.

Mr. GUDE. Since the challenge to chlorine as not being the total solution to all water purification problems, haven't the professionals come up with a system of completely removing all carcinogens and all viruses from water, either by laser beam or ozone? Can't you recommend for the professional sanitarians a system to now take care of the suspected problems?

Mr. ZENER. No, Mr. Gude. I know some of these techniques are talked about, but my impression is that none of them are at the point where we can say this is it, this is a substitute for chlorination.

After all, we have to remember that chlorination is what removes bacteria and hopefully viruses from a water system. If we do something which requires elimination of chlorination, we better be awfully sure that the substitute, whatever it is, works.

Mr. GUDE. When the committee staff suggested you bring a professional with you, was this by letter or——

Mr. ZENER. We just had a chat, I believe yesterday morning, by telephone.

Mr. GUDE. Were you requested to bring professionals in any particular area?

Mr. ZENER. We were discussing pesticides at the time.

Mr. GUDE. I think it is very important, Mr. Chairman, if we are really going to get into this area of what EPA is doing that we have professional people here.

Mr. MOORHEAD. Just so the record is clear, I wrote to the Administrator on February 13 enclosing the testimony of the three witnesses who were formerly in the pesticide enforcement area. Again on February 25 I wrote to him saying you are requested to address those issues identified in the testimony forwarded with my letter to you of February 13.

I also mentioned the problems of pesticide regulation enforcement and hazardous and toxic substances control. But I left the selection of the witnesses to the Administrator, and presumably the Administrator selected Mr. Zener.

When we were advised that Mr. Zener was coming, it is Mr. Schuenke's memory of 2 days ago that he called Mr. Zener and said maybe you ought to bring a technical person with you.

Mr. GUDE. Maybe there's a communications problem over at EPA, but it would appear if we are really going to get to the bottom of this we should have another hearing and have professional people in order to really get into the basis of some of these contentions and the validity of them.

Mr. ZENER. This is secondhand information, but what I was told was that the staff originally had thought of having Mr. Train himself come, so we were under the impression that this was not going to be a technical session with that initial request.

I am sorry if there was a misunderstanding. Certainly, at the time of the chairman's initial letter if we had known that this was going to be a technical session we could have made further inquiries as to the specific technical questions you wanted to get into so that we could have brought the right people. And we would certainly be happy to do that as long as there is enough time to establish the framework so we could get the right people.

Mr. GUDE. Thank you, Mr. Chairman.

Mr. MOORHEAD. Mr. Fountain?

Mr. FOUNTAIN. Thank you, Mr. Chairman.

I received a call from my commissioner of agriculture who wanted me to ask you some questions but I am not quite sure I understand the facts on which this question was based, because it was taken over the telephone and I'm not sure my girl got it right.

He does make reference to the Environmental Protection Agency's nine principles of carcinogenicity which was prepared by the council of Agriculture and Technology Report, January 19, 1976; are you familiar with that?

Mr. ZENER. Yes, sir.

Mr. FOUNTAIN. We might make that part of the record.

Mr. MOORHEAD. Without objection, it will be made part of the record.

[The information referred to follows:]

Question. What are the nine principles of carcinogenicity? (Previously referred to in question No. 26.)

Answer. There are the nine principles:

1. A carcinogen is any agent which increases tumor induction in man or animals.

2. Well-established criteria exist for distinguishing between benign and malignant tumors; however, even the induction of benign tumors is sufficient to characterize a chemical as a carcinogen.

3. The majority of human cancers are caused by avoidable exposure to carcinogens.

4. While chemicals can be carcinogenic agents, only a small percentage are.

5. Carcinogenesis is characterized by its irreversibility and long latency period following the initial exposure to the carcinogenic agent.

6. There is great variation in individual susceptibility to carcinogens.

7. The concept of a "threshold" exposure level for a carcinogenic agent has no practical significance because there is no valid method of establishing such a level.

8. A carcinogenic agent may be identified through analysis of tumor induction results with laboratory animals exposed to the agent, or on a post hoc basis by properly conducted epidemiological studies.

9. Any substance which produces tumors in animals must be considered a carcinogenic hazard to man if the results were achieved according to the established parameters of a valid carcinogenesis test.

Mr. FOUNTAIN. I'm not sure I understand it, but he says, and I am quoting:

In the Aldrin/Dieldrin suspension areas the EPA enunciated a series of concepts for evaluating the carcinogenicity of chemicals.

The same concept was cited in a decision rendered on the Louisiana request for use of DDT on cotton. The concepts were brought into sharper focus and were elaborated into nine explicit statements in suspension hearings on chlordane and heptachlor.

The nine propositions now considered by EPA to have scientific authority and established by legal precedent. The propositions are being used as criteria for regulatory decisions.

The scientific error of confusing uncenogicity with carcenogenicity is now being incorporated into official public regulations although EPA professes to be constantly seeking input; in fact EPA consistently rejected that list.

That must be a quote from him. This is not a quote from you, is it?

Mr. ZENER. That's right.

Mr. FOUNTAIN. I guess this is a quote from the Secretary.

In fact, EPA consistently rejected efforts including those of some of its own scientific staff to have a scientific evaluation of the nine propositions which EPA called principles introduced into the suspension hearings on chlordane and heptachlor. Policies of national importance which are based on science and should incorporate best judgments of qualified scientists regarding the validity and applicability of the science evolved.

Evidently this is a statement which the Secretary's staff was making for him over the telephone to a member of my staff, and the questions he poses, in view of what I have heard you say, may not be appropriate for you, but does EPA consider their cancer propositions or principles to have scientific authority?

What is the scientific basis or authority upon which you base this?

Mr. ZENER. Mr. Fountain, the discussion of cancer in the aldrin-dieldrin decision was based on testimony in the hearings in that case given by scientific personnel, in particular, one of the witnesses who was the Associate Director of the National Cancer Institute. So those statements were based on scientific testimony.

It's ironic how the Agency gets criticized from both sides. You heard testimony last month criticizing the Agency because we have scientists in the Agency right now who are asking themselves whether the statement of cancer principles in the aldrin-dieldrin decision should be modified in some respects. I think it's an entirely legitimate question for an agency to ask itself at any time. So I guess the short answer is that those statements were based on scientific testimony. We have scientists in the Agency now who continue to think about these problems and I think that is as it should be.

Mr. FOUNTAIN. The other question he asked was, and I guess this is a matter of opinion: "Should various Federal agencies be allowed to establish their own principles of carcinogenicity or should national principles be developed through a group such as the National Cancer Institute?"

Mr. ZENER. I think it would probably be a good thing. If there were such a thing as a uniform national cancer policy dictating decisions or governing decisions by a regulatory agency to the extent that that could be done under the different legal authorities.

But pending development of such a policy regulatory decisions have to be made. You can't simply sit back and wait until there is some all-encompassing policy before going out and taking action to protect the public.

Mr. FOUNTAIN. Mr. Chairman, I want to thank you for your comment and your statement in which you emphasized that the law requires the protection of the environment. This is a goal which is at the heart of EPA's mission, and one which cannot be reasonably deferred, and I appreciate that. But I also appreciate your next statement which indicates that to defer or ignore the protection that the law intended to be provided to the American farmer also, which you emphasize, as I did the other week, that pesticides do play an important part in the life of agriculture. In fact, the killing of insects and all the other things which destroy food and other crops by pesticides has made it possible for the American farmer to be able to produce enough, as I said before, to sell last year about $22½ billion abroad in agricultural commodities. It has helped our balance of payments tremendously.

Farmers need pesticides. At the same time I don't think any of our farmers want to use any pesticide that endangers either the consumer, or the general public, or themselves, and I think also that they want to be sure they are not wasting their money, that pesticides are good for the purposes for which they are intended.

I realize that your job is not an easy one. My Subcommittee on Intergovernmental Relations and Human Resources has jurisdiction over HEW and the Food and Drug Administration and I sympathize with them. They don't have an easy job. Sometimes we are asking critical questions because we don't have time to look at all the good things all the agencies do. It's the critical things that are brought to our attention.

You do have a difficult job and you can't do these things overnight. Some people think we ought to be able to clean up the environment overnight. We can do that and destroy a lot of jobs and people can starve to death in the process. So we must establish a balance.

I want to ask you is it a requirement of the EPA pesticide registration program, that a pesticide be not only safe but efficacious as is the case of the Food and Drug Administration in connection with drugs?

Mr. ZENER. As I understand it, that is a requirement of law, yes, sir.

I would like to add a little bit to the remarks you made about the benefits of pesticides. If you look at any one of the cancellation decisions we have made, aldrin-dieldrin, heptachlor and chlordane, for example, there is a very careful discussion of the particular uses that the pesticide in question has, and the discussion goes through crop by crop, insect by insect, addressing the question of whether, if this pesticide is canceled, an adequate substitute product will be available.

In some cases substitutes are available and in some cases they are not, and in most of these decisions what you have is a cancellation as to some uses and not as to other uses, the intent being that you don't want to cancel a use for which an adequate substitute is not available.

This aspect of our decisions hasn't been publicized too much. If you look at the press and some of the critical statements that have been directed at us, you get the impression that we have just sort of wiped that pesticide right off the books without even thinking about the problems that those pose to agriculture but if you actually look at the decisions you will find that there is a very careful consideration of the effect of these decisions on agriculture.

Mr. FOUNTAIN. I notice in your statement you say that you do review pesticides to see if their use will cause unreasonable adverse effects on the environment and you may cancel registration if the Administrator so determines, and where there is an imminent hazard the Administrator may suspend or refuse registration.

Will you explain to us the process through which the Agency goes in making this determination? Who is involved?

Mr. ZENER. Perhaps I should describe the process which has been set up. You might say there is an old process and a new process. We'll talk about the new process.

I am not sure I can describe it in all its detail, but generally a schedule has been set to review applications for reregistration. That schedule was established initially in a Federal Register notice in essence scheduling the applications, so when the applications come in the data is looked at.

If certain levels of acute or chronic toxicity are exceeded and those levels are set forth in the registration regulations that I referred to, the chemical is then subject to special review within the Agency and there is a very careful review of those two levels of toxicity.

There is also a review of the economic data, that is, what is the use of this pesticide and what would be the consequences of cancellation, and in this connection there would be consultation with the Department of Agriculture on the question of the uses and the benefits of use.

Part of the procedure, the part that was mandated by the recent amendments to the act, involves a formal notification to the Secretary of Agriculture in case the Administrator proposes to issue a notice of cancellation.

In addition, there is a reference of the question to a scientific advisory panel also established by the recent amendments to the act. After all this review and consultation a notice would be issued. It would be either a notice of intent to reregister, a notice of intent to cancel or a notice of intent to hold a hearing under section 6(b)(2) of the act.

At that point a request for hearing might be made. In the case of a notice of intent to reregister it may be a member of the public or an environmental group that makes a request for hearing, and in the case of a notice of intent to cancel it might be the registrant or an agricultural organization that makes the request for the hearing.

Where the notice is a notice of intent to cancel, the hearing is a formal adjudicatory hearing under the statute which involves evidence, cross-examination, a decision by an independent law judge, and an appeal to the Administrator if one of the parties takes the appeal; from the administrative decision, of course, there is appeal to the courts.

That's it, roughly.

Mr. FOUNTAIN. Is the so-called efficacy requirement intended to protect the American farmer from pesticides that don't perform well and protect them from products with exaggerated claims which would not prove out in the field? Is that a part of EPA's responsibilities?

Mr. ZENER. Yes, sir.

Mr. FOUNTAIN. So the efficacy requirement in the registration of a pesticide is one of the basic requirements of the pesticide law?

Mr. ZENER. Yes, sir.

Mr. FOUNTAIN. How do you explain the fact that when—I believe you did say you are not prepared to answer all of the criticism of GAO, that much of it is out of your field—but if you can't, maybe you can submit for the record an explanation of the fact that when the GAO examiners looked for efficacy data for the sample of 100 pesticides they found it to be missing for 50 of the 100 pesticides. Are you in a position to respond to that?

Mr. ZENER. I would have to supply it for the record.

I would assume again that this is something that is going to be remedied on reregistration.

[The information follows:]

Question. In their report, the GAO examiner found efficacy data for a sample of 100 pesticides to be missing for 50 to 100 of them. Why?

Answer. It should be understood that the requirement for the submission of efficacy data on each individual product considered for registration first became firmly established upon promulgation of Section 3 regulations for registration and reregistration. These regulations became effective August 4, 1975. Under procedures for registration prior to this time, applicants were allowed to rely on previously established use patterns in support of registrations. These use patterns were published in Compendia and summaries of registered pesticide uses by EPA and its predecessor organization USDA, and provided the basis for acceptance. In addition, general knowledge on the part of the reviewer or other members of USDA was considered acceptable to confirm efficacy, thus specific data were not included or required. Therefore, it would not appear unusual that at this time certain registration files do not contain specific efficacy data.

Mr. FOUNTAIN. How many pesticides are registered?

Mr. ZENER. A rough figure is 35,000.

Mr. FOUNTAIN. So you do have a gigantic task?

Mr. ZENER. Yes, sir.

Mr. FOUNTAIN. Did you begin with a substantial amount of information from other authorities with respect to certain of these pesticides before you start your examination of any of them you haven't even checked on or had a chance to check on? Or do you know?

Mr. ZENER. I had better not answer that.

Mr. FOUNTAIN. Well, I don't want you to answer a question you are not prepared to answer.

Mr. MOORHEAD. Can you get an answer for Mr. Fountain?

Mr. ZENER. Yes, sir.

Mr. FOUNTAIN. Would you supply that for the record?

Mr. ZENER. Yes, sir.

[The information follows:]

Question. Before an examination of a pesticide is made, do the examiners begin with a substantial amount of information from other authorities?

Answer. The Agency's examination of a pesticide product for reregistration involves, first, a review of the data already submitted by the registrant and on file in support of the product's registration. These data may consist of scientific reports or studies conducted by private, university-affiliated, govern-

ment-related or other researchers, from this country or abroad. Thus, the supporting data come from "authorities" in many varied fields of scientific discipline.

The Agency will examine the supporting safety and efficacy data already filed on each product, and will determine on the basis of existing data gaps into which category the product should be placed, as I discussed earlier. The product's reregistration will then proceed according to the steps required of its particular category.

Further regarding the matter of "information" that we have on hand, Agency pesticide product reviewers are themselves qualified, well-informed scientists with background appropriate to their work at EPA. In reviewing an application, the examiners are well aware of and make appropriate use of information on product hazard developed through our own internal reviews, monitoring programs, administrative actions such as cancellation and suspension, and outside studies and reports prepared by such groups such as NCI and NAS. In general, as new knowledge on the effects and properties of pesticidal chemicals becomes available, our scientists incorporate it into their consideration of any particular pesticide product. Also, our registration regulations require registrants to submit additional information on adverse effects as it comes to light at anytime after a product is registered.

Mr. FOUNTAIN. Thank you, Mr. Chairman.

Mr. MOORHEAD. I would like to bring up one question and particularly get the benefit of your experience. One of the criticisms by the GAO was that the EPA didn't check up on the independent laboratories that tested these pesticides. It has no program of accreditation. GAO compared it with what they consider a good record of the Food and Drug Administration and suggested that the EPA and FDA consider a joint program of laboratory accreditation.

I'll ask the witness first to comment on that suggestion, and then because of your experience with FDA, Mr. Fountain, if you want to make any comment.

Mr. ZENER. I think it's a good suggestion. At least as far as my own personal knowledge is concerned, our awareness of a possible serious problem on reliability of laboratory data is pretty recent. It was called to our attention by Commissioner Schmidt within the last 2 months or so, and since we have become aware of the problem, we are attempting to address it in several respects.

We have a program whereby outside toxicologists will be reviewing some of the existing data in our files, and we are developing regulations concerning data submission.

Also, we are considering some of these regulatory proposals and all this has been done in consultation with FDA. There's some question as to how far we can go under our existing authority.

Mr. MOORHEAD. Thank you, Mr. Zener.

Mr. FOUNTAIN. I would concur. I think it would be a good idea for the Food and Drug Administration and EPA to do some coordinating in this field; at least on paper the Food and Drug Administration has a good program. We have found that at times they have been derelict in making the kind of inspection of laboratories that ought to be made.

This has been true in the past if not in recent history, but I do think as efficient and as competent as the laboratory technicians and the scientists may be, it takes somebody else to come in sometimes and find out that things aren't just as you think they were. I have a constituent sometimes who comes in and reminds me that my office isn't running quite right. When I do some observing once in a while, I find

that their criticism is constructive and justified and I make some changes as quickly as I can.

But I would concur with what the witness has said.

Mr. MOORHEAD. Thank you, Mr. Fountain.

Mr. Zener, the GAO reports that in their sample of 100 pesticides, 60 of them had two or more ingredients. Does EPA test or require the testing of the pesticide as it will be marketed or only the separate ingredients?

Mr. ZENER. I had better supply the answer for the record.

[The information follows:]

EPA requires the testing of the product in some cases and that of individual ingredients in others.

When testing for potential hazard from direct exposure to the formulated product, under our new regulations, data on the formulated product will be required. On the other hand, when testing for the potential oncogenic, mutagenic, teratogenic, reproductive, and metabolic hazard we normally require data on an active ingredient basis.

Similarly, efficacy and general and environmental chemistry data may also be required on either the formulated product or on the active ingredient.

Mr. MOORHEAD. Well, I'll supply the answer for the record. You do it ingredient by ingredient and if you want to correct it you can do that later.

Is EPA aware that some chemicals in combination have toxic effects that are greater than the effects of the individual ingredients?

Mr. ZENER. Yes, sir.

Mr. MOORHEAD. That's what they call synergism?

Mr. ZENER. Yes, sir.

Mr. MOORHEAD. And that can't be identified by testing the ingredients one by one; is that correct?

Mr. ZENER. Yes, sir.

Mr. MOORHEAD. Are you aware of the National Academy of Sciences' study which showed that a number of pesticides in combination have a synergistic effect on the environment?

Mr. ZENER. I am not aware of that particular study but I am aware of the conclusion.

Mr. MOORHEAD. Why doesn't EPA require testing of the actual formulation of the pesticide? Don't these actual formulations present the real as opposed to the theoretical hazard?

Mr. ZENER. I will have to supply the answer for the record.

[The information follows:]

Question. In regard to the issue of a synergistic effect on the environment, why does not EPA require testing of the actual formation of a pesticide?

Answer. Combinations of ingredients in formulated products are by no means the only combinations of pesticide chemicals to which man and the environment are chronically exposed. As soon as a pesticide is released into the environment, complex processes of chemical combination and transformation begin. As is stated in the National Academy of Sciences publication, Principles for Evaluating Chemicals in the Environment, "there are so many different possibilities for potential interactions that it is unrealistic to demand that all of them be tested in advance." In general, the state of the art is not developed to the point of confident prediction and detection of interactions. Granting that present knowledge is cause for concern, until more is known about mechanisms of interaction, it is difficult to determine what regulatory or testing requirements would be most effective.

Mr. MOORHEAD. Does EPA require testing for the safety of inert ingredients found in pesticides just as it does for the active ingredients?

Mr. ZENER. Again, I don't know.

Mr. MOORHEAD. Again, I will supply the answer for the record which you may correct. EPA has exempted many inert but toxic substances found in pesticides.

If an inert ingredient is toxic and it will remain on food or feed, do the EPA regulations require that a tolerance be set?

Mr. ZENER. I don't know the answer to that, sir.

[The following statement was submitted:]

Yes, if the inert ingredient is toxic, a tolerance is required for residues remaining on foods. In Section 408 of the Federal Food, Drug, and Cosmetic Act, either a tolerance or an exemption from the requirements of a tolerance is required for any ingredient in a pesticide formulation, including inert ingredients. Whether a tolerance limitation or an exempton is required depends on the toxicity of the chemical/s involved. This is a scientific judgment.

Mr. MOORHEAD. Again, the answer is yes, but if I am wrong you correct me.

GAO reports that many inert ingredients with varying degrees of toxicity have been exempted from the requirements of tolerance.

EPA does not require the same safety evaluation for inerts as required for active ingredients even though residues remain in or on on food. Can you explain that?

Mr. ZENER. I will supply it for the record, sir.

[The information follows:]

The Agency has in the past required the safety testing of inert ingredients on a case-by-case basis. We will continue to require testing of inerts which are suspected of being hazardous. Among others, EPA has required testing of some eleven inert ingredients[1] during the past several months. We rejected an alternative of requiring safety testing of *all* inert ingredients because we do not believe the additional protection provided justifies the enormous costs necessary to meet such requirement.

However, a proposal has been submitted and is currently under review for the investigation and classification of inert chemicals in pesticide formulations. The project is expected to begin sometime in May 1976. The contract consists of two phases. In Phase I, the contractor will review all the inert ingredients found in formulations as registered by EPA, group the inerts by appropriate families (e.g. solvents, detergents, etc.), and classify them toxicologically. In Phase II, those inerts whose safety has been found to be questionable will be thoroughly investigated. If data are not available for investigation, test protocols will be formulated, and tests will be conducted.

Many substances that appear as inert ingredients in pesticides are extremely common in other uses as well, and there is a potential interface with other existing regulatory programs which must be considered. If Toxic Substance legislation is passed, it may well provide the most appropriate mechanisms for regulating many substances which occur as inert ingredients in pesticides.

As an example of the action we take when evidence comes to light concerning adverse effects of inerts, the EPA immediately took steps to identify products containing vinyl chloride, an inert, last year when its carcinogenic potential was ascertained. Our action was to prohibit the future sale of such products, and to remove those products which were being marketed. This Agency has canceled and suspended the registrations of all indoor aerosol spray pesticide products containing vinyl chloride, and has recalled all such products from the market.

Mr. MOORHEAD. In this case the record shows that the comments by EPA on the GAO report that EPA recognizes the need for that

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[1](1) p-hydroxybenezensulfonic acid—formaldehyde condensate and its sodium salt, (2) copper phthalocyanine, (3) diphenyl oxide sulfonate, (4) sodium xylene sulfonate, (5) sodium 1,4-dicyclohexysulfosuccinate, (6) sodium 1,4-hexylsulfosuccinate, (7) sodium 1,4-diisobutylsulfosuccinate, (8) sodium 1,4-dipentylsulfosuccinate, (9) sodium 1,4-ditridecysulfosuccinate, (10) dodecylbenzene, and (11) *N*-methyl-2-pyrrolidone.

improvement but was turned down by OMB in its request for more funds to do the job.

Wasn't vinyl chloride one of the inert ingredients used in pesticides?

Mr. ZENER. Yes, and my recollection is that we took action on that.

Mr. MOORHEAD. After the cancer-causing properties of vinyl chloride were discovered in 1974 the EPA found that its use in a number of pesticides presented an imminent hazard and in 1975 it canceled all 32 pesticides containing vinyl chloride.

If EPA required long-term testing, wouldn't we be more likely to avoid cases like vinyl chloride?

Mr. ZENER. Surely.

Mr. MOORHEAD. What lesson has EPA learned from the vinyl chloride episode?

Mr. ZENER. One lesson is that it would be better if some of these chemicals were tested before they got on the market.

Mr. MOORHEAD. But you are not doing that; is that correct?

Mr. ZENER. According to what you say, no, with respect to inert ingredients.

Mr. MOORHEAD. On page 7 of your statement you state that EPA has taken a number of cancellation actions. I am aware of the cancellation for DDT, aldrin/dieldrin, heptachlor/chlordane and mercury. What are some of the others?

Mr. ZENER. There was cancellation of predator control chemicals. That's all I can recall at the moment.

Mr. MOORHEAD. They are not being used again, the predator controls?

Mr. ZENER. Some are and some are not. You have to distinguish between 1080, strychnine, and sodium cyanide. We have an experimental program on sodium cyanide. It's 1080 and strychnine which are the ones that present the problems and lead to killing nontarget species such as the eagle.

Mr. MOORHEAD. It was your testimony that there were a number of cancellations. I listed four, you added a fifth, that is only partially in effect now.

Mr. ZENER. Each of those covered a large number of formulations. We are talking only about the inert ingredients. These were in terms of the actual numbers of formulations covered which was very large.

Mr. MOORHEAD. In passing upon registration you rely upon private laboratories to supply the data. Is that correct?

Mr. ZENER. Data from private laboratories is submitted, yes, sir.

Mr. MOORHEAD. How does EPA verify the reliability of these data from the laboratories?

Mr. ZENER. I think to answer that question you would need somebody from the pesticide registration division.

[The information follows:]

Private laboratories do develop data in support of pesticide registrations. After consultation both within and outside the Agency, including meetings with the Food and Drug Administration and the National Cancer Institute, we have developed a three part action plan to review more thoroughly the adequacy of past testing and ensure that future laboratory testing is properly performed. The Administrator has recently testified before the Senate Subcommittee on Health (Committee on Labor and Public Welfare) on our efforts and plans to ensure adequacy of laboratory testing, including this action plan. A copy of his statement is attached for more detailed information. (April 19, 1976.)

In brief, the first part sets up an auditing program to examine laboratory records of toxicity test reports to determine whether they reflect the reported test procedures and results. This audit will help us to reevaluate the quality and sufficiency of existing data in support of registration. We will also selectively audit laboratory records for new reports as an incentive as well as a check for careful, responsible testing programs.

Second, EPA is preparing a manual describing generally what EPA expects will be included in toxicity test reports. This handbook should be in draft form by June 1, 1976. In this manual, EPA will identify as explicitly as possible the types of information that should be included in toxicity test reports, including information regarding proper test methods, post-mortem examinations of animals, and statistical evaluation of test results. It should be emphasized, however, that EPA's manual will not establish one fixed procedure for toxicity testing. Testing of different chemicals often requires different approaches. But regardless of how a test is performed, it is essential that the test report provide sufficient information to enable the reviewing EPA scientists to make their own informed judgments as to the adequacy of the testing and its implication for pesticide registration and tolerance-setting.

Third, we will propose needed amendments to existing regulations for pesticide registration. One would require each test to identify, and be signed by, those persons principally responsible for 1) performing or supervising the testing, 2) preparing the report, and 3) reviewing and approving the final submission to EPA. We will also propose an amendment to provide additional requirements for the retention and disclosure of data. In response to a GAO recommendation, we will propose that reports with disclaimers of applicability be regarded as unacceptable by the Agency. We will be issuing a statement detailing our plans for these regulatory changes later this month.

PREPARED STATEMENT OF RUSSELL E. TRAIN, ADMINISTRATOR, ENVIRONMENTAL PROTECTION AGENCY

Good morning, Mr. Chairman and Members of the Subcommittee. I am Russell E. Train, Administrator of the Environmental Protection Agency. I am present today to discuss the status of the laboratory testing of pesticide products submitted to the Environmental Protection Agency for registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and for the setting of food tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA). My testimony follows that given by Deputy Administrator John R. Quarles on January 20, 1976, before this same Subcommittee. Mr. Quarles' statement focused upon three areas: (1) a description of the EPA pesticide registration and tolerance-setting system, (2) a review of our experience with testing laboratories concerning the adequacy of their performance, and (3) a discussion of the steps EPA would undertake to improve the quality of pesticide safety testing. At that time, we at EPA expressed concern about the quality of some laboratory data submitted to the Agency in support of petitions for pesticide registrations and food tolerances. Although we believe that private laboratories generally provide competent and honest services, there have been indications that serious problems may exist. In his January testimony, Mr. Quarles described EPA findings in the Heptachlor/Chlordane and Aldrin/Dieldrin suspension hearings which reflected questionable laboratory practices. In addition, the issues of laboratory independence from pesticide manufacturers and the complete disclosure of all testing results were also discussed.

As part of an effort to determine the existence and scope of laboratory testing inadequacies, EPA initiated a six-week review of existing pesticide registration and food tolerance petitions. Over the past several weeks, Dr. Melvin D. Reuber, an independent pathologist and EPA consultant, has been examining a small sample of toxicity test reports filed with EPA. In his review, Dr. Reuber focused upon reports on tests designed to assess the effects on rats of dietary pesticide exposure over extended periods of time. Such studies are intended to determine whether long term ingestion of pesticides will cause adverse effects, including tumors. An interim report on Dr. Reuber's review accompanied by an EPA statement explaining its scope, significance and limitations has been made available to your Subcommittee. There is, therefore, no need for me to dwell on these findings. They obviously

indicate that EPA must take steps to review more thoroughly the adequacy of past testing and ensure that future laboratory testing is properly performed.

In the period since your previous hearing, EPA personnel have consulted not only with Dr. Reuber, but also with other scientists both within and outside the Agency. We have held meetings with officials of the Food and Drug Administration and the National Cancer Institute to discuss alternative ways in which EPA might deal with laboratory testing problems. Through this process, EPA has developed a three-part action plan.

First, EPA will initiate an auditing program in which laboratory records of toxicity test reports will be examined to determine whether they accurately reflect the reported test procedures and results. We hope to have this auditing system underway by July 1st of this year. Through this program, EPA will reevaluate many reports previously submitted, to determine whether they can still be considered sufficient to support the pesticide registrations and tolerances issued over the past 25 years. Also, EPA will selectively audit laboratory records related to many new reports, including those to be submitted in the next few years to satisfy reregistration data requirements. Thus, pesticide manufacturers and testing laboratories will be put on notice that EPA will be looking more carefully than ever before at their testing programs. This should provide an incentive for them to do a better job since there are strong sanctions available to EPA, including the rejection of testing results submitted as supporting data for pesticide registrations. In appropriate cases, EPA could take regulatory actions to deny registrations or undertake cancellation proceedings; in potential cases of fraud, criminal sanctions could be sought.

A program such as this obviously requires advance planning. It is vitally important that audit personnel be carefully selected and trained so that the audit program will operate effectively. The auditors will be entrusted with a task which will require patient and painstaking examination of voluminous laboratory records. They must be familiar with the process of toxicological testing so that their time and effort can be efficiently used to evaluate laboratory procedures and results.

EPA personnel will be responsible for supervising the auditing program and making regulatory determinations based on audit reports. It is our intention, however, to contract with one or more qualified organizations for the actual auditing services. National Cancer Institute officials have informed us that they have an analagous program which has been markedly successful in upgrading the quality of carcinogenicity testing. The preliminary steps required for the solicitation of bids on such work is now being prepared and will be completed within the next few weeks. In the meantime, EPA is working with FDA to develop a training program for audit personnel. FDA's National Center for Toxicological Research is expected to conduct the training program with assistance from EPA's scientific staff.

The auditing program will be reviewed after six months of operation to determine whether expansion of the program and additional actions are needed. Laboratory certification and inspection and a requirement for confirmatory testing will be considered at that time.

Second, EPA is preparing a manual describing generally what EPA expects will be included in toxicity test reports. This handbook should be in draft form by June 1, 1976. In this manual, EPA will identify as explicity as possible the types of information that should be included in toxicity test reports, including information regarding proper test methods, post-mortem examination of animals, and statistical evaluation of test results. It should be emphasized, however, that EPA's manual will not establish one fixed procedure for toxicity testing. Testing of different chemicals often requires different approaches. But regardless of how a test is performed, it is essential that the test report provide sufficient information to enable the reviewing EPA scientists to make their own informed judgments as to the adequacy of the testing and its implications for pesticide registration and tolerance-setting.

Third, EPA will propose needed amendments to its existing regulations dealing with pesticide registration. One such amendment would require that each test report identify, and be signed by, the persons principally responsible for (1) performing or supervising the testing, (2) preparing the report, and (3) reviewing and approving the final submission to EPA. Also, in response to a recommendation from the General Accounting Office, EPA will propose that test reports containing disclaimers as to their applicability be regarded as unacceptable by the Agency. In addition, EPA will propose an amendment to its regulations to make additions to existing requirements con-

cerning the retention and disclosure of data by pesticide registrants. A statement detailing EPA's intentions with respect to these regulatory changes will be issued later this month.

We have also had discussions with personnel at the Food and Drug Administration and the National Cancer Institute concerning a cooperative program for improving the quality of toxicity testing. In a recent letter to the Food and Drug Administration, we have suggested that results of audits and inspections of laboratories that test both drugs and pesticides be exchanged between our Agencies. We have also suggested that we would like to pursue a program establishing minimum Federal standards for toxicity testing that could be uniformly enforced by appropriate Federal agencies. However, since such a program may require an extended start-up time, EPA is going ahead with its own auditing program at this time.

Mr. Chairman, no discussion of our efforts to protect the public health from pesticide hazards would be complete without a description of the massive task now underway to reevaluate the registrations of all pesticides currently manufactured in this country. Pursuant to the 1972 amendments to the FIFRA, the EPA is directed to undertake a reappraisal of pesticide products approved under the earlier FIFRA to determine if they meet a new statutory test that they will not pose "unreasonable adverse effects" to man and the environment. We have been mandated by Congress to complete this review, of approximately 35,000 Federal and 10,000 State registered products now on the market, before October 21, 1977. By that time, we must determine not only whether each pesticide shall remain on the market, but also whether it should be restricted for sale only to persons trained and certified competent in the use of pesticides.

On July 3, 1975, EPA issued regulations identifying the types of data which will be required of pesticide registrants prior to the granting of new registrations or reregistrations. These include key health-related tests, dealing with cancer, birth defects, and other chronic effects. Prior registration rules lacked this specificity with respect to the contents of the manufacturer's registration petition.

On February 17 we published a list of pesticides categorized according to the acceptability of their supporting data in view of the new regulations. Those pesticides found to be lacking necessary long and short term data were identified, and time schedules for the registrants to fill the data gaps or lose registration were specified. The action plan which I have described today should serve as a strong incentive assuring that the additional data required to obtain reregistration will be valid and will provide a proper basis for EPA decision-making.

I have ordered steps to ensure that the resources available for this reregistration process are deployed so as to focus early attention on pesticides for which there is an indication of potential unreasonable adverse effects. A screening mechanism established in our regulations will single out such compounds for intensive safety review under the management of a newly established Office of Special Pesticide Review reporting to the Deputy Assistant Administrator for Pesticide Programs. Personnel from this group and the Office of General Counsel will draw on the scientific and technical resources of the Agency and outside groups to assure that the initial decision regarding reregistration is well supported by the facts. This decision may be to proceed with registration, convene an information hearing, or issue a Notice of Intent to Cancel. If the latter action is taken, the law requires us to prepare an agricultural impact statement and submit that document plus our proposed action to the Secretary of the Department of Agriculture, a Scientific Advisory Panel, and the House and Senate Agriculture Committees. In addition, the registrant may exercise his right to a hearing, in which benefits as well as the risks are assessed in an adjudicatory framework. On the other hand, if the facts indicate that we should proceed with registration, other interested parties may request a public hearing.

We believe this systematic approach to the question of pesticide safety is superior to the ad hoc mechanism under which our earlier cancellations were initiated. Not only is the selection of pesticides to be subject to administrative action made on a more rational basis, but the Agency will be in a stronger position at the time when an adjudicatory process begins. While it may appear that this process is time-consuming and expensive, it is worth noting that our successful cancellations of DDT, Aldrin and Dieldrin, and the suspension of Heptachlor and Chlordane, each consumed many months of hearing time and

hundreds of thousands of dollars before the pesticides were removed from the market.

I am confident that actions to protect the public from unreasonable pesticides risks will proceed more expeditiously, and with a greater degree of overall priority, and on a broader base of technical information through the use of procedures we will employ in undertaking reregistration. The burden of proof of safety will, as it always has been, be on the proponents of registration.

In conclusion Mr. Chairman, I believe that we at EPA have taken a number of steps which will ensure that the data received from pesticide manufacturers is of appropriate quality so that we can make the important regulatory decision that are mandated by Federal law. We view this as a vital function of our Agency.

I will be pleased to answer any questions you may have.

Mr. MOORHEAD. Well, I might as well get these questions to you. Does EPA have a program of inspection of the laboratories?

Mr. ZENER. No, sir; and there is a question as to our legal authority to do so.

Mr. MOORHEAD. Maybe you can supply for the record the legal question so we can get that cleared up.

[The information follows:]

Neither FIFRA nor the Food, Drug, and Cosmetic Act gives EPA the authority to conduct an inspection, as we use the term, without the consent of the owner of the laboratory. We have used the term "inspection" to mean an entry into a laboratory for the purpose of evaluating the equipment, procedures, personnel qualifications or other operating conditions which affect the reliability of its work product. It does not include a review of the laboratory records and data with respect to specific studies and reports.

With respect to an applicant for registration, EPA has the authority to require submission of "a full description of the tests made and results thereof." FIFRA § 3(c)(1)(D). This provides adequate authority to require submission of all laboratory documentation relating to a particular study.

With respect to registrants, FIFRA § (6)(a)(2) imposes a duty to submit "additional factual information regarding unreasonable adverse effects on the environment." In addition, as a practical matter, any registrant who refused to provide backup laboratory data and records would run the risk that EPA would consider the study deficient and might undertake adverse regulatory action with respect to the registration, in an appropriate case. Accordingly, EPA does not need additional legal authority to obtain backup laboratory records and data relating to the reports submitted to it.

However, FIFRA and the Food, Drug and Cosmetic Act do not give EPA the authority to regulate directly the business of conducting a testing laboratory. However, if improper procedures are employed in a test, either due to deficiencies in equipment or personnel training, EPA may conclude that a specific study does not provide a reliable basis for favorable regulatory action. EPA is initiating, on a selective basis, an auditing program to review back-up data and documentation of specific reports.

After six months the Agency intends to evaluate the need for additional auditing or legislative authority.

Mr. MOORHEAD. Does EPA have a procedure to license or accredit these laboratories to assure that the equipment and facilities are adequate and that the personnel are qualified?

Mr. ZENER. No, sir. That is one of the issues we are now considering.

Mr. MOORHEAD. Then you do believe that further action should be taken by EPA to verify the data submitted by the private laboratories?

Mr. ZENER. Yes, sir; definitely.

Mr. MOORHEAD. When you answer that question about the legal authority you might consider presenting to us proposed legislation which would clarify that. This committee is not a legislative com-

mittee but we can recommend legislation to the appropriate legislative committees.

Let me ask you a little bit about tolerance levels.

Is EPA required to establish tolerance levels for residues of pesticides on food and feed?

Mr. ZENER. Yes.

Mr. MOORHEAD. Are there some instances where EPA has not been able to set tolerance levels for pesticides registered for use in agricultural crops?

Mr. ZENER. That's my understanding.

Mr. MOORHEAD. If the data for setting a tolerance is not available, how can you permit registration to continue? You did find you were above tolerance level in chlordane, for example. There are other things out for which you don't know the tolerance level, and yet you don't take any action to remove the registration.

Mr. ZENER. It's hard to discuss that without getting into a specific case. There would have to be actual residue levels and at least some toxicity or other data indicating a substantial question of safety with respect to the chemical.

Mr. MOORHEAD. The risk or hazard against which the pesticide controls are directed includes not only hazard to human health but also hazard to the environment.

Mr. ZENER. Yes, sir.

Mr. MOORHEAD. Isn't it true that pesticide hazard to the environment, contaminating streams and fish and wildlife, have a way of ultimately threatening human health?

Mr. ZENER. In some cases, yes. I'm not sure that's a simple yes or no answer.

Mr. MOORHEAD. But even if there isn't any link to human health, don't your regulations include requirements for environmental chemistry testing?

Mr. ZENER. Yes, sir.

Mr. MOORHEAD. I think you mentioned the example of the killing of the eagles by predator poisoning.

Mr. ZENER. That's a prominent example; yes, sir.

Mr. MOORHEAD. How do you explain the fact that of 32 pesticide chemicals for which environmental chemistry is required, the GAO found required data on leeching and runoff to be missing in 75 percent of the cases and the required data on water degradation and photochemical degradation and microbiological data was missing in at least 50 percent of the cases?

Mr. ZENER. I would have to supply that for the record.

[The information follows:]

The first formal notification of guidelines for studies to determine the environmental impact of pesticides came on June 23, 1970, when USDA issued P.R. Notice 70-15. (At that time USDA had the authority to register pesticides.) A copy of this Notice is attached for details. It is important to note two things about the Notice. First, it does not set forth definite requirements for studies to be done and the circumstances under which they must be done. Rather it provides, "A brief discussion of the studies needed. . . . These comments are indicative and not all inclusive." Secondly, no time schedule for completion and submission of test data was established. Because these guidelines were new, and not altogether clear, studies have not been submitted for all pesticide products, particularly those which have been registered for a considerable length of time. For some of the newer pesticide chemicals data

have been submitted. It is our expectation that our *Guidelines for Registering Pesticides in the United States*, when completed, will make clear what studies are necessary and under what circumstances. Question 18 discusses our plans for filling environmental chemistry data gaps for both new registrations and reregistrations.

[PR Notice 70–15]

U.S. Department of Agriculture,
Agricultural Research Service,
Pesticides Regulation Division,
Washington, D.C., June 23, 1970.

Notice to Manufacturers, Formulators, Distributors, and Registrants of Economic Poisons

Attention: Person responsible for Federal registration of economic poisons.

GUIDELINES FOR STUDIES TO DETERMINE THE IMPACT OF PESTICIDES ON THE ENVIRONMENT

The use of pesticides may result in residues of the parent compound and/or its degradation products in treated areas and possibly in other areas as well. In connection with registration of pesticides for outdoor use, certain studies are necessary to provide information on their impact on the environment.

The basic questions which need to be resolved are listed below: (A brief discussion of the studies needed follows each question. These comments are indicative and not all inclusive.)

1. What is the rate of dissipation of the pesticide in the soil?

Studies should usually be continued until less than ten percent (10%) of the original amount of parent compound and degradation products remains. Some pesticides may require studies until dissipation is complete. Studies should include analyses for single or repeated applications depending on the use pattern.

2. What is the mechanism of degradation of the pesticide residues?

These studies may be carried out in the laboratory, but may need to be confirmed with field studies. Examples of field studies that may be required are:

(a) Photodecomposition studies in or on soil and water, using sterile and nonsterile samples.

(b) Degradation and metabolism studies of the effect of microorganisms, and the effect of the residues on microorganisms.

(c) Degradation studies in water.

(d) Duration of the biological activity (for example, phytotoxicity).

3. Do the residues leach through the soil?

Laboratory studies may suffice. If leaching is found to occur, further data will be necessary, for example, the determination of residue levels in ground water.

4. Are the residues moved from the site of application by runoff water?

Laboratory studies may suffice, but may need to be confirmed with field studies, such as: (a) Analysis of soil in untreated areas receiving runoff water. (b) Analysis of pond water receiving runoff water.

5. Is the pesticide bound in soils; that is, are residues present that are not readily extractable?

If radiochemical tracer or other studies indicate that the pesticide is bound, additional studies may be needed, for example: (a) Identification of the residue. (b) Phytotoxicity of the residue. (c) Determination as to whether bound residues may be released from the soil by plants such as rotational crops other than those initially grown in treated areas.

6. What levels of the parent compound and principal metabolites will accumulate in fish, rabbit and bird tissue and what dosage related symptoms are exhibited during the laboratory test period?

Such feeding studies should employ a dosage range encompassing both a no-effect level and an effect level. Need for determination of residues in fish, when pesticides are applied to terrestrial sites, will be dependent upon data from leaching and runoff studies.

Harold G. Alford,
Assistant Director.

Mr. MOORHEAD. Aside from blanket waiver of required environmental chemistry data, the GAO reports that EPA has no system to follow up a registrant's compliance with EPA requests for environmental chemistry data and no policy to cancel pesticide registrations when data is not provided.

Does the Agency propose to take any corrective action in this regard?

Mr. ZENER. I would have to supply that for the record.

[The information follows:]

On June 23, 1970, the Agency formally notified persons responsible for Federal registration of pesticides of the environmental chemistry studies generally necessary to determine the effects of pesticides on the environment by P.R. Notice 70-15. Environmental chemistry has been submitted in support of some applications for registration.

Environmental chemistry data were not included in the new regulations as a data requirement for all applications for reregistration. It was the Agency's intent to require environmental chemistry studies for reregistration on a case by case basis where such studies would be particularly relevant. The regulations contemplated that all presently registered products intended for outdoor application would need an environmental chemistry evaluation prior to renewal of the registrations. The new regulations do require an environmental chemistry evaluation for new registration of a pesticide product intended for outdoor application.

The present scheme allows reregistrants more time than is necessary to conduct the required testing and puts new registrants of products which are identical or substantially similar to previously registered products at a serious disadvantage. The Agency is now considering a change in this time schedule for submittal of environmental chemistry data to provide for equitable consideration of all products. Whenever environmental chemistry data are required to support reregistration and are not submitted in a timely fashion, the registration of the pesticide product must be denied or canceled, as appropriate.

Mr. MOORHEAD. Would you find it a little ironic that the Environmental Protection Agency has decided to waive the requirement of data on the environmental impact of pesticides?

Mr. ZENER. I am not sure there has been a waiver. I just don't know.

[The information follows:]

Our procedures and basic standard for waiving any data requirement are set forth in Section 162.8(a)(3) of our regulations for registration, reregistration and classification of pesticides and discussed in the preamble to the regulations. Briefly, although we have attempted to consider all pesticides in developing data requirements we realize that our regulations and Registration Guidelines may not have taken into account all relevant factors for all pesticides. As the discussion on waivers in the preamble points out, "Waiver of a data requirement is permissable only if the Administrator determines (1) that the composition, degradability, proposed patterns of use or other chemical or physical properties of the pesticide, relating to an evaluation of the effects on man or the environment are fundamentally different from the properties considered by the Agency in establishing the data requirements of those regulations or the Registration Guidelines, and therefore, (2) that the data are not necessary in order for him to determine whether such specific pesticide or product will cause unreasonable adverse effects on man or the environment". Scientific judgment on the data supplied for a waiver is at the heart of such a determination. The pertinent portions of the preamble and Section 162.8(a)(3) are attached for further detail.

In general, an applicant must initiate the waiver process by submitting a written statement of his reasons for requesting a waiver from a data requirement. In the case of approval of a new registration, if a waiver has been granted, the notice of approval shall list any data requirement waived and state the basis for the waiver. In the case of reregistrations, the Administrator may initiate the waiver by indicating this in his solicitation of applications. The notice of solicitation shall list any data requirement waived and briefly state the basis for the waiver.

These are the general standards and procedures for obtaining a waiver of a data requirement. I have previously discussed the situation with regard to waiver of environmental chemistry requirements for reregistration.

[From the Federal Register, Vol. 40, No. 129, July 3, 1975]

(b) Several commenters argued that the data requirements of these regulations and the Registration Guidelines, even taking into account the conditional nature of many of the data requirements, are inapplicable to certain pesticides or pesticide products and are not necessary for a determination of whether such pesticide product will generally cause unreasonable adverse effects on man or the environment. The Agency has attempted to consider all pesticides in developing the data requirements. The Agency recognizes, however, that these regulations and the Registration Guidelines may not have taken into account all relevant factors for all pesticides. Accordingly, the proposed regulations at § 162.8(b)(1)(i) had provided for a waiver of data requirements upon petition of the applicant. That provision has been modified and a new § 162.8(a)(3) has been included to specify the detailed procedures and basic standard to be applied by EPA for waiver of a data requirement specified in these regulations of the Registration Guidelines. Waiver of a data requirement is permissible only if the Administrator determines (1) that the composition, degradability, proposed patterns of use or other chemical or physical properties of the pesticide, relating to an evaluation of the effect on man or the environment, are fundamentally different from the properties considered by the Agency in establishing the data requirements of these regulations or the Registration Guidelines, and therefore (2) that the data are not necessary in order for him to determine whether such specific pesticide or product will generally cause unreasonable adverse effects on man or the environment. Generally, an applicant must initiate the process and submit a written statement setting forth his reasons for requesting a waiver from a data requirement. In the case of reregistration, however, the Administrator may initiate the waiver of a data requirement by so indicating in his solicitation of applications for reregistration. The Administrator will make a written finding with respect to waiver of a data requirement. In the case of the approval of any application for which notice of application was published in the FEDERAL REGISTER pursuant to § 162.6(b)(6), if the Administrator determines to waive a data requirement, the notice of approval issued pursuant to §162.1(d)(2) shall list any data requirement which has been waived and briefly state the basis for such waiver. In the case of waiver of a data requirement initiated by the Administrator in the solicitation of applications for reregistration, the notice of solicitation shall list any data that have been waived and briefly state the basis for such waiver. Notice to the public of the waiver of a data requirement satisfies EPA's responsibility under the Act, these regulations, and the general principles of Administrative Law to set forth the rationale for any departure from its regulations.

(c) A commenter requested that EPA require the applicant for both new registration and reregistration to submit all relevant information available from scientific literature and other sources on the potential adverse effects of a pesticide. In the proposed regulations at § 162.6(c)(3)(viii), this provision by its terms applied only to reregistration, although the Agency intended that the requirement apply to all registrations. Moreover, we believe that this provision more properly belongs in §162.8.

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(c) *Five Year Cancellation.* (1) *General.* The Administrator shall issue a notice of intent to cancel the registration of a pesticide product five years after the date of such registration. The registration shall be cancelled unless the registrant, or other interested person with the concurrence of the registrant, requests that the registration be continued in effect. Such a request must be made by the registrant, or other interested person with the concurrence of the registrant, by the date specified in the notice. The Administrator shall continue in effect a registration only upon determination that the registration complies with all requirements of the Act and the current regulations promulgated thereunder, including all data requirements as specified in the Registration Guidelines for new registration.

(2) *"Federal Register" Notice.* The Administrator shall publish in the FEDERAL REGISTER notice that the registration will be cancelled if the registrant, or other interested person with the concurrence of the registrant, does not request that the registration be continued in effect. Such notice shall be published at

least 30 days prior to the expiration of the five year period and the effective date of the cancellation notice. The FEDERAL REGISTER notice shall state that the notice of intent to cancel is being issued under the authority of section 6(a)(1) of the Act and this subsection of Part 162.

(3) *Continued Sale and Use of Existing Stocks.* The Administrator may permit the continued sale and use of existing stocks of a pesticide cancelled pursuant to this subsection. Such continued sale and use shall be subject to the conditions and for such uses as the Administrator specifies. The Administrator may only permit such sale and use if he determines that:

(i) such sale and use is not inconsistent with the purposes of the Act and the regulations promulgated thereunder; and

(ii) such sale and use will not have unreasonable adverse effects on man or the environment.

§ 162.7 Disposition of applications.

(a) *General.* All applications for new reregistration, amended registration, or supplemental registration, and all resubmissions of such applications, will be processed as described below.

(b) *Notice of Receipt of Application for Registration.* The Agency will acknowledge receipt of each application for registration by returning to the applicant a notification of the date of receipt by the Agency.

(c) *Time for Action with Respect to Application.* As expeditiously as possible, the Agency shall approve or deny all applications for registration. Where practicable the Agency shall make its determination within 90 days after the date of receipt of the application. Registration applications which require consultation with other Federal agencies, may take longer.

(d) *Approval of registration.* (1) *Criteria for Approval.* The Administrator shall register a pesticide product or approve amended and supplemental registration if he determines that, when considered with any restrictions imposed:

(i) The composition is such as to be effective for all uses set forth on the label (see §§ 162.8 and 162.10);

(ii) The product is not misbranded as defined in section 2(q) of the Act, and its labeling complies with the applicable requirements of the Act, § 162.10, and the Registration Guidelines;

(iii) The test data and other material required to be submitted with the registration application comply with the requirements of the Act, §162.8, and the data requirements of the Registration Guidelines;

(iv) The pesticide will perform its intended function without unreasonable adverse effects on the environment and when used in accordance with widespread and commonly recognized practice will not generally cause unreasonable adverse effects on the environment. The criteria for determining unreasonable adverse effects on the environment are set forth in §162.11;

(v) A tolerance or exemption from the tolerance requirement has been obtained, as provided in sections 406, 408, or 409 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 316, 316a, and 318), if the proposed labeling bears directions for use on food or if the intended use of the pesticide results or may reasonably be expected to result, directly or indirectly, in residues of the pesticide becoming a component of food; and

(vi) The product has been approved under the provisions of the Food, Drug and Cosmetic Act if the product contains any drug claims on its labeling in addition to the pesticidal claims.

(2) *Notice of Approval.* The Administrator shall promptly publish in the FEDERAL REGISTER a notice of approval of the registration for any pesticide product for which notice of application was published under § 162.6(b)(6) for pesticides having an active ingredient not registered at the time of the application or for pesticides with a changed use pattern.

(e) *Denial of Registration.* (1) *Notification.* The Administrator shall deny registration if the pesticide product fails to meet any of the requirements of paragraph (d) of this section or if there is insufficient data to make the required determination. Promptly after making such a determination, he shall notify the applicant by certified letter of the denial of registration and shall set forth the reasons and factual basis for the determination and the conditions, if any, which must be satisfied in order for the registration to be approved.

(2) *Opportunity for Remedy by Applicant.* (i) The applicant will have 30 days from the date of receipt of the certified letter to take the specified corrective action.

(ii) The applicant may petition the Administrator to withdraw his application. The Administrator may, in his discretion, deny any petition for withdrawal and proceed to issue notice of denial in accordance with paragraph (3) of this section.

(3) *"Federal Register" Publication.* If the applicant fails to remedy the deficiency of his registration application, the Administrator shall promptly publish in the FEDERAL REGISTER a notice of denial of registration. Such notice shall set forth the reasons and factual basis for the denial and shall contain the name and address of the applicant, the product name, the name and percentage by weight of each active ingredient in the product, the proposed patterns of use, and the proposed classification.

(4) *Appeal Rights.* Within 30 days following publication of the denial in the FEDERAL REGISTER, the applicant or any interested party with the written authorization of the applicant may request a hearing pursuant to section 6(b) of the Act and Part 164 of these regulations.

(f) *Disposition of Material Submitted in Support of Registration.* The test data and other information submitted in support of the registration application shall become a part of the official file of the Agency for that registration. Except as provided by section 3(c)(1)(D) and section 10 of the Act, within 30 days after the registration of a pesticide, the data called for in the registration statement together with such other scientific information as the Administrator deems relevant to his decision shall be made available for public inspection.

§ *162.8 Data in support of registration and classification.*

(a) *General.* (1) The applicant shall submit test data and other information necessary to support all claims made for the product and to establish that the product meets the requirements of section 162.7 of this Part. In submitting required data, the applicant must clearly mark any portions thereof which in his opinion are trade secrets or commercial or financial information, pursuant to Section 10 of the Act, and submit such marked material separately from other materal submitted with the application.

(2) The data required by paragraphs (b), (c), and (d) of this section shall be submitted according to the specifications of the Registration Guidelines. Nothing included in or omitted from the Registration Guidelines, shall, however, relieve the applicant of the responsibility to apply all relevant available knowledge in designing tests and evaluating results.

(3) An applicant for registration or reregistration may submit written evidence that the composition, degradability, proposed patterns of use and such other chemical or physical properties of a specific pesticide or product relating to an evaluation of the effects on man or the environment are fundamentally different from the factors considered by the agency in the establishment of the data requirements of the Registration Guidelines and that therefore some or all of the data requirements of the Registration Guidelines are inapplicable to the specific pesticide or product, provided however, that in the case of the reregistration of a pesticide, the Administrator may initiate a waiver of a data requirement of the Registration Guidelines in his solicitation of an application for reregistration. After considering the evidence submitted by the applicant, and such other information as may be available to him, the Administrator will make a written finding with respect to whether such properties of the specific pesticide or product are fundamentally different from the factors considered by the Agency in establishing the data requirements of the Registration Guidelines. If the Administrator determines that such properties of the specific pesticide or product are fundamentally different from the factors considered by the Agency he may waive a data requirement specified in the Registration Guidelines when he determines that the data so required is not necessary in order for him to determine whether such specific pesticide or product will generally cause unreasonable adverse effects on man or the environment. In the case of the approval of any application for new registration in which the Administrator has determined to waive a data requirement specified in the Registration Guidelines, when he determines that the data so required is not necessary in order for him to determine whether such specific pesticide or product will generally cause unreasonable adverse effects on man or the environment. In the case of the approval of any application for new registration in which the Administrator has determined to waive a data requirement specified in the Registration Guidelines, the notice of approval issued pursuant to § 162.7(d)(2) shall list any data requirement in the solicitation of application for reregistration, the notice of solicitation shall list any data requirement which has been waived and briefly

state the basis for such waiver. As information becomes available concerning properties of specific pesticides or products which are found to be fundamentally different from the factors considered by the Agency in establishing the Registration Guidelines, consideration will be given to appropriate revision of the Registration Guidelines.

(4) The applicant shall submit any factual information regarding adverse effects of the pesticide on the environment or man which have been obtained by him or come to his attention including, but not limited to, published or unpublished laboratory studies and accident experience.

(b) *Data Requirements for New Registration.* (1) *General.* Unless additional data are requested by the Agency pursuant to paragraph (d) of this Section, or the applicant secures a waiver of a data requirement pursuant to paragraph (a)(3) of this section, pesticide products subject to new registration, under § 162.6(b)(2) shall be supported by the following data to determine their use classification(s) and registrability.

(2) *Efficacy.* Data are required to substantiate efficacy claims made for the pesticide product. Evidence of product efficacy will be demonstrated through laboratory and/or field-testing procedures which simulate actual use conditions. Actual test procedures will vary according to the characteristics of the chemical, the type of formulation, the target pest, the use patterns, and the methods and time of application. Information shall be submitted by the applicant as specified in the Registration Guidelines to include:

(i) Data to support the minimum effective dosage and effective dosage range.

(ii) Description of application techniques, including equipment used in application, method, timing and site of application.

(iii) Evaluation of the action of the product in destroying, repelling or mitigating a pest; accelerating or retarding the rate of growth or otherwise altering the behavior of plants; defoliating plants; or injuring plant parts for the purpose of accelerating the drying of plant tissue.

(iv) Measurement of toxic effects to plants or animals that are host to the pest, as appropriate.

Mr. MOORHEAD. GAO reports that you have. That is one of the reasons why I think that this letter of Mr. Alm is totally inadequate.

Do you have any questions, Mr. Gude?

Mr. GUDE. No questions.

Mr. MOORHEAD. Mr. Fountain?

Mr. FOUNTAIN. No questions, Mr. Chairman.

Mr. MOORHEAD. I think that should conclude our hearing.

I presume you would be willing to answer any questions the subcommittee might wish to submit to you in writing?

Mr. ZENER. Certainly.

[The questions and answers follow:]

Question. 1. Why were EPA's national interim primary drinking water regulations not published within the time required by section 1412(a) of the Safe Drinking Water Act?

Answer. The Interim Primary Drinking Water Regulations were proposed in the *Federal Register* on March 14, 1975 as required. Subsequently, EPA conducted four public hearings across the Nation to solicit comments. EPA received several thousand pages of comments from the States, environmentalists, other Federal Agencies, and the public. In accordance with EPA's regulatory development process, it was necessary to categorize, evaluate, and resolve each comment. This period for comment evaluation and resolution required more than the 90 days allowed by section 1412(a) of the Safe Drinking Water Act. EPA delayed the promulgation of these regulations for a few months to obtain the benefits of public involvement in the technical, programmatic review of these regulations. EPA promulgated the Interim Primary Drinking Water Regulations on December 24, 1975. Additional revisions including radioactivity have been developed, and regulations for other chemicals are being considered (e.g., Aldrin, Dieldran, DDT, Chlordane, Heptachlor, Heptachlor epoxide). Revisions of the Interim Regulations will become effective in June 1977.

Question 2. Why did not those interim standards impose limitations on known cancer-causing chemicals such as Aldrin and Dieldrin?

Answer. The Interim Primary Drinking Water Regulations included maximum contaminant levels for pesticides based upon recent data on the effects of acute and chronic exposure to both organo-chlorine and chlorophenoxy pesticides. The list, however, did not include aldrin or dieldrin. EPA believes that it is not possible to establish a "safe" level for substances suspected of being carcinogenic and that maximum contaminant levels for these substances must be based upon their presence in drinking water and ability to treat and to detect these substances. The Agency is awaiting the results of an intensive nationwide survey to determine the extent of contamination of the drinking water by these persistent pesticides. Based upon findings of the levels currently present in drinking water and the projected levels when the 1975 ban on the chemicals are effective, EPA will establish levels for these pesticides as appropriate.

Question 3. Why has not the EPA established primary limitations on residues of Heptachlor or Chlordane even though they have been identified as a cancer hazard to man?

Answer. Maximum contaminant levels for heptachlor and chlordane were proposed in the Interim Primary Drinking Water Regulations based on chronic toxicity. At that time, these substances had not been identified as potential carcinogens. While the Interim Primary Drinking Water Regulations were being promulgated, cancellation and suspension hearings on these pesticides were being conducted. Therefore, they were deleted from the list of pesticide maximum contaminant levels with the understanding that this decision may be reconsidered. (Subsequently they have been determined as potential carcinogens and use has been prohibited by EPA.) EPA is re-examining available data in an effort to establish maximum contaminant levels based upon carcinogenicity.

Question 4. Why have no interim limitations been set in the drinking water standards for vinyl chloride, asbestos, chloroform, carbon tetrachloride, benzene, and trichloroethylene?

Answer. In accordance with the legislative intent expressed in the House Report on the Safe Drinking Water Act, the Interim Primary Drinking Water Regulations were based upon an update and revision of the 1962 Standards. Consequently, interim limitations for vinyl chloride, asbestos, chloroform, carbon tetrachloride, benzene, and trichloroethylene were not included.

The establishment of limitations on substances in drinking water requires the determination of health effect levels, the existence of monitoring techniques and a knowledge of the prevalence of the substances in drinking water. In the case of asbestos, the health effects of ingested asbestos have not been determined and the present monitoring techniques are costly, time consuming and of questionable accuracy. In relation to a number of specific organic contaminants, additional monitoring is underway in the 112 cities National Organic Monitoring Survey to determine the extent of distribution in drinking water and sources and control methods.

General monitoring techniques for the organic chemicals that may serve as indicators of organic pollutants are under active development. EPA has a major research program underway to derive information on occurrence, monitoring techniques and treatment possibilities to enable the development of appropriate regulations.

Based upon study results and research developments, major regulations for organics will be either promulgated as an addition to the Interim Primary Drinking Water Regulations or in the Revised Drinking Water Regulations.

Question 5. What is the view of EPA as to the feasibility of carbon filtration techniques to deal with pollutants and contaminants in drinking water?

Answer. Carbon filtration techniques will play a prominent role for removal of certain contaminants in drinking water. Carbon is a selective adsorbent for chemicals but, however, has a limited capacity requiring regeneration at fairly frequent intervals. EPA is actively exploring all of the implications of the use of granular activated carbon including costs, availability, operating questions, regeneration frequency, and effectiveness for removal of specific substances. Several large-scale demonstration projects plus extensive laboratory studies are underway. In the interim, with respect to chloroform and related compounds, promise has been shown by a modification in chlorine application which reduces the formation of chlorinated organic chemicals.

Question 6. Why were representatives of the EPA willing to discuss the list of 102 pesticides which emerged from an initial screening of registered pesticides with reporters from the Wall Street Journal but were not willing to release the list to the public or to inform congressional committees of its existence or to permit the Agency's legal enforcement staff to examine it?

Answer. As Mr. Train noted in his letter of February 26 to Chairman Moorhead, we had not published the list because of its preliminary nature and the possibility of misunderstanding it. However, since Attorneys Howard, Sizemore, and Reukauf specifically indicated this list as a cause of their resignation, we felt that discussing the list with the press to some extent would help prevent needless misunderstandings and concern. Complete silence on the issue would have been seriously misleading as the list itself was a first step in a complex process which relies heavily on full public participation for its success. And, in fact, the list, with a full explanation of its nature and purpose, was first released to this Committee.

Question 7. Does the EPA believe that a cancer hazard must be proved to be associated with a pesticide before it may take measures to ban such pesticide?

Answer. No, it is not necessary to prove the carcinogenicity of a particular pesticide before the Agency can take administrative actions against the continued registration of the pesticide. Section 6 of FIFRA authorizes the Administrator to issue a notice of intent to cancel if it *appears* "that a pesticide—or its labeling . . . does not comply with the provisions of the Act, or when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment." Unreasonable adverse effects are "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." Thus, for example, Administrator Train issued a notice of intent to cancel for chlordane and heptachlor because their continued registration and use appeared "to pose a substantial question of safety" based on evidence indicating, but not proving, carcinogenicity.

The hearings which may result from such a notice provide the opportunity to gather all pertinent evidence and to further define the risks involved with continued use as well as the benefits. Further, in cancellation proceedings the Agency does not have the burden of proving the hazard of a pesticide; rather FIFRA and case law place the burden of demonstrating the safety of a suspect pesticide on the registrant.

In addition, carcinogenicity is not the only criterion for taking administrative actions against continued registration of a product. The criteria for determining whether a rebuttable presumption against registration or reregistration has arisen (see question 3 for details on rebuttable presumption) include both acute and chronic hazards. These are: 1) acute hazard to man and domestic animals; 2) acute hazard to wildlife; 3) induction of oncogenic or mutagenic effects in experimental mammalian species or in man; 4) any other chronic or delayed toxic effects in test animals at any dosage up to a level substantially higher than that to which humans may be exposed; 5) reasonable anticipation of significant local, regional, or national population reduction in nontarget species or fatality to endangered species; and 6) lack of emergency treatments such as antidotal, palliative or first aid treatments for amelioration of toxic effects in man resulting from a single exposure. Thus, the Agency can take action against a pesticide whenever any one of these criteria is met or exceeded.

Question 8. What actions does the EPA propose to take with respect to the 102 pesticides identified in the preliminary screening and on what time schedule?

Answer. As the February 26 letter to Chairman Moorhead indicated, a copy of which is attached for the hearing record, these 102 pesticides represent the completion of the first step in identifying and processing those pesticides which trigger the rebuttable presumption criteria. The rebuttable presumption criteria are those levels of certain standard indicators of adverse effects at which, in the Agency's judgment, prima facie evidence of potentially unreasonable risk has been shown. The second step is to verify through extensive scientific review the test data which initially placed the pesticides in question on the list. A schedule is being developed for the order in which data on each of these pesticides will be verified. If the data are verified for a particular pesticide, the third step is to notify the affected registrants that the rebuttable presumption criteria have been triggered. At the same time, notice of the rebuttable presumption will be published in the *Federal Register* soliciting public comment and other relevant information. All notices of rebuttable presumption will be issued by February 15, 1977, to allow time for final action on all pesticides which triggered the criteria by October 21, 1977, the statutory deadline. Fourth, within 45 days, or at most 105 days (if the registrant seeks and receives an extension) of receipt of the notice, registrants and all interested parties may submit evidence to rebut the presumption of unreasonable risk, including both risk and benefit information. The fifth and final step is the determination as

to whether or not the product may be registered on the basis of a thorough risk/benefit analysis by EPA. If a decision to initiate cancellation is made, external review by the Department of Agriculture and the Scientific Advisory Panel as required by the 1975 amendments to FIFRA will be sought. It may take as many as 240 days from the issuance of notification of rebuttable presumption to complete the process.

Over 60% of the 102 compounds have already been the subject of significant scientific review, through cancellation and suspension hearings, internal reviews, information gathering hearings, and monitoring programs. These include 24 arsenicals, 23 mercurials, 7 EBDC compounds, 7 cadmium compounds, 6 compounds containing dioxin, chlordane and mirex. Most mercury products were recently canceled by Mr. Train, and most chlordane products were suspended in December 1975. The compounds not already canceled will move into the special pesticide review process at appropriate phases with much information already at our disposal. This leaves only 33 of the 102 compounds which will need to proceed completely through the five steps described above.

Enclosure.

U.S. ENVIRONMENTAL PROTECTION AGENCY,
Washington, D.C., February 26, 1976.

Hon. WILLIAM S. MOORHEAD,
Chairman, Conservation, Energy, and Natural Resources Subcommittee,
Committee on Government Operations,
House of Representatives,
Washington, D.C.

DEAR MR. CHAIRMAN: Thank you for your letter of February 13 requesting a list of the 100 alleged pesticide carcinogens cited in testimony before your Committee by former Agency attorneys.

At the start, I would like to emphasize that EPA has not developed a list which has been defined as an enumeration of carcinogens. What we have been compiling, in accordance with the mandates of the new pesticides law, is a list of compounds which will require thorough evaluation prior to reregistration. Up to now, we have refrained from publishing the list because of its preliminary nature and the misunderstanding we felt might arise as a result of its publication. We feel now, as a result of the testimony before your Committee and the recent press coverage, however, that even greater misunderstanding is inevitable if we do not publish the list. I have therefore directed the public release of the list, and I attach it for your information. I would like to devote the rest of this letter to providing a more thorough explanation of what the list is, and is not.

As you know, according to the recent FIFRA amendments, all pesticide products which have been previously registered must be reregistered by this Agency by October 21, 1977. Each pesticide product must be reviewed and a determination made as to whether or not to register it for a particular use, and whether this use should be classified as general or restricted. This reregistration process is to be conducted in accordance with the new regulations for the registration, reregistration and classification of pesticides under Section 3 of the FIFRA (40 FR 28242, July 3, 1975), which became effective on August 4, 1975. In these regulations, a systematic means was set forth for achieving rapid and efficient reregistration of these 35,000 or so pesticide products, which incorporate approximately 1400 active ingredients. Specific plans and implementation schedules have also been developed so as to minimize reregistration problems and delays.

One point at which we have attempted to simplify this reregistration process is in the consideration of unreasonable adverse effects, a key element in every registration decision under the amended FIFRA. A full, formal evaluation of the relative costs and benefits of each use of each pesticide product would be extremely costly to perform and practically impossible when considered in light of administrative constraints, and it furthermore would be unnecessary in most cases. We have thus attempted to follow a more rational and practical course by setting forth a means for identifying those pesticides which might necessitate a more thorough risk/benefit analysis as part of the registration process. Specifically, the regulations present criteria which represent the Agency's judgment of the levels at which certain standard indicators of adverse effects are considered to show *prima facie* evidence of potentially unreasonable

risk. It is important to realize that these criteria represent a screening mechanism only, and thus can give rise only to a presumption of unreasonable risk, and not a final determination. This presumption is, by definition, rebuttable. The registrant, users, and the public are given every opportunity to demonstrate that the risk is not as substantial as originally presumed, that it may be reduced through labeling or other use restrictions, or that the benefits of the product outweigh the risks involved in its use, and thus that the product should be registered. The public nature of this process also assures that data which may support the initial presumption will be obtained as well.

For the orderly implementation of these rebuttable presumption provisions, a new organization unit has been established—the Office of Special Pesticide Reviews. This unit is responsible for identifying and processing rebuttable presumption cases, a procedure which involves five basic steps. The first step is a preliminary review of our data files and the relevant literature to determine which pesticides, if any, may trigger the rebuttable presumption criteria. Second, if a pesticide does trigger any of the rebuttable presumption criteria, an extensive scientific review is conducted to assess the validity of the test data which has placed the pesticide in question. Third, upon the completion of this review and a determination that the rebuttable presumption has been verified, the affected registrant will be notified as to the results. Concurrently, a notice will be published in the *Federal Register* stating the existence of a rebuttable presumption and soliciting from the public any information it may wish to submit in regard to the pesticide. Fourth, the registrant and all interested parties may submit evidence to rebut the presumption of the pesticide's hazard, including any information regarding risks or benefits accruing from its use. The final step is a determination as to whether or not the product may be registered, which is only to be decided after a thorough risk/benefit analysis by the EPA, as well as a consideration of the recommendations of the Department of Agriculture and the Scientific Advisory Panel as required by the 1975 amendments to the FIFRA.

As you can see, this procedure provides for a comprehensive review and evaluation of any pesticide which may trigger the rebuttable presumption criteria. We have just issued a notice in the *Federal Register*, a copy of which is enclosed, to further explain this part of the reregistration process. As you will note, after a preliminary screening, each pesticide will be placed in one of five categories: (1) those which do not trigger a rebuttable presumption and for which sufficient data are available for reregistration; (2) those which do not trigger a rebuttable presumption but which must complete long-term testing requirements; (3) those which do not trigger a rebuttable presumption but which must complete short-term testing requirements; (4) those which do trigger a rebuttable presumption; and (5) those which have not yet been adequately reviewed for placement in one of the above categories.

The list you have requested represents the results of our screening of registrations to determine which compounds—on the basis of existing registration or tolerance data, unverified studies which have appeared in the scientific literature, or chemical similarity to canceled pesticides—may, upon review, trigger a rebuttable presumption. I want to stress that these pesticides are only candidates for rebuttable presumption, and that it is only after a further assessment of the data that any decisions in their regard can be made. As the review of each pesticide is completed, the appropriate notices to the registrant and the *Federal Register* will be issued as planned. I cannot overemphasize the tenuous nature of the attached working list, especially in view of press accounts which have described it. To characterize these chemicals as a "list of carcinogens" or even as a list of unduly hazardous pesticides would be premature, and would ignore the carefully constructed evaluation and balancing process developed in the FIFRA and the Section 3 regulations.

As soon as the Committee's calendar permits, the Agency will certainly be willing to appear to discuss further the charges made in earlier testimony. Our Office of Legislation will make the appropriate arrangements whenever you are prepared to receive us. Please let me know if there is any other information we can provide at this time.

Sincerely yours,

RUSSELL E. TRAIN,
Administrator.

Enclosures.
(See p. 87.)

Question 9. Why were Attorneys Howard, Sizemore, and Reukauf not permitted to see the list of 102 pesticides?

Answer. To the best of our knowledge, Attorneys Howard, Sizemore, and Reukauf did not request to see the list. If a member of our staff did refuse such a request, we would have expected the attorneys to contact Mr. Edwin L. Johnson, the Deputy Assistant Administrator for Pesticide Programs, for his assistance in reviewing the list. However, because Mr. Johnson was not contacted by the attorneys about such a problem, we do not believe they made a specific request to see the list.

Question 10. Do you believe that the withholding of the list of 102 pesticides from the public and the Congress was consistent with the Administrator's instruction of October 10, 1975, that ". . . the Agency should carry out a more open evaluation of risks and benefits . . .?"

Answer. The list was not "withheld." Rather, it was not published as it was simply an internal working document. The Administrator's instruction of October 10 describes this open evaluation as a process in which, "by involving interested parties and by soliciting external scientific and technical *review of our data and analysis* [emphasis added], as appropriate, we can insure that decisions continue to be based on the objective evaluation of all available data."

That is, the open review and evaluation are to be carried out on a body of data which the Agency has initially assembled and organized in light of the rebuttable presumption criteria. Any final decision is reached only after this outside evaluation has been made. Just as we have organized and summarized a large amount of information to provide coherent, understandable, and useful answers to these questions, so too, the first steps of the rebuttable presumption process (which I will describe in detail later), represent a preliminary organization and summation of data in order to facilitate, not frustrate, an open review and evaluation. A final decision on the continued registration of any one of these 102 pesticides comes only after public review.

It is also important to note that we have a public responsibility not only to share information with interested parties, but also to ensure that the information disseminated is accurate and validated. To issue a preliminary screening list before we have done our necessary homework would, in our opinion, be irresponsible, and only give rise to alarm where none is warranted. That is why the public involvement step comes *after* validation, so that the public will not waste valuable resources or cease using worthwhile products on the basis of sketchy, or even wrong, information. Releasing solid, validated information is clearly in the public interest; releasing preliminary indications is, in our opinion, not.

Question 11. Why did the EPA fail to set standards or limits for toxic chemicals as a part of the pretreatment standards for discharges into municipal systems under the Federal Water Pollution Control Act?

Answer. The Agency believed that toxic pollutant pretreatment standards could not be promulgated until the direct discharge standards for the same pollutants were developed. Pretreatment and direct discharge standards must be consistent, one to the other. The difficulties associated with the development of standards for toxic pollutants are more fully discussed in the response to question 14.

Question 12. What action is EPA taking or proposing to take to remedy this deficiency?

Answer. Pretreatment standards for toxic chemicals pursuant to § 307(b) of the Act for the substances designated and addressed pursuant to § 307(a) of the Act are being drafted currently and will be promulgated at or about the same time that proposed direct discharge regulations are promulgated.

Question 13. When does the EPA plan to promulgate such pretreatment standards?

Answer. The toxic pollutant pretreatment effluent standards are undergoing review and development within the Agency prior to interagency review. These standards are for the pollutants designated as toxic under § 307(a) of the Act and are in support of the direct discharge standards. It is anticipated that these standards will be published either concurrently with the direct discharge standards or shortly thereafter, and that this will take place for six designated toxic pollutants by midsummer, 1976.

Question 14. Why has the EPA failed to establish toxic effluent standards under section 307 of the Federal Water Pollution Control Act?

Answer. On July 6, 1973, the Agency published in the *Federal Register* a proposed list of nine toxic pollutants pursuant to section 307(a)(1) of the Act, 38 FR 18044. The nine substances were: aldrin/dieldrin, benzidine, cadmium, cyanide, DDT (DDD, DDE), endrin, mercury, polychlorinated biphenyls, and toxaphene. Following receipt of public comment, the list was promulgated on September 7, 1973, together with a discussion of the Agency's selection criteria and a response to comments received on the proposed list, 38 FR 24342 *et seq.* The promulgated list consisted of the same nine substances previously proposed.

On December 27, 1973, the Agency published proposed toxic pollutant effluent standards for each of these nine substances, together with a summary of the factors considered in setting the standards, and a list of point source categories of discharges proposed for coverage, 38 FR 35388 *et seq.* As recited in that notice of proposed rulemaking, the standards proposed therein were developed under severe time constraints imposed by court order in response to litigation commenced by the Natural Resources Defense Council, *NRDC* v. *Fri*, Civ, Action No. 849-43 (D.D.C., June 19, 1973, as modified), with the result that the Agency had not had time to develop data in certain areas. In accordance with section 307(a)(2) of the Act, a formal rulemaking hearing on the proposed standards was scheduled.

A prehearing conference was held on January 25, 1974, followed by a 30-day evidentiary hearing during April and May. Thirty-eight objecting parties participated, most of whom where representatives of industries or industry associations who would be affected by the proposed standards. During these hearings industry objectors introduced evidence which highlighted the following:

(1) Questions were raised as to whether the technology existed to monitor and detect the presence of some of the toxic pollutants in effluents at the low levels of concentration prescribed in the proposed standards with any degree of accuracy or reliability.

(2) The proposed standards were based in part upon certain hydrological considerations, including the flow rate and volume of rivers, and the propensity of a pollutant to disperse following discharge and become less concentrated in the area in the immediate vicinity of the discharge (substantially the equivalent of a "mixing zone"). It was argued that these assumptions were oversimplified, and evidence was presented indicating that attempts in the proposed standards to prescribe different discharge levels based upon flow rates and volume of the receiving waters could result in unrealistic and unfair discrimination among dischargers, as well as major administrative problems. No evidence was submited to indicate a reasonable alternative approach.

(3) The standards for each substance included a provision for allowable discharges based upon a conservative seven day "low flow" of the water body for a recurrence frequency of ten years. The low flow for an estuary was defined in section 129.01(c) of the proposed standards as the low flow for its tributaries, with the result that allowable discharge for industries located on them could be unduly restrictive. The Agency staff offered new hydrodynamic data late in the hearing in response to this problem, but this evidence was excluded from the record by the Administrative Law Judge as beyond the scope of rebuttal. With respect to this latter evidentiary problem, the Agency is amending its rules of practice, 40 CFR Part 104, to prevent the recurrence of such an impediment to the full development of the rulemaking record, 41 FR 1765 (January 12, 1976).

(4) Many industries presented evidence to show that the technology available to them either could not achieve the proposed effluent limitation levels, or could not be installed within the one-year compliance time contained in the statute (cf §307(a)(6) and 307(d)). Other industries presented evidence to show that even where such control technology might be available, it could only be installed at very substantial expense. Further evidence was introduced to show that promulgation of the proposed standards would force large segments of major American industries to shut down. No evidence was available in the record by which to test the validity or strength of these claims.

In addition, there were some gaps in the Agency's data concerning the identification and extent of point source discharge of the substances. This in turn affected the Agency's ability to promulgate standards for the range of point sources proposed for coverage.

Following the completion of these hearings, which had proceeded within the extremely short 6-month time frame following proposal of standards as prescribed in section 307(a)(2), the Agency concluded that because of the problems and data gaps in the hearing record referred to above it could not promul-

gate responsible and defensible standards based upon that record. This is not to say that the effluent standards originally proposed by EPA are indefensible, but rather to emphasize that at the time of the hearing on those proposed standards, the Agency did not have available to it the necessary data to fully substantiate the proposed standards or to respond effectively to the problems raised by the objectors. The status of the hearing record is critical, because under sections 307(a)(2) and (3) it is the sole basis for the promulgation of final standards, and the hearing record on the proposed toxic standards revealed that those standards could not be defended based on its contents.

At the same time the Agency was deeply concerned with the fact that it was then behind the time schedule which Congress prescribed for the setting of standards under section 307(a), and that to take the time to gather additional data would cause the Agency to fall farther behind that timetable. The result was one apparently not anticipated by Congress at the time section 307(a) was drafted, namely, that the hearing record, though voluminous, might not contain sufficient evidence upon which defensible standards could be promulgated. The proposed standards could not be defended on the record, and no specific modification could be "justified based upon a preponderance of evidence adduced at the hearings" (Section 307(a)(2)).

Faced with the choice between (a) promulgating standards on an insufficient record which were subject to almost certain challenge in court with the likely result of protracted litigation followed by a remand, or (b) taking the time to gather additional data to fill the gaps and make a fresh proposal, the Agency has elected the latter course as the more responsible. The Agency believes that the purpose of the Act is better served by proposing responsible and defensible standards, though late, than by rushing to meet a timetable which experience has shown to be too optimistic.

Question 15. What actions is EPA taking or proposing to take to promulgate these requirements of the 1972 amendments to the Federal Water Pollution Control Act?

Answer. Since the 1974 hearing a number of measures have been taken by the Agency to remedy the problems elicited at the hearing and to provide the data base necessary for standards under section 307(a). The results of these efforts, insofar as they relate to the four substances for which standards are proposed at this time, are discussed more fully below. The principal areas of data gathering are briefly identified as follows:

First, the Agency has substantially expanded its data base with respect to the toxicity and environmental behavior and effects of the substances. This is in accord with the language of section 307(a) which requires the Administrator, both in the selection of substances and in the publication of standards, to consider "the toxicity of the pollutant, its persistence, degradability, the usual of potential presence of the affected organisms in any waters, the importance of the affected organisms and the nature and extent of the effect of the toxic pollutant on such organisms. . . ."

The data include human health effects to the extent available. Although human beings are not enumerated in section 307(a) among the organisms sought to be protected thereunder, other sections of the Act as well as the legislative history make it clear that Congress intended human health effects to be considered under section 307(a). Section 402(k), dealing with implementation of limitations and standards through the National Pollutant Discharge Elimination System (NPDES) permit program, accords special weight to "any standard imposed under section 307 for a toxic pollutant injurious to human health." The definition of "toxic pollutant" in section 502(13) describes a number of illustrative health effects of concern in human as well as aquatic organisms, and expresses concern with "ingestion through food chains" of toxic pollutants. Man as a consumer of fish and other aquatic organisms, occupies a critical position in such food chains, and is thereby directly exposed to any toxic pollutant present in such organisms. He may also be exposed through ingestion of or contact with the water itself in which such pollutants are or may be present.

The legislative history of the Act further indicates that one of its fundamental objectives was protection of human health. The following language appears in the Report of the Senate Committee on Public Works discussing the definition of "toxic pollutant" in section 502(13) referred to above: "A definition of toxic substances is provided to assist the Administrator in implementing his authority under section 307 to regulate toxic discharges. The definition provides a benchmark for evaluating those pollutants which in certain concentrations would have a particularly adverse impact on humans as well as other forms of life." S.

Rept. No. 92–414, 92nd Cong., 1st Sess., October 28, 1971, p. 77, reprinted in "A Legislative History of the Water Pollution Control Act Amendments of 1972" (hereinafter cited as "Legis. Hist.") at p. 1495.

The Report then proceeds to describe some of the features of a toxic pollutant which the Committee expected the Administrator to consider in the exercise of his authority under section 307 including, among others, "the seriousness and irreversibility of any effects on man or the environment that might occur" and "the possibility for incorporation into biological organisms and man in concentrations which the latest scientific knowledge suggest will produce effects on man and organisms," S. Rept., 92–414 at p. 78; Legis. Hist. at p. 1496. The public health concern is also reflected in the Report at p. 3–4, Legis. Hist. at p. 1421–2.

Second, the Agency has given further attention to measuring and monitoring technology capability in considering new standards. Third, it has reconsidered its hydrological assumptions. Fourth, the Agency has gathered additional data and has reassessed its previously accumulated data with respect to discharge of particular pollutants by particular industrial point sources categories.

In addition, though not specifically required to do so under the language of section 307(a), the Agency has gathered data on available control technologies as well as on the economic impact of the imposition of such controls. Section 307(a) is, by its terms, concerned primarily with protection of environmental health, including that of aquatic organisms, humans, and others along the food chain (c.f. section 502(13)). Thus the Agency could set standards on the authority of this section without regard to technology constraints or economic impact. However, the statute does not preclude consideration of such factors, and in light of the claims raised by industry objectors at the previous hearings the Agency has concluded that the interests of responsible rulemaking are best served by giving at least some consideration to technological factors and the likely impact, if any, of the proposed regulations on the national economy. This approach has received judicial approval in other contexts.

Consideration of technological factors, and by implication economic impact, appears in the legislative history of the Act with reference to section 307(a)(5), which requires the Administrator to "designate the category or categories of sources to which the effluent standard, or prohibition shall apply." Congress clearly expected different levels of standards for different categories of industrial sources.

Section 307(a)(5), as explained in the Committee reports, authorizes EPA to establish toxic standards at different levels for different categories of point sources. The only basis for establishing different levels for different point source categories would appear to be technological or economic differences in the various control techniques involved. If the standards were to be based solely on health or environmental effects there would be no basis for distinguishing among point source categories.

A further indication that the Administrator is allowed to give some consideration to such factors can be inferred from the language of sections 307(a)(1) and (2). These sections require that, both in publishing a list of toxic pollutants and in developing effluent standards for them, the Administrator shall take into account "the importance of the affected organisms." The statute does not say in relation to what the importance is to be considered. However, if the importance of the affected organisms is to be given a meaningful role in determining the stringency of the standards, it is a reasonable inference that Congress had in mind a consideration of their importance in relation to other important social and economic values.

Based upon the foregoing considerations, the Agency has concluded that it is authorized to give at least some consideration to the economic impact, including the availability of control technology, in setting standards under section 307(a), even though such factors must always be given less weight than the environmental and public health factors for which the standards must, under section 307(a)(4), provide "an ample margin of safety."

Apart from the Act itself, economic impact must be considered by the Agency under Executive Order No. 11821, 39 F. R. 41501 (signed November 27, 1974). This order and the implementation guidelines issued by the Office of Management and Budget, OMB Circular A–107, require federal agencies, including EPA, to assess the economic and inflation impact of proposed regulations and standards and make a determination as to whether or not the proposal is likely to have a significant impact on inflation. If it is concluded that such impact is likely, an Inflation Impact Statement (IIS) must be prepared by the Agency

which evaluates, among other things, the probable effects of the regulations on costs, productivity, competition, and supplies of goods and services. In compliance with this Executive Order, it is the Agency's practice to make sufficient examination and assessment of the likely economic impact of its regulations to determine whether or not an IIS is required, and to prepare such a statement in all cases where it is required. Such an assessment has been made in connection with the present proposed rulemaking.

Question 16. When does EPA propose to promulgate standards under section 307?

Answer. The EPA has proceeded to the point of interagency review for the direct discharge toxic pollutant effluent standards for four of the substances (pesticides) with proposed rulemaking expected in midsummer, 1976. Additional proposed rulemaking efforts for benzidine and PCB's are expected shortly thereafter.

Proposal of pretreatment regulations is expected contemporaneously with the direct discharge standards or shortly thereafter.

Questions 17 and 18. Why has the EPA failed to publish a final list of hazardous pollutants under section 311 of the Federal Water Pollution Control Act? Has not the EPA been charged with this duty under section 311 since 1970?

Answer. Under section 12 of the 1970 Act, the President was authorized to designate a list of hazardous substances. After such a designation, the President would be empowered to take mitigating actions to remove discharged substances. No liability or penalty provisions were established in section 12 of the 1970 Act.

The authority to designate hazardous substances was transferred to EPA shortly after formation of the Agency in December of 1970. EPA soon launched several contract and in-house studies aimed at defining the hazardous substance problem and providing a basis for their designation. During the summer of 1972, a proposed designation list was drafted and in final stages of review. At this time, however, it became apparent that significant amendments in the form of §311 were imminent. Because these amendments would require additional regulations to implement the hazardous substance program, it was decided to delay proposal of the designation until the fate of the bill became known. Passage of the Federal Water Pollution Control Act Amendments of 1972 created §311 and added, among other things, the following new provisions for the control of hazardous substances: (1) That a determination of actual removability must accompany the designation of hazardous substances; (2) that a determination of the harmful quantity of each hazardous substance must be made before mandatory reporting, removal liabilities, and civil penalties were activated; (3) that a determination of units of measurement and penalty rates be made within six months of any designation of nonremovable hazardous substances; (4) that a civil penalty could be assessed for the discharge of nonremovable substances; (5) that dischargers of removable hazardous substances could be held liable for removal costs; (6) that a criminal penalty could be levied for failure to notify the Federal government of a hazardous substance discharge in excess of the harmful quantity; and (7) that prevention and removal regulations are required.

Thus, in order to take the first step in implementing §311, it was necessary to promulgate regulations which: (1) designated hazardous substances; (2) determined their actual removability; (3) established the harmful quantity of each substance; and (4) determined penalty rates for nonremovable substances either concurrently or within a short time period.

The complex interrelationships and requirements of these four key regulations raised several technical and administrative questions. One of these is that removability must be determined for materials whereas experience has shown that the characteristics of the water body receiving the discharge is the controlling factor dictating the removability of the chemical. As an example, even very soluble chemicals can be removed from water by chemical or physical means if the receiving water is a contained body such as a small lake. On the other hand, virtually no substance can be removed effectively from a rapidly flowing river.

Another area of technical concern is the determination of the harmful quantity. This determination must also be made on the properties of the substance. Again, the technical reality is that the potential for actual harm is often dictated by the size and character of the receiving water. An attempt was made to establish various harmful quantities which depended on the size and character of water bodies. For example, the harmful quantity would be different for a small stream than for a large river, lake, estuary, or offshore waters.

The problem encountered in this approach is that the harmful quantity triggers mandatory reporting and criminal penalties for failure to do so. Transportation sources such as trucks and railroads would experience discharges to a myriad of different types of water bodies. It would be very difficult for them to know when a report is required. Operators are ill-equipped to differentiate between large, medium and small streams, lakes, or estuaries. There are technical difficulties in defining where a river ends and an estuary begins, or which quantity applies when the discharge is to a tributary to a lake. Because criminal penalties are possible, the reportable discharge (harmful quantity) for transportation sources should be simple, clear, and applicable to all water bodies. Derivation of a harmful quantity for fixed facilities meets similar but less complex problems. Because the receiving water is known, it could be argued that the harmful quantity should be individually tailored for every facility by considering the flow and biological character, as well as the size of each receiving water body. However, such an approach is not amenable to a single national regulation.

In regard to the penalty rate, it is recognized that the rate applies to substances themselves rather than sources or circumstances of discharges. The sources of hazardous substances discharges range from gallon-size containers to tank trucks to massive tank ships and barges. A penalty rate which would result in a significant level of penalty for discharges equal to the volume of a tank truck would yield penalties exceeding the $5 million limit for the discharge of volumes equal to those of the average barge. Conversely, a penalty rate which would yield a penalty of $5 million for the discharge of a volume equal to that of the average barge of the most toxic chemical would result in insignificant penalties for tank-truck-sized discharges.

The solutions to these and other complex problems in implementing §311 were not easy matters. The decisions leading to the publication of proposed rules on December 30, 1975, were backed by detailed technical studies, coordination within EPA and with other Federal agencies, as well as the interested public. As a result of the proposed rules, 144 written comments were received and reviewed. Although some problem areas yet remain, final promulgation of the four key regulations is anticipated in the next few months.

Question 19. Has the EPA recommended that §311 be changed because it is not implementable?

Answer. Administrator Train's testimony on H.R. 9560 supported the proposed amendments to §311 on the basis that they would alleviate some of the remaining problems related to hazardous substances discharges and quite possibly lead to a more defensible set of regulations.

We believe §311 can be implemented in the manner proposed in EPA's four regulations on December 30, 1975. However, it must be recognized that legal challenges will almost certainly be made to those regulations. If those challenges are successful, we may find it necessary to actively seek amendments to § 311.

Question 20. Do you believe another agency could more expeditiously carry out the requirements of section 311?

Answer. In view of the vast amount of background already established by the EPA, the publication of proposed rules, and the anticipated final rule promulgation in the near future, we believe it would be unwise to transfer authority for section 311 at the present time.

Question 21. Why did the EPA exclude from its proposed list of pollutants under section 311 cancer-causing pollutants?

Answer. Carcinogenesis, mutagenesis, teratogenesis, and other long-term chronic toxic effects were considered as possible criteria for the selection of hazardous substances under section 311. These effects were not included in the derivation of the initial list of hazardous substances proposed on December 30, 1975, because the priority problem to be addressed by section 311 was that of the non-routine, non-continuous, spill-type discharge. Data dealing with chronic effects traditionally have been developed by exposing test animals to the material for long periods of time. Few, if any, data are available which document the expression of cancer as a result of a single exposure to a chemical. It was our belief that basing the initial list on acute toxicity data, which are generally available and accepted, would place the rules on a more firm and readily available basis.

It is our intent to expand the initial list as data and resources permit. We will continue to examine data relative to cancer and other chronic effects. When adequate supporting documentation is developed, EPA will expand the selection criteria and the application of section 311.

Question 22. What program does EPA have underway to identify and set standards for toxic emissions under the Clean Air Act?

Answer. A formal procedure exists within EPA for selection, review and assessment of candidate toxic materials as well as the scheduled review of criteria for existing air quality standards. Under this procedure: candidate air pollutants are selected by the National Academy of Sciences and EPA experts; scientific background documents are prepared by EPA staff, the National Academy of Sciences and EPA contractors; public critique is received by experts outside the Agency via EPA's Science Advisory Board; finally a recommendation on the need for and nature of regulatory action is made. If regulatory action is determined necessary, appropriate standards for each pollutant are established; alternatives provided under the Clean Air Act include hazardous air pollutant standards, national ambient air quality standards or standards of performance for new sources.

Question 23. Is EPA satisfied that only beryllium, mercury, asbestos and possibly vinyl chloride are the only toxic emissions that need to be regulated under the Clean Air Act?

Answer. Beryllium, asbestos and mercury are currently regulated under national emission standards for hazardous air pollutants, while regulations for controlling vinyl chloride as a hazardous air pollutant have been proposed. Consequently, we assume that the term "toxic emissions" as used above is synonymous with "hazardous emissions" under the Clean Air Act. These four pollutants are the only ones identified to date for which the health effects were determined to be sufficiently severe and the data base adequate to support their regulation as hazardous air pollutants. A number of other potential air pollutants are currently under study within EPA; an example list is enclosed. Should any of these pollutants be found to cause adverse human health effects at ambient concentrations, EPA will take appropriate action.

Enclosure.

AIR POLLUTANT ASSESSMENT REPORTS CURRENTLY BEING PREPARED WITHIN OFFICE OF AIR QUALITY PLANNING AND STANDARDS

POLLUTANTS

Acetylene	Formaldehyde
Acrylonitrile	Maleic anhydride
Acetone	Methyl alcohol
Adipic acid	Methyl methacrylate
Benzene	Nitrobenzene
Carbon tetrachloride	O-xylene (1,3 dimethylbenzene)
Cresols	Perchloroethylene
Cyclohexanone	Phthalic anhydride
Dimethyl terephthalate	Toluene
Ethylene dibromide	Trichloroethylene
Ethylene dichloride	Vinylidene chloride

Question 24. What actions is the EPA taking in response to the recommendations in the GAO report of December 4, 1975?

Answer. We are in the process of preparing a letter to Chairman Brooks which will detail our response to the GAO report. As soon as this letter has been sent to Chairman Brooks, we will be pleased to forward a copy to Chairman Moorhead as well.

Question 25. What is the scope of EPA's research effort in the area of setting standards for toxic emissions under the Clean Air Act?

Answer. To support the EPA's standard setting process under the regulatory authority of the Clean Air Act as amended, the EPA conducts a multidisciplinary research program to develop the adequate scientific data base on a variety of toxic atmospheric pollutants that potentiate harmful health and welfare effects. In order to develop the necessary scientific information, the research program is oriented toward identifying the effects of toxic substances once they are released to the atmosphere, developing methods to measure and characterize the toxic emissions at the source and in the ambient air and developing control technologies to minimize their release into the air. A considerable amount of EPA's research effort addresses pollutants emitted from mobile and stationary sources. For example, in the area of mobile sources, the research effort focuses on pollutants such as sulfuric acid, hydrogen cyanide, nitrosamines, hydrogen sul-

fide, polynuclear aromatics, heavy metals, organics, emitted from catalyst and non-catalyst equipped vehicles.

In the stationary source area, research is conducted to support regulations under New Source Performance Standards and national emissions for Hazardous Air Pollutants. The major stationary source pollutants studied include asbestos, beryllium and mercury, vinyl chloride and other chlorinated hydrocarbons, and heavy metals.

To accelerate EPA's current research program and to initiate new studies in the area of carcinogen research, EPA received incremental FY–76 funds to determine the concentrations, sources and health effects associated with potential carcinogens found in selected urban atmospheres.

Question 26. What is the EPA's response to criticism from the agricultural community that the Agency's nine "principles of carcinogenicity" do not have an adequate scientific basis? Is further work underway to improve the reliability of these principles?

Answer. Dr. Roy E. Albert, Deputy Assistant Administrator for Health and Ecological Effects, has written a letter of April 2 to Mr. C. E. Howes, President of the Council for Agricultural Science and Techniques (CAST), discussing the CAST task force's report on the nine "principles of carcinogenicity" and describing the Agency's current views on the regulation of carcinogens. A copy of this letter is attached to provide the committee with our response to the criticism raised by the CAST task force.

Dr. Albert also heads the Cancer Assessment Group (CAG). The CAG is developing procedures for evaluating and describing risks and subsequently to review the health aspects of all cancer decisions in the Agency. These risk assessment procedures are being presented to other Federal agencies, such as HEW (NIH, NIEHS and FDA) as well as outside scientists for review. These procedures will give EPA an agreed-upon methodology to deal with carcinogens and other chronic pollutants.

MASTER SHEET
REREGISTRATION CATEGORY IV ALPHABETICAL

SS	PM#	COMMON NAMES	CHEMICAL AND BIOLOGICAL NAMES	TRADE AND OTHER NAMES	USES	REASON IN IV	
013601	32		Ammonium arsenite			Cancer	Decision undergoing
064601	99		Anilinocadmium dilactate			Cancer; Testicular atrophy	
006801	23		Arsenic acid; Orthoarsenic acid		H,X	Cancer	Decision undergoing
006802	12		Arsenic pentoxide			Cancer	Decision undergoing
006901	12		Arsenic sulfide		R	Cancer	Decision undergoing
007001	23		Arsenic trioxide		R	Cancer	Decision undergoing
008801			Benzene, Benzol		I		
008901	15	BHC	Benzene hexachloride, other isomers		I	Cancer	Hearing underway - awaiting results of study (Fed. Reg. Notice prepared last year - not released)
062501	13		2-(p-tert-Butylphenoxy)-1-methylethyl 2-chloroethyl sulfite	Aramite, Aracide	I	Cancer	
012501	23	Cacodylic acid	Dimethylarsinic acid	Silvisar 510	H,X	Cancer	Decision Undergoing

012502	23	Cacodylic acid, sodium salt	Dimethyl-arsenic acid, sodium salt			Cancer	Decision underway
021005	21		Cadmium-calcium-copper-zinc-sulfate-chromate complex		F	Cancer	Testicular atrophy
012901	21		Cadmium carbonate		F	Cancer	Testicular atrophy
012902	21		Cadmium chloride		F	Cancer	Testicular atrophy
012903	21		Cadmium sebacate		F	Cancer	Testicular atrophy
012904	21		Cadmium succinate		F	Cancer	Testicular atrophy
012905	21		Cadmium sulfate		F	Cancer	Testicular atrophy
013806	23		Cadmium acid methanearsonate			Cancer	Decision undergoing
013501	12		Calcium arsenate; Tricalcium arsenate			Cancer	Decision undergoing
013602	12		Calcium arsenite; Monocalcium m-arsenite			Cancer	Decision undergoing
014501	21		Calcium ethylenebisdithiocarbamate	Dithane-calcium	F	Thyroid cancer	
013801	12		Calcium propanearsonate			Cancer	Decision undergoing
016501	11		Carbon tetrachloride		I	Cancer	
079301	21	Chloranil	Tetrachloro-p-benzoquinone	Spergon	F	Possible carcinogen	

058201	15	Chlordane	60% Octachloro-4, 7-methanotetra-hydroindane and 40% related compounds	Ortho-klor	I	Cancer	Hearing in progress
028801	13	Chloro-benzilate	Ethyl 4,4'-di-chlorobenzilate		I	Cancer	
020701		Chloroform	Trichloromethane			Cancer	
018401	99		Chloromethoxy-propylmercuric acetate			Embryo-toxic	Hearing in progress
025004	24		Coal tar, creosote		I,F,D	Cancer	
075003	11	Compound 1080	Sodium fluoro-acetate		M,R	Pop-ulation reduction to non target organ-isms	Hearing delayed awaiting results of study
022401	12		Copper arsenite			Cancer	Decision undergoing
025801	99		Cyanogon chloride				
011301	21	DBCP	1,2-Dibromo-3-chloropropane	Nemagon; Fumazone	N,I,F	Stomach Cancer	
078801	25	Di-allate	S-(2,3-Dichloro-allyl)diisopropyl-thiocarbamate	Avadex	H	Cancer	
014502	21		Diammonium ethylene bis-dithiocarbamate	Amoban		Thyroid Cancer	
001401	34		Dichloro-s-tri-azine-2,4,6-(1H 3H, 5H) trione; Dichloroisocy-anuric acid		A,S		
038001	16	Dimethoate	O,O-Dimethyl S-[(methylcarbamoyl) methyl] phosphor-odithioate		I	Cancer	
039303	35		Dimethyldode-cylaminoacetate	Penar	CANCELLED		

066001	22		Di(phenylmercury) dodecenylsuccinate		F	Embryo-toxic	Hearing in progress
038001			Di-n-propylmaleate isoasfrole condensate; n-Propyl isome			Cancer	
063301	35		Disodium cyano-dithiomidocarbonate		D		
013802	23	DSMA	Disodium methanearsonate		H	Cancer	Decision undergoing
010001	17		Beta, beta'-dithiocyano diethyl ether	Lethane A79	I		
013805	23		Dodecylammonium methanearsonate			Cancer	Decision undergoing
041601	11		Endrin			Hazard to non target and endangered species	
041505	22		Ethylmercury phosphate		F	Embryo-toxic	Hearing underway
041801	12	EPN	O-Ethyl O-p-nitrophenyl phenyl-phosphonothioate		I	Delayed neuro-toxicity	
028701	25	Erbon	a-(2,3,5-Trichlorophenoxy) ethyl 2,2-dichloropropionate		H	Dioxin	Delayed Hearing
042002		Ethylene dibromide	1,2-Dibromoethane		F	Stomach Cancer	
044801	15	Heptachlor	Heptachlorotetrahydro-4,7-methanoidene and related compounds		I	Cancer	Hearing underway (active)

045302	99		3,4,5,6,7,7-Hexachloro-N-(methylmercuri)-1,2,3,6-tetrahydro-3,6-endomethanopthalimide	Memmi		Embryotoxic	Hearing undergoing
048001	23		Lead acetate		F	Cancer	
013502	16		Lead arsenate		I,F,P	Cancer	Decision undergoing
013503	16		Lead arsenate, basic			Cancer	Decision undergoing
009001	15	Lindane	Camme isomer of benzene hexachloride		I		
013808	23	MAMA	Monoammonium methanearsonate		H	Cancer	Decision undergoing
014504	21	Maneozeb	Zinc ion and manganese ethylenebisdithio carbamate	Dithane M-45; Manzate 200	F	Thyroid Cancer	
014505	21	Maneb	Manganese ethylenebisdithiocarbamate	Manzate; Dithane M-22	F	Thyroid Cancer	
074901	25	Merphos	Tributyl phosphorotrithioate	Folex	X	Delayed Neurotoxicity	
052001	22		Mercuric chloride	Corrosive sublimate	F	Embryotoxic	Hearing
052102	22		Mercuric oxide		F	Embryotoxic	Hearing
052201	22		Mercurous chloride	Calomel	F	Embryotoxic	Hearing
052301	22		Mercury, metallic		F	Embryotoxic	Hearing
053201	99		Methyl bromide; Bromomethane		H,I,F N,R		

051902	22		Methyl mercury quinolinolate	Matasol	F	Embryo-toxic	Hearing
039201	12	Mirex	Dodecachlor-ooctahydro-1,3,4-metheno-1H-cyclo-buta[cd]pentalene		I	Cancer	Hearing
052001	22		Mercuric chloride	Corrosive sublimate	F	Embryo-toxic	Hearing
052102	22		Mercuric oxide		F	Embryo-toxic	Hearing
052201	22		Mercurous chloride	Calomel	F	Embryo-toxic	Hearing
052301	22		Mercury, metallic		F	Embryo-toxic	Hearing
053201	99		Methyl bromide; Bromomethane		H,I,F N,R		
051902	22		Methyl mercury quinolinolate	Matasol	F	Embryo-toxic	Hearing

039201	12	Mirex	Dodecachloroocta-hydro-1,3,4-meth-eno-1H-cyclobuta [cd]pentalene	I	Cancer	Hearing
016801	25	Monuron	3-(p-Chlorophen-yl)-1,1-dimethyl-urea	H	Cancer	
013903	23	MSMA	Monosodium acid methanearsonate	H	Cancer	Decision undergoing
014803	21	Nabam	Disodium ethylene-bisdithiocarbamate	F	Thyroid Cancer	
013804	25		Octyl ammonium methanearsonate	F	Cancer	Decision undergoing
015603	17		Oil of camphor sasafrassy	I	Cancer	
012602	22		10,10'-Oxybis-phenarsazine		Contains Arsenic (Cancer)	Decision undergoing
012601	22		10,10'-Oxybisphen-oxarsine	F,S	Contains Arsenic (Cancer)	Decision undergoing

022601	99	Paris green	Copper aceto-arsenite			Cancer	Decision undergoing
063001	24	PCP	Pentachlorophenol		H,I,F K	Photo-degrades to Dioxins	
063901	24		Phenarsazine chloride		H	Cancer	Decision undergoing
066003	22		Phenyl mercuric acetate	PMA	D	Embryo-toxic	Hearing
066004	22		Phenylmercuric ammonium acetate		F	Embryo-toxic	Hearing
066023	22		Phenylmercuric ammonium propionate		F	Embryo-toxic	Hearing
066005	22		Phenylmercuric borate		F	Embryo-toxic	Hearing

006006	22	Phenylmercuric carbonate	F	Embryo-toxic	Hearing
066024	22	Phenylmercuric 2-ethylhexoate; Phenylmercuric octanoate	F	Embryo-toxic	Hearing
066010	22	Phenylmercuric formamide	F	Embryo-toxic	Hearing
066012	22	Phenylmercuric lactate	F	Embryo-toxic	Hearing
066022	22	Phenylmercuric oleate	F	Embryo-toxic	Hearing
066018	22	Phenylmercuric propionate	F	Embryo-toxic	Hearing
066021	22	Phenylmercuric triethanol ammonium lactate	F	Embryo-toxic	Hearing

066502	11		Phosphorous		R,I		
			Polychlorinated terphenyls	Arodor	I	Cancer	
014601	21	Polyram	Mixture of ammoniate of [Ethylenebis(dithiocarbamato)]zinc and ethylenebis [dithiocarbamato]		F	Thyroid Cancer	
014507	21		Potassium ammonium ethylene-bisdithiocarbamate	Kaybam	F	Thyroid Cancer	
091403	34		Potassium-dichloro-s-triazinetrione; potassium dichloroisocyanurate; Potassium dichlorocyanerate	CDE 59, ACL 59	D,A,S		
052107	22		Potassium mercuric iodide; Potassium tetraidomercuriate		F	Embryotoxic	Hearing underway

101701	25	Promamide	3,5-Dichloro-N-(1,1-dimethyl-2-propymyl)-benzamide	Kerb	H	Cancer	
069501	22		Pyridylmercuric acetate		F	Embryo-toxic	Hearing
058301	14	Ronnel	0,0,-Dimethyl 0-(2,4,5-Trichlorophenyl) phosphorothioate	Korlan; Trolene	I	Derived from 2,4,5-T' (dioxins)	
097901	11		Safrole		R	Cancer	
052501	23	Silvex	2,4,5-Trichlorophenoxypropionic acid, salts, and esters		H	Dioxin contaminant	Delayed hearing
013603	23		Sodium arsenite; Sodium metaarsenite		H,I	Cancer	Decision undergoing

074002	11	Sodium cyanide		I	Population reduction to non-target organisms	Hearing delayed awaiting results of study
001404	34	Sodium dichloro-s-triazinetrione; Sodium dichloro-isocyanonate	CDB 60	D,A,S		
078901	99	Sodium ethylmercurithisalicylate; [O-(Carboxyphenyl)thio]ethyl mercury	Thimersol		Embryotoxic	Hearing underway
013401	12	Sodium pyroarsenate			Cancer	Decision undergoing
099701	12	Sperm oil		I	Endangered Species	

020481	12	Strobane	Terpene poly-chlorinates	I		
076901	11	Strych-nine	Strychnine (alkaloids)	R,B,M	Popula-tion reduc-tion to non tar-get or-ganisms	Hearing delayed awaiting results of study
076902	11	Strych-nine	Strychnine sulfate	R,B,M	Popula-tion reduc-tion to non tar-get or-ganisms	Hearing delayed awaiting results of study
087101	17	Sulfoxide	1,2,-(Methylene-dioxy)-4-[2(octyl-sulfinyl)-propyl] benzene; m-Octyl sulfoxide of isosafrole	I	Cancer	
082001	23	2,4,5-T	2,4,5-Trichloro-phenoxyacetic acid, salts and esters	H	Dioxin Contam-inant	Delayed Hearing

080001	11		Thallium sulfate		R,M	Population reduction to non target organisms	Hearing delayed awaiting results of study
010101	17		Beta Thiocyanoethyl esters of mixed fatty acids containing 10 to 18 carbon atoms	Lethane 60	I		
078802	25	Triallate	S-(2,3,3-Trichloroallyl)diisopropylthiocarbamate	Avadex BW	H	Cancer	
001402	34		S-Triamine-3,4,6-triol, potassium salt; Cyanuric acid, potassium salt; Potassium cyanurate		D,A		

074801	25		S,S,S-Tributyl phosphorotrithioate	Def	X	Delayed Neurotoxicity	
067901	16	Trichlorfon	Dimethyl (2,2,2-trichloro-1-hydroxyethyl)-phosphonate	Dipterex; Dylox	I	Cancer	
064210	22		2,4,5-Trichlorophenol and salts		F	Dioxin contaminant	Delayed hearings
001408	34		Trichloro-s-triazinetrione; Trichloroisocyanuric acid		D,A,S		
021004	21		Zinc mercury chromate			Embryotoxic	Hearing underway
014506	21	Zineb	Zinc ethylenebisdithiocarbamate		F	Thyroid Cancer	

U.S. ENVIRONMENTAL PROTECTION AGENCY,
OFFICE OF RESEARCH AND DEVELOPMENT,
Washington, D.C., April 2, 1976.

Mr. C. E. HOWES,
President,
Council for Agricultural Science and Technology,
Post Office Box 157,
Blacksburg, Va.

DEAR MR. HOWES: Mr. Train asked me to respond to your letters of December 5, 1975, and January 19, 1976, with the appended CAST task force report entitled, "The Environmental Protection Agency's Nine 'Principles' of Carcinogenicity."

There are many statements in the CAST report that disturb me, regarding chemical carcinogenesis and the consideration of both risks and benefits in decision making, but I will confine my comments to topics where, I believe, the report's characterization of EPA policy is most at odds with the Agency's actual policy concerning pesticides.

It is exceedingly difficult and perhaps impossible to summarize in a few sentences the scientific aspects of a field as complicated as chemical carcinogenesis. The summary statements prepared by the EPA's legal counsel in one of the Aldrin-Dieldrin briefs were meant to be interpreted only in the context of the large amount of scientific testimony to which these statements related. The Administrator's statements on these matters in various regulatory decisions have likewise been based upon the information presented in testimony by various scientists and in numerous scientific reports.

I am particularly disturbed by certain suggestions in the task force report that the pesticides suspended or cancelled by EPA have not been "proved" to cause cancer in man. This places the burden of proving safety on the public, rather than placing the burden of proving safety on the industry involved, as required by law.

It might be helpful to briefly describe the EPA's current views on the regulation of carcinogens. The EPA must regard any environmental agent that shows evidence of potential carcinogenic activity for humans as a grave threat to health. This is so because there is extensive evidence that physical and chemical agents in the environment play a significant causal role in human cancer.

At the present time, we must rely heavily on chronic exposure tests on rodents to identify suspect carcinogens. There is solid evidence for the general credibility of these animal tests, although a much better understanding of the reasons for the similarities and differences is needed. The uncertainties in the scientific basis for relating animal cancer tests to human health have led to vigorous differences of opinion on the interpretation of test results with respect to regulatory action.

The EPA's position is that any positive evidence of tumorigenicity in animals should be regarded as a signal that the agent could be a human carcinogen, and should prompt serious consideration of regulatory action. Each suspect agent must be evaluated carefully in terms of the quality and adequency of the carcinogenesis data including estimates of the impact of current exposure to human cancer.

The report states that EPA "overlooks the benefits associated with the use of the chemicals." This is incorrect. The ultimate regulatory decision for suspect carcinogens is based on a careful weighing of the health risks and the socio-economic consequences of regulatory action to the extent authorized by law (40 C.F.R. § 162.11 (a) (5) (iii)). I have attached a copy of our procedures, which require the consideration of both risk and benefits in decisionmaking on pesticides, for your use.

We look forward to further communications from you on this difficult but important subject.

Sincerely yours,

ROY E. ALBERT, M.D.
Deputy Assistant Administrator for
Health and Ecological Effects.

Enclosure.

[From the Federal Register, Vol. 40, No. 129, July 3, 1975]

§ 162.11 Criteria for Determinations of Unreasonable Adverse Effects.

(a) *Criteria for Issuance of Notice of Intent to Deny Registration, Cancel Registration, or to Hold a Hearing.* (1) *Presumption.* (i) A rebuttable presumption shall rise that a notice of intent to deny registration pursuant to section 3(c)(6) of the Act, a notice of intent to cancel registration pursuant to section 6(b)(1) of the Act, or a notice of intent to hold a hearing to determine whether the registration should be cancelled or denied, as appropriate, shall be issued, upon a determination by the Administrator that the pesticide meets or exceeds any of the criteria for risk set forth in subparagraph (3). Upon such determination, the Administrator shall issue notice by certified mail to the applicant or registrant, as the case may be, stating that the applicant or registrant has the opportunity to submit evidence in rebuttal of such presumption in accordance with subparagraph (4) of this section. The applicant or registrant shall have forty-five (45) days from the date such notice is sent to submit evidence in rebuttal of the presumption; provided, however, that for good cause shown the Administrator may grant an additional sixty (60) days in which such evidence may be submitted.

(ii) At any time an applicant or registrant may petition the Administrator to withdraw his application or terminate his registration. The Administrator may, in his discretion, deny any petition for withdrawal or for termination and proceed in accordance with these regulations.

(2) *Rebuttal of Presumption.* The party seeking new or continued registration may rebut the presumption arising under subparagraph (1) by sustaining the affirmative burden or proof set forth in subparagraph (4) of this § 162.11(a). After review of the evidence submitted in rebuttal of the presumption, the Administrator shall determine in accordance with subparagraph (4) of this § 162.11(a) whether the applicant or registrant has sustained his affirmative burden and shall issue notice of such determination in accordance with subparagraph (5) of this section.

(3) *Risk Criteria.* A rebuttable presumption shall arise if a pesticide's ingredient(s), metabolite(s), or degradation product(s) meet or exceed any of the following criteria for risk, as indicated by tests conducted with the animal species and pursuant to the test protocols specified in the Registration Guidelines, or by test results otherwise available.

(i) *Acute toxicity.* (A) *Hazard to Humans and Domestic Animals.* (1) Has an acute dermal LD_{50} of 40 mg/kg or less as formulated; or

(2) Has an acute dermal LD_{50} of 6 g/kg or less as diluted for use in the form of a mist or spray;

(3) Has an inhalation LC_{50} of 0.04 mg/liter or less as formulated.

(B) *Hazard to Wildlife.* (1) Occurs as a residue immediately following application in or on the feed of a mammalian species representative of the species likely to be exposed to such feed in amounts equivalent to the average daily intake of such representative species, at levels equal to or greater than the acute oral LD_{50} measured in mammalian test animals as specified in the Registration Guidelines.

(2) Occurs as a residue immediately following application in or on avian feed of an avian species, representative of the species likely to be exposed to such feed in amounts equivalent to the average daily intake of such representative species, at levels equal to or greater than the subacute dietary LC_{50} measured in avian test animals as specified in the Registration Guidelines.

(3) Results in a maximum calculated concentration following direct application to a 6-inch layer of water more than ½ the acute LC_{50} for aquatic organisms representative of the organisms likely to be exposed as measured on test animals specified in the Registration Guidelines.

(ii) *Chronic Toxicity.* (A) Induces oncogenic effects in experimental mammalian species or in man as a result of oral, inhalation or dermal exposure; or induces mutagenic effects, as determined by multitest evidence.

(B) Produces any other chronic or delayed toxic effect in test animals at any dosage up to a level, as determined by the Administrator, which is substantially higher than that to which humans can reasonably be anticipated to be exposed, taking into account ample margins of safety; or

(C) Can reasonably be anticipated to result in significant local, regional, or national population reductions in nontarget organisms, or fatality to members of endangered species.

(iii) *Lack of Emergency Treatments.* Has no known antidotal, palliative, or first aid treatments for amelioration of toxic effects in man resulting from a single exposure.

(4) *Burden of Proof.* Upon finding in accordance with subparagraph (1) of this § 162.11(a) that notice pursuant to sections 3(c)(6) or 6(b)(1) of the Act, or notice of intent to hold a hearing to determine whether the registration should be cancelled or denied, as appropriate, shall issue on the basis that a pesticide meets or exceeds any of the criteria for risk set forth in subparagraph (3), the party seeking new or continued registration may rebut the presumption by sustaining the burden of proving:

(i) In the case of a pesticide which meets or exceeds the criteria for risk set forth in paragraphs (a)(3)(i), or (iii) that when considered with the formulation packaging, method of use, and proposed restrictions on and directions for use and widespread and commonly recognized practices of use, the anticipated exposure to an applicator or user and to local, regional or national populations of nontarget organisms is not likely to result in any significant acute adverse effects; or

(ii) In the case of a pesticide which meets or exceeds the criteria for risk set forth in paragraph (a)(3)(ii) that when considered with proposed restrictions on use and widespread and commonly recognized practices of use, the pesticide will not concentrate, persist or accrue to levels in man or the environment likely to result in any significant chronic adverse effects.

(iii) That the determination by the Agency that the pesticide meets or exceeds any of the criteria for risk was in error.

(5) *Notice of Administrator's Determination.* (i) If after review of the evidence submitted in rebuttal, the Administrator determines that the applicant or registrant, as the case may be has rebutted the presumption by sustaining the affirmative burden of proof set forth in subparagraph (4) of this § 162.11(a) then, if the application or registration is otherwise in compliance with the Act and these regulations, in accordance with section 3(c) and 6(b) of the Act he will register the pesticide for such use or continue any such registration already in effect. In the case of an application for registration for which notice of approval is required to be published pursuant to § 162.7(d)(2), such notice shall state that the Administrator has determined that the presumption has been rebutted within the time provided for submission of rebuttal evidence. Such notice shall refer to the appropriate clause of § 162.11(a)(4)(i)-(ii) upon which the Administrator bases his determination that the presumption has been rebutted.

(ii) If the applicant or registrant, as the case may be, fails to submit any evidence in rebuttal, or if after review of the evidence submitted in rebuttal the Administrator determines that the applicant or registrant has not rebutted the presumption by sustaining the affirmative burden of proof set forth in subparagraph (4) of this § 162.11(a), then he shall issue a notice in accordance with sections 3(c)(6), or 6(b)(1) of the Act or, issue notice of intent to hold a hearing to determine whether the registration should be cancelled or denied, as appropriate, for the use(s) of the pesticide subject to such presumption and not rebutted. The Administrator shall issue such notice within one hundred and eightly (180) days from the date notice is sent to the applicant or registrant in accordance with subparagraph (1) of this § 162.11(a).

(iii) At the time that a registrant or applicant submits evidence in rebuttal of the presumption, he may submit evidence as to whether the economic, social and environmental benefits of the use of the pesticide subject to the presumption out-weigh the risk of use. In determining whether to issue a notice pursuant to section 3(c)(6) or section 6(b)(1) or to issue notice of intent to hold a hearing to determine whether the registration should be cancelled or denied, in accordance with paragraph (a)(5)(ii) of this section 162.11, the Administrator may, in his discretion, take into account staff recommendations resulting from preliminary analysis, if any, concerning the balancing of risks against benefits. Any such preliminary analysis shall be completed within one hundred and fifty (150) days from the date notice is sent to the applicant or registrant in accordance with subparagraph (1) of this § 162.11(a). If based on such analysis the staff recommendation is that benefits appear to outweigh risks, the Administrator may, in his discretion, issue notice of intent to hold a hearing to determine whether the registration should be cancelled or denied rather than a notice pursuant to section 6(b)(1) or section 3(c)(6) of the Act. If the recommendation is that the benefits do not appear to outweigh the risks, the

Administrator shall issue a notice pursuant to section 3(c)(6) or section 6(b)(1) of the Act, as appropriate.

(6) *Additional Grounds for Issuance of Notice of Intent to Deny or Cancel Registration or to Hold a Hearing.* A notice pursuant to sections 3(c)(6) or 6(b)(1), or a notice of intent to hold a hearing to determine whether the registration should be cancelled or denied, as appropriate, shall be issued by the Administrator with respect to any pesticide which does not meet or exceed the criteria for risk set forth in subparagraph (3) of this §162.11(a), if the Administrator determines:

(i) That, based on toxicological data, epidemiological studies, use history, accident data, monitoring data, or such other evidence as is available to the Administrator, the pesticide poses a substantial question of safety to man or the environment, or

(ii) That the pesticide or its labeling or other material required to be submitted does not comply with the requirements of the Act or when used in accordance with widespread and commonly recognized practice, the pesticide generally causes unreasonable adverse effects on the environment.

(b) *Criteria for Issuance of a Final Order of Denial or Cancellation of Registration.* (1) *Burden of Proof.* (i) If the Administrator issues a notice pursuant to sections 3(c)(6) or 6(b)(1) of the Act in accordance with subparagraphs 5(ii) or (6) of § 162.11(a), he shall issue a final order denying or cancelling the registration unless the applicant or registrant or other affected party as provided by law, requests a hearing in accordance with sections 3(c)(6) or 6(b)(1) of the Act and 40 CFR Part 164 and sustains the affirmative burden of proving that the pesticide ingredient(s), metabolite(s) or degradation product(s) does not cause unreasonable adverse effects on the environment or man by showing:

(A) In the case of a pesticide which meets or exceeds the criteria for risk set forth in subparagraphs 3(i), and (iii) of § 162.11(a), that when considered with the formulation, packaging, method of use, proposed restrictions on use and the directions for use, and widespread and commonly recognized practice of use, the anticipated exposure to an applicator or user and to local, regional or national populations of non-target organisms is not likely to result in any significant acute or subacute adverse effects; or

(B) In the case of a pesticide which meets or exceeds the criteria for risk set forth in subparagraph 3(ii) of § 162.11(a), that when considered with proposed restrictions on use and widespread and commonly recognized practices of use, the pesticide will not concentrate, persist or accrue to levels likely to result in any significant chronic adverse effects; or

(C) In the case of a pesticide which meets or exceeds the criteria for risk set forth in subparagraph (3) (i), (ii) or (iii) of § 162.11(a), the risks are outweighed by economic, social and environmental benefits of use of the pesticide.

(ii) If the Administrator issues a notice of intent to hold a hearing to determine whether the registration should be cancelled or denied, in accordance with subparagraphs (5)(ii) and (6) of § 162.11(a) the Administrator shall issue a final order cancelling the registration unless:

(A) The notice is withdrawn prior to the commencement of the hearing upon a determination by the Administrator that there is insufficient public interest in the proceeding to warrant holding the hearing or that it would not otherwise serve the public welfare; or

(B) The Administrator determines that based on the record:

(1) In the case of a pesticide which meets or exceeds the criteria for risk set forth in subparagraphs (3) (i) and (iii) § 162.11(a), that when considered with the formulation, packaging, method of use, proposed restrictions on use and the directions for use, and widespread and commonly recognized practice of use, the anticipated exposure to an applicator or user and to local, regional or national populations of nontarget organisms is not likely to result in any significant acute adverse effects; or

(2) In the case of a pesticide which meets or exceeds the criteria for risk set forth in subparagraph (3)(ii) of § 162.11(a), that when considered with proposed restrictions on use and widespread and commonly recognized practices of use, the pesticide will not concentrate, persist or accrue to levels likely to result in any significant chronic adverse effects; or

(3) In the case of a pesticide which meets or exceeds the criteria for risk set forth in subparagraph (3) (i), (iii), of § 162.11(a), the risks are out-

weighed by the economic, social and environmental benefits of use of the pesticide.

(2) *Additional Grounds for Issuance of a Final Order of Denial or Cancellation of Registration.* (i) If the Administrator issues a notice of denial of registration or a notice of intent to cancel registration in accordance with subparagraph (6) of § 162.11(a), he shall issue a final order denying or cancelling registration unless the applicant or registrant or other affected party as provided by law:

(A) Requests a hearing in accordance with sections 3(c)(6) and 6(b)(1) of the Act and 40 CFR Part 164; and

(B) Sustains the affirmative burden of proving that the pesticide does not cause unreasonable adverse effects on the environment or man;

(ii) If the Administrator issues a notice of intent to hold a hearing to determine whether the registration should be cancelled or denied, in accordance with subparagraph (6) of § 162.11(a), he shall issue a final order cancelling registration unless;

(A) The notice is withdrawn prior to the commencement of the hearing upon a determination by the Administrator that there is insufficient public interest in the proceeding to warrant holding the hearing or that it would not otherwise serve the public welfare; or

(B) The Administrator determines that based on the record of the hearing the pesticide does not cause unreasonable adverse effects on the environment or man.

(c) *Use classification.* (1) *Classification criteria for new registrations.* Except as provided in paragraph (c)(4) of this section, a specific use(s) of a pesticide product not previously registered shall be classified for general use if each of the applicable criteria set forth in paragraph (c)(1)(i)–(iii) of this section is met. Otherwise, the product use(s) shall be classified for restricted use unless a review of the labeling pursuant to paragraph (c)(3) of this section indicates that the product use may be classified for general use or the benefits from unrestricted use of the pesticide outweigh the risks of unrestricted use of the pesticide. Each of the separate criteria as set forth below must be applied for the product use(s) to be classified unless the formulation, packaging, or method of use of the product can reasonably be expected to eliminate the route of exposure. New data submitted to support classification must conform to the specifications of the Registration Guidelines.

(i) *Domestic applications.* A pesticide use(s) intended for domestic application will be a candidate for general use classification if the pesticide formulation:

(A) Has an acute dermal LD_{50} greater than 2,000 mg/kg;

(B) Has an inhalation LC_{50} greater than 2 mg/liter;

(C) Causes no corneal opacity, or causes eye irritation reversible within 7 days or less;

(D) Causes no more than moderate skin irritation within 72 hours;

(E) Has an acute oral LD_{50} greater than 1.5 g/kg for the formulation as diluted for use; and

(F) Causes, under conditions of label use or widespread and commonly recognized practice of use, only minor or no discernible subacute, chronic, or delayed effects on man or other nontarget organisms from single or multiple exposures to the product ingredient(s), their metabolite(s), or degradation product(s).

(ii) *Nondomestic applications.* A pesticide use(s) intended for nondomestic application will be a candidate for general use classification if the pesticide formulation:

(A) Has an acute dermal LD_{50} greater than 200 mg/kg;

(B) Has an acute dermal LD_{50} greater than 16 g/kg for the formulation as diluted for use as a mist or spray;

(C) Has an inhalation LD_{50} greater than .2 mg/liter;

(D) Is not corrosive to the eye or causes corneal opacity reversible within 7 days;

(E) Is not corrosive to the skin and causes no more than severe skin irritation within 72 hours; and

(F) Causes under conditions of label use, or widespread and commonly recognized practice of use, only minor or no discernible subacute, chronic, or delayed toxic effects on man or other nontarget organisms from single or multiple exposures to the product ingredient(s), their metabolite(s), or degradation product(s).

(iii) *Outdoor applications.* A pesticide use(s) intended for outdoor application will be a candidate for general use classification if it meets the applicable set of criteria set forth immediately above for either domestic or nondomestic application, as appropriate, and if the pesticide:

(A) Occurs as a residue immediately following application in or on the feed of a mammalian species representative of the species likely to be exposed to such feed in amounts equivalent to the average daily intake of such representative species, at levels less than 1/5 the acute oral LD_{50}, measured in mammalian test animals as specified in the Registration Guidelines.

(B) Occurs as a residue immediately following application in or on the feed of an avian species representative of the species likely to be exposed to such feed in amounts equivalent to the average daily intake of such representative species, at levels less than 1/5 the subacute dietary LC_{50} measured in avian test animals as specified in the Registration Guidelines.

(C) Results in a maximum calculated concentration following direct application to a 6-inch layer of water less than 1/10 the acute IC_{50} for aquatic organisms representative of the organisms likely to be exposed as measured in test animals as minor or no discernible adverse effects on the physiology, growth, population levels, or reproduction rates of nontarget organisms, resulting from exposure to the product ingredients, their metabolites or degradation products, whether due to direct application or otherwise resulting from application, such as through volatilization, drift, leaching or lateral movement in soil.

(2) *Classification criteria for previously registered products.* All pesticide products registered by this Agency prior to October 21, 1974 have been assigned a Toxicity Category [see § 162.10(h)(1)]. Unless the applicant for reregistration submits or has submitted the toxicity data on the product use(s) required in paragraph (c)(1) of this section, the existing Toxicity Category determinations shall be used to establish whether the pesticide use(s) is a candidate for general or restricted use classification. Except as provided in paragraph (c)(4) of this section, specific use(s) of a product shall be classified for general use if the applicable criteria set forth in paragraph (c)(2) (i)–(iii) of this section are met. Otherwise, the product use shall be classified for restricted use unless a review of the labeling pursuant to paragraph (3) below indicates that the use may be classified for general use or the benefits from unrestricted use of the pesticide outweigh the risks of unrestricted use of the pesticide. Each of the separate criteria as set forth below must be applied for the product use(s) to be classified unless the formulation, packaging, or method of use of the product can reasonably be expected to eliminate the route of exposure.

(i) *Domestic applications.* A pesticide use(s) intended for domestic application shall be a candidate for general use classification if the pesticide formulation:

(A) Does not meet the criteria of Toxicity Category I or II; and

(B) Causes, under conditions of label use, or widespread and commonly recognized practice of use, minor or no discernible subacute, chronic, or delayed effects on man or other nontarget organisms from single or multiple exposures to the product ingredients, their metabolites, or degradation products.

(ii) *Nondomestic applications.* A pesticide use(s) intended for nondomestic application shall be a candidate for general use classification if the pesticide formulation:

(A) Does not meet the criteria of Toxicity Category I; and

(B) Causes, under conditions of label use, or widespread and commonly recognized practice of use, only minor or no discernible subacute, chronic, or delayed toxic effects on man or other nontarget organisms from single or multiple exposures to the product ingredients, their metabolites, or degradation products.

(iii) *Outdoor applications.* A pesticide use(s) intended for outdoor application will be a candidate for general use classification if it meets the applicable set of criteria set forth immediately above for either domestic or nondomestic application as appropriate, and if the pesticide:

(A) Occurs as a residue immediately following application in or on the feed of a mammalian species representative of the species likely to be exposed to such feed in amounts equivalent to the average daily intake of such representative species, at levels less than one-fifth the acute oral ID_{50} measured in mammalian test animals as specified in the Registration Guidelines.

(B) Occurs as a residue immediately following application in or on the feed of an avian species representative of the species likely to be exposed to such

feed in amounts equivalent to the average daily intake of such representative species at levels less than one-fifth the subacute dietary LC_{50} measured in avian test animals as specified in the Registration Guidelines.

(C) Results in a maximum calculated concentration following direct application to a 6-inch layer of water less than one-tenth the acute LC_{50} for aquatic organisms representative of the organisms likely to be exposed as measured in test animals as specified in the Registration Guidelines.

(D) The pesticide causes, under conditions of label use, or widespread and commonly recognized practice of use, only minor or no discernible adverse effects on the physiology, growth, population levels, or reproduction rates of non-target organisms, resulting from exposure to the product ingredients, their metabolites, or degradation products, whether due to direct application or otherwise resulting from application, such as through volatilization, drift, leaching or lateral movement in soil.

(3) *Adequacy of label and labeling.* The directions, warnings, and cautions for any product use(s) not meeting the criteria set forth in paragraphs (c)(1) and (2) of this section shall be further evaluated according to the criteria set forth below to determine the adequacy of the label or labeling to prevent unreasonable adverse effects on man or the environment. If these criteria are met, the labeling for the affected uses will be considered adequate to prevent unreasonable adverse effects on the environment without further regulatory restrictions, and the affected uses will be classified for general use. The criteria for evaluating labeling adequacy are as follows:

(i) To follow label directions, the user of a pesticide product would not have to perform complex operations or procedures requiring specialized training and/or experience;

(ii) Failure to follow the use directions in any minor way would result in minor or no discernible adverse effects;

(iii) Widespread and commonly recognized practices of use would not nullify label directions relative to prevention of unreasonable adverse effects on man and the environment;

(iv) The directions do not call for specialized apparatus, protective equipment or material unless they would be expected to be available to the general public;

(v) Following directions for use would result in only minor or no discernible adverse effects of a delayed or indirect nature, such as through bioaccumulation, persistence, or pesticide movement from the original application site, on nontarget organisms.

(4) *Other Hazards.* Any product use(s) which meets the general use criteria of paragraph (c) (1), (2), or (3) of this section shall nonetheless be classified for restricted use if the Agency determines that based on human toxicological data (including epidemiological studies), use history, accident data, monitoring data, or such other evidence as the Administrator identifies the product use(s) may pose a serious hazard to man or the environment which can reasonably be prevented by classification for restricted use.

(5) *Other regulatory restrictions.* Any product use(s) classified for restricted use under the provisions above may be limited to use by or under the direct supervision of a certified applicator. The Administrator may additionally or alternatively impose other restrictions by regulation. Such regulatory restrictions may include, but are not limited to, seasonal or regional limitations, limitation of use to approved pest management programs, or a requirement for monitoring of residue levels after use, and may be utilized to reduce human health and environmental hazards associated with persistent, bioaccumulative, or mobile, or highly toxic pesticides. Any such regulation shall be reviewable in the appropriate Court of Appeals upon petition of a person adversely affected filed within 60 days of the publication of such regulation in final form.

(d) *Change in classification from general to restricted use.* (1) *Determination and notification.* If the Administrator determines that a change in classification of any pesticide product use(s) from general to restricted use is necessary to prevent unreasonable adverse effects on man or the environment he shall, by certified mail, notify the registrant of such pesticide of such determination at least 30 days before reclassifying, and shall publish notice of the proposed reclassification in the FEDERAL REGISTER.

(2) *Appeal rights.* Within 30 days following publication of the notice in the FEDERAL REGISTER, the registrant, or a person adversely affected by the notice may request a hearing as provided for in section 6(b) of the Act and Part 164 of these regulations.

Mr. MOORHEAD. And also where there have been technical questions asked of you that you were unable to answer that you will supply those answers for the record.

Mr. ZENER. Yes, sir.

Mr. MOORHEAD. I must say that I leave this hearing somewhat persuaded that the GAO report conclusion is justified and that it has not been rebutted by today's hearing.

They concluded:

> The American consumer has not been adequately protected from the potential hazards of pesticide use because of inadequate efforts to implement provisions of the Federal laws regulating pesticides.

I hope that when your technical people answer some of the questions that have been posed that you can rebut that statement.

If there are no further questions the subcommittee will stand adjourned.

[Whereupon, at 12:10 p.m., the subcommittee adjourned, to reconvene subject to the call of the Chair.]

70-134 O - 76 - 8

APPENDIXES

Appendix 1.—Excerpts From Federal Register, Vol. 41, No. 32, February 17, 1976 [1]

U.S. Environmental Protection Agency,
Washington, D.C., February 20, 1976.

To Whom It May Concern: The enclosed document "Data Requirements to Support Reregistration of Pesticide Active Ingredients and Preliminary Schedule of Call-ins" (41 FR 7218), is the first in a series of Federal Register notices announcing the schedule which the Office of Pesticide Programs will follow in calling in pesticide products for reregistration.

That this is the first of several similar documents must be emphasized; the enclosed list of pesticide active ingredients is not final. All of the active ingredients currently assigned to reregistration category V will be reassigned to categories I through IV as the relevant data are reviewed, and as noted (p. 7219), the initial assignments to category IV, i.e. those active ingredients which are subject to a rebuttable presumption against reregistration, will be announced as soon as the basis of the presumption is verified and the affected registrants have been notified.

The Federal Register notices announcing these category reassignments will begin in early April and will appear monthly thereafter.

[From the Federal Register, Vo. 41, No. 32, February 17, 1976]

Environmental Protection Agency

[FRL 488–8; OPP–33002]

PESTICIDE PROGRAMS

Data Requirements To Support Reregistration of Pesticide Active Ingredients and Preliminary Schedule of Call-Ins

This notice announces the schedule which will be followed by the Office of Pesticide Programs (OPP) of the Environmental Protection Agency (EPA) in calling in pesticide products for reregistration in accordance with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

APPLICABLE LAW AND REGULATIONS

FIFRA amendments enacted in October 1972 (P.L. 92–516, 86 Stat. 973, 7 U.S.C. 136 et seq.) set forth a statutory standard for determining whether or not a pesticide will be registered. The standard is whether or not the pesticide will or will not generally cause unreasonable adverse effects on man or the environment. EPA was authorized to adopt regulations to implement this standard and did so on July 3, 1975 (40 CFR 162, 40 FR 28242); these regulations became effective August 4, 1975.

The amendments enacted in October 1972 also provide that all pesticides registered under the EPA regulations in effect prior to the amendments were to be reregistered in accordance with the amended FIFRA and the regulations promulgated thereunder. In accordance with other provisions of the 1972 amendments, all pesticides also must be assigned a general-use or restricted-use classification. On November 28, 1975, pursuant to Public Law 94–140, the deadline for completion of this process was extended from October 21, 1976, to October 21, 1977.

[1] Complete document is in the subcommittee's files.

The process of bringing previously registered products into compliance with the new FIFRA requirements is called "reregistration." It is a one-time process which should not be confused with the process of registration renewal, which, under Section 6(a) of FIFRA, occurs every five years for every registered pesticide product.

The EPA regulations appearing at 40 CFR 162 (more specifically, at Sections 162.1 through 162.23) set forth the basic substantive requirements, including labeling and data requirements, for reregistration. On addition, EPA issued Procedural Guidelines on September 9, 1975 (40 FR 41788); they appear at 40 CFR 162.41 through 162.51. Proposed Guidelines (40 CFR 162.40 and 40 CFR 162.63 through 162.82) identifying and describing generally acceptable ways of satisfying registration data requirements were published June 25, 1975 (40 FR 26802).

DATA REQUIREMENTS

Data requirements for both registration and reregistration are set forth at 40 CFR 162.8. Subsection 162.8(c) spells out the specific data requirements for reregistration; subsection 162.8(d) provides that additional data other than those specifically identified in subsection 162.8(c) may also be required. Subsection 162.8(a) sets forth rules for waivers of data requirements.

For the convenience of readers of this notice, the specific data requirements for reregistration, and the conditions under which they are applicable, are summarized below:

A. Toxicity data necessary for determination of the acute oral (dietary) LD50 for mammalian species, the subacute dietary LC50 for avian species, and the acute LC50 for aquatic organisms (unless use patterns do not result in exposure of such species or organisms).

B. Data to evaluate the teratogenicity of the active ingredient(s) if uses of the pesticide may reasonably be expected to result in exposure to human females.

C. Data to evaluate the oncogenicity of the active ingredient(s) if the active ingredient(s), its metabolite(s), or degradation product(s) contains a substance structurally related to a known or suspected oncognetic agent or if a residue tolerance or exemption from the requirement to obtain a tolerance is necessary.

D. Chronic feeding studies of the active ingredient(s) if a tolerance or exemption from the requirement to obtain a tolerance is necessary or if use in residences, enclosed working spaces, or their immediate vicinity is intended.

E. Reproduction studies of the active ingredient(s) if a tolerance or exemption from the requirement to obtain a tolerance is necessary.

F. Foliar residue and exposure information for products containing cholinesterase-inhibiting ingredients or any other ingredients specified in the Registration Guidelines.

G. Information in support of safe methods of disposal of pesticide formulations and containers.

If any of the foregoing requirements can be satisfied by data previously submitted in support of pesticide registration, such data need not be resubmitted; they can be included by reference in a reregistration application. If previously submitted data are to be considered, however, then the requirements of Section 3(c)(1)(D) of FIFRA regarding compensation for such data will be applicable.

DATA WAIVERS

Under 40 CFR 162.8(a)(3), data requirements may be selectively waived for individual applications by the Administrator, either on his own intiative or in response to an applicant's petition. Such a waiver may be granted only on the basis of a written finding that the properties of an active ingredient or pesticide product or the use patterns of a specific pesticide product, which are pertinent to an evaluation of the effects of that pesticide or pesticide product on man or the environment, are fundamentally different from the factors taken into account by EPA in establishing the data requirement(s) in question. In other words, a waiver may be granted if the data in question are not needed by EPA to determine whether the active ingredient or pesticide product will generally cause unreasonable adverse effects on man or the environment.

There will be many different situations in which data waivers might be initiated by EPA or requested by registrants. Each one must be evaluated on the basis of the pertinent facts. When EPA takes the initiative in granting data

waivers, notification of the waiver will be included in the Reregistration Guidance Packages supplied to the registrants of the products involved (see below for a description of Reregistration Guidance Packages). When each Guidance Package is completed, a copy will be made available for public inspection in the Office of the Federal Register Section, Technical Services Division (WH–569), Office of Pesticide Programs, Environmental Protection Agency, Room 401, East Tower, 401 M St. SW, Washington, DC 20460, from 8.30 a.m. to 4:00 p.m., Monday through Friday (202–755–4854), to provide information to any interested parties on EPA's implementation of the data waiver provisions of 40 CFR 162.

Waivers of data requirements may be requested either in advance of or at the time of submittal of reregistration applications. Such requests must be made in writing and must be addressed to the appropriate product manager. They must identify the specific data requirements to be waived, the specific active ingredients and/or pesticide products for which the waiver is requested, and must provide a detailed explanation of the basis for the requested waiver.

REBUTTABLE PRESUMPTIONS

As explained above, the statutory standard for determining whether or not a pesticide is to be registered or reregistered is whether or not it will generally cause unreasonable adverse effects on man or the environment. 40 CFR 162.11 (a)(3) sets forth criteria for distinguishing between those pesticides which appear to cause unreasonable adverse effects and those which do not appear to do so. Pesticides that do not meet or exceed these criteria, and which do not in any other way appear to cause unreasonable adverse effects, will be registered, *provided*, of course, that applicable labeling, data, and other requirements are satisfied.

Pesticides which meet or exceed the criteria set forth at 40 CFR 162.11(a)(3) will have to undergo a more detailed evaluation. They will be subject to a rebuttable presumption against reregistration, which can be overcome by evidence showing either that EPA was in error in determining that a rebuttable presumption existed or that the risk can be reduced to such an extent that significant adverse effects are unlikely to occur. When neither of these showings can be made, registrants will have an opportunity to obtain registration by showing that the benefits of the use or uses of the product exceed the risks. A more detailed explanation appeared in the preamble to 40 CFR 162 in the FEDERAL REGISTER published July 3, 1975 (40 FR 28212) and at 40 CFR 162.45(d) in the Procedural Guidelines issued September 9, 1975 (40 FR 41788). Pesticides which are subject to a rebuttable presumption against registration will not be processed for reregistration until the presumption to overcome or until it is determined that benefits exceed risks.

REREGISTRATION PROCESS

Pesticides which are not subject to a rebuttable presumption against registration will be called in for reregistration processing in accordance with a schedule established by OPP's Registration Division. As indicated in the Procedural Guidelines at 40 CFR 162.43(f), the Registration Division will call pesticides in by batches. A batch will consist of products grouped on the basis of similarity of pesticide formulations and broad use patterns. At the scheduled time, all registrants of products included in a batch will be furnished a Reregistration Guidance Package and will be asked to submit their reregistration applications for each product.

Reregistration Guidance Packages will include a schedule for submittal of reregistration applications, guidance on compliance with Section 3(c)(1)(D), proposed classification of products in the batch, requisite wording of precautionary statements required on labeling, acceptable statements on storage and disposal, and guidance on data requirements (explained below in more detail). Applications should not be submitted until they are requested. Unsolicited applications for reregistration will be returned without review.

To assist registrants in identifying data that can be used to meet reregistration requirements, EPA is examining its files to locate previously submitted data that are relevant. The data are then reviewed to determine if they are sufficient to meet the reregistration data requirements set forth at 40 CFR 162.8(c). Data determined to be sufficient will be cited in a bibliography ap-

pearing in the Reregistration Guidance Packages. Again, it is emphasized that provisions of Section 3(c)(1)(D) will be applicable in cases of reliance on previously submitted data.

Where examination of the Registration Division's files indicates that required data are not in EPA's possession, registrants will be required to submit these data within a specified time period. Thus, for example, if required data on a particular active ingredient are not available in the Agency's files, all registrants of products containing that active ingredient will be required either to submit the necessary data or to indicate reliance upon specific data being submitted by another registrant (unless, of course, a waiver is granted). When new studies must be performed to develop missing data, affected registrants are encouraged to cooperate with one another in order to avoid duplication of effort and expense. To facilitate such cooperation, the Reregistration Guidance Packages for each batch of products will be accompanied by the names and addresses of all registrants whose products are in the batch.

REREGISTRATION CATEGORIES

For purposes of reregistration, active ingredients of products registered under the regulations which were superseded by the new registration regulations will be assigned to one of five categories based on EPA's review of the relevant data available in the Registration Division's files, published literature, and other sources. The definitions of these categories are as follows:

Category I: An active ingredient is assigned to Category I if all data requirements for reregistration are either satisfied by data available in the Agency's files or are waived. Pesticide products containing only Category I active ingredients will be candidates for full reregistration when applications are solicited by the Registration Division. Reregistration of such products will remain in effect until the first five-year renewal is required, unless, in the interim, suspension or cancellation action is taken.

Category II: An active ingredient is assigned to Category II if data available in the Agency's files are not sufficient for reregistration and if the necessary testing cannot reasonably be expected to be completed prior to October 1977. Thus, when the missing data relate to teratogenicity or oncogenicity, or to the results of chronic feeding, reproduction, foliar residue, or exposure studies, assignment of the active ingredient to Category II will be in order. A product containing any Category II active ingredients will be a candidate for conditional reregistration when applications are solicited by the Registration Division, provided that the available data indicate that the product otherwise meets the requirements for reregistration. Conditional reregistrations will be effective for a specified time period reasonable to allow completion of the required testing and submittal of the required data.

Category III: An active ingredient is assigned to Category III if the data available in the Agency's files are not sufficient for reregistration and if the necessary testing can reasonably be expected to be completed by October 1977. Thus, where data on acute or subacute toxicity to mammalian or avian species or aquatic organisms are missing, assignment to Category III will not be considered for either full or conditional reregistration until the necessary data or aquatic organisms are missing, assignment to Category III will be in order. A product containing any active ingredients assigned to Category III will not be considered for either full or conditional reregistration until the necessary data are provided. If required data have not been submitted by the time for the scheduled call-in, registrations of all products containing the ingredient in question will be subject to cancellation.

Category IV: An active ingredient is assigned to Category IV if it equals or exceeds any of the risk criteria set forth in 40 CFR 162.11(a)(3) and is thus subject to a rebuttable presumption against reregistration. Assignment to Category IV takes precedence over assignment to Categories I, II, or III; thus when the properties of an active ingredient are such as to give rise to a rebuttable presumption against reregistration, the chemical is not assigned to any of the other categories. However, the properties of some individual products may equal or exceed the rebuttable presumption criteria, even though the properties of the ingredient did not.

Whenever a rebuttable presumption arises, whether against reregistration of an ingredient, of a product, or of certain uses of a product, all affected registrants will be notified of the presumption directly, by certified mail.

There is no list attached of ingredients in Category IV. Initial assignments to this category will be announced in the *Federal Register* as soon as the basis of the presumption is verified and the affected registrants have been notified.

Category V: An active ingredient is assigned to Category V if EPA's review of the relevant data has not reached the point at which it can be assigned to one of the other categories. Assignments of these active ingredients to other categories will be announced periodically in the *Federal Register.*

SPECIAL CONSIDERATIONS

Assignment to the above categories is made from evaluation of data pertaining to active ingredients. Differing characteristics of individual product formulations and use paterns may result in some variations in data requirements. The reregistration guidance package will specify the applicable data requirements for the products included in the package.

For those products involving mixtures of active ingredients the requirements for each component chemical must be satisfied. Thus, if any of the active ingredients fall in Category III, the required data must be provided before the product will be considered for reregistration. Upon satisfaction of the Category III requirements, the product would be considered for full or conditional reregistration, depending upon the category to which the other active ingredients have been assigned.

STATUS OF PESTICIDES IN LITIGATION

Pesticide ingredients which are involved in administrative hearings are now assigned to Category V, and will not be reassigned to other categories or processed for reregistration until the proceedings are concluded. On the date of publication of this notice, no suspension actions were pending, and the following pesticide ingredients were the subject of administrative hearings: Chlordane/Heptachlor, Mirex, and Mercury compounds. If a final determination permitting continued registration is made before October 21, 1977, the products involved will be categorized and considered for reregistration. If proceedings are not concluded by October 21, 1977, guidance as to any actions necessary to allow continued registration will be provided.

PUBLIC PARTICIPATION

The appended lists, grouped by reregistration category, include all active ingredients contained in currently registered products. These lists identify with coded entries the unsatisfied data requirements for ingredients in Categories II and III, and for all ingredients, the Product Manager (PM) responsible for pesticides containing each ingredient. Keys to the abbreviations used precede the lists.

All communications regarding any aspect of reregistration should be addressed to the appropriate Product Manager. Addressing such communications to other EPA personnel will result in delays.

Any registrant or other interested party who has information which might affect the category assignments shown in the appended lists is encouraged to submit the information to the appropriate Product Manager for Agency consideration. Any such submissions should be in writing and should include a complete citation of the data in question (including, if the data were previously submitted, a complete reference to the registration action for which they were submitted) and/or a copy of the data. Persons who attempt to transmit this information by telephone will be asked to put it in writing.

Copies of all maerials received by the Product Managers in response to this notice, providing they are not protected from disclosure under Section 10 of FIFRA, will be available for public inspection in the office of the Federal Register Section, Technical Services Division (WH-569), Office of Pesticide Programs, Environmental Protection Agency, Room 401, East Tower, 401 M St. SW., Washington, D.C. 20460, from 8:30 a.m. to 4:00 p.m., Monday through Friday.

As ingredients are reassigned from Category V to other categories, and as other shifts of assignment, if any, are made, they will be announced in subsequent FEDERAL REGISTER notices.

GUIDE TO USE OF CATEGORY LISTS

Sequence. The entries in each of the category lists are sequenced alphabetically by preferred chemical name, ignoring any nonsignificant prefix characters. When there is an accepted common name listed, it appears in the entry to the right of the "equals" sign (=).

Uses. The following abbreviations for pesticide uses as employed in the lists of Categories in the column headed "USES" are generally equivalent to the classes of pesticides described in 40 CFR 162.3(ff):

A=Algaecides (as apart from other herbicides).
B=Bird poisons and repellents.
D=Antimicrobial agents (disinfectants, etc., except those specified elsewhere).
F=Fungicides (for crop, industrial, and mildewcide uses).
H=Herbicides (excluding algaecides).
I=Insecticides, acaricides, and insect repellents.
K=Invertebrate animal poisons (molluscicides and anti-fouling chemicals).
M=Mammal poisons and repellents (not including rodenticides).
N=Nematicides.
P=Plant regulators.
R=Rodenticides.
S=Slimicides (principally for paper mills and water cooling systems).
T=Attractants (mainly for insects).
W=Fish poisons and repellents.
X=Defoliants and desiccants.
Z=Amphibian and reptile poisons and repellents.

P.M. Product managers represented by numbers in the column headed "PM" in the Category lists are as follows:

Product manager No.	Name	Telephone No. (area code 202)
11	Miller, William H	755-9315
12	Sanders, Frank T	755-9315
13	Rea, James M	755-9315
15	Gardner, Timothy A	496-9425
16	Gee, Franklin D. R	426-9425
17	Harrison, Gerald	426-9425
21	Wilson, Eugene M	426-2456
22	Lee, John H	426-2456
23	Mountfort, R. F	755-1397
24	Jacoby, Henry M	755-2197
25	Taylor, Robert J	755-7012
31	Tavano, Joseph M	426-2635
32	Geathers, Elmer D	426-9488
33	Banks, James M	755-9041
34	Castillo, Arturo E	426-9490
	Unassigned—Contact	426-2454
	Dave Bowen, Information Officer, Registration Division	

The mailing address for the product managers is: Registration Division (WH-567), Attn: (product manager name) (PM#——), Office of Pesticide Programs, Environmental Protection Agency, 401 M St. SW., Washington, D.C. 20460

Data gaps. The following abbreviations are used in the column headed "DATA GAPS" to indicate unsatisfied data requirements for ingredients in Categories II and III. With respect to the long-term tests, the time period considered reasonable for development and submittal of each kind of study is shown. *This time period will run from the date of receipt of notice of call-in for reregistration, and will coincide with the maximum period for which conditional reregistration may be granted.* When more than one long-term study is required for a single ingredient, the longest time allowed will determine the period of conditional reregistration. Earliest possible data development and submission is nonetheless strongly encouraged in order to minimize the possibility of expiration of the conditional reregistration before review can be completed.

The time period considered reasonable for development and submittal of any required short-term tests is six months, beginning from the date of direct notice to affected registrants of short-term gaps.

	Time allowed for submission (in months)
Long-term tests (category II):	
TER=Teratogenic	12
REP=Reproduction	24
ONC=Oncogenic, oral administration	36
ONC(D)=Oncogenic, dermal administration	36
CHR=Chronic Feeding	36
RN=Foliar residue and exposure	48
Short-term tests (category III):	
AO=Acute oral LD50	--
AD=Acute dermal LD50	--
AI=Acute inhalation LC50	--
EI=Eye irritation	--
DI=Dermal irritation	--
SS=Skin sensitization	--
SD=Subacute dermal	--
MA=Mammalian acute oral (dietary) LD50	--
AV=Avian subacute dietary LC50	--
AQ=Aquatic organism acute LC50	--

Call-in

In the appended lists of ingredients assigned to Categories I, II, and III, the figure in the column headed "CALL-IN" indicate the approximate time at which Reregistration Guidance Packages soliciting applications for reregistration will be distributed. The codes used equate to calendar periods as follows:

Code:	*Calendar period*
1	February to June, 1976.
2	July to September, 1976.
3	October to December, 1976.
4	January to March 1977.
5	April to June, 1977.
6	July to August, 1977.
7	September to October, 1977.

A copy of the list containing the data requirements to support reregistration of pesticide active ingredients and the preliminary schedule of call-ins for these active ingredients will be available for public inspection in the U.S. Environmental Protection Agency Public Information Reference Unit, Room 2922 (EPA Library), 401 M St. SW., Washington, D.C. 20460, as well as in the office of the Federal Register Section, Technical Services Division (WH-569), Office of Pesticide Programs, Room 401, East Tower, 401 M St. SW., Washington, D.C. 20460.

Dated: February 5, 1976.

EDWIN L. JOHNSON,
Deputy Assistant Administrator
for Pesticide Programs.

EPA OFFICE OF PESTICIDE PROGRAMS, SAFETY DATA REQUIREMENTS TO SUPPORT REREGISTRATION OF PESTICIDE PRODUCT ACTIVE INGREDIENTS, CATEGORY I ACTIVE INGREDIENTS. READY FOR FULL REREGISTRATION

(The active ingredients listed below are those for which data in the Environmental Protection Agency's files have been found to be sufficient to support reregistration. Applications for full reregistration of products containing only ingredients in category I will be called in according to the indicated schedule)

Line No.	Chemical code	Chemical name	Uses	PM	Data gap	Call in
1	086003	3-(alpha-acetonylbenzyl)-4-hydroxycoumarin=warfarin, sodium salt of.	R	11		2
2	004002	Allethrin coil	I	17		3
3	004001	Allyl homolog of cinerin I=allethrin	I	17		3
4	066501	Aluminum phosphide	I	11		1
5	013906	Aluminum sulfate	A	25		3
6	101101	4-amino-6-tert-butyl-3-(methylthio)-as-triazin-5(4H)-one.	H	25		5
7	005601	Ammonium sulfate	I, F	25		3
8	054501	Bacillus popilliae and B. lentimorbus. Note: milky white disease.	I	17		3
9	006401	Bacillus thuringiensis (Berliner)	I	17		3
10	008001	Basic copper chloride	F	22		3
11	008101	Basic copper sulfate	F	22		3
12	018501	O,O-bis(P-chlorophenyl)acetimidoylphosphoroamidothioate.	R	11		1
13	011102	Borax or sodium tetraborate decahydrate	D	33		3
14	011001	Boric acid	I	15		3
15	097401	Tert-butylcarbamic acid, ester with 3-(M-hydroxyphenyl)-1,1-dimethylurea=karbutilate.	H	25		3
16	075605	Calcium chloride	D	25, 31, 33		5
17	014701	Calcium hypochlorite	D	34		1
18	015602	Camphor	I, D, F	17		4
19	015601	Camphor oil	I	17		4
20	029002	Chlorinated C3 hydrocarbons (1,2-dichloropropane, 1,3-dichloropropene and other related compounds.	I, N	11		2
21	020501	Chlorine	A, D	34		3
22	019402	P-chlorophenoxyacetic acid, diethanolamine salt of	H, P	24		2
23	081501	Chloropicrin	I, F, N	11		1
24	009901	3-chloro-P-toluidine hydrochloride	B	11		2
25	004004	D-trans chrysanthemum monocarboxylic acid ester of D-2-allyl-4-hydroxy-3-methyl-2-cyclopenten-1-one.	I	17		3
26	022703	Copper ammonium carbonate	F	22		3
27	022901	Copper carbonate	F	22		3
28	023701	Copper chloride (dihydrate)	F	22		3
29	023401	Copper hydroxide	F, I	22		3
30	022702	Copper in the form of an ammonium complex	F	22		3

REPORT TO THE CONGRESS

BY THE COMPTROLLER GENERAL OF THE UNITED STATES

Federal Pesticide Registration Program: Is It Protecting The Public And The Environment Adequately From Pesticide Hazards?

Environmental Protection Agency

Food And Drug Administration (HEW)

GAO found the following conditions:

- --Safety and efficacy data has not been submitted to support marketing many pesticides. (Safety data include information on cancer, genetic changes, birth defects, and reproduction.)
- --Safety and efficacy data is not required for the pesticides as marketed, only for individual active ingredients.
- --Reviews of inert ingredients (such as vinyl chloride) are not subjected to the full range of safety testing.
- --Many labels do not comply with requirements.
- --Pesticide residue tolerances are not monitored or reviewed.
- --The safety of pesticide residues in some foods has not been determined.
- --Statutory registration requirements are not carried out on a timely basis.

RED-76-42

DEC. 4,1975

COMPTROLLER GENERAL OF THE UNITED STATES
WASHINGTON, D.C. 20548

B-133192

To the President of the Senate and the
Speaker of the House of Representatives

This is the third in a series of GAO reports issued to alert the Congress to the shortcomings in the Environmental Protection Agency's efforts to protect man and the environment from the effects of harmful pesticides.

We made our review pursuant to the Budget and Accounting Act, 1921 (31 U.S.C. 53), and the Accounting and Auditing Act of 1950 (31 U.S.C. 67).

Copies of this report are being sent to the Director, Office of Management and Budget; the Secretary of Agriculture; the Secretary of Health, Education, and Welfare; the Chairman, Council on Environmental Quality; and the Administrator, Environmental Protection Agency.

Comptroller General
of the United States

Contents

ABBREVIATIONS

BHC	Benzene hexachloride
EBDC	Ethylene bisdithiocarbamate
ETU	Ethylene thiourea
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
FEPCA	Federal Environmental Pesticide Control Act
FFDCA	Federal Food, Drug and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
GAO	General Accounting Office
HEW	Department of Health, Education, and Welfare
ppm	parts per million
PCNB	Pentachloronitrobenzene
PR	Pesticide regulation

Glossary

Acceptable daily intake	Man's daily intake of a substance during his lifetime which appears to be without appreciable health risk on the basis of all facts known at the time.
Active ingredient	An ingredient in a pesticide which will (1) prevent, destroy, repel, attract, or mitigate any pest, (2) accelerate or retard the growth rate or maturation rate or otherwise alter the behavior of ornamental or crop plants or the product thereof (plant growth regulator), (3) cause the foliage to drop from a plant (defoliant), and (4) artifically accelerate the drying of plant tissue (dessicant).
Acute toxicity	The property of a substance or mixture of substances which causes adverse effects in an organism through a single exposure.
Adulterated	Food or a pesticide formulation containing chemicals or substances at variance with the amounts prescribed by law.
Carcinogenic	The property of a substance or a mixture of substances which produces or incites cancer in a living tissue.
Cholinesterase inhibitor	A substance that inhibits action of cholinesterase, a nervous system enzyme, thereby disrupting nerve activity which can result in death.

Chronic feeding study	A study during the lifetime of test animals involving multiple exposures to substances in their food. The study's purpose is to find a maximum level that induces no toxicological effect and to determine the nature and degree of long-term toxic effects.
Compendium of Registered Pesticides	A compilation of pesticide chemical uses registered by EPA.
Disinfectant	An agent or substance that frees from infection; especially, a chemical that destroys vegetative forms of harmful microorganisms excepting bacterial spores.
Effective	As applied to pesticides the composition of a pesticide product is such to warrant the proposed claims for it.
FEPCA registration program	A program to reregister all existing pesticides registered by EPA (interstate pesticides), as well as those not previously registered by EPA (intrastate pesticides) during the 2-year period ended October 1976. The program was required by the Federal Environmental Pesticide Control Act (FEPCA) of 1972.
Fungicide	Preparations intended for preventing, destroying, repelling, or mitigating any fungi (mushrooms, molds, mildews, rusts, etc.).
Herbicide	Preparations intended for preventing, destroying, repelling, or mitigating unwanted plants or weed plants declared to be pests.

Insecticide	All preparations intended for preventing, destroying, repelling, or mitigating insects.
Inert ingredient	An ingredient in a pesticide other than an active ingredient. Such ingredients are usually added as a solvent, thickener, propellent, or other such uses to enhance the effectiveness or to facilitate the use of the pesticide.
Mrak Commission	A commission established by the Secretary of HEW in 1969 to study pesticides and their relationship to environmental health.
Mutagenic	The property of a substance or mixture of substances which induces genetic changes in subsequent generations.
Negligible residue	An amount of a pesticide residue that is regarded as toxicologically insignificant. EPA has considered this to be less than .1 ppm.
Nontarget species	Those plants and animals (including man) that are not intended to be controlled, injured, killed, or detrimentally affected in any way by a pesticide.
Oncogenic	The property of a substance or a mixture of substances which produces or incites tumor formations in living tissue.

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Pesticide tolerance	A scientifically and legally established limit for the amount of chemical residue permitted to remain in or on a harvested food or feed crop as a result of the application of a chemical for pest-control purposes.
Residue	Active ingredient(s) and dissimilation products that can be detected in crops, soil, food, water, and other components of the environment following the use of the pesticide.
Rodenticide	Preparations intended for preventing, destroying, repelling, or mitigating rodents and closely related species declared to be pests.
Safe	As applied to pesticides, a pesticide product which will perform its intended functions without unreasonable adverse effects on man and the environment, that is, without any unreasonable risk to man or the environment, considering the economic, social, and environmental costs and benefits of the use of the pesticide.
Subacute toxicity	The property of a substance or mixture of substances which causes adverse effects in an organism on repeated exposure within 90 days of the initial exposure.
Synergism	The cooperative action of separate substances so that the total effect is greater than the sum of the effects of the substances acting independently.

Teratogenic	The property of a substance or mixture of substances which produces or incites birth defects, ordinarily not hereditable, in or on an animal embryo or fetus.
Translocation	The attachment of a broken-off segment of one chromosome to another; especially, the exchange of parts between dissimilar chromosomes.

COMPTROLLER GENERAL'S REPORT TO THE CONGRESS

FEDERAL PESTICIDE REGISTRATION PROGRAM: IS IT PROTECTING THE PUBLIC AND THE ENVIRONMENT ADEQUATELY FROM PESTICIDE HAZARDS?

Environmental Protection Agency
Food and Drug Administration
Department of Health, Education, and Welfare

D I G E S T

The American consumer has not been adequately protected from the potential hazards of pesticide use because of inadequate efforts to implement provisions of the Federal laws regulating pesticides which require that

--only effective pesticides be registered (those that will not cause unreasonable adverse effects on human health and the environment) and

--residues of pesticides in food be adequately checked so that consumers are not exposed to harmful levels.

GAO has issued three other reports on shortcomings in the Environmental Protection Agency's program to regulate the use of pesticides.

The Environmental Protection Agency and Food and Drug Administration should determine the additional funds, staff, equipment, and facilities needed to carry out their responsibilities to protect the public from unsafe and ineffective pesticides and should present this information to the Congress. This report contains more than a dozen recommendations for improving the pesticide registration and tolerance programs. (See pp. 22, 36, 48, 65, and 73.)

Registrants have not submitted required studies on such issues as pesticide effects on reproduction, birth defects, and permanent genetic changes for many registered pesticides. The absence of information on pesticides to which much of the population is exposed daily--such

as those in foods and in the environment--means that the Environmental Protection Agency cannot be sure that human health or the environment is being adequately protected.

The Environmental Protection Agency should require this information for all future registrations and registration renewals. (See pp. 7 to 10 and 13 to 15.)

The Agency assesses a pesticide's safety by studying individual active ingredients, not the pesticide as marketed.

There is little or no information on the long-term effects of the pesticide as marketed on human health and the environment, particularly when the formulation contains two or more ingredients which, when combined, may be more toxic than the individual ingredients.

The Environmental Protection Agency should determine whether testing pesticides as marketed should be required. (See pp. 11 to 13.)

Also, its testing requirements for inert ingredients in pesticide formulations are less stringent than those for active ingredients.

Some of the inert ingredients, such as vinyl chloride, may be as hazardous to man and the environment as are the active ingredients. (See pp. 18 to 21.)

GAO's review of 100 randomly selected pesticides noted many instances where required precautionary statements were missing from approved labels and/or required data was missing from Environmental Protection Agency files. (See pp. 27 to 35.)

The law requires that a tolerance (the maximum pesticide residue concentration allowed in food) be established for all pesticides which remain in or on a treated food. Although the Environmental Protection Agency establishes all tolerances for pesticides remaining in food, the Food and Drug Administration is responsible for making sure that residues do not exceed tolerances. (See p. 38.)

Many pesticide tolerances were established before certain safety testing was required. The Environmental Protection Agency does not review periodically the adequacy of data supporting tolerances for pesticide residues on food to insure that such residues are not injurious to consumers.

Consequently, many types of safety data have not been obtained for pesticides with food tolerances. (See pp. 38 to 44.)

Many tolerances, currently in effect, were established in the 1950s without residue data, and therefore, total human exposure to residues of certain pesticides is not known and may exceed safe levels. (See pp. 42 to 44.)

The Food and Drug Administration's residue testing program is limited to about 90 of the approximately 230 active pesticide ingredients for which the Environmental Protection Agency has established tolerances. Food should be periodically tested for all pesticides which might enter the food chain.

The Environmental Protection Agency has registered pesticides for uses resulting in residues on food products, although tolerances for the residues have not been established. (See pp. 44 to 47.)

The Environmental Protection Agency has established a system of interim tolerances to allow using a pesticide while reviewing the tolerance petition. Interim tolerances were sometimes established in cases where (1) questions of safety existed, (2) inadequate data on residue levels was provided, and (3) petitioners submitted no data to support the safety of the proposed uses. (See pp. 51 to 64.)

Under present legal requirements of the Federal Environmental Pesticide Control Act, the Environmental Protection Agency must register about 46,000 pesticides by October 1976 and in addition must process its normal workload. Presently, the Agency does not have the necessary staffing or funding to sufficiently review and register these pesticides within the time frame provided or to assure the public that these pesticides are safe and effective when used according to label directions.

To compound the problem, the Agency was about 9 months late in issuing regulations to be followed in registering the pesticides. (See pp. 67 to 70.)

Pesticide registrations are valid for 5 years and must, by law, be renewed or canceled at the end of this period. However, the Environmental Protection Agency has not been renewing pesticide registrations as required; many pesticides whose registrations are over 5 years old still are being marketed. (See pp. 70 to 72.)

The Environmental Protection Agency stated that the report is an exhaustive and generally excellent study of pesticide registration and tolerance setting. The Agency noted that GAO's observations of the program covered a period during which major changes were made in organization, procedures, and regulations and that many of the problems would be corrected by its new registration regulations or by changes to existing programs in line with recommendations in the report.

However, the Environmental Protection Agency said it would not require the full range of data to support registration under the 1972 act because of limited staff and time. Data including mutagenicity or permanent genetic changes, environmental chemistry, and efficacy (for agricultural pesticides) will not be required. (See pp. 23 and 24.)

The Environmental Protection Agency did not agree to require the full range of safety testing of inert ingredients (see p. 25) or to consider further the need for testing of pesticides as formulated (see pp. 25 and 26). GAO does not concur with the Environmental Protection Agency's waiver of required data for registration under the act or with its intention to require only limited data for inert ingredients and for pesticides as formulated. GAO believes this data necessary for the Environmental Protection Agency to carry out its mandate to register only effective pesticides which will not cause unreasonable adverse effects to man or the environment.

The Department of Health, Education, and Welfare agreed to coordinate future pesticide residue testing with the Environmental Protection Agency but did not concur with GAO's recommendation that the pesticide surveillance program be expanded to include periodic testing of food for all pesticides with tolerances. Health, Education, and Welfare said that its surveillance program detects over 90 of the more persistent and toxic pesticides which for the past 10 years have been well within prescribed limits in food.

GAO recognizes Health, Education, and Welfare's need to concentrate its monitoring activities on those pesticides presenting the greatest hazard. However, GAO does not believe that residues of the more persistent and toxic pesticides are reliable indicators of other pesticide residues. The existing surveillance program should not preclude the periodic testing for other pesticides. (See pp. 49 and 50.)

CHAPTER 1

INTRODUCTION

Pesticides are substances used to control harmful insects, diseases, rodents, weeds, bacteria, and other pests that attack man's food and fiber supplies and threaten his health and welfare. In 1973 (the latest year of available data), 1,289 million pounds of pesticides with a value of $1,493 million were produced in the United States. About 1 billion pounds are used domestically each year--55 percent for agriculture; 30 percent for industrial, institutional, and governmental use; and 15 percent for home and garden use.

Approximately 29,000 pesticide products--including insecticides, rodenticides, herbicides, fungicides, and disinfectants--made from 1 or more of about 1,800 chemicals were registered with the Environmental Protection Agency (EPA) as of January 1975. These pesticides are identifed as follows.

	Number	Percent
Insecticides	14,210	49
Rodenticides	928	3
Herbicides	5,046	17
Fungicides	4,002	14
Disinfectants	4,814	17
Total	29,000	100

Pesticides are a mixed blessing. They are beneficial in that they save lives by controlling disease-bearing insects; minimize crop damage due to insects, weeds, and other pests; and protect households from infestations of flies, roaches, rats, mice, and other pests. Because of these benefits, pesticides have become increasingly important in agriculture production, public health and sanitation, protection of natural resources, and improvement of man's well-being. However, they are also hazardous because they are poisonous to people, animals, and the environment if used improperly or without sufficient knowledge of their side effects. Pesticides can contaminate water, air, or soil and can accumulate in man, animals, and the environment. In addition, persistent pesticides can create potential future hazards to man and wildlife because residues may build up in the food chain and cause widespread contamination of the environment.

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The basic legal authority for regulating pesticides is in (1) the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) of 1947 (7 U.S.C. 135), as amended by the Federal Environmental Pesticide Control Act (FEPCA) of 1972 (7 U.S.C. 136), and (2) the Federal Food, Drug and Cosmetic Act (FFDCA) of 1938, as amended (21 U.S.C. 301). Authority for administering FIFRA was transferred from the Department of Agriculture along with the responsible organizational elements to EPA on December 2, 1970, pursuant to Reorganization Plan No. 3 of 1970 which established EPA.

Because our earlier reports[1] indicated weaknesses in EPA's and FDA's efforts to protect man and his environment from the effects of harmful pesticides and because of the widespread concern about these effects, we reviewed EPA's policies and practices for pesticide registration and establishment of tolerances.

PESTICIDE REGISTRATION

Pesticides are regulated by the Federal Government to insure that quality products are available to the public and that when properly used, these products will provide consumers with effective pest control without unreasonable adverse effects on man or the environment. EPA is the Federal agency with primary responsibility for regulating pesticides.

EPA registers a pesticide when it determines that

--the pesticide's composition is such as to warrant its proposed claims (product efficacy),

--the pesticide's labeling and other material required to be submitted comply with requirements,

--the pesticide will perform its intended function without unreasonable adverse effects on the environment (product safety), and

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[1] Reports on "Environmental Protection Agency Efforts to Remove Hazardous Pesticides From the Channels of Trade" (B-133192, Apr. 26, 1973); "Pesticides: Actions Needed to Protect the Consumer from Defective Products" (B-133192, May 23, 1974); and "Questions on the Safety of the Pesticide Maleic Hydrazide Used on Potatoes and Other Crops Have Not Been Answered" (B-133192, Oct. 23, 1974).

--when used in accordance with widespread and commonly recognized practice, the pesticide will not generally cause unreasonable adverse effects on the environment.

(FEPCA defines unreasonable adverse effects as any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide.) EPA also requires the registration number on the label to indicate that EPA has accepted the pesticide.

Registration is valid for 5 years and must, by law, be renewed at the end of this period, or it is canceled. EPA is required to review registered pesticides to determine if they are still safe and effective in the light of developing scientific data.

On October 21, 1972, FEPCA amended FIFRA to provide for more effective registration, regulation, labeling, manufacture, distribution, and use of pesticides. All FEPCA provisions must be effective by October 21, 1976. The most important change was that all pesticides, except those intended solely for export, be registered with EPA before distribution or sale rather than, as previously required, that only those sold in interstate commerce be registered. FEPCA provisions discussed in this report require EPA to

--establish regulations and guidelines for registering and classifying pesticides,

--register all intrastate and new pesticides and reregister currently registered interstate pesticides by October 21, 1976, in accordance with the newly established regulations,

--classify all pesticides for general or restricted use on the basis of the degree to which they adversely affect the environment.

PESTICIDE TOLERANCES

If a pesticide remains in or on food or feed, FFDCA requires that a tolerance (the maximum pesticide residue allowed in food) be established for that pesticide. Tolerances are established on the basis of data submitted by the petitioner on the nature, level, and toxicity of the pesticide's residues. The Registration Division in EPA's Office of Pesticide Programs establishes all tolerances for pesticide residues remaining in food either

under section 408 (pesticide chemicals in or on raw agricultural commodities) or section 409 (pesticide food additives) of FFDCA. A pesticide is classified as a food additive if it is applied to processed foods or if the concentration of the pesticide increases as the raw agricultural commodity is processed. Before EPA's existence, tolerances were established by the Food and Drug Administration (FDA) of the Department of Health, Education, and Welfare (HEW).

FDA is still responsible under FFDCA for enforcing tolerances. FDA tests samples of food to determine if any residues exceeding tolerance levels remain on the food, rendering the food adulterated. Adulterated foods may not be sold in interstate commerce.

SCOPE OF REVIEW

We reviewed EPA's policies and practices for registering and establishing tolerances for pesticides. We examined pertinent legislation, documents, reports, and records on evaluating pesticide safety and effectiveness; setting tolerance and residue levels; and registering, labeling, and residue testing of pesticides.

We interviewed responsible agency officials at EPA and FDA headquarters in Washington, D.C. We also obtained information from agency officials at EPA regional offices in Philadelphia, Atlanta, and San Francisco and from the Department of Agriculture headquarters in Washington, D.C.

In addition, we randomly sampled product files of 100 registered pesticides to determine the adequacy of EPA registration actions. A breakdown of our sample according to the type of pesticide follows.

	Number and percent
Insecticides	48
Rodenticides	3
Herbicides	16
Fungicides	11
Disinfectants	22
Total	100

The percentages are similar to those for all registered pesticides as shown on page 1 of this report. Our review of the sampled pesticides included

--an evaluation of their labels to determine if they complied with EPA regulations,

--an examination of the registration and tolerance files to ascertain whether the registrant provided sufficient data to show that the pesticide was not hazardous to man or the environment if used correctly, and

--a review to determine the timeliness and type of EPA reviews.

CHAPTER 2

ADEQUATE SAFETY AND EFFICACY DATA NOT AVAILABLE AT EPA

A pesticide's registration is required by law to be supported by sufficient evidence to show that it is safe and effective when used as directed. Before a pesticide can be registered, EPA requires the manufacturer-formulator to provide to EPA for its review various studies on the active ingredients in each type of pesticide to insure the pesticide's safety to man and the environment and its effectivess. EPA permits registration of pesticide products which are similar to previously registered products without submission of additional safety or efficacy data.

EPA does not have adequate assurance that man and the environment are protected because:

--The required studies for many registered pesticides being marketed have not been submitted to EPA.

--Studies are not required for pesticides as marketed, only for the active ingredients. There is little or no information on the long-term effects on man and the environment of those pesticides that combine two or more active ingredients.

--Some inert ingredients used in pesticide formulations may be hazardous to man or the environment, but EPA's testing requirements for inerts are less than those for active ingredients. Vinyl Chloride which was recently found to be a carcinogen is an inert ingredient.

EPA should evaluate the hazards associated with pesticides containing more than one ingredient as a basis for determining if pesticides as marketed should be tested. Also EPA should (1) reassess its policy on inert ingredient and develop appropriate guidelines for testing those that may present a health hazard and (2) require mutagenicity testing for pesticides processed under the FEPCA registration program.

SAFETY TESTING DATA NOT SUBMITTED

Our review of files of 100 randomly sampled pesticides showed that, contrary to EPA requirements, manufacturers have not submitted to EPA safety studies on many active pesticide ingredients. Without such studies EPA does not have adequate assurance that man is being adequately protected from possible pesticide hazards.

A primary purpose of the pesticide regulation program is to protect the public from injury and to avoid subjecting the public to the dangers of experimentation. EPA's policy is to evaluate the hazards associated with a pesticide's use to insure that only those that can be handled and used safely are registered. Some hazards evaluated include the pesticide's degree of toxicity (poison) and whether it may be oncogenic (causing cancer or other tumors), mutagenic (causing permanent genetic changes), or teratogenic (causing birth defects). It is also EPA's policy to evaluate whether a pesticide could (1) affect reproduction, (2) make another pesticide hazardous, or (3) combine with other chemicals to create a compound more hazardous than any of the resultant compound's original components. Because different formulations of the same pesticide behave differently, one formulation could be relatively safe while another could be toxic.

EPA officials said that the burden of proof is on the registrant for showing a pesticide's safety; consequently, EPA relies primarily on test data submitted by the registrant. To determine potential adverse effects on man, the registrant generally tests the pesticide on laboratory animals.

EPA requirements for safety testing to support pesticide registration have increased over the years to better protect man and the environment. The more important safety testing requirements are detailed in the table below.

Testing requirement	Date first required	Purpose of requirement
Acute toxicity	1954	Single exposure of animals to a chemical to determine the level that will result in mortality in 50 percent of the animals exposed.

Testing requirement	Date first required	Purpose of requirement
Subacute toxicity	1954	Multiple exposure of animals to a chemical to determine its toxicity over a period of 30 to 180 days, the most common period being 90 days.
Chronic feeding-oncogenicity (note a)	1963	Multiple exposure of the chemical during most of the animal's life to determine long-term toxic effects and whether the chemical will result in an increased number of tumors. The periods range as follows: 18 months for mice, 2 years for rats, and 2 to 7 years for dogs.
Reproduction	1963	A three-generation study with rats to determine if multiple exposure of the animals to a chemical will affect their ability to reproduce.
Teratogenicity	1970	A test to determine if exposure to the chemical will cause birth defects.
Mutagenicity	1972	A test to determine if exposure to the chemical will cause permanent genetic changes.

Many additional safety tests may be required depending on the circumstances under which the pesticide is used and its frequency and length of exposure to nontarget species such as man.

[a]Oncogenicity previously referred to by EPA as carcinogenicity.

Chemicals for which tolerances were set for residues in food were subject to all the requirements set out above from the date of the first requirement. There were 36 active-ingredient chemicals in our sample of 100 pesticides for which residue tolerances in food had been established. Our review of EPA's various toxicology and registration files and literature references for the 36 chemicals indicated that safety data was lacking as follows.

Type data	Chemicals lacking data	Percent of total
Acute toxicity	0	0
Subacute toxicity	0	0
Chronic feeding	7	19
Reproduction	7	19
Teratogencity	14	39
Mutagenicity	23	64

We provided a list of the sampled chemicals to EPA officials who verified that the data was not in their files. (See examples of pesticides with insuffient data on pp. 39 to 42.)

According to EPA, oncology data can, with suitable testing procedures, generally be obtained as an adjunct to the chronic feeding study; hence there should be oncology data for those chemicals with chronic feeding studies. However, the Registration Division's pesticide science officer said many available chronic feeding studies may not be sufficient for oncology review. He said that this is particularly true of feeding studies which use dogs. He explained that these studies usually cover only 2 years, whereas the possibility of an increase in tumor incidence could not be excluded unless the study covered most of the animal's life, or about 7 years.

The Registration Division's pesticide science officer said that he had formed a task force in January 1975 to determine what long-term tests EPA lacked for each active ingredient used in pesticide formulations. He said that registrants would be told which of their products lacked safety data and that these products would receive temporary registration for a period sufficient to satisfy data requirements. This means that an entire safety evaluation may not be completed until 2 or 3 years after a registrant is notified if tests such as a 2-year chronic feeding study are required.

Although pesticides without food tolerances are subject to some but not all of the safety data requirements

described on pages 7 and 8, required data for these pesticides was also lacking. For example, 23 active-ingredient chemicals were in the disinfectants in our sample. According to EPA's current testing requirements, disinfectants usually require both acute and chronic toxicity data. Although we found acute toxicity data on 20 of the 23 chemicals (neither we nor EPA officials could locate the file for 1 chemical) only 5 of the 23 had the required chronic toxicity studies. Thus, the effects, including cancer potential, of long-term exposure to these pesticides are not known.

EPA officials said that required safety data may not be available because (1) the pestcide was registered before establishment of the requirement, (2) an inadequate renewal review (required at 5-year intervals) was made and the data was not requested, or (3) the data could have been submitted but later lost during various moves and/or reorganizations.

Because of the absence of safety data for many chemicals which much of the population is exposed to daily in their food and environment, EPA cannot insure that the public is being adequately protected from possible pesticide hazards. We believe that EPA should not wait for FEPCA registration review to notify affected registrants that required safety data on their products is missing but should do so as soon as EPA identifies the deficiency and should set a deadline for submission. The registration of those pesticides for which data is not submitted by the deadline should be canceled until data is provided. In August 1975 an EPA official said that a list of pesticide chemicals lacking required data for FEPCA registration will be published in the Federal Register in the near future. He also said that a reasonable time will be allowed for each type study. If the data is not submitted within that time, the affected pesticide registrations will not be renewed.

Need for mutagenicity testing under FEPCA registration program

Although EPA has required mutagenicity testing since 1972, this data was not available for 64 percent of the agricultural pesticides in our sample (see p. 9), and EPA is not, except in unusual cases, requiring this testing under the FEPCA registration program. Because of the hazards presented by mutagens, we believe that mutagenicity testing would be necessary to protect the public and should be a requirement for FEPCA registration.

The Registration Division pesticide science officer said the mutagenicity testing requirment was not included under the FEPCA registration program because most independent laboratories do not presently have the capability to do such testing in live animals. However, it seems unlikely that independent laboratories would develop this capability without EPA enforcing this requirement.

The problem of mutagens in the environment was described in the Mrak Commission's report. The report stated that exposure of individuals to mutagens may lead to cancer and to birth defects. However, the report expressed greater concern for the descendants of exposed individuals, because changes caused by mutagens may lead to a wide range of abnormalities, mental retardation, physical and mental diseases, or many other inherited weaknesses and debilities to which man is susceptible. Since these effects may appear only in future generations when the damage is already irreversible, the Mrak Commission recommended (1) prompt identification of chemical mutagens to which the population is exposed and (2) that pesticides with mutagenic properties be rigorously restricted or banned unless thorough and impartial study convincingly demonstrates that the benefit outweighs the risk.

The Director of EPA's Criteria and Evaluation Divison said that live animals should be tested for mutagenicity. He explained that the best test involves feeding chemicals to test animals and determining if translocations result within the chromosomes of the animal's sperm. Translocation in the chromosomes would cause genetic changes in the animal's offsprings. The Director said that testing animals overcomes most of the objections to previous tests using cells in culture or insects; these test results cannot be readily related to man. He also said that the major objection to this test is its cost--about $23,000 per test. He added that he did not believe this cost excessive in light of the potential hazard to exposed populations.

We believe that EPA should expand its requirements under the FEPCA registration program to include live-animal or other suitable mutagenicity testing of appropriate pesticides.

PESTICIDES AS MARKETED ARE NOT BEING TESTED

Our review showed that, for the most part, EPA is requiring safety testing for only individual active ingredients and not for the pesticide as marketed which usually contains several ingredients. The combination of several

ingredients may cause harmful effects whereas the ingredients by themselves do not.

In our sample of 100 pesticides were 60 formulations containing 2 or more active pesticide ingredients. Except for some acute and subacute toxicity tests, EPA requires that safety testing be done on the individual ingredients only and not on the combined ingredients. Such testing does not insure that the pesticide as formulated will have the same long-term effects on man as do the individual ingredients.

EPA recognizes that chemicals in combination may have toxic effects which are greater than the effects of the individual chemicals. These are referred to as synergistic effects. For example, a 1972 study done for EPA by the National Academy of Sciences showed the following active ingredients when used in combination had synergistic effects on fish.

DDT --------- BHC	Parathion --- Malathion
Parathion --- Copper Sulfate	Carbaryl --- Malathion
Parathion --- Diazinon	Carbaryl --- Copper Sulfate
Parathion --- Methoxychlor	

In another test synergistic effects were demonstrated when mixtures of malathion, Phosdrin, and carbaryl were injected into chicken eggs. The mixture (1) caused deformed embryos at levels where single pesticides generally do not and (2) reduced the hatchability of eggs far more than did the individual pesticides.

EPA officials said that acute (short-term) studies in nonmammals, such as the foregoing, cannot be reliably correlated to results in man. One said there is no evidence to conclude that one chemical may combine with another to produce carcinogenic, teratogenic, or mutagenic effects in man or other mammals. The official also stated that he did not know of studies which would prove or disprove such interaction. He believed that little effort had been expended in this area to date.

Another official said that the cost of testing and the infinite number of chemical combinations that man is exposed to in his food and environment each day would preclude any possibility of testing all combinations. This official said that the burden for additional testing would fall primarily on the small manufacturer who generally would not be able to absorb the additional cost.

We believe that EPA has not sufficiently considered the area of synergistic interactions of pesticides. EPA should determine on a test basis whether chemicals that have proven to be synergistic in acute toxicity tests --such as those done on fish--may have long-term effects in mammals that are not revealed by testing the individual compounds. The result of this work would provide a basis for determining whether tests should be done on other chemicals which are combined in pesticide formulations.

EFFICACY DATA NOT IN EPA FILES

Efficacy data was not available in EPA files for many of the 100 pesticides reviewed. When data was available, it was often on individual active ingredients rather than on the pesticide as marketed. To carry out its responsibility to insure that only effective pesticide products are registered, we believe that EPA should have efficacy data on each pesticide product, not just on the individual active ingredients. Data on the pesticide product is necessary because different combinations of active and inert ingredients can change the efficacy of a product. EPA laboratory officials responsible for testing the efficacy of pesticides said that efficacy of a pesticide could be affected by such factors as the order in which chemical ingredients are combined, minor changes in the purity of the ingredients, and differences in the inert ingredients.

Pesticide Regulation Notice 69-8, issued on April 21, 1969, specified that for agricultural pesticides:

> "***Data are required to show that the proposed formulation can be used effectively and safely without resulting in illegal residues in or on food or feed. Data on the use of the active ingredients in other formulations will not serve as a basis for registration for mixtures."

Since the notice was issued, EPA has included in its draft guidelines, a similar but less specific requirement for all pesticide formulations.

We found efficacy data on only 42 of 93 (45 percent) pesticides sampled (efficacy data was not required for 7 of 100 because they were to be combined with other chemicals into a new pesticide which would then require efficacy data). We provided EPA a list of the 51 pesticides lacking data to determine if additional data could be found. These officials could provide us with no additional data on the

specific products sampled. One official said some data on similar products may be available for 12 of the 51 pesticides. He also said that many product files would have to be searched to determine if data was available.

The Chief, Efficacy Review Section, said that on several occasions he had been unable to locate efficacy data that he personally knew was previously available. He said that this necessitated writing to the registrant and having the data resubmitted. The official stated that he believed such data had been misplaced or destroyed as a result of a program to reorganize the registration files into files on efficacy, toxicology, and registration documents and correspondence. Another official said this program began in 1966.

An EPA official said that EPA does not plan to require efficacy data on currently registered agricultural pesticides because of the extent of data requirements and the limited registration period allowed by FEPCA. The official said that this waiver was made because of extensive use data on agricultural pesticides and because EPA believed that testing efforts should be concentrated on higher priority safety testing. The officials also stated that efficacy data would be required on other products such as home and garden products, and on new uses for existing pesticides.

Due to the variability of toxicity when various active and inert ingredients are combined, we believe that it is necessary for EPA to have efficacy data on registered pesticide products. EPA should take steps to insure that efficacy data is available. Currently, EPA has no evidence that at least 51 of the 100 pesticides in our sample are effective. Although EPA officials state that such data will be required during FEPCA registration for all but agricultural pesticides, efficacy data is not required in the registration regulations which became effective August 4, 1975.

Efficacy data on animal repellents

Before 1972 EPA registered animal repellents on the basis of testimonials--statements of satisfied users. Beginning in December 1972 this policy was changed, and registrants were required to submit objective data on the efficacy of their products. Registrants were given 1 year from the date of notification to provide efficacy data or the registration would be canceled.

Our random sample of 100 pesticides contained two animal repellents. The registrants had been notified of the new efficiacy requirement; however, neither had submitted satisfactory data as of March 1975.

One registrant was notified of the requirment during December 1972. The latest letter in the registration file is dated June 20, 1973. Adequate efficacy data had not been submitted at that time, and there was no indication that EPA followed up to obtain the data since that date.

The other registrant was not notified of the requirement until February 4, 1974. On December 9, 1974, the registrant submitted an efficacy study for a similar (not identical) repellent. In January 1975, EPA told the applicant that an efficacy study must be made using the registered product. No time limit was placed on submitting the study. As of June 1975, efficacy data had not been submitted. We believe EPA should not continue registrations of those products for which adequate data is not submitted within a reasonable time.

An EPA official said that more aggressive action had not been taken on the efficacy requirement for repellents because satisfactory test procedures were not available. He said that EPA is currently developing test procedures which may be satisfactory for general use in the near future.

PESTICIDES LACK ENVIRONMENTAL TESTING DATA

Test data necessary to insure that a pesticide will not adversely affect the environment has not been provided for many pesticides currently registered and marketed, and EPA does not generally require the submission of this information for pesticide uses registered before June 1970. Pesticides which have greatest impact on the environment are those that are applied to fields, pastures, and forests and which leach into ground water or which run off into waterways.

Requirements for environmental chemistry data were defined in Pesticide Regulation (PR) Notice 70-15 which was issued on June 23, 1970. An EPA official stated that environmental chemistry reviews are currently required for new pesticide registrations and for approving new uses for registered pesticides that are markedly different from existing uses. Environmental chemistry reviews were not made on registration renewals or on new registrations involving previously registered pesticide chemicals used for similar purposes. Also, these reviews will not be made under

the FEPCA registration program. EPA officials said this data will be required in subsequent registration renewal reviews. An EPA official stated that EPA has no system to follow up a registrant's compliance with EPA requests for environmental chemistry data and has no policy to cancel pesticide registrations when data is not provided.

Thus, according to EPA policy, environmental chemistry data is not required to be submitted for those pesticides registered before June 23, 1970, for use on fields, pastures, and forests and which may get into water, unless approved uses are added.

We selected certain of the PR Notice 70-15 requirements to determine if pesticides in our random sample of 100 complied with requirements. The requirements selected were studies to determine:

--The pesticide's degradation or decomposition (1) in soil, (2) in water, and (3) when exposed to light (photochemical degradation).

--Whether the pesticide destroys beneficial micro-organisms and the micro-organisms' effect on the toxicity and efficacy of the pesticide (micro-biological studies).

--Whether the pesticide leaches through the soil into ground water.

--Whether the pesticide moves from the application site in runoff water.

There were 32 pesticide chemicals in our sample for which environmental chemistry data was required. The extent to which environmental chemistry data has not been provided for these 32 chemicals is summarized in the following table.

Type of data	Number lacking studies	Percent of total
Degradation:		
Soil	11	34
Water	17	53
Photochemical	17	53
Microbiological	16	50
Leaching	24	75
Runoff	24	75

The absence of required data is illustrated for the following pesticide chemicals.

2,4-D dimethylamine salt--This is a widely used herbicide primarily for controlling weeds along canals and irrigation ditches. During 1972, about 22.5 million pounds were produced in the United States. An EPA environmental chemistry review of this pesticide completed in April 1973 showed that several studies were lacking or inadequate, including

--a microbiology study under anaerobic (oxygenless) conditions,

--a photochemical degradation study with lake water,

--leaching, adsorption, and runoff studies for ditchbanks, and

--adsorption studies with hydrosoil (mud).

The writeup on this review stated that additional data was needed to support the registration but could not be requested from the registrant at that time and referred to an internal EPA policy memorandum dated April 28, 1972. The writeup further stated that EPA hoped to ask for PR Notice 70-15 (requirements for environmental chemistry) data in the future. The April 1972 memo states that:

> "The requirement of any necessary data on established chemicals is to be done on a blanket basis through direct communications to the manufacturer. Requirements of this type should be handled as a separate issue from individual product registration. The acceptance of additional products or additional uses for established chemicals is not to be held up pending development of such data."

An EPA official said that as of March 1975, this data had not been requested for 2,4-D dimethylamine salt.

Also, we found that even when EPA did request data for previously registered pesticide chemicals, it often was not furnished as indicated in the following example.

Guthion--Guthion is a broad spectrum insecticide which is used to control insects in over 50 food or animal feed crops. During 1971 about 2.7 million pounds were applied to crops in the United States. In 1972 EPA reviewed a request to register guthion for a new use. An EPA letter dated March 27, 1972, advised the registrant

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that an environmental review indicated that chemistry data was inadequate. The letter stated that the data, including the 6 studies listed above, should be submitted within 1 year. Two environmental chemistry reviews completed during January and March 1975 showed that none of the requested guthion data had been provided.

Many pesticides have never been reviewed

Because of the foregoing examples, we requested that the Environmental Chemistry Review Section review a list of the chemicals which have tolerances for pesticide residues in food and animal feeds and identify those that have never undergone environmental chemistry data review. From this list of approximately 250, EPA identified 120 chemicals (about 50 percent) which have never undergone review.

The 120 pesticide chemicals represent a significant volume of pesticides used in the United States. Failure to obtain environmental data on many widely used pesticides does not insure that EPA is fulfilling its mandated responsibility to protect the environment from unreasonable adverse effects. We believe EPA should revise its policy and require complete environmental chemistry data for all pesticides applied to fields, pastures, and forests, regardless of the date of the pesticides' original registration.

NEED TO ESTABLISH POLICY FOR REGULATING INERT INGREDIENTS

In addition to the active ingredients in pesticide formulations, there may also be other ingredients, which are described as inert--ingredients which by themselves will not prevent, destroy, repel, or mitigate a pest. These ingredients are generally added as solvents, thickeners, propellents, or other uses to enhance the effectiveness or to facilitate the use of the pesticide. Inert ingredients range from innocuous substances, such as water, sugar, and salt, to toxic chemicals, such as vinyl chloride and formaldehyde.

FFDCA requires that toxic substances which remain in or on food or feed must have a tolerance or must have been exempted from the requirement of a tolerance. Many inert ingredients with varying degrees of toxicity have been exempted from the requirements of tolerances. EPA does not require the same safety evaluation for inerts as are required for active ingredients even though residues may remain in or on food or feed. Also, FDA does not test food for residues of inert ingredients.

The necessity for thoroughly evaluating the potential danger of inert ingredients is demonstrated by the disclosure in 1974 by 2 pesticide manufacturers that vinyl chloride, an inert propellent used in some pesticide aerosols, causes a rare form of liver cancer. After the disclosure of vinyl chloride's carcinogenicity, EPA evaluated its use in aerosols and found that it presented an imminent hazard in the home, food-handling establishments, hospitals, or enclosed areas. During April 1974 EPA requested manufacturers to recall pesticides containing vinyl chloride. This recall was followed in January 1975 by a cancellation order for 32 pesticides containing vinyl chloride.

Vinyl chloride has been produced commercially in the United States since 1939; by 1974 production was in excess of 7 billion pounds annually. The public has been exposed to this compound in the work environment of chemical plants and from pesticide and cosmetic aerosols.

The overall health effects of this exposure will not be fully known for several years because the cancer incubation period is believed to be 15 years or longer. The chances of eliminating potentially hazardous inert ingredients in pesticides would be enhanced if satisfactory long-term testing were required.

EPA is not developing regulations or guidelines governing safety evaluation of inert ingredients equivalent to those being developed for active ingredients. (See pp. 7 and 8.) The review process for inert ingredients used on food and feed crops was described in an internal Toxicology Branch memo dated October 1972 as follows:

> "Toxicologists in the past have not considered the inerts to be in the same class of poisons as are pesticides; accordingly they have tended to be much more lenient in their requirements for the demonstration of safety of residues of these compounds. A determination of exemption is made more on the basis of lack of demonstrated hazard than of demonstrated safety.
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> * * * * *
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> "***the process for exempting materials from the requirements of tolerances is still a seat-of-the-pants operation. I think we should either set up a Standards Committee to develop criteria, or we could promulgate [the criteria described in] this memo***."

The criteria discussed in the memo included a determination of safety on the basis of the material's

--structural similarity to a compound whose toxicity has been adequately defined,

--tolerance under food additive regulations,

--presence on FDA's "generally recognized as safe" list,

--low residue level on food or feed, and

--small percentage of the total pesticide formulation.

An EPA official told us that the foregoing criteria were used to evaluate inert ingredients.

If the inert ingredient could not be exempted under the foregoing criteria, the registrant might have to provide EPA with 90-day subacute (in 2 species) and 2-year chronic feeding (in 2 mammalian species) studies.

Provisions for other types of tests, such as 3-generation rat reproduction, teratogenicity, and mutagenicity studies, which are required for active ingredients, are required only on a case-by-case basis.

Some of the exempted inert ingredients are relatively toxic and EPA requires that they be applied a number of days before harvesting to allow the pesticide residue to dissipate. For example, EPA requires that the inert ingredients maleic acid and maleic anhydride be applied no later than 21 days before harvest; some active ingredients have no limitations on when they can be applied and in some cases can be applied after harvest. An EPA official said that if the preharvest interval was not observed, the residues may be greater than the submitted safety data would justify. Another EPA official said that FDA does not test for such residues, and in many cases residues for inert ingredients could not even be determined because analytical methods have not been developed.

The Chief, Chemistry Branch, stated that exemptions should be limited to those materials whose toxicity allows safe use under a wide range of conditions with widely varying residue levels. He also said that tolerances should be established for those relatively toxic inert ingredients whose safe use is predicated on imposing a rigid use pattern to insure that residues will be below a certain level.

EPA's Criteria and Evaluation Division recognizes that inert ingredients have not been evaluated from the standpoint of their potential adverse effects on man and the environment. The Division requested $1.5 million each for fiscal years 1975, 1976, 1977, and 1978 to identify and test inert ingredients. It proposed that all such ingredients be reviewed and that a list of suspect ingredients be developed. The suspect chemicals would then be subject to testing to ascertain those with potential toxic effects and the research needed for each. This work would then be done in-house by EPA or contracted out to other agencies or private firms to provide additional information on the toxicological properties and synergistic or antagonistic effects with other chemicals in pesticide formulations. The Office of Management and Budget deleted from EPA's proposed fiscal year 1975 and 1976 budgets the funds needed to evaluate inert ingredients during those years.

EPA should require sufficient safety and environmental data on inert ingredients in pesticide formulations to insure that they do not adversely affect man or the environment. EPA should evaluate the hazards associated with inert ingredients as proposed by the Criteria and Evaluation Division.

CONCLUSIONS

Many pesticide registrations are not supported by animal and environmental safety and efficacy studies currently required by EPA. Before August 4, 1975, EPA did not require that studies be provided as new requirements were established or as a condition of registration renewal. The seriousness of this void is demonstrated by the fact that teratogenicity and mutagenicity studies which became a requirement for certain pesticides in 1970 and 1972, respectively, had not been submitted for most of the required pesticides included in our review.

Because of the absence of data for many pesticides which much of the population is exposed to daily in their food and environment, EPA has little assurance that human health and the environment are being adequately protected from possible pesticide hazards. Registrants should be notified of data requirements when established, and EPA should require them to submit data within a reasonable time or should cancel the registrations if the data is not submitted.

EPA assesses a pesticide's safety by evaluating individual active ingredients and not the combined

ingredients as marketed in a pesticide. There is little or no information on the long-term effects on man and the environment of using pesticides as formulated. Synergistic interactions of ingredients are known to make certain chemicals more toxic in short-term tests. We believe that EPA should determine if these chemicals with synergistic properties also cause long-term effects not revealed by testing the individual active ingredients.

EPA's testing requirements for inert ingredients in pesticide formulations are less than those for active ingredients. Some inert ingredients may be as hazardous to man and the environment as are active ingredients, as has already been demonstrated in the discussion of the inert ingredient vinyl chloride (a carcinogen). EPA should reassess its policy on inert ingredients and should develop appropriate guidelines for testing those that may present a health or an environmental hazard.

RECOMMENDATIONS

We recommend that the Administrator, EPA:

--Identify and notify registrants of required safety (including mutagenicity) and efficacy studies which are not available for their pesticides and cancel the registration of those pesticides for which data has not been submitted within a reasonable time.

--Require complete data submissions as a basis for the FEPCA registration of pesticides. This policy should also be applied to future registration renewals.

--Consider requiring the safety and environmental testing of pesticides as marketed, particularly tests which pertain to the possible synergism of ingredients.

--Require complete testing of inert ingredients used in pesticide formulations that may present health or environmental hazards.

AGENCY COMMENTS AND OUR EVALUATION

EPA advised us by letter dated September 11, 1975, that our report was an exhaustive and generally excellent study of pesticide registration and tolerance setting. (See app. I.) However, EPA felt that its mandate and program were not fairly represented because:

--The report does not recognize that, generally, standards of efficacy and safety are not clear cut and that EPA must therefore exercise reasonable judgment in developing standards and regulations while considering the social and economic costs of regulation to all affected sectors of society.

--GAO's observation of the program was during a period of tremendous change and the report does not adequately reflect major changes in organization, procedures, and regulations which, although too new to evaluate, should correct many of the problems identified by GAO.

The Federal Government regulates pesticides to insure that quality products are available to the public and that when used properly, these products will provide consumers with effective pest control without unreasonable adverse effects on human health or the environment.

We agree with EPA that generally standards of efficacy and safety are not clear cut and consequently judgment is needed in regulating pesticides. Questions in the report pertain to instances where, although required, sufficient data has not been obtained to enable EPA to make a reasoned judgment on whether the potential adverse effects are outweighed by economic considerations.

We acknowledge that our review was made during a period of change, but appropriate reference has been made in the report to any changes affecting the matters discussed therein. Also, most if not all the requirements discussed in the report and contained in the new regulations dated August 4, 1975, had been in effect before that time. Furthermore, in view of EPA's past performance where requirements were ignored or circumvented, we agree with EPA's comment that, it is too early to evaluate the success of changes made.

EPA generally agreed with our recommendations and pointed out certain corrective measures which had already been taken. With regard to deficiencies in supporting data, EPA stated that

"***in accord with the requirements of amended FIFRA,***guidelines have been developed 'specifying the kinds of information which will be required to support the registration of a pesticide...' ***in preparation for reregistration, the data base supporting the safety of each registered active

ingredient has been reviewed, and any gaps have been identified. If there are gaps which require studies of short duration, products containing an affected chemical will not be reregistered until the gap is filled. If missing data require long-term studies, affected products will be granted non-renewable reregistration for a period reasonable to allow development and review of the missing data.

"If the data are not submitted, the registrations involved will lapse. If data are submitted, then the acceptability of the registration will be judged on the basis of the data."

As for requiring the full range of data to support reregistration, EPA stated that it had considered and rejected this approach because EPA itself and industry were faced with severe resource and time constraints for reregistration. EPA said that it had thus determined to concentrate resources in the area of highest priority, which is potential human hazard. EPA also stated that the remaining, less critical gaps in efficacy and environmental data will be addressed in the course of future renewals, at which time all products will be subject to all data requirements current as of the renewal date.

If properly implemented, EPA's new registration regulations and procedures should correct many of the data deficiencies noted in the report. However, collecting mutagenicity safety testing data (see p. 10), as well as efficacy and environmental chemistry data, will be considerably delayed. This delay is not desirable because of:

--The potential health hazards of public exposure to pesticides where the mutagenicity effects have not been assessed.

--Past exemptions granted registrants subject to these data requirements; for example, environmental chemistry data has been a requirement for pesticides used on fields, pastures, and forests and which may get into water, since 1970; however, EPA has waived the requirement for pesticides registered before that date.

The time required to develop the data which is being waived is relatively short compared to the 2- to 3-year period which will be required to obtain chronic feeding studies for some pesticides. In waiving the data requirement until the product comes up for 5-year renewal could result in such data not being obtained for a period of 7

to 8 years (for example, 2 to 3 years to complete a chronic feeding study and up to an additional 5 years before the 5-year renewal review anniversary is reached). This does not appear consistent with EPA's mandate to register pesticides which will not cause unreasonable adverse effects to man or the environment, because potential adverse effects cannot be evaluated until appropriate studies have been done.

In response to our comments on inert ingredients, EPA stated that

> "***many substances that appear as inert ingredients in pesticides are extremely common in other uses as well, and there is a potential interface with other existing regulatory programs which must be considered. If Toxic Substance legislation is passed, it may well provide the most appropriate mechanisms for regulating many substances which occur as inert ingredients in pesticides. There is, in any case, a possibility of significant regulatory overlap.
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> "***the Agency has the authority to require, on a case-by-case basis, testing of inert ingredients which may be hazardous. This authority has been exercised frequently, and during just the past six months in connection with***[11] inert ingredients,***"

Although EPA's assertion that inert ingredients may be more appropriately regulated under other legislation may be correct, this legislation has not been passed, and until it is and such a program becomes operable, inert ingredients must be regulated under the existing pesticide program. We agree that EPA has authority to require testing of potentially hazardous ingredients. The data requested by EPA on the 11 inert ingredients mentioned above was not the full range of tests that would be required of active ingredients used on food or feed crops. Only subacute (90-day) feeding studies were requested on nine inerts and chronic (2-year) feeding studies were requested on two. No teratogenicity, reproduction, or mutagenicity studies were requested on any of the 11 inert ingredients. Again, we do not believe that EPA can assess the hazards associated with a chemical's use unless appropriate studies are performed.

On our recommendation concerning safety and environmental testing of pesticides as marketed, EPA stated that it had

considered such an approach but had rejected it because of the economic impact that would result. EPA pointed out that combinations of ingredients in formulated products are by no means the only combinations of pesticide chemicals to which man and the environment are chronically exposed. As soon as a pesticide is released into the environment, complex processes of chemical combination and transformation begin. As is stated in the National Academy of Sciences 1975 publication, Principles for Evaluating Chemicals in the Environment, "there are so many different possibilities for potential interactions that it is unrealistic to demand that all of them be tested in advance."

EPA's acknowledgement that the interaction of pesticides and other chemicals in the environment is a matter of concern, we believe, supports our recommendation that EPA needs to consider testing pesticides as marketed. EPA's statement that all interactions cannot be tested should not be a basis for total inaction. The acute testing that EPA currently requires for some formulated pesticides does not address the problem of long-term effects such as cancer, mutagenicity, or impairment of reproductive capacity. The logic of not testing pesticides as marketed is far from convincing, particularly from the aspect of consumer protection.

In considering the need for long-term testing of pesticides as formulated, EPA should minimize overall economic impact to the pesticide industry by establishing guidelines which control the need for testing. Factors that should be considered are the pesticides' persistence, use patterns, and volume of use.

CHAPTER 3

MANY LABELS DO NOT COMPLY WITH EPA REQUIREMENTS

Many pesticide products on the market are misbranded. By law, a pesticide is deemed to be misbranded when the label does not contain precautionary statements adequate to protect man and the environment. Also, it is unlawful for any person to hold, distribute, sell, or offer for sale misbranded pesticides. EPA is responsible for enforcement of the law.

In our sample of 100 registered pesticides, we found many instances where required precautions were not included on the labels or where final printed labels had not been submitted to EPA. In some cases the absence of required material did not permit EPA to determine if precautions for bees, birds, fish, and wildlife were required. EPA officials advised us that (1) statements missing from the labels resulted from oversights or (2) registrations and/or labels were approved on the condition that required label statements would be added.

EPA officials also said that EPA did not have sufficient manpower to follow up and insure tnat requested labeling changes were made.

PESTICIDE LABELS LACK PROPER BEE, BIRD, FISH, AND WILDLIFE PRECAUTIONS

EPA guidelines require that if a pesticide may cause a hazard to bees, birds, fish, and/or wildlife, precautionary statements are required which specify the nature of the hazard and how to minimize or prevent injury, damage, or death to these nontarget species. The type of precautionary statements required are dependent on the toxicity of the pesticide to exposed species. The toxicity of the pesticide is determined by tests conducted by the applicant/registrant or from data available from published studies.

Our random sample of 100 pesticides contained 28 agricultural pesticides whose use would result in considerable environmental exposure and, therefore, would require bee, bird, fish, and other wildlife precautions. Of the 28 agricultural pesticides, we found and EPA officials agreed that 22 (79 percent) had one or more of the following shortcomings.

	Bee	Fish	Bird	Other wildlife
Precaution missing	5	3	6	2
Precaution was inadequate	3	1	5	0
No data in EPA files to determine precaution requirements	[a]2	1	8	0
	10	5	19	2

[a]No data on one chemical which was in two pesticides.

Bees

Bees are of economic importance as honey producers and crop pollinators. Pesticide poisoning of bees is a major problem of beekeepers. The importance of bees was discussed in a 1973 report prepared by the House Appropriations Committee investigative staff. The report stated:

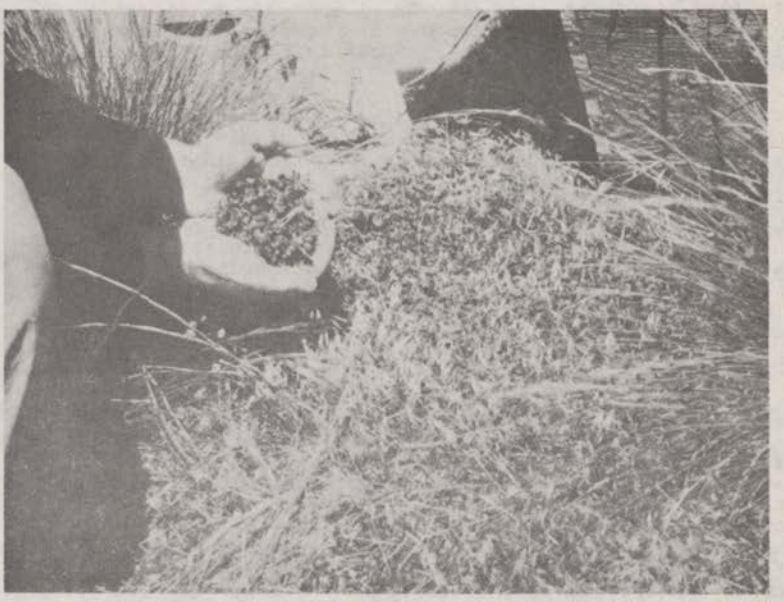
> "***Loss of honeybees, for whatever reason, means a loss in pollination; and at least 90 important crops grown in the United States are dependent, to a large degree, on honeybees for pollination. Severe loss of bees resulting from pesticide poisoning can, therefore, mean a serious reduction in yield of those crops.***
>
> "Without the honeybee, melon growers would have no crops to harvest. Producers of alfalfa seed and other seed crops would have very poor seed set without bees to pollinate their plants. Deciduous fruit and nut crops are dependent also upon bees for pollination.***"

Deciduous fruits and nuts include apples, peaches, plums, pears, cherries, almonds, and walnuts.

Bees may roam up to 5 miles from their hives. The extent of pesticide damage to a colony is affected by such factors as the number of bees from the colony in or near a treated area, the time of day the pesticide is applied, the method of application, the wind drift, and the toxicity of the pesticide.

To prevent and reduce damage to honeybees and other pollinating insects, Pesticide Regulation Notice 68-19, issued on November 29, 1968, required registrants to include labeling statements for designated pesticides which were toxic to bees. This notice required that the bee statement

be added to approved labels as they were revised or, at the latest, when the labels were submitted for registration renewal.



Honeybees killed by accidental exposure to the pesticides parathion and carbaryl, North Collinston, Utah.

CREDIT: Agricultural Research Service, Department of Agriculture, M.D. Levin.

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The identification and proper labeling of pesticides toxic to bees should help minimize the Government's expenditures under the Beekeepers Indeminity Payment Program authorized by the Agricultural Act of 1970 (7 U.S.C. 135b note). This program provides for reimbursing beekeepers who, through no fault of their own, lose bees exposed to pesticides registered by EPA. As of June 30, 1974, about $13.3 million had been paid under the program. Estimated obligations for fiscal years 1975 and 1976 were $1.8 and $3.0 million, respectively.

EPA identified 87 pesticide chemicals which were highly or moderately toxic to bees and which required label precautionary statements. One precaution states that the pesticide is "highly toxic to bees exposed to direct treatment or residues on crops," whereas the other states that the product is "toxic to bees and should not be applied when bees are actively visiting the area." Thirteen of the 28 agricultural pesticides in our random sample contained chemicals which required bee toxicity precautions. Labels for 5 of the 13 (38 percent) did not contain a bee toxicity precaution and 3 others (23 percent), although they contained bee statements, did not, according to EPA officials, contain the proper precaution.

The types of label statements required for each chemical in a pesticide product are summarized in EPA's Compendium of Registered Pesticides. EPA officials said its reviewers used the compendium to insure that required statements are included on each pesticide's approved label. We found that the compendium did not have bee toxicity precautions for 28 of 63 listed chemicals and that 1 that was listed had the wrong precaution. We also found that another 22 chemicals used in pesticides which are toxic to bees were not listed in the compendium. EPA officials told us that if the bee statement were not included in the compendium, the reviewers would probably overlook the need for the statement. These officials also stated that the compendium is deficient in certain data areas because there is insufficient assigned staff--a total of six--to keep it updated in a timely manner.

We informed EPA officials about the eight pesticides in our sample which did not contain the required bee statement or which contained an incorrect bee statement. As a result, EPA sent letters to registrants requiring that the proper bee statement be placed on the labels of five sampled pesticides. An EPA official said the Agency did not send letters to the other three because EPA has not reviewed the products since Pestidice Regulation Notice 68-19 was issued.

When EPA establishes a new requirement, it does not review those pesticides already registered to insure compliance with the requirement until EPA renews these pesticides' registrations; renewal may not occur for several years. For example, EPA had not reviewed 40 percent of the pesticides in our sample for over 6 years and, therefore, it could not insure that changes were made. We believe that EPA should implement a procedure requiring that pesticides reviewed before the effective date of a labeling requirement be reviewed within 1 year of the effective date for compliance with the new requirement.

Bird, fish, and other wildlife

FIFRA requires precautionary statements on the labels of pesticides which may cause a hazard to birds, fish, and/or other wildlife. The statements define the nature of the hazard and appropriate precautions to warn of potential accident, injury, or damage to nontarget species.

In the 28 agricultural pesticides included in our sample, 15 were not properly labeled. Of the 28, 10 (36 percent) did not have 1 or more required bird, fish, and wildlife precautionary statements, and 6 (21 percent) had inadequate precautionary statements. In addition, EPA files on eight (29 percent) lacked bird and/or fish data necessary to determine whether precautionary statements were needed. EPA officials stated that missing or incorrect precautionary statements on pesticides on which data was available were probably due to errors on the part of the reviewers.

In May 1975 an EPA biologist said that bird and fish toxicity data was not available on many chemicals used in pesticide formulations which were required to have such data. We requested EPA to review the list of about 1,800 pesticide chemicals; EPA officials identified 230 and 170 chemicals on which EPA did not have required bird and fish data, respectively.

Although EPA's policy has been to require fish, bird, and wildlife data, this requirement was waived before August 5, 1975, for those chemicals which

--are ingredients in pesticides that have been marketed for several years or

--are ingredients in new pesticides which are registered because of their similarity to previously registered products. (These are known as established use pattern registrations.)

EPA officials said that this waiver of requirements has been EPA policy for several years. The policy was formalized in an internal memo dated September 5, 1974, which stated:

> "***unless the data lack is serious enough to pull similar products from the files and impose the same requirements on all registrants, we cannot legally require the second or hundredth registrant to compile such data."

Adherence to such a policy appears to be at variance with FIFRA, as amended, which states that

> "The Administrator shall register a pesticide if he determines that***when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment."

Such a determination cannot be made if the registrant is not required to submit necessary data.

The biologists responsible for determining whether fish, bird, and wildlife statements are needed on a pesticide's label rely primarily on an EPA Biologists Compendium (not the same compendium previously discussed) in their work. EPA biologists said the compendium was the quickest and most convenient reference source. They also said the compendium contained many errors and had not been significantly updated in the last 2 years. One biologist estimated that it would take two biologists working 6-day weeks about 6 months to correct and update the compendium. EPA currently does not have any professional or clerical staff assigned to do this work. It would appear that an accurate and up-to-date compendium would be a necessity for EPA to effectively insure that all pesticides registered are properly labeled and contain appropriate precautionary statements on potential hazards to birds, fish, and other wildlife. An EPA official said that bird and fish data will be a requirement for FEPCA registration.

OTHER LABELING DEFICIENCIES NOTED

We also reviewed the registration files and labeling of the sampled pesticides to determine the extent of compliance with certain requirements. We noted several deficiencies which we discussed with EPA officials. These deficiencies and the number on which EPA took action are detailed below. EPA officials said the Agency did not act on the remaining deficiencies because they were not considered serious or because the products were being canceled.

Type of deficiency	Number of pesticides: Subject to requirement	Number of pesticides: With discrepancies	Percent with discrepancies	Number on which EPA took action
No container disposal statement	64	15	23	5
Inappropriate disclaimer	100	8	8	1
Confusing or contradictory statement	100	5	5	1
No statement for residual insecticide	5	3	60	0
Final printed label not furnished	100	32	32	0

The lack of followup capability in EPA is demonstrated in two areas. The first relates to EPA's procedure of approving pesticide registrations on condition that certain defects in the label will be corrected. EPA's form letter for such labels states that:

> "***certain defects, given below, have been noted. These corrections must be incorporated when the finished labeling is prepared. Five copies of the finished labeling must be submitted."

As noted in the table above, files of 32 percent of the pesticides included in our sample did not contain the final printed label as required. EPA does not maintain followup files to insure that periodic and timely followup action can be taken. Also, EPA officials stated that they do not have sufficient manpower to follow up and insure that requested labeling changes were made.

Secondly, EPA has no system to insure that PR notices issued by it or its predecessor, the Department of Agriculture, have been complied with. PR notices are statements directing the manufacturers, formulators, distributors, and registrants of economic poisons (pesticides) to take certain action on their pesticide registrations. For example, PR Notices 68-14 and 70-12, respectively, provide:

PR Notice 68-14

"***Because of the likelihood of contamination of food, residual type insecticides should not be used in the edible products area of food processing plants.

"Labeling for products containing residual insecticides with directions for use in any food processing plant whether stated in general terms or specifically must bear the following statement in a prominent position: 'Do not apply in the edible products areas of food processing plants'."

PR Notice 70-12

"In reviewing formula data submitted for sterilizers, sporicides, germicides, disinfectants and sanitizers, it is apparent that certain manipulations, both physical and chemical in nature are required for successful compounding. In many cases these are not described with sufficient clarity, so that reliable evaluations as to precise replications can be made insofar as efficacy and safety are concerned.

"As an added public protection measure, all applications for the registration of new sterilizers, sporicides, germicides, disinfectants and sanitizers must be accompanied by:

a. a complete statement of formula listing the percentages by weight of all ingredients present as set forth in PR Notice 67-3 and on the reverse side of PR Form 9-199;

b. a complete description of the production control procedures employed; and

c. the analytical chemical methods used therein and shown to be applicable to each formula proposed.

"This same information must be submitted for existing registrations on such products within six months from the date of this notice."

As noted in the table above three of the five pesticides in our sample subject to PR Notice 68-14 did not contain the

required statement for residual insecticides on the label. In addition, we noted that 82 percent of the disinfectant files in our sample lacked descriptions of production control procedures and analytical methods required by PR Notice 70-12. These notices were issued in 1968 and 1970, respectively.

We discussed these deficiencies with EPA officials and suggested that a checklist for all requirements including followup notations might be beneficial in carrying out their review responsibilities.

EPA officials responsible for registration actions agreed that discrepancies existed in the labeling or data submissions of the pesticides noted above. They said that, generally, these discrepancies resulted from (1) oversights on the part of registration reviewers, (2) the lack of followup capability within the Registration Division, or (3) in a few cases, registering the product before implementing the requirement. These officials also said that their reviewers rely on knowledge in their areas of specialization to insure that the label contains all required statements and that all required data is submitted. They also did not believe that a checklist would be beneficial.

CONCLUSIONS

Many pesticides on the market are misbranded. During our review we noted many instances where required precautionary statements were missing from final printed labels. By definition in the law, the missing statements constitute misbranding the product. We also noted several instances where, although a precautionary statement was included in the label, it did not conform to EPA requirements. The mislabeling of these pesticides occurred because EPA did not have systematic procedures for reviewing registrations and for taking appropriate action when required data was missing. This situation has been aggravated because EPA had not assigned sufficient staff to complete and update reference compendiums used by its registration reviewers and had no system to monitor compliance with pesticide regulation notice requirements. Thus, certain data, such as the toxicity of a pesticide to bees, birds, and fish, even though available, may have been overlooked because reference compendiums had not been updated.

EPA's policy of not requiring missing environmental test data for chemicals in agricultural pesticides which are registered or for new pesticides which are similar to registered pesticides is not consistent with its legislative mandate to protect the environment. We believe

that environmental test data is necessary for all pesticides whose uses will result in widespread exposure of wildlife, vegetation, land, air, or water.

RECOMMENDATIONS

We recommend that the Administrator, EPA, establish procedures to insure that all pesticides are adequately labeled. Following are some items that should be considered when developing these procedures.

--An effective method, such as review checklists, should be developed and used by label reviewers to insure that all labeling and data requirements are met.

--A system should be established by which EPA can efficiently follow up those pesticides where registration has been approved pending EPA's receipt of the requested label or other required material.

--More emphasis and personnel should be provided to correct and upgrade data compendiums used in the registration process.

--A system is needed to insure that pesticides reviewed before the effective date of a labeling requirement are reviewed within 1 year for compliance with the requirement.

AGENCY COMMENTS AND OUR EVALUATION

In commenting on our report (see app. I), EPA stated:

"Many changes have been made in the course of preparing for reregistration which should result in correction of most current labeling problems identified by GAO. Most important is the batch approach to rereigstration, which has the following characteristics:

(a) Before reregistration applications are solicited from the registrants, EPA reviews a group of products similar in chemistry and use.

(b) This review considers the sufficiency of supporting data, the use classification, required precautionary statements, and any required changes in other labeling elements.

(c) The product of this review is a 'Label Guidance Package', specific to the particular batch, itemizing label text and format requirements.

(d) The Label Guidance Package for each batch will be sent to all registrants of affected products, to aid them in developing acceptable labels for submission.

(e) The Label Guidance Package will also be provided to the reviewers to use as a reference standard in considering applications for products in each batch.

"Another significant change has been made in the regulations, which now require submission of final printed labeling prior to acceptance of the application, whether for new or amended registration. This should eliminate altogether the problem addressed by GAO's second recommendation."

We recognize that EPA is in the process of changing requirements for the FEPCA registration program. However, as of August 1975 we were not able to evaluate these changes because they had not been implemented. Also, a list of pesticide chemicals lacking required data had not been published by EPA and the Label Guidance Package for each batch was not completed or available for GAO review. Furthermore, the labeling deficiencies discussed in this report were items which were at variance with EPA written policy. We cannot conclude from our review that a written requirement in EPA regulations or guidelines will be appropriately enforced.

CHAPTER 4

BETTER ASSURANCES NEEDED THAT PESTICIDE RESIDUES IN FOOD ARE SAFE

FFDCA requires that a tolerance (the maximum pesticide residue concentration allowed in food) be established for all pesticides which remain in or on a treated food. While EPA is responsible for establishing these tolerances, FDA is responsible for insuring that residues do not exceed tolerances.

Pesticide residues in food and feed may be unsafe because EPA established residue tolerances without enough safety or residue data and because EPA does not require the submission of test data when new test requirements are established. In addition our review showed that:

--Tolerances were not periodically reviewed to insure that they were supported by data meeting current EPA requirements.

--Human exposure to a pesticide from all foods may have exceeded the acceptable daily intake--daily intake of a substance which appears to be without appreciable health risk.

--FDA tests for about 90 of the over 230 residues in food. FDA could not insure that the remaining 140 do not exceed approved tolerance levels.

In addition, many pesticide tolerances were established before several important safety tests were required. EPA does not periodically review the adequacy of data supporting already established tolerances and does not require the submission of test data when new safety test requirements are established. Thus, safety data such as teratogenicity, mutagenicity, and reproduction studies have not been provided by the registrants to support the safety of some established tolerances.

NEED TO PERIODICALLY REVIEW TOLERANCES

Although requirements for safety data required from registrants for establishing more recent tolerances have been steadily strengthened (see pp. 7 and 8), EPA has not implemented a program to periodically reevaluate the adequacy of existing tolerances in terms of current requirements. The acting Chief, Toxicology Branch, said that tolerances

are reassessed only when a petition is filed by a registrant requesting additional tolerances for new uses of the pesticide or as new studies become available. EPA does not normally require registrants to submit test data for existing tolerances when it establishes new safety test requirements.

Consequently, adequate data is not available to establish the safety of many current tolerances, and data on the residues themselves remaining in or on food may be inadequate or lacking. Also, we found instances where total human exposure to a pesticide in food may exceed the acceptable daily intake; this may be the case for many other pesticides. Missing safety and residue data are not always required and tolerances exceeding the acceptable daily intake are not reduced when subsequent tolerance petitions are reviewed.

Inadequate safety data

Carcinogenic, teratogenic, and mutagenic tests have not been completed to support the tolerances for many of the 36 pesticide chemicals with food or feed tolerances included in our sample. (See p. 9 for listing.) In addition, we noted several cases where tolerances for additional uses have been granted for a pesticide after a new data requirement was established without submission of such data. The following examples illustrate this point.

Example 1

As of February 1975, residue tolerances for the insecticide carbophenothion had been granted for over 50 foods. Carbophenothion tolerances were first established in the 1950s when mutagenicity and teratogenicity studies were not required. EPA did not, however, require that the manufacturer/registrant submit teratogenicity or mutagenicity studies when other carbophenothion tolerances were established after requirements for these studies were adopted; as a result, studies have never been submitted.

In addition, EPA did not establish a finite (measurable) residue tolerance for carbophenothion in milk even though its policy is to do so. Tolerances were established in 1963 for carbophenothion in almond hulls, sugar beet tops, citrus, and forage, all of which may be fed to diary cattle. EPA was aware that residues of 0.002 parts per million (ppm) would occur in the milk of dairy cattle eating feed containing as little as 3 ppm carbophenothion.

In October 1973 an EPA chemistry reviewer said feeding data showed that appropriate residue tolerances were required to cover residues that may occur in milk, meat,

and meat by-products. Tolerances were established in meat, but no tolerance has been set in milk. EPA regulations state that when data shows that finite residues may occur in milk from feeding a treated raw agricultural commodity to dairy cattle, a tolerance will be established on the raw agricultural commodity only if, on the basis of toxicological and other data, a tolerance can also be established for the finite residues in milk.

We believe EPA should enforce its requirements for the submission of mutagenicity and teratogenicity studies for carbophenothion. We also believe that EPA should establish a finite tolerance for carbophenothion in milk if supported by toxicological data, or the tolerance for residues in feed for dairy cattle should be canceled.

Example 2

Many tolerances for arsenical (arsenic-containing) pesticides were established in March 1955 as a result of FDA hearings--known as the Spray Residue Hearings of 1950. These included tolerances for lead arsenate, calcium arsenate, sodium arsenate, magnesium arsenate, and copper arsenate, which are used on a variety of crops.

In December 1969 the Mrak Commission recommended that exposure to certain persistent pesticides, including arsenicals, be restricted to specific essential uses which will create no known hazard to man. PR Notice 70-8, issued in March 1970, stated that additional teratogenic studies were needed for the arsenical pesticide, cacodylic acid (dimethylarsenic acid).

EPA established tolerances for residues of cacodylic acid in cottonseed and cattle in January 1972. Teratogenic data was required beginning in 1970. An EPA toxicologist reviewing the petition discounted the existing teratogenic studies because they were done on tadpoles rather than on a mammal. Although teratogenic studies were not submitted, EPA established a tolerance for cacodylic acid without requesting submission of such studies. Our review of the tolerance petition indicates that no additional teratogenic studies or references to such studies were submitted by the petitioner.

The above toxicology review was completed in July 1971, 2 months after publication of an article in a scientific periodical, the Archives of Environmental Health, linking sodium arsenate to birth defects in golden hamsters. EPA apparently was not aware of the study until a citizen submitted it in February 1973 as the basis for objections

to setting permanent tolerances for sodium and potassium arsenite in cattle and horses. After reviewing the submitted study and an earlier study also involving hamsters, an EPA toxicologist stated that "there is no doubt that relatively high doses of sodium arsenate. . .injected intravenously on the 8th day of gestation to pregnant females induced malformations in the golden hamster." He discounted the significance of the report, however, because the compound was not administered in a manner parallel to the normal human intake--oral ingestion. In spite of its own requirement for teratogenic study and the question of arsenical exposure causing birth defects, EPA again did not request additional data. EPA established permanent tolerances for sodium and potassium arsenite in cattle and horses on June 6, 1973.

In a letter to GAO dated April 1, 1975, EPA said the exposure level at which cacodylic acid will cause birth defects is not known, and that on the basis of available information, cacodylic acid does not appear to be an essential chemical for any of its registered uses. EPA stated that technically it was at fault in granting a registration in March 1972 for cacodylic acid on cotton and that a moratorium on the registration of arsenical pesticides should have been in effect.

EPA also wrote that:

> "Based solely on scientific grounds, as of March 22, 1972, the PRD [Pesticide Registration Division] apparently had insufficient evidence to object to the registration of CA as a cotton defoliant. However, it is also reasonable to conclude that EPA should have considered this action in light of (1) PR Notice 70-8 and (2) that the Special Pesticide Review Group had just made its recommendations as to the status of uses of arsenic containing pesticides. In the final analysis however, all presently registered uses of arsenical pesticides will be examined and evaluated, with recommendations set forth, by an in-depth review [being] made by our Criteria and Evaluation Division."

The continued registration of arsenical pesticides for nonessential uses is highly questionable, particularly in light of disclosures by two large chemical companies that employees in their arsenic-producing plants have an increased incidence of cancer. We also believe that EPA's position that it "had insufficient evidence to object to the registration" is contrary to the intent of FIFRA which

places on the registrant the burden of proving that a pesticide is safe. Because EPA believed that a valid teratogenic study had not been made, EPA could have denied registration until the study was provided. If EPA, in its review of cacodylic acid and other arsenicals, finds that continued registration is required, we believe that complete safety studies should be obtained by October 1976 before the pesticides are reregistered.

Inadequate residue data

During 1950 the Spray Residue Hearings were held to review data on the safety of, need for, and residues of pesticides used on raw agricultural commodities. As a result of the data accumulated during the Spray Residue Hearings, tolerances were established on March 11, 1955, for 28 pesticides used on about 50 crops.

Our review of the residue data submitted in support of the tolerances established for residues on 10 crops showed that at the time tolerances were established, residue data was not available for most of the crops. Also, some tolerances were established without considering technical and research advances in residue testing made between 1950 and 1955. As shown by the following table, few of the tolerances established accurately reflected the available residue data.

Crop	Total tolerances	Residue data not available	Tolerance differs from data		Tolerance reflects residue data
			Above	Below	
Apples	20	8	5	5	2
Beans	16	10	3	3	0
Celery	12	8	1	3	0
Corn	13	11	1	0	1
Lettuce	13	11	1	0	1
Peaches	16	8	3	4	1
Peas	12	10	2	0	0
Spinach	11	8	2	1	0
Strawberries	15	13	2	0	0
Tomatoes	15	4	7	3	1
	143	91	27	19	6

Of the 52 crop uses for which some residue data was available, 27 tolerances were set at residue levels above the corresponding data. For example, tolerances for methoxychlor were established at 14 ppm in beans and lettuce--about 100 times greater than expected residues which were 0.15 ppm or less. It is EPA's policy to set tolerances at the maximum

residues likely to occur from proper application provided they do not exceed acceptable safety levels. Tolerances set at artificially high levels may unnecessarily subject the public to pesticide residues resulting from misapplication. The possibility of excessive residues is of added importance because the safety of the higher levels has not been assessed, and FDA does not always test for residues in their enforcement program.

In contrast, 19 tolerances were established at levels lower than the maximum residues found. For example, a tolerance of 7 ppm combined fluorine was established on apples, although residue data indicated that residues on washed fruit could be as high as 31.4 ppm. Setting tolerances at levels considerably below the maximum residues found may result in residues that exceed the tolerance even though the pesticide was applied according to label directions.

Acceptable daily intake of pesticides not considered

EPA determines the acceptable daily intake for residues of each pesticide which may be present on agricultural commodities. Acceptable daily intake for man is usually 1 percent of the pesticide concentration which was found to have no toxic effect in the most sensitive animal species tested. Because inhibition of cholinesterase by organophosphate and carbamate pesticides is a more sensitive indicator of toxicity, the acceptable daily intake for man is set at 10 percent of the no-toxic-effect level. The acceptable daily intake is set at only a fraction of the no-effect level to allow for variations in the toxicity within animal species and man.

EPA determines the total possible exposure to pesticide residues that could be present in each food commodity in the average diet of a 60-kilogram (about 132 pounds) man. The residues from each food commodity are then totaled and compared to the acceptable daily intake. If the total residues from all commodities are below the acceptable daily intake, then the tolerances established are considered to be safe.

We found instances where the total pesticide exposure exceeded acceptable daily intake as shown by the following example. (Another example is discussed on p. 63.)

Example 3

Available toxicity data indicates that the acceptable daily intake for parathion, an organophosphate insecticide,

is 0.3 milligrams per day for a 60-kilogram man. Tolerances for residues of parathion have been established for about 70 agricultural commodities which comprise over 34 percent of a 60-kilogram man's diet. Total exposure to parathion from these uses could be 0.51 milligrams per day--0.21 milligrams above, or almost twice, the acceptable daily intake.

It does not appear that total exposure to parathion from all sources was considered when some tolerances were established. The acceptable daily intake of parathion had already been exceeded when EPA established interim tolerances for parathion residues in sugarbeets, sugarcane, sweetpotatoes, and rye in August 1972.

FDA DOES NOT TEST FOR MOST PESTICIDE RESIDUES IN FOOD

In addition to the questions on the adequacy of supporting documentation for pesticide tolerances established by EPA, FDA does not effectively test for most pesticide residues for which EPA has established residue tolerances in food.

FDA has two major programs to monitor the amount of pesticide residues in food products and performs special purpose tests initiated by itself or when requested by other agencies, such as EPA. An FDA official told us that in addition to its testing, residue testing is also performed by the Department of Agriculture (for meat and poultry), various State agencies, and the food industry; therefore, a substantial portion of the Nation's food supply routinely undergoes pesticide residue examination.

The primary FDA regulatory program for enforcing pesticide tolerances is the pesticide surveillance program which is conducted on a continuing basis at all 17 FDA district offices. Samples of food commodities are collected at the grower or shipper level. Program objectives are to

--determine on a geographical basis pesticide levels of individual food commodities,

--survey on a nationwide basis total pesticide residue levels of selected food commodities,

--monitor imported food commodities and deny entry to those with illegal pesticide residues, and

--identify pesticide residues occurring in excessive levels as a basis for compliance followup.

The second program, called the total diet study, is an information-gathering program and does not serve as a basis for regulatory action against specific products. Market baskets, each containing 117 food items, are collected 6 times a year by FDA inspectors in 4 areas of the United States. FDA collects 20 market baskets representing the diet for an adolescent male--usually the biggest eater in the general population--and 10 market baskets each representing the diets of a 6-month infant and 2-year toddler. The items in each market basket are separated into commodity groups, and each composite group is blended into a homogeneous slurry--a uniform mixture of similar food commodities. The slurries are then analyzed for over 90 various pesticide residues.

Under both the total diet study and the pesticide surveillance program, FDA uses a multiresidue test which is capable of detecting 54 parent-compound pesticide chemicals--primarily organochlorine and organophosphate chemicals--and about 90 of their metabolites in almost any type of food. An FDA official stated that these pesticides are highly toxic or quite persistent in the environment and could pose a potentially serious threat to public health.

FDA also emphasized that using the multiresidue test does not preclude testing foods for other pesticides if there is evidence or suspicion of misuse or special interest in the incidence and levels of a certain pesticide residue. For example, the total diet study measures lead, mercury, zinc, and arsenic residues in all samples.

An FDA official told us that FDA does not test for all pesticide residues because the results of FDA's surveillance program over a period of years has indicated that pesticide levels found in most raw agricultural commodities are generally well below established tolerances. He said FDA believes that the results of this testing should indicate the overall seriousness of the pesticide residue problem because FDA concentrates its efforts on widely used and persistent pesticides which are found to be violative in only about 3 percent of the samples. He also stated that FDA relies on programs of its own, EPA, State, and local agencies to insure that good agricultural and manufacturing practices are followed in using pesticides because it is generally recognized that use of a pesticide in a manner consistent with label directions greatly limits the occurrence of violative levels of pesticides in food.

While we do not question (1) the emphasis placed on testing food for organochlorine and organophosphate insecticide residues because of their toxicity, persistence,

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and/or widespread use and (2) efforts to insure good agricultural and manufacturing use of pesticides, we do not believe that this should preclude periodic testing of other pesticides for which tolerances have been established. The 3 percent rate of violative samples noted in FDA's comments above indicates that illegal residues occur despite efforts to the contrary. We believe that this occurrence demonstrates a need for FDA to initiate a systematic procedure to insure that all pesticides with tolerances are tested in FDA's surveillance program over a period of years.

Limited testing of herbicides and fungicides

As of July 1, 1974, 233 permanent tolerances were in effect. In nonfatty foods, FDA's multiresidue test would measure either partial or complete residues of only 54 of the 233 pesticides. As shown by the table below, FDA's detection capabilities were primarily limited to insecticides.

Type of pesticide	Number of tolerances	Detection capabilities		
		Complete	Partial	None
Insecticides	93	27	8	58
Herbicides	72	5	4	63
Fungicides	40	2	4	34
Other	28	3	1	24
Total	233	37	17	179

The absence of reliable data on herbicide residues is important because herbicide usage is greater than insecticide usage. Only 9 out of 72 herbicide tolerances can be detected and enforced using the multiresidue test.

Similarly, the most widely used fungicides, the ethylene bisdithiocarbamates (EBDC's), are not detected by the multiresidue test. In 1973 an EPA Special Pesticide Review Group labeled a decomposition product of the EBDC's, ethylene thiourea (ETU), a potential carcinogen. It also stated that ETU may be present in a wide variety of agricultural commodities, including milk. Because FDA does not test for ETU and because EPA has not requested testing, the exposure to this possible carcinogen is unknown.

Because testing in both the pesticide surveillance program and total diet study is limited primarily to organophosphate and organochlorine insecticides, total public exposure to pesticide residues is unknown. For example, 47 permanent tolerances have been established for residues in

milk. Residues of only 10 of these pesticides are detected in FDA's testing programs. Among those pesticides which may remain--in unknown amounts--in milk are such commonly used pesticides as piperonyl butoxide, pyrethrins, dalapon, paraquat, dicamba, DDVP, carbofuran, and pyrazon.

Lack of EPA input into residue testing program

FDA submits to EPA weekly sample analysis reports listing pesticide residues found to be above tolerances. EPA's Chemistry Branch identified the following areas in which the FDA reports can be used.

--To identify problem areas such as those pesticides which regularly exceed tolerances.

--To identify commodities containing residues which may not have been considered when tolerances were established.

--To establish action levels--the level where residues at or exceeding tolerances will require action to remove the food or feed from interstate commerce.

The usefulness of FDA's residue testing reports is limited, however, by the lack of data on most pesticide residues other than organochlorine and organophosphate insecticides. Despite the potential usefulness of the FDA reports and EPA's responsibility for setting and reviewing tolerances, EPA has had little or no input into the scope--either by commodity or pesticides--of the FDA programs. Although FDA indicated a willingness to consider EPA requests, no requests had been made. An FDA official emphasized, however, that time and budget restrictions would be an important factor in expanding the testing program. Another FDA official stated that suitable multiresidue methods are not available for most registered pesticides, and as such, these pesticides are not routinely included in FDA's surveillance program.

CONCLUSIONS

Adequate data supporting the safety of many pesticide tolerances has not been submitted, and data on many pesticide residues is not available. In addition, total exposure to pesticide residues in foods may exceed the acceptable daily intake, which could adversely affect human health.

We believe EPA should review all existing pesticide tolerances to insure compliance with current criteria for safety and residue data and for total human exposure. In addition, tolerances should be reviewed periodically to insure their consistency with new data on the pesticide.

FDA should expand its pesticide monitoring program to determine residue levels at least periodically. These tests could be timed to coincide with EPA's 5-year registration renewal reviews. To assess total exposure to pesticide residues, the total diet study should be expanded to test for all pesticide residues, not for just a limited number. In this way FDA might identify particular pesticides which should be included in enforcement testing.

RECOMMENDATIONS

We recommend that the Administrator, EPA:

--Review the adequacy of supporting safety and residue data for all existing tolerances and require manufacturers to submit any missing data.

--Evaluate total human exposure to each pesticide residue and insure that total residues do not exceed the acceptable daily intake.

--Periodically review all tolerances and revise as necessary.

--Work with FDA to develop a program whereby over a period of years all pesticides with tolerances would be tested in FDA's surveillance program.

We recommend that the Secretary of HEW through the Commissioner, FDA:

--Expand its surveillance program so that over a period of years all pesticides with tolerances are tested in the surveillance program.

--Coordinate with EPA on all future samplings of pesticide residues in food.

AGENCY COMMENTS AND OUR EVALUATION

In commenting on our report (see app. I), EPA stated that:

"GAO's criticisms are well-founded, and we are very much concerned about tolerance-setting

problems. In the recent past our emphasis on the implementation of FIFRA has allowed for insufficient attention to the problems identified here. Now that the necessary regulations for registration have been promulgated, we can turn more of our attention to review of the tolerance regulations and procedures, to reassessment of tolerances already regulated, and to a comprehensive evaluation of the whole scientific basis for tolerance setting. We accept and will implement GAO's recommendations in this area."

In commenting on our report (see app. II), HEW concluded that:

"We do not concur with the proposed expansion of the pesticide surveillance program at this time. In essence, we do not believe there is a significant need for surveillance of all pesticides since there are means other than residue testing for ensuring the safe use of pesticides and our current assessments of the total food supply do not indicate the presence of excessive pesticide levels.

"In assessing FDA's surveillance program it is essential to understand that the control of pesticides in food encompasses more than merely testing samples of food for the presence of illegal residues. The relationship of good agricultural and manufacturing practices to the regulatory control of pesticides in food is an equally, if not more important consideration. It is generally recognized that if food is treated with a pesticide in a manner consistent with its labeled directions, there is only a very remote possibility that violative levels of residues would occur. It is for this reason that FDA, EPA, State and local agencies conduct establishment inspections to make certain that pesticides are being properly used."

HEW did not believe that expansion of residue testing addressed the relative seriousness of pesticide residues in food because:

--Pesticide residues for over 90 of the more persistent and toxic pesticides (or their metabolites) are found

in less than 3 percent of the 7,000 to 8,000 shipments of food and feed tested each year.

--The results of the FDA total diet studies for the past 10 years indicate that the consumer's average daily dietary intake for over 90 of the more persistent and toxic pesticides or their metabolites is well within established acceptable daily intake limits.

--A fiscal year 1974 examination of 500 food samples for 32 pesticides not recovered in the routine surveillance program detected only 4 samples with residues above tolerance.

HEW further stated that, on the basis of the foregoing, there is little reason to expect that residues of less persistent pesticides are occurring in the Nation's food supply to any major degree.

Although pesticide control encompasses more than testing food for residues, we believe that this is a very important part of control. The fact that FDA is detecting violative residues in the small number of shipments sampled indicates that other aspects of pesticide control in food are not altogether effective. In fact the 3 percent rate of violation appears high when considering that FDA is testing for less than one-fourth of the pesticides with tolerances.

Further, we do not agree with FDA's inference that organochlorine and organophosphate residues are reliable predictors of the residues which will result from other pesticide uses. Nor should this testing preclude periodically testing other pesticides.

In commenting on our recommendation that FDA coordinate with EPA on all future samplings of pesticide residues in food, HEW stated:

"We agree with this recommendation. In fact, the June 12, 1975 Memorandum of Understanding on Pesticide Enforcement contains provisions along these very same lines. Accordingly, it is FDA's intention to formally request that EPA review and comment on the scope and overall adequacy of the FDA surveillance program and total diet studies including the types of foods and pesticides covered by these activities. FDA would then modify these programs as appropriate, based on EPA suggestions."

CHAPTER 5

SAFETY OF INTERIM TOLERANCES NOT ESTABLISHED FOR REGISTERED PESTICIDES

Under the law any pesticide residue on food shall be deemed unsafe unless a tolerance--or an exemption from the requirement of a tolerance--has been established and the amount of residue remaining is within the limits of that tolerance. A permanent tolerance is to be established only after EPA is satisfied that the data submitted by the petitioner is adequate to support the safety of the proposed tolerance.

Any food product containing residues of a pesticide for which a tolerance has not been established or containing residues in excess of established tolerances is adulterated under FFDCA. FFDCA prohibits the movement of adulterated foods in interstate commerce and provides for removing such products from interstate commerce and for penalties for violators. However, FDA's residue testing program is primarily limited to insecticides, and many pesticides, particularly those with interim tolerances, are not monitored.

EPA has permitted the registration of pesticides resulting in residues on food without establishing tolerances, usually because the safety and/or amount of residues remaining have not been determined. For example, some uses of chlordane result in residues in milk; however, tolerances for such residues have not been set. Thus, using the product according to label directions could adulterate milk.

EPA has established a system of interim tolerances to allow using a pesticide while the review of the tolerance petition is in progress. Interim tolerances were usually established when (1) questions of safety existed, (2) inadequate data was provided on residue levels, and (3) petitioners submitted no data to support the safety of the proposed uses. Such tolerances are not consistent with EPA's mandate to protect human health.

"NO RESIDUE" TOLERANCES

Before April 1966 registrations were granted for agricultural pesticides on a "no residue" basis if data was submitted to show that no detectable residue remained on the crop or food product as a result of the proposed use. Any detectable residue of such pesticides would render the crop adulterated and subject to seizure under FFDCA.

Advances in analytical chemistry made it possible to detect minute amounts of residue which were previously undetected. As a result, residues were detected for pesticides previously registered on a no-residue basis.

In June 1965 a committee appointed by the National Research Council, National Academy of Sciences, recommended eliminating the no-residue method of registering pesticides. The committee recommended that the existing no-residue tolerances be converted to "negligible" (generally less than .1 ppm) residue tolerances if their use resulted in residues of a negligible or permissible fraction of the pesticide's acceptable daily intake. In April 1966 the Departments of Agriculture and Health, Education, and Welfare in implementation plans published in the Federal Register agreed that:

> "***new uses of pesticides on food crops which may reasonably be expected to result in small residues in or on food should not be registered ***unless a finite residue level is formally provided for by tolerances***.
>
> * * * * *
>
> "***If the available data do not establish the safety of a pesticide for a particular use, such use will be deemed to be hazardous and ***[EPA] would not register the pesticide for such use."

They concluded that:

> "***The changeover, including processing of petitions, should be effective as soon as possible, but in no event should such no-residue***registrations be continued later than December 31, 1970."

Because many tolerance petitions were filed shortly before the December 31, 1970, deadline, the deadline was extended to December 31, 1971. No action was taken to formally extend the deadline between January and March 1972. To avoid further extensions of the no-residue registrations, EPA began issuing interim tolerances in April 1972; as of February 1975 there were interim tolerances for 22 pesticides in or on over 50 crops. Interim tolerances permit continuing no-residue registrations while petitions for permanent tolerances are pending.

In addition to pesticides with interim tolerances, some pesticide registrations were extended beyond the

December 31, 1971, deadline without either a permanent or interim tolerance. Available safety data was inadequate for determining tolerances for these pesticides.

PESTICIDES MARKETED WITHOUT A TOLERANCE

Although interim tolerances were established for most of the no-residue uses for which petitions were still pending, the Toxicology Branch recommended against establishing interim tolerances for certain uses of chlordane, endrin, heptachlor, silvex, meta-systox R, and morestan because of unanswered questions about the safety of the proposed uses. Most of these pesticides are widely used. In a memo dated June 2, 1972, the Chief, Toxicology Branch, stated the following objections to the proposed interim tolerances.

"Chlordane: The requested milk tolerance for chlordane, 0.3 ppm in milk fat, is at least twice as high as available toxicity data can support as safe to the young infant on all-milk diet. Moreover, maximum residues which could occur in average daily diet, if all tolerances requested in PP# OF0935 are granted, will be at least twice as high as available toxicity data can support as safe to the adult.

"Endrin: All tolerances for endrin are established at zero. The present request for 0.05 ppm of endrin in milk and eggs may not be adequate to cover residues from proposed uses. The no-effect level for endrin is 0.5 ppm in the dog, and 1 ppm in the rat and there is concern over the effects of endrin on the reproductive capacity in dogs. Further toxicity studies are recommended before this request can be judged safe.

"Heptachlor/heptachlor epoxide: The requested milk tolerance, 0.3 ppm in milk fat, if expressed only in terms of residues of heptachlor/heptachlor epoxide, is appreciably higher than the available toxicity data can support as safe to the young infant on an all-milk diet. Furthermore, maximum residues which could occur in average daily diet, if all tolerances requested in PP#CF0935 are granted, exceed those that available toxicity data can support as safe to the adult.

* * * * *

"Silvex: This is an ester of 2,4,5-T and the presence of 2,3,7,8-tetrachlorodibenzo-p-dioxin[1] has not been ruled out with certainty. The toxicity data in our files will only support tolerances for residues at the negligible level. Data available to Chemistry Branch does not enable them to estimate whether the levels in milk from use of Silvex on pasture grass are negligible or not. An interim tolerance for this compound is not in the best interest of the public health.

"Meta-systox R: The no-effect level for this cholinesterase inhibiting compound is 1 ppm based upon 90-day feeding studies. The level which could be supported in the total diet would be 0.005 ppm. Chemistry Branch states that a tolerance higher than the requested 3 ppm on alfalfa and clover is necessary to cover expected residues from proposed uses. Since CB [Chemistry Branch] has insufficient data at hand to estimate the level of Meta-systox R that might transfer to milk, it is my opinion that an interim tolerance for this use of Meta-systox R is not safe. Neither chronic studies nor a reproduction study which is generally recommended, if residues appear in milk, are available.

"Morestan: Tolerances requested are not negligible and this cannot be considered as falling under the 'no residue registration' category for issuing tolerances. The toxicity data available does not support the safety of the requested tolerances for this compound."

On August 16, 1972, the Acting Director, Pesticide Tolerance Division, recommended that the Pesticide Registration Division cancel the registration of pesticide uses on crops for which setting interim tolerances was not recommended because of unresolved safety questions. EPA did not act on the recommendation and these pesticide uses were not covered by tolerances. Only meta-systox R and morestan eventually were covered by a tolerance.

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[1]A highly toxic contaminant which causes birth defects.

Because of the strong objections of EPA's Toxicology Branch to setting even interim tolerances for these uses and the possibility of adulterating food products by using the pesticides, in a letter dated September 17, 1974, we asked EPA to justify the continued registration of these pesticides.

EPA, in its October 31, 1974, response, stated that

> "***The fact that pesticide residues in a crop may render it adulterated under the FFDCA in the absence of a tolerance or exemption from the requirement of a tolerance does not require***the institution of cancellation proceedings under FIFRA. ***The Seventh Circuit Court of Appeals in Continental Chemiste Corporation v. Ruckelshaus, 461 F. 2d 331 (1972), held that 'adulteration' of a food due to pesticide contamination does not foreclose registration of that pesticide under FIFRA, because the definition of product safety under FFDCA is not incorporated in FIFRA."

EPA further stated that it agrees with the position on tolerances taken by the former Chief, Toxicology Branch (see page 54), except for meta-systox R and morestan for which interim tolerances were established on August 16, 1972. Permanent tolerances for meta-systox R and morestan were established in November 1972 and July 1974, respectively.

The former Chief, Toxicology Branch, recommended (1) canceling endrin, chlordane, and heptachlor because the available toxicity data did not support the tolerances and (2) canceling 2,4,5-T and silvex because the chemistry data was insufficient to determine appropriate tolerance levels. EPA maintains, however, that

> "***Since the hazard was no greater than had occurred throughout the years of registration under 'zero tolerance' (no residue) there seemed to be a weak case for cancellation."

EPA's contention that the hazard is no greater is immaterial, because the extent of the hazard has not been determined and prevents EPA from fulfilling its mandate to protect human health.

We believe that the Continental Chemiste case does not preclude canceling or suspending pesticide registrations

for which tolerances have not been established. Further, the United States Circuit Court of Appeals for the District of Columbia in Environmental Defense Fund v. United States Department of Health, Education and Welfare, 428 F. 2d 1083 (1970) stated:

> "If Congress intended that either department [formerly HEW and the Dept. of Agriculture but now only EPA] defer to the other, the House and Senate reports suggest that ordinarily Agriculture's decisions as to whether to register a pesticide under FIFRA for use on food crops should depend upon HEW's decision to grant a tolerance." (Material in brackets supplied.)

In footnote 11 of the opinion the court further referred to the legislative history of section 346a (section 408 of FFDCA) showing a linkage between tolerances under the section and registration.

> "The Congressional Committee Reports summarized the departmental responsibilities as follows:
>
> > Under this bill [the present FFDCA provisions], a regulation establishing a tolerance for a pesticide chemical used on raw agricultural commodities may be initiated by an applicant for registration of an economic poison under the Federal Insecticide, Fungicide, and Rodenticide Act or by the Secretary of Health, Education, and Welfare. It is anticipated that, in the usual case, registration of a new economic poison would be withheld by the Department of Agriculture pending the issuance of the tolerance.
>
> H.R. Rep. No. 1385, supra Note 8, at 3, U.S. Code Cong. & Admin. New 1954, p. 2628. * * * Similarly, the Department of Agriculture should presumably deregister a pesticide for use on food crops if HEW revokes an existing tolerance. Precisely this pattern was followed recently when Agriculture revoked registrations of lindane and benzene hexachloride for use on certain crops because HEW had cancelled tolerances for these pesticides. USDA Release No. 943-70, March 25, 1970." (Underscoring supplied.)

The House and Senate reports (House Report No. 1385, p. 3, and Senate Report No. 1635, p. 3, 83d Congress, 2d Sess.) anticipated that registration would be withheld pending issuance of a tolerance in the ordinary case, leaving open the possibility of registration without a tolerance in exceptional cases. Also, cancellation ("deregistration") would presumably be required, according to the court, if an existing tolerance were revoked.

We believe the foregoing decisions clearly demonstrate that the Congress intended that pesticide registration resulting in residues in or on food or feed would be withheld or canceled unless required tolerances could be established. EPA should revise its policy accordingly.

Subsequently, on July 30, 1975, the EPA Administrator suspended the manufacture of chlordane and heptachlor as an imminent human cancer hazard. In his order the Administrator stated:

> "I have found that these compounds cause cancer in laboratory animals and that laboratory tests are reliable indications of the human cancer hazard. In addition, although any single component of human exposure--such as intake through poultry--may not appear to be significant, it alone poses a cancer hazard to certain of the more susceptible individuals and together with the several other components of human exposure presents a serious human cancer threat. This threat is made even more alarming by evidence that human exposure begins in the mother's womb and continues without interruption throughout life. In addition, because these chemicals are ubiquitous, the major sources of human exposure are largely unavoidable by individual action."

QUESTIONABLE INTERIM TOLERANCES ESTABLISHED

Some interim tolerances were established in cases where (1) questions of safety existed, (2) inadequate data was provided on residue levels, and (3) petitioners submitted no data to support the safety of the proposed uses. EPA has not established guidelines governing interim tolerances.

Questions of safety

As shown by the following examples, interim tolerances have been set for pesticide uses on which questions of safety exist involving the carcinogenicity or teratogenicity of the pesticides.

Example 1

In December 1969 the Mrak Commission recommended that human exposure to pentachloronitrobenzene (PCNB) be minimized because of tests showing PCNB to be both a carcinogen and a teratogen. Although EPA notified manufacturers that additional carcinogenicity and teratogenicity studies were required, a manufacturer refiled a petition for PCNB tolerances on peanuts and 10 other agricultural commodities in December 1970 without submitting additional studies.

In December 1972 EPA established an interim tolerance for PCNB. The interim tolerance was established because (1) additional studies on carcinogenicity and teratogenicity were being conducted, and (2) the purity of the pesticide used in the earlier test and produced by another manufacturer was unknown.

Because the available data did not indicate the safety of the proposed uses, we question EPA's establishing an interim tolerance before additional carcinogenicity and teratogenicity studies were completed. In addition, PCNB produced by the petitioner contained hexachlorobenzene impurities. EPA's residue chemists said the proposed uses would result in residues in meat and milk and would require tolerances of 0.2 ppm in milk and in meat, fat, and meat by-products of cattle, goats, horses, and sheep. They stated that these residues would be almost entirely hexachlorobenzene. Any residues of PCNB or hexachlorobenzene in meat and milk would render the product adulterated because neither an interim nor a permanent tolerance have been established for these ingredients.

Because the petitioner did not propose tolerances in meat and milk, the Toxicology Branch did not review the safety of the probable residues in meat and milk, even though the crops for which tolerances were granted were fed to animals and would have resulted in such residues. Thus the public, through the establishment of interim tolerances for PCNB use on certain agricultural commodities, may be exposed to products adulterated with residues of a possible carcinogenic and teratogenic pesticide.

Example 2

In September 1970 a petition was filed requesting the establishment of a permanent tolerance for the fungicide dithane M-45 in potatoes and milk, and in meat, fat, and meat by-products from dairy and beef cattle. Because of questions about the carcinogenic properties of ETU, an impurity and metabolite of dithane M-45 and other EBDC pesticides, in November 1971 EPA notified the petitioner that it was unable to complete its toxicology review until the question of ETU residues was resolved.

However, in May 1972 the Toxicology Branch recommended establishing interim tolerances for dithane M-45 and two other EBDC pesticides because of higher tolerances in other EBDC pesticides. The Toxicology Branch justified this recommendation on the basis that the requested interim tolerances were less than permanent tolerances granted for similar EBDC pesticides, and, consequently, "although toxicity data does not completely support the safety of these compounds, TB [Toxicology Branch] must recommend them for interim tolerance." EPA would be better fulfilling its mandate to protect human health by canceling those tolerances not supported by safety data rather than by justifying additional tolerances on the basis of those established without adequate data.

On December 2, 1972, interim tolerances were established for the three EBDC pesticides. Although an interim tolerance of 1 ppm was established for dithane M-45 in potatoes, no interim tolerance for dithane M-45 or ETU was established in milk, even though dairy cattle are fed potatoes. The Chemistry Branch of EPA's Registration Division concluded that residues of ETU in milk would likely be between 0.01 and 0.02 ppm and could run as high as 0.05 ppm.

Because of the serious questions concerning the safety of EBDC fungicides, it seems inappropriate to approve additional tolerances for dithane M-45 until these questions are resolved. Rather, it would seem more appropriate to eliminate all nonessential uses of EBDC fungicides until the question of safety is resolved.

The Department of Agriculture indicated that EBDC fungicides are probably the most important single fungicide group and that many of the uses have no alternatives. There are alternatives for the two EBDC fungicides for which interim tolerances have been set and for the use of dithane M-45 on potatoes. The interim tolerance for

dithane M-45 is especially questionable because of the expected ETU residues in milk and the inability to detect ETU residues.

Inadequate residue data

The Chemistry Branch reviews the residue data submitted with tolerance petitions to determine whether the proposed tolerance levels are adequate to cover the expected residues. In several cases EPA set interim tolerances at levels requested by the registrant even though the Chemistry Branch found that residues would be higher. EPA's Toxicology Branch did not evaluate the safety of consuming foods containing residues at the higher level and, consequently, the public may be exposed to pesticide residues exceeding safe levels. If the residues occurred at levels above tolerances, the food would be adulterated. However, since most of the pesticides and/or crops for which interim tolerances were established are not included in FDA's pesticide monitoring program, such adulterated foods will not be detected and removed from commerce.

The following examples illustrate these points:

Example 3

In December 1967 a petition was submitted requesting tolerances for the herbicide 2,4-D on a number of agricultural commodities including grasses and milk. The petition was rejected because expected residues for some commodities, including meat and milk, would exceed the requested tolerances. After repeated resubmissions and rejections, an interim tolerance of 300 ppm was established for 2,4-D residues in grasses in 1972. The interim tolerance did not, however, cover residues of 2,4-D in meat and milk.

EPA's Compendium of Registered Pesticide Uses places no time restrictions on meat animals' grazing on 2,4-D treated grasses; however, dairy animals may not be grazed until 7 days after treatment. In a June 1972 review of the tolerance petition, an EPA residue chemist estimated from the data provided that the maximum 2,4-D residues on grasses would be about 2,000 ppm at the time of application and 400 ppm 7 days later. As a result, the residue chemist concluded that 2,4-D residue levels in meat and milk would exceed the proposed tolerance levels of 0.1 ppm in meat, 1 ppm in kidney, and 0.05 ppm in milk but did not estimate what the residues would be.

In a subsequent review dated December 14, 1973, the residue chemist concluded that:

> "After reevaluation, we now find a tolerance level of 0.2 ppm will be needed for combined residues of 2,4-D and 2,4-DCP (a metabolite of 2,4-D) in milk. This adjustment is based upon the residue data for grasses, which indicate up to 700 ppm residues could be present after 7 days at the maximum proposed use rate of 6 lbs ai/A [active ingredient/ acre]. If the maximum proposed rate for overall applications were to be reduced to 3 lbs. ai/A (by specifying the 6 lbs ai/A rate was only for spot treatment), a 0.1 ppm tolerance level for combined residues (2,4-D/2,4-DCP) in milk would be adequate.
>
> * * * * *
>
> "The petitioner now proposes meat tolerances of 1 ppm for liver and kidney and 0.1 ppm for other tissues. A 7-day PSI [Pre Slaughter Interval]***for livestock is also proposed; this limitation should be added to the label.
>
> "The proposed tolerance levels are adequate to cover combined residues of 2,4-D/2,4-DCP in meat from the feed uses of grasses per se, provided there is a 7-day PSI; however, these tolerance levels are not adequate to cover residues from ingestion of grass hay; and, we have no residue data on alfalfa and clover and/or their hays with which to judge what levels of tolerances will be needed to cover secondary residues in livestock incurred from their ingestion.
>
> * * * * *
>
> "This deficiency remains unresolved pending the petitioner's response. At present we can draw no final over-all conclusions re the levels of tolerances for meat which will be needed."

Although EPA's Toxicology Branch reviewed the safety of the proposed tolerances, they did not review the safety of the residue levels which the chemist said would likely occur. The former Chief, Toxicology Branch, told us,

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however, that the toxicity of 2,4-D is so low that she would not hesitate to approve the higher tolerance level.

We question establishing an interim tolerance for 2,4-D on grasses at 300 ppm when EPA expects residues to be as much as 6 times that level. Such action is especially questionable because FDA was not requested to monitor the tolerance. In addition, because tolerances were not set for milk and meat, the presence of 2,4-D in meat or milk at any level would render them adulterated; meat and milk from livestock grazed on treated grasses contain 2,4-D residues.

Example 4

In December 1970 a pesticide manufacturer submitted a petition requesting a tolerance for toxaphene in alfalfa hay and in milk. An interim tolerance of 0.05 ppm in milk and 1 ppm in alfalfa hay was established in August 1972.

In a June 6, 1972, letter, EPA notified the manufacturer to

> "Revise label restrictions to flatly prohibit the feeding or grazing to livestock of feed items which now bear the restrictions, 'Do not feed to dairy animals or animals being finished for slaughter'."

In a letter dated November 2, 1972, EPA explained its objections and stated that with the precautionary labeling currently on the product "excess residues may result in meat or milk." In that letter EPA also stated that toxaphene residues found by FDA and Agriculture in meat and milk were of low order.

FDA notified EPA in December 1972 that the State of Arizona and the Los Angeles District of FDA were alledgedly finding toxaphene in milk at 3 to 4 times the established 0.05 ppm interim tolerance. FDA wanted to know whether the tolerance petition contained any gas chromatograms of what toxaphene looks like after being fed to cows.

An EPA residue chemist indicated that the above data was not available in the petition but agreed that it was needed, stating in a December 1972 memo that:

> "In view of the above recent problem of toxaphene in milk, the petitioner should be informed that in addition to data already requested, we need to know what changes, if

> any, occur in toxaphene after ingestion by the dairy animal. Also, we will need a validated analytical method for toxaphene in milk. Gas chromatographs of both samples and standards should be submitted."

Since that time EPA has, at the request of the manufacturer, extended the deadline for responding to EPA's June 1972 rejection on seven occasions; the latest extention placed the petition in abeyance until September 11, 1975. On September 15, 1975, the manufacturer submitted the requested data which was still under EPA review as of October 21, 1975.

In evaluating the safety of the proposed milk tolerance, EPA's Toxicology Branch allowed total public exposure to toxaphene residues from agricultural commodities to exceed the acceptable daily intake. Toxaphene tolerances are established for over 50 agricultural commodities comprising about 32 percent of the diet of a 60-kilogram man. Total exposure to toxaphene residues from these uses could exceed 2.79 milligrams a day--almost 4 times the acceptable daily intake of toxaphene which is only 0.75 milligrams.

We believe that tolerances should not be permitted--even on an interim basis--which in the aggregate could exceed the acceptable daily intake.

No safety data provided

Some interim tolerances currently in effect were not established as extensions of no-residue registrations. These interim tolerances were established because of special requests and frequently did not contain any safety data or references to data to prove the safety of the proposed uses. In such cases EPA's toxicologists had to obtain data to support the safety of the proposed tolerances from other sources (such as earlier petitions and published articles). In so doing, however, we believe EPA assumed the responsibility of proving the safety of the proposed uses rather than having the registrants supply the safety data. This is illustrated in the following examples.

Example 5

Because of an expected shortage of 2,4-D during the 1974 growing season, three States filed requests for a temporary tolerance for the herbicide picloram in barley and wheat. None of the requests contained any data or references to data on the safety of the proposed uses.

The Toxicology Branch determined, on the basis of toxicity data submitted in a 1967 petition, that residues of 0.5 ppm picloram in barley and wheat would be safe. After the review by the Toxicology Branch, however, the Chemistry Branch determined that tolerances would also be required in horses, hogs, poultry, and eggs. The Toxicology Branch found the tolerance levels proposed by the Chemistry Branch in hogs, horses, poultry, and eggs to be safe, and interim tolerances were approved on June 19, 1974.

Example 6

On August 29, 1973, a petition was filed requesting an interim tolerance for benzene hexachloride (BHC) in imported paprika. The petition was filed because FDA was detaining several lots of imported paprika found to contain BHC residues. The paprika was considered adulterated because no tolerance had been granted for BHC in paprika.

The Director of the Registration Division required the Toxicology and Chemistry Branches to complete their reviews of the paprika petition in 2 days. The petition contained neither data on the safety of BHC nor references to studies in earlier petitions or published articles. The petition contained residue data on only five lots which FDA found to be in excess of the 1 ppm tolerance. Despite the lack of data provided with the petition, the Toxicology Branch completed their review in 1 day, the Chemistry Branch in 2 days. On the basis of these reviews, EPA established an interim tolerance for BHC in paprika.

Accepting submitted petitions without proper supporting data and placing unreasonable time constraints on reviewers could create a potentially hazardous situation. Although the level of BHC entering the diet from paprika is minor, BHC is on the list of suspected carcinogens of the National Institute for Occupational Safety and Health. Establishing interim tolerances without proper safety data, even for minor uses, sets a bad precedent.

CONCLUSIONS

EPA has permitted registration of pesticides for use on food crops without adequate data to support the safety of the resulting residues. Also, we found instances where commonly used pesticides were registered for use on crops resulting in residues on food for which tolerances had not been established. In allowing the continued use of chlordane, endrin, heptachlor, and silvex on food crops

without a tolerance, EPA has, in effect, condoned adulterating food products which would result from these uses. More importantly, EPA is allowing the public to be exposed to residues which its Toxicology Branch has determined to be over the safe exposure level.

EPA has established interim tolerances for residues of many pesticides because it lacks adequate data to determine the safety of the expected residues. Although establishing an interim tolerance allows using the pesticide without the treated food product being considered adulterated, it does not insure that such residues can be safely consumed.

EPA should review the justification for interim tolerances in light of its responsibility to protect the public from pesticide hazards. If it determines that some types of interim tolerances are an essential part of the tolerance program, then EPA should propose guidelines and legislation, if needed, covering their use. The status of all existing interim tolerances should be reviewed for conformity with proposed guidelines. We also believe interim tolerances should not be established where there are questions on the adequacy of safety or residue data.

Registered pesticides should not be permitted to be used on crops for which interim tolerances cannot be established while petitions for a permanent tolerance are pending.

RECOMMENDATIONS

We recommend that the Administrator, EPA:

--Evaluate the need for interim tolerances and if determined essential, propose guidelines for their establishment.

--Reassess the need for and adequacy of data submissions for all interim tolerances; interim tolerances found unnecessary or lacking sufficient data should be canceled if the data is not submitted by a set deadline.

--Cancel the registrations of pesticide food uses for which neither permanent nor interim tolerances exist.

AGENCY COMMENTS

In commenting on our report, EPA stated that GAO's criticisms are well-founded and that is accepts and will implement the recommendations.

CHAPTER 6

STATUTORY REGISTRATION REQUIREMENTS NOT CARRIED OUT IN A TIMELY AND ADEQUATE MANNER

FEPCA, enacted on October 21, 1972, required EPA, among other things, to register all pesticides during the 2-year period ending October 1976 (FEPCA registration program), regardless of any previous registration. EPA must register about 46,000 pesticides in addition to processing its normal workload during this 2-year period. Presently, EPA does not have the necessary capability to review and register these pesticides within the time frame provided or to assure the public that these pesticides are safe and effective. To compound the problem, EPA was late in issuing regulations and guidelines for registering and classifying pesticides.

Pesticide registrations are valid for 5 years and must, by law, be renewed or canceled at the end of this period. However, EPA has not renewed or canceled pesticide registrations as required, and, as a result, many pesticides whose registrations are over 5 years old are being marketed, although their registrations have not been renewed.

ALL PESTICIDES CANNOT BE ADEQUATELY REGISTERED BY OCTOBER 1976 AS REQUIRED BY FEPCA

In addition to the 46,000 FEPCA registrations, EPA's projected workload during the 2-year period includes 13,000 anticipated new pesticide registrations and 14,000 amended registrations (applications for changes, such as changes in product formulations, uses, or labeling).

EPA estimates that the net effect of the FEPCA registration program on the normal workload will be an increase of approximately 35 percent over the levels of fiscal years 1973 and 1974.

The FEPCA registration program workload of about 46,000 pesticides is composed of about 29,000 currently registered pesticides that must be reregistered and 17,000 intrastate pesticides that were not previously required to be registered by EPA.

EPA's Registration Division staff was increased from 217 to 222 positions between fiscal years 1973 and 1976, an increase of only 5 positions. Of these positions, there were 156 professional staff positions as compared to 138 at

the beginning of fiscal year 1974. According to EPA, position increases in fiscal years 1974 and 1975 were moderate and were not adequate to handle the burden of FEPCA registration. Moreover, no increase in positions has been approved for fiscal year 1976.

According to EPA officials, EPA has had difficulty in keeping up with its normal workload at the current staffing level even after the registration renewal process was suspended. EPA officials said that the recent reorganization of the Registration Division had improved its efficiency and effectiveness in processing registration applications.

Our review of EPA's weekly workload reports showed that there were about 1,550 registration applications on hand awaiting review on July 1, 1972, when EPA suspended the renewal program. As of April 25, 1975, about 1,720 registration applications on hand were awaiting review, an increase of approximately 370 applications over the backlog on hand when the Registration Division was reorganized in December 1974. EPA officials said the time needed to process an application has been reduced as a result of the reorganization. Because the reorganization was only recently implemented, we did not review this aspect of the program.

FEPCA required that by October 21, 1974, EPA establish regulations for registering and classifying pesticides in accordance with provisions of the act and that all pesticides be registered under such regulations. Regulations issued by an executive authority of the Government have the same effect as laws. Guidelines, used in conjunction with regulations, provide information necessary to clarify and implement the regulations. Also, guidelines provide registrants with specific information on what kind of data is needed to support pesticide registrations.

EPA's proposed regulations did not appear in the Federal Register for public comment until October 16, 1974--just 5 days before the mandated deadline for completing the regulations. EPA is required to solicit public comment on the proposed regulations before they can be finalized. After public comments were received and evaluated by EPA, the final regulations were published in the Federal Register in final form on July 3, 1975, and became effective August 4, 1975. Proposed guidelines for registering pesticides were published in the Federal Register on June 25, 1975.

An EPA official said that regulations and guidelines were not completed in time to meet the legislative deadline because difficulties were encountered in (1) resolving

questions on technical aspects of registration requirements, such as the controversy over whether mice or rats should be used as the test animals for pesticide toxicity testing, (2) determining if a clause similar to the Delaney Clause[1] should be included, (3) determining the precise wording of various sections of the regulations and guidelines, and (4) reaching accomodation with other Federal agencies and various interest groups.

An EPA official also said that establishing the final regulations and guidelines was further delayed because of recent court decisions on EPA's responsibility for canceling pesticide registrations. Because of these decisions which dealt with questions of safety and "risk versus benefit," certain changes had to be incorporated into the regulations. EPA could not start the FEPCA registration program until the regulations were issued and, consequently, EPA lost about 9 months of the 2-year period provided by the act.

FEPCA requires that all intrastate pesticides not previously required to be registered by EPA must be registered with EPA between October 22, 1974, and October 21, 1976. EPA estimated in April 1974 that it would be requested to register about 14,700 intrastate pesticides; however according to an EPA official, this data was based on preliminary information from EPA's regional offices and represented their best guess based on their knowledge of the area.

In November 1974 we contacted EPA region III, IV, and IX officials to determine how many intrastate pesticides were registered with the States and Territories in those regions but not with EPA. Officials in regions IV and IX said about 14,300 pesticides in 12 States and single Territory in their regions will have to be registered. A region III official was not able to provide us with an estimate of the number of pesticides in his region which were not registered with EPA. EPA's rough estimate of April 1974 was 9,970 for these two regions.

EPA completed a study in March 1975 which showed that about 17,370 intrastate pesticides were registered by the States which were not previously registered by EPA. This figure was relatively close to EPA's original estimate for the entire country--a difference of about 15 percent. We did not make a detailed analysis of EPA's latest study.

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[1]The Delaney Clause is an amendment to FFDCA which prohibits using chemicals in food which are known to cause cancer in man or animals by any type of exposure.

REGISTRATIONS NOT RENEWED AT REQUIRED 5-YEAR INTERVALS

Pesticide registrations are valid for 5 years. At the end of this period the registrant may request renewal of the pesticide's registration or the registration is to be canceled. Before a product registration can be renewed, EPA requires that the pesticide undergo a complete review to insure that it complies with all current labeling and data requirements. This includes a chemical, a human safety, a use-effectiveness, and an environmental safety review.

EPA does not currently have a formal pesticide registration renewal program; since December 1970 it has had one in only 15 months. The registration renewal program was first suspended for a 4-month period between May and August 1971 because of backlogs in registration work.

In July 1972 EPA again suspended registration renewals and they have not been resumed. EPA officials told us that this suspension occurred because all pesticides currently registered must be reregistered between October 22, 1974, and October 21, 1976, and renewing the registration after July 1972 would serve no purpose because they would have to be reregistered again within a 2- to 4-year period. Also, the suspension would allow EPA to reduce its backlog of new, amended, and supplemental registrations. This backlog, however, was not appreciably reduced.

We reviewed the registration files for 100 randomly selected pesticides as of June 30, 1974, to determine the timeliness of renewal reviews made by EPA. Of the 100 sampled pesticides, 78 should have been renewed within the 5-year period ending June 30, 1974. Of the 78 pesticides, 14 were renewed within the proper time frame; however, the remaining 64 pesticide registrations had not been renewed at the end of the 5-year period as required. Also, 48 pesticides registered for 6 or more years have not received renewal reviews since their initial registration; 33 of these were initially registered before July 1967 and should have undergone renewal reviews before July 1972 when EPA suspended its renewal program. Thus, although EPA had a renewal program before July 1972, it was not effective in insuring that required registration renewals were being conducted.

EPA officials said it had been their policy to automatically extend a pesticide's registration for 5 years each time the pesticide's label is reviewed. EPA officials stated that generally a label review would not have included all four reviews required in the registration or

the registration renewal reviews as previously mentioned. There were 18 pesticides in our sample of 100 that had not had a registration renewal review in over 10 years but each had received a label review which EPA used to renew the 5-year registration period.

An EPA official stated that a request to add an additional use to the label generally required only a use review to insure that the pesticide will be effective for the new pest usage; as a result of this review, EPA considered the pesticide registration as having been renewed.

Of the 100 sampled pesticides, 40 had not undergone any type of review for 6 or more years. Also, 48 pesticides in our sample registered for 6 or more years had not received a renewal review since their initial registration; however, 39 of these had received label reviews which may have substituted as a renewal review.

We examined the record jackets of these pesticides to determine what types of reviews were made. However, these files do not contain evidence showing the type of review that was conducted during each label and/or renewal review. Consequently, we could not determine what reviews were made or the basis on which the reviewers judged that the registrant complied with all current EPA requirements.

Our review of the adequacy of labeling and data submissions (human and environmental safety, use-effectiveness, and chemistry data) indicated that these reviews were not thorough and that registrants were not requested to comply with current EPA requirements. These areas are discussed in greater detail in chapters 2 and 3. We believe that these inadequacies emphasize the need for EPA to eliminate its practice of extending the 5-year renewal data at each label change.

As shown in chapter 2 of this report, many studies are required by EPA before a product can be registered. Many of these studies have not been submitted by the registrants of currently registered pesticides. Some of these studies, including chronic (long-term) feeding and oncogenic studies, take 2 or more years to complete. Consequently, if EPA had reviewed these pesticides as they came up for renewal, it could have notified the registrants that such studies would be required before their product could be reregistered, thereby expediting the FEPCA registration program.

As outlined in its issued regulations, EPA will grant temporary registrations for less than 5 years for those products which lack certain required studies. If EPA had

notified the manufacturers of these requirements, studies might have been available before the FEPCA registration period expires in October 1976. Many products (40 percent in our sample) have not been reviewed for excessive periods of time and will probably require extensive safety and label reviews to insure that they comply with current requirements. In chapter 2 we question whether establishing temporary registrations will afford the consumer protection against unsafe and ineffective pesticides.

CONCLUSIONS

EPA is experiencing an increase in its registration workload, particularly during the FEPCA registration program--October 1974 to October 1976. EPA's workload during the 2-year period will total about 73,000 pesticide registrations and renewals. This is 3 times the normal workload. There will be a permanent increase in EPA's registration workload of about 35 percent due to the requirement that all pesticides must now be registered rather than only those shipped in interstate commerce as was the case before the passage of FEPCA. However, EPA has not taken adequate measures to provide for additional personnel with appropriate backgrounds to properly handle this increased workload.

EPA did not complete the required registration regulations and guidelines--a prerequisite for the FEPCA registration program--until 9 months of the 2-year period had expired. Registrants or potential registrants could not prepare the required data for submission until they knew what was required. Such requirements are contained in the completed regulations. However, there were some steps that EPA could have taken to speed up the registration process. For example, several pesticides lacked basic data requirements which were included in the final regulations and guidelines. EPA should have identified those pesticides which lacked these studies--some of which take 2 years to complete--and should have notified the registrant that studies would be required or their registration would expire by October 1976.

We believe that EPA cannot accomplish the required registrations and reregistrations by the October 1976 deadline because it

--lost more than one third of the 2-year registration period as a result of delays in completing the regulations,

--has not increased its staff enough to handle the increased workload, and

--expects to have no major decrease in its ongoing registration work.

Also, EPA officials were unable to provide us with any assurance that EPA could conduct the FEPCA registration program in a 2-year period.

On the basis of our findings on shortcomings in EPA's program for protecting man and the environment in this and three previous pesticide reports, EPA appears to have insufficient resources to carry out its responsibilities in a timely and effective manner.

We believe that EPA should determine its needs--personnel, facilities, equipment, and/or additional funds--to adequately fulfill its pesticide responsibilities. Special consideration should be given to EPA's ability to complete the FEPCA registration program by the legislatively mandated date of October 1976. EPA should present its needs to the Congress to resolve the problem.

EPA's suspension of its registration renewal program has resulted in many registrations not being reviewed at 5-year intervals as required. In fact many have not been renewed for over 10 years. We believe that the absence of a systematic 5-year review and the practice of extending registrations on the basis of label reviews contributed to many of the labeling and data deficiencies discussed in chapters 2 and 3.

RECOMMENDATIONS

We recommend that the Administrator, EPA:

--Determine Agency needs--funds, personnel, facilities, equipment, or time--to (1) adequately review all pesticides currently produced within the required FEPCA time frame and (2) administer the entire pesticide program in an effective and efficient manner and bring such needs to the attention of the Congress.

--After completing the reregistration program, reimplement the 5-year renewal program to insure that each pesticide is periodically reviewed for compliance with labeling and data requirements.

AGENCY COMMENTS AND OUR EVALUATION

In commenting on our report (see app. I), EPA stated that:

> "While the workload burden of reregistration is admittedly great, we are less certain than GAO that the statutory deadline of October 1976 cannot be met, or at least closely approached. It remains to be seen whether or not our planning projections concerning Congressional appropriations for FY 1976, volumes of activity, productivity and registrant cooperation are sound."

We agree with EPA that many uncertainties remain concerning the FEPCA registration program. Even if EPA does succeed in completing review action which is doubtful, many pesticides will not have certain required data such as 2-year feeding studies until well after the October 1976 deadline. (See p. 9.) EPA stated that it will grant temporary registration for a reasonable time to enable registrants to obtain the data for these pesticide products. Had EPA identified and notified affected registrants in a more timely manner, such data could generally have been available before October 1976.

In commenting on the 5-year renewal program EPA stated:

> "We agree with GAO's findings, and accept their recommendation. We will reinstate the five year renewal program after completing reregistration, with the following changes from past practice:
>
> (a) Each product will be required at the time of renewal to meet the same standards for supporting data and labeling as would a new product registered at that time; and
>
> (b) The renewal anniversary date will not be reset by amendments approved during the five-year period."

APPENDIX I

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

SEP 17 1975

OFFICE OF
PLANNING AND MANAGEMENT

Mr. Henry Eschwege
Director, Resources and Economic
Development Division
U. S. General Accounting Office
Washington, DC 20548

Dear Mr. Eschwege:

This letter is in reply to your letter of July 18, 1975 to Mr. Train accompanying copies of the proposed report entitled "Federal Pesticide Registration Program: Is It Adequately Protecting the Public and the Environment from Pesticide Hazards." We appreciate the opportunity to review and comment on this report prior to its issuance to Congress. The report was very well done and was a great help in reviewing the directions and priorities of our program.

I am enclosing the comments prepared by the Office of the Deputy Assistant Administrator for Pesticides Programs for the Agency.

If there is any additional information desired, please let us know.

Sincerely yours,

Alvin L. Alm
Assistant Administrator
for Planning and Management

Enclosure

APPENDIX I

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

SEP 11 1975

SUBJECT: OPP Comments on Draft GAO Report Entitled: "Federal Pesticide Registration Program: Is It Adequately Protecting the Public and the Environment from Pesticide Hazards" B-133192

FROM: Deputy Assistant Administrator
for Pesticide Programs (WH-566)

TO: Malcolm Stringer
Director, Office of Audit (PM-209)

General Comments:

The subject report is an exhaustive and generally excellent study of pesticide registration and tolerance setting. There are, however, two broad respects in which the EPA mandate and program are not fairly represented.

First, the report is based on the concept that pesticides are regulated to assure their effectiveness and safety without regard to the cost of regulation, and that there are generally recognized, clear-cut standards of efficacy and safety. Neither efficacy nor safety is an absolute, either-or quality. When finite standards are set, they cannot be precise or invariable; they serve simply as useful indicators. A regulatory agency, such as EPA, is faced with a demand for floating standards, which become stricter and more extensive as our knowledge grows concerning pesticides, their effects, and their environmental fate. As such standards become stricter, compliance becomes increasingly more expensive, so that society finds itself faced with ever-increasing costs to achieve decreasing increments of safety and efficacy. Reasonable judgment must be exercised in the development of standards and regulations, bearing in mind the social and economic costs of regulation to all affected sectors of the society. This need for judgment is not adequately recognized in the draft report.

The second respect in which the report is weak stems from GAO's observation of the program during a period of tremendous change. GAO's review began shortly after the 1972 amendments to FIFRA became law, and lasted through the point of issuance of new regulations for virtually all aspects of pesticide regulation. During this period, major changes have been made in organization, procedures, and regulations. One result of all these changes was some apparent confusion on the part of GAO concerning registration requirements, demonstrated by inaccurate juxtapositions of new and old material. This was most evident in the discussion of data requirements, in which it was assumed incorrectly that the conditions under which certain studies are required by the new regulations (effective August 4, 1975) were the same as the conditions of requirement in the past. Another result of the changes is that several of the problems identified by GAO have been corrected. While it is obviously too soon to evaluate the success of all the changes made, in the interests of accuracy they should at least have been mentioned.

The remainder of these comments are directed to the specific recommendations made in the draft report. Because of considerable overlap among some of the chapters, the recommendations, while identified by page and number, are grouped for purposes of discussion under headings summarizing GAO's findings.

Specific Comments:

1. Defficiencies in Supporting Data

Findings:

Many registrations and tolerances are supported by less than complete sets of data, in terms of current requirements. When requirements have changed, EPA has not pursued missing data aggressively.

Recommendations:

a) Notify registrants and petitioners of gaps in supporting data, and cancel registrations or tolerances when such data are not submitted within a reasonable time (p. 28, 1 and p. 59, 1).

b) Require the full range of data to support reregistration and future renewals (p. 28, 2).

Response:

Several steps have been taken to correct this problem. First, in accord with the requirements of amended FIFRA at Section 3(c)(2), guidelines have been developed "specifying the kinds of information which will be required to support the registration of a pesticide..." These guidelines, published for comment June 25, 1975, represent the first systematic compilation of registration data requirements. Second, in preparation for reregistration, the data base supporting the safety of each registered active ingredient has been reviewed, and any gaps have been identified. If there are gaps which require studies of short duration, products containing an affected chemical will not be reregistered until the gap is filled. If missing data require long-term studies, affected products will be granted non-renewable reregistration for a period reasonable to allow development and review of the missing data.

If the data are not submitted, the registrations involved will lapse. If data are submitted, then the acceptability of the registration will be judged on the basis of the data.

While neither the Guidelines nor the reregistration program affect tolerances directly, another recent change was the inclusion among the data requirements for registration of full long-range effects testing whenever a tolerance is required. Thus many of the gaps in tolerance-supporting data will be filled in the course of reregistration.

On the question of requiring the full range of data to support reregistration, we considered and rejected this approach. In spite of its obvious attractions, as GAO points out elsewhere in the report, we are faced with severely constrained resources and time for reregistration. The industry, both in manufacturing and testing, is similarly constrained. Thus we determined to concentrate resources in the area of highest priority, which is potential human hazard. A double standard was created in the regulations, limiting the scope of data requirements for reregistration to safety data; including hazard to fish and birds, chronic mammalian effects, oncogenesis, teratogenesis, and reproduction studies; while requiring the full range of data to support new registrations.

The remaining less critical gaps in efficacy and environmental data will be addressed in the course of future renewals, at which time all products will be subject to all data requirements current as of the renewal date.

2. Applicability of Data Requirements

Findings:

Inert ingredients are not required to be tested as rigorously as active ingredients, although they may pose significant hazards.

Little is known about long-term effects of exposure to combinations of active ingredients, and the potential for synergistic effects is cause for concern.

Recommendations:

a) Require complete testing of inert ingredients which may present hazards (p. 29).

b) Consider requiring testing of pesticides as marketed (p. 28, 3).

Response:

Three points need to be made concerning testing requirements for pesticidally inert ingredients. First, many substances that appear as inert ingredients in pesticides are extremely common in other uses as well, and there is a potential interface with other existing regulatory programs which must be considered. If Toxic Substance legislation is passed, it may well provide the most appropriate mechanisms for regulating many substances which occur as inert ingredients in pesticides. There is, in any case, a possibility of significant regulatory overlap.

Second, as GAO points out in the report, funding requests by the Office of Pesticide Programs for a general study of inert ingredients in pesticides have been repeatedly denied.

APPENDIX I

Finally, the Agency has the authority to require, on a case-by-case basis, testing of inert ingredients which may be hazardous. This authority has been exercised frequently, and during just the past six months, in connection with the following inert ingredients, among others:

p-hydroxybenezenesulfonic acid-formaldehyde condensate and its sodium salt
copper phthalocyanine
diphenyl oxide sulfonate
sodium xylene sulfonate
sodium 1,4-dicyclohexylsulfosuccinate
sodium 1,4-hexylsulfosuccinate
sodium 1,4-diisobutylsulfosuccinate
sodium 1,4-dipentylsulfosuccinate
sodium 1,4-ditridecylsulfosuccinate
dodecylbenzene
N-methyl-2-pyrrolidone

As for considering a requirement for testing products as marketed, rather than simply their individual ingredients, we did consider this in the development of the new regulations and guidelines. Certain testing requirements of the regulations, particularly studies of acute effects, can only be satisfied by tests performed on the formulated product. We rejected the approach that all required safety testing be performed on the formulated product, because of the awesome economic impact that would result. Compliance with such a requirement, because of limited testing facilities, would take years, and would cost several billions of dollars.

It is also worth pointing out in this context that combinations of ingredients in formulated products are by no means the only combinations of pesticide chemicals to which man and the environment are chronically exposed. As soon as a pesticide is released into the environment, complex processes of chemical combination and transformation begin. As is stated in the National Academy of Sciences 1975 publication, Principles for Evaluating Chemicals in the Environment, "there are so many different possibilities for potential interactions that it is unrealistic to demand that all of them be tested in advance." In general, the state of the art is not developed to the point of confident prediction and detection of interactions. Granting that present knowledge is cause for concern, until more is known about mechanisms of interaction, it is difficult to determine what regulatory or testing requirements would be most effective.

3. Labeling Deficiencies

Findings:

Many labels do not meet requirements, and when labeling requirements have changed, EPA has not pursued compliance aggressively.

Recommendations:

Establish procedures to ensure that all pesticides are adequately labeled, with consideration of:

(a) Label reviewer checklists

(b) Follow-up on final printed labeling when registration is granted pending its submission

(c) More emphasis on upgraded reference compendia

(d) Follow-up review of affected product labels when requirements change (p. 42).

Response:

Many changes have been made in the course of preparing for reregistration which should result in correction of most current labeling problems identified by GAO. Most important is the batch approach to reregistration, which has the following characteristics:

(a) Before reregistration applications are solicited from the registrants, EPA reviews a group of products similar in chemistry and use.

(b) This review considers the sufficiency of supporting data, the use classification, required precautionary statements, and any required changes in other labeling elements.

(c) The product of this review is a "Label Guidance Package", specific to the particular batch, itemizing label text and format requirements.

(d) The Label Guidance Package for each batch will be sent to all registrants of affected products, to aid them in developing acceptable labels for submission.

(e) The Label Guidance Package will also be provided to the reviewers to use as a reference standard in considering applications for products in each batch.

Another significant change has been made in the regulations, which now require submission of final printed labeling prior to acceptance of the application, whether for new or amended registration. This should eliminate altogether the problem addressed by GAO's second recommendation.

4. Tolerance-setting Criteria

Findings:

Interim tolerances have been granted in the absence of complete data on safety and on residues, when a question of safety was known to exist.

Permanent tolerances for certain chemicals have been granted such that total dietary exposure may potentially exceed the estabished Acceptable Daily Intake.

Registrations have been granted for some food or feed uses in the absence of required tolerances.

Recommendations:

(a) Evaluate total human exposure to each pesticide residue to ensure that total residues do not exceed the Acceptable Daily Intake (p. 59, 2).

(b) Periodically review all tolerances and revise as necessary.

(c) Evaluate the need for interim tolerances, and if they are essential, provide guidelines for their establishment (p. 79, 1).

(d) Cancel registrations of food or feed uses for which no tolerances exist (p. 79, 2).

Response:

GAO's criticisms are well-founded, and we are very much concerned about tolerance-setting problems. In the recent past our emphasis on the implementation of FIFRA has allowed for insufficient attention to the problems identified here. Now that the necessary regulations for registration have been promulgated, we can turn more of our attention to review of the tolerance regulations and procedures, to reassessment of tolerances already regulated, and to a comprehensive evaluation of the whole scientific basis for tolerance setting. We accept and will implement GAO's recommendations in this area.

5. Resource Deficiences

Findings:

EPA's workload increases have outpaced staff and funding increases; resources are now inadequate to carry out responsibilities.

EPA has moved slowly to implement the reregistration provisions of amended FIFRA, and thus will not meet the statutory deadline.

Recommendations:

Determine and present to Congress Agency needs both to meet the deadline for reregistration and to carry out the full pesticide program effectively and efficiently (p. 91-92, 1).

Response:

While the workload burden of reregistration is admittedly great, we are less certain than GAO that the statutory deadline of October 1976 cannot be met, or at least closely approached. It remains to be seen whether or not our planning projections concerning Congressional appropriations for FY 1976, volumes of activity, productivity and registrant cooperation are sound.

As for resource needs after the workload peak of reregistration is past, we are actively working on projecting them, and will certainly bring them to the attention of Congress.

6. Renewal Program Deficiencies

Findings:

The five-year renewal program has been ineffective, and has contributed to deficiencies in labeling and supporting data.

Recommendations:

After completion of reregistration, reinstate five-year renewals (p. 91-92, 2).

Response:

We agree with GAO's findings, and accept their recommendation. We will reinstate the five year renewal program after completing reregistration, with the following changes from past practice:

(a) Each product will be required at the time of renewal to meet the same standards for supporting data and labeling as would a new product registered at that time; and

(b) The renewal anniversary date will not be reset by amendments approved during the five-year period.

Edwin L. Johnson

 APPENDIX II

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20201

SEP 19 1975

Mr. Gregory J. Ahart
Director, Manpower and
Welfare Division
United States General
Accounting Office
Washington, D.C. 20548

Dear Mr. Ahart:

The Secretary asked that I respond to your request for our comments on your draft report to the Congress entitled, "Federal Pesticide Registration Program: Is it Adequately Protecting the Public and the Environment from Pesticide Hazards." They are enclosed.

We appreciate the opportunity to comment on this draft report before its publication.

Sincerely yours,

John D. Young
Assistant Secretary, Comptroller

Enclosure

APPENDIX II

DEPARTMENT COMMENTS ON THE DRAFT GAO REPORT TO CONGRESS ENTITLED "FEDERAL PESTICIDE REGISTRATION PROGRAM: IS IT ADEQUATELY PROTECTING THE PUBLIC AND THE ENVIRONMENT FROM PESTICIDE HAZARDS?"

GAO RECOMMENDATION:

The Secretary, HEW, through the Commissioner, FDA, [should] expand its market surveillance program so that over a period of years all pesticides with tolerances are tested for in the surveillance program.

DEPARTMENT COMMENT:

We do not concur with the proposed expansion of the pesticide surveillance program at this time. In essence, we do not believe there is a significant need for surveillance of all pesticides since there are means other than residue testing for ensuring the safe use of pesticides and our current assessments of the total food supply do not indicate the presence of excessive pesticide levels.

In assessing FDA's surveillance program, it is essential to understand that the control of pesticides in food encompasses more than merely testing samples of food for the presence of illegal residues. The relationship of good agricultural and manufacturing practices to the regulatory control of pesticides in food is an equally, if not more important consideration. It is generally recognized that if food is treated with a pesticide in a manner consistent with its labeled directions, there is only a very remote possibility that violative levels of residues would occur. It is for this reason that FDA, EPA, State and local agencies conduct establishment inspections to make certain that pesticides are being properly used.

This preventive approach of FDA and EPA has been augmented by a Memorandum of Understanding on Pesticide Enforcement which was published in the Federal Register of June 12, 1975. Among other things, this cooperative agreement calls for EPA to immediately notify FDA whenever that agency encounters an incident of pesticide misuse in which food may be implicated and provides for the coordination of the agencies' investigation and surveillance of pesticide practices. Similarly, officials of most State and local agencies advise FDA of improper pesticide practices encountered in their inspections. In addition, USDA, EPA, FDA and State extension agencies have on-going educational and advisory programs for the agricultural community and the food industry regarding the safe and proper use of pesticides in food production.

Additionally, we do not believe that the recommended action is commensurate with the relative seriousness of pesticide residues in food. Each year, FDA samples about 7000-8000 shipments of food and feed for pesticide residues. As indicated in the GAO report, less than 3% of these shipments contain residue levels in excess of established tolerances. The incidence of pesticide residues in most raw agricultural commodities is generally of a low order and their levels are frequently well below established tolerances. In addition, the results of the FDA total diet studies each year for the past 10 years indicate the consumer's average daily dietary intake for over 90 of the more persistent and toxic pesticides (or their metabolites) is well within acceptable daily intake limits established for these pesticides by the World Health Organization and the Food Agricultural Organization of the United Nations.

It is acknowledged that the present FDA Surveillance Program and the Total Diet Studies place emphasis on organochlorine and certain organophosphate pesticides and chlorophenoxy acid herbicides, and the above findings primarily relate to these pesticides. However, these pesticides are, or have been widely used, and they are persistent in the environment and bioaccumulate in living organisms such that their residues occur in milk, eggs and meat. Therefore, these findings should serve as an indication of the relative seriousness of the overall pesticide residue problem. FDA believes that on the basis of the findings for these pesticides, there is little reason to expect that residues of less persistent pesticides are occurring to any significant degree at violative levels in the nation's food supply. This conclusion is further supported by the fact that in fiscal year 1974, FDA examined approximately 500 selected food samples for 32 pesticides other than those not recovered by analytical methods employed in the routine surveillance program and only 4 samples were found to contain residues above tolerance.

In summary, we believe that a comprehensive assessment of the regulation of pesticides does not support the need for the periodic testing of all pesticides that have tolerances. Although it might be reassuring to extend testing to pesticides that have a low toxicity, rapid dissipation rates or a small volume of usage, we do not foresee any significant benefit to the public that would justify the additional costs of the expansion.

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GAO RECOMMENDATION:

The Secretary, HEW, through the Commissioner, FDA, [should] coordinate with EPA on all future efforts to sample pesticide residues in food.

DEPARTMENT COMMENT:

We agree with this recommendation. In fact, the June 12, 1975 Memorandum of Understanding on Pesticide Enforcement contains provisions along these very same lines. Accordingly, it is FDA's intention to formally request that EPA review and comment on the scope and overall adequacy of the FDA surveillance program and total diet studies including the types of foods and pesticides covered by these activities. FDA would then modify these programs as appropriate, based on EPA suggestions.

APPENDIX III

APPENDIX III

PRINCIPAL OFFICIALS OF EPA AND HEW RESPONSIBLE FOR ACTIVITIES DISCUSSED IN THIS REPORT

	Tenure of office From	To
EPA (note a)		
ADMINISTRATOR:		
Russell E. Train	Sept. 1973	Present
John R. Quarles, Jr. (acting)	Aug. 1973	Sept. 1973
Robert W. Fri (acting)	Apr. 1973	Aug. 1973
William D. Ruckelshaus	Dec. 1970	Apr. 1973
ASSISTANT ADMINISTRATOR FOR WATER AND HAZARDOUS MATERIALS:		
James L. Agee	Aug. 1974	Present
James L. Agee (acting)	Apr. 1974	Aug. 1974
ASSISTANT ADMINISTRATOR FOR HAZARDOUS MATERIALS CONTROL (note b):		
Charles L. Elkins (acting)	Oct. 1973	Apr. 1974
David D. Dominick	June 1971	Sept. 1973
ACTING COMMISSIONER OF PESTICIDES:		
Raymond E. Johnson	Dec. 1970	May 1971
DEPUTY ASSISTANT ADMINISTRATOR FOR PESTICIDES PROGRAMS:		
Edwin L. Johnson	Mar. 1975	Present
Edwin L. Johnson (acting)	Dec. 1974	Mar. 1975
Dr. Henry J. Korp (acting)	Oct. 1974	Dec. 1974
Dr. Henry J. Korp	Dec. 1972	Oct. 1974
Dr. William M. Upholt	May 1971	Dec. 1972
HEW (note a)		
SECRETARY OF HEALTH, EDUCATION, AND WELFARE:		
David Mathews	Aug. 1975	Present
Caspar W. Weinberger	Feb. 1973	Aug. 1975
Frank C. Carlucci (acting)	Jan. 1973	Feb. 1973
Elliot L. Richardson	June 1970	Jan. 1973
Robert H. Finch	Jan. 1969	June 1970
Wilbur J. Cohen	Mar. 1968	Jan. 1969
John W. Gardner	Aug. 1965	Mar. 1968

APPENDIX III

APPENDIX III

	Tenure of office From	To
ASSISTANT SECRETARY FOR HEALTH:		
Theodore Cooper	May 1975	Present
Theodore Cooper (acting)	Jan. 1975	May 1975
Charles C. Edwards	Mar. 1973	Jan. 1975
Richard L. Seggel (acting)	Dec. 1972	Mar. 1973
Merlin K. Duval, Jr.	July 1971	Dec. 1972
Roger O. Egeberg	July 1969	July 1971
Philip R. Lee	Nov. 1965	Feb. 1969
COMMISSIONER, FOOD AND DRUG ADMINISTRATION:		
Alexander M. Schmidt	July 1973	Present
Sherwin Gardner (acting)	Mar. 1973	July 1973
Charles C. Edwards	Feb. 1970	Mar. 1973
Herbert L. Ley, Jr.	July 1968	Dec. 1969
James L. Goodard	Jan. 1966	June 1968
Winton B. Ranking (acting)	Dec. 1965	Jan. 1966

[a]All pesticide functions in the Department of Agriculture and the pesticide tolerance-setting function of HEW were transferred under Reorganization Plan No. 3 of 1970 to EPA on December 2, 1970.

[b]Before July 24, 1973, the title of this position was Assistant Administrator for Categorical Programs.