PESTICIDES AMENDMENTS TO HAZARDOUS SUBSTANCES ACT

HEARINGS

BEFORE THE

SUBCOMMITTEE ON ENERGY, NATURAL RESOURCES, AND THE ENVIRONMENT

OF THE

COMMITTEE ON COMMERCE

UNITED STATES SENATE

NINETY-FIRST CONGRESS

SECOND SESSION

ON

S. 3866

TO AMEND THE HAZARDOUS SUBSTANCES ACT TO PROVIDE FOR MORE EFFECTIVE PROTECTION AGAINST THE HAZARDS CAUSED BY ECONOMIC POISONS

MAY 26, AND SEPTEMBER 29, 1970

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PESTICIDES AMENDMENTS TO HAZARDOUS SUBSTANCES ACT

TUESDAY, MAY 26, 1970

U.S. SENATE,
COMMITTEE ON COMMERCE,
SUBCOMMITTEE ON ENERGY, NATURAL RESOURCES,
AND THE ENVIRONMENT,
Washington, D.C.

The subcommittee met at 10:35 a.m., in room 5110, New Senate Office Building, Hon. Philip A. Hart (chairman of the subcommittee) presiding.

Present: Senator Hart.

OPENING STATEMENT BY THE CHAIRMAN

Senator HART. The committee will be in order.

We are considering in these hearings S. 3866.

It seeks to strengthen the control that the Federal Government shall have in the matter of regulating pesticides. To regulate pesticides properly is one of the most important of man's efforts to maintain a decent, habitable place in which to live.

The authority to permit the use of a pesticide is an awesome power. The enormous benefit or harm that may flow from any given pesticide registration dictates that the utmost care be taken in deciding which pesticides will or will not be approved for use.

Yet recent events suggest that the regulation of pesticides in this country is inadequate. The simple fact that so many hard pesticides have been in use for so long points to a continuing absence of proper concern or effective regulation for the environmental damage these chemicals may cause. Contamination of food with pesticide residues has become so prevalent in recent years that today it is pretty hard to find any food which does not carry with it a quantity of DDT.

In recent hearings before this subcommittee we found that the compound 2,4,5–T, in use for over two decades, may cause birth defects in humans. This subcommittee earlier this month learned that currently used mercury fungicides release a significant amount of toxic contaminants into the environment. Unfortunately, the list goes on, revealing rather clearly that enough attention has not been paid to the human health and environmental damage that pesticides may cause.

In an attempt to respond to these problems to some degree, I introduced the bill which I cited at the outset, S. 3866. Under its provisions, the Secretary of HEW would be authorized to prevent the movement in commerce of any pesticide whenever the protection of the public health and safety requires such an action. He would be

Staff member assigned to this hearing: Leonard Bickwit, Jr.

required also to review all labels prior to the registration of any pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act, and to approve only those labels which most effectively protect the public health.

Finally, the bill would make criminal the misuse of a pesticide in violation of any approved label. When the FIFR Act became law more than 20 years ago, the primary concern was with efficacy, not safety of pesticide use. Under such conditions, the giving of ultimate authority over pesticide regulation to the Department of Agriculture made sense. An increased awareness of the environmental dangers caused by pesticides, however, suggests now a change would be desirable in the orientation of pesticide regulation. Given the acknowledged significance of safety factors in decisions regarding pesticides, it seems appropriate to consider the expansion of the role of the Federal agency whose primary function is the protection of the public health.

The bill that is before us, if passed, would not strip the Department of Agriculture of its distinct powers. It would, however, subject the exercise of those powers to independent check by an agency who does have a different orientation and makeup, and, to some extent, different objectives. It is the primary purpose of the hearings which begin today to determine whether such a check is in fact necessary.

(The bill and agency comments follow:)

91ST CONGRESS
2D SESSION

S. 3866

IN THE SENATE OF THE UNITED STATES

MAY 20, 1970

Mr. HART introduced the following bill; which was read twice and referred to the Committee on Commerce

A BILL

To amend the Hazardous Substances Act to provide for more effective protection against the hazards caused by economic poisons.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That (a) section 2 (f) (2) is amended by striking out the word "The" and inserting in lieu thereof "Except as otherwise provided, the".

(b) Section 2 (q) (1) of such Act is amended by striking out "or (B)" and inserting in lieu thereof the following: "(B) any economic poison which the Secretary by regulation classifies as a 'banned hazardous substance' on the basis of a finding that the degree or nature of the hazards involved

in the presence or use of such poison as currently labeled is such that the objective of the protection of the public health and safety can be adequately served only by keeping such poison out of the channels of interstate commerce, or (C)".

(c) Section 2(q)(2) of such Act is amended by inserting "or clause (C)" immediately after the words "clause (B)", and by inserting after the words "*Provided*, That" the following: "(i) if the Secretary finds that the use of any economic poison presents an imminent hazard to the public health, he may by order published in the Federal Register give notice of such finding and thereupon such poison shall be deemed to be a 'banned hazardous substance' pending the completion of proceedings relating to the issuance of such regulation, and (ii)".

(d) Section 2 of such Act is further amended by inserting at the end thereof the following:

"(r) The term 'economic poison' has the same meaning as prescribed under section 2 of the Federal Insecticide, Fungicide, and Rodenticide Act".

SEC. 2. Section 4 of the Hazardous Substances Act is amended by adding at the end thereof the following new subsection:

"(i) The use by any person of an economic poison in a manner that is prohibited by the express terms on the label of such poison".

SEC. 3. (a) The heading of section 10 of the Hazardous Substances Act is amended to read as follows: "ADMINISTRATION".

(b) Section 10 of such Act is amended by adding at the end thereof the following new subsection:

"(c) In order to assure that the safe use of any economic poison is, to the extent practicable, stated on the label, the Secretary of Health, Education, and Welfare shall consult with the Secretary of Agriculture on the labeling of economic poisons prior to the registration of any such economic poison pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act. No economic poison shall after the date of enactment of this Act be registered pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act without the prior approval of the Secretary of the proposed label. The Secretary shall not approve any such label without first finding that the label as proposed constitutes better protection of the public health and safety than any other reasonable alternative".

SEC. 4. Section 17 of the Hazardous Substances Act is amended by inserting a comma and "except as otherwise provided" before "of the Federal Insecticide, Fungicide, and Rodenticide Act.".

47-740—70——2

OFFICE OF THE DEPUTY ATTORNEY GENERAL,
Washington, D.C., July 23, 1970.

Hon. WARREN G. MAGNUSON,
Chairman, Committee on Commerce,
U.S. Senate, Washington, D.C.

DEAR SENATOR: This is in response to your request for the views of the Department of Justice on S. 3866, a bill "To amend the Hazardous Substances Act to provide for more effective protection against the hazards caused by economic poisons."

S. 3866 would amend the Hazardous Substances Act to include within its terms all "economic poisons" as that term is defined in the Federal Insecticide, Fungicide, and Rodenticide Act. The bill further provides that the Secretary of Health, Education, and Welfare shall consult with the Secretary of Agriculture on the labeling of economic poisons prior to their registrations. The Secretary of Health, Education, and Welfare is authorized to make a finding that the use of any economic poison presents an imminent hazard to the public health. Upon such a finding, the poison shall be deemed a banned hazardous substance. This finding by the Secretary may be challenged by an affected party who may file objections and request a public hearing.

With the exception of the two provisions of the bill granting powers to the Secretary of Health, Education, and Welfare concerning economic poisons, the authority of the Secretary of Agriculture under the Federal Insecticide, Fungicide, and Rodenticide Act is not affected by this bill.

Whether this legislation should be enacted involves questions as to which the Department of Justice defers to the Department of Health, Education, and Welfare.

The Office of Management and Budget has advised that there is no objection to the submission of this report from the standpoint of the Administration's program.

Sincerely,

RICHARD G. KLEINDIENST,
Deputy Attorney General.

DEPARTMENT OF AGRICULTURE,
OFFICE OF THE SECRETARY,
Washington, D.C., September 25, 1970.

Hon. WARREN G. MAGNUSON,
Chairman, Committee on Commerce,
U.S. Senate, Washington, D.C.

DEAR MR. CHAIRMAN: This is in reply to your requests for a report on S. 3866, and the proposed amendment No. 794. The bill and the amendment are entitled "To amend the Hazardous Substances Act to provide for more effective protection against the hazards caused by economic poisons."

The bill and the amendment would amend the Federal Hazardous Substances Act by:

(a) qualifying the exemption under Section 2(f)(2) of the Act (15 U.S.C. 1261 Suppl. IV) pertaining to economic poisons regulated under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (FIFRA);

(b) extending the definition of a "banned hazardous substance" to include any economic poison regulated under FIFRA which the Secretary of Health, Education, and Welfare shall classify as a banned hazardous substance whenever there is a reasonable doubt as to the safety of the economic poison for man or the environment and there are less serious doubts as to the safety of any reasonable alternative to such poison, or whenever the protection of man or the environment otherwise requires;

(c) defining the term "imminent hazard" (p. 2 lines 7–12 of Amendment No. 794);

(d) providing that the Secretary of Health, Education, and Welfare shall administer Section 4 of the FIFRA and including certain provisions for the cancellation and suspension of economic poisons under Section 4 of the FIFRA;

(e) defining the term "economic poison" as used in the bill as having the same meaning as under Section 2 of the FIFRA;

(f) including as a prohibited action under the Act for any person to use an economic poison in a manner prohibited by the expressed terms of the label on such economic poison;

(g) including as a prohibited action the sale or offer for sale of any economic poison which has been designated a banned hazardous substance and which has moved in interstate commerce;

(h) including as a prohibited action the sale or offer for sale of any economic poison which has moved in interstate commerce and for which there is in effect no registration under the FIFRA;

(i) providing that no economic poison shall be registered under the FIFRA without the prior approval of the Secretary of Health, Education, and Welfare, who shall not approve any such label without first finding that the label as proposed constitutes better protection of the public health and safety than any other reasonable alternative. The Secretary of HEW shall consult with the Secretary of Agriculture in order to assure that the safe use of any economic poison is, to the extent practicable, stated on the label;

(j) qualifying the provisions of Section 17 of the Federal Hazardous Substances Act as they apply to the FIFRA.

On July 9, 1970, the President submitted to the Congress, Reorganization Plan No. 3 of 1970. Upon taking effect the plan would establish the Environmental Protection Agency. When established, this Agency will have full responsibility for regulating the use of pesticides.

The recent annual report of the Council on Environmental Quality contained (p. 140) the following statement: "The Administration is considering a broad range of legislative and administrative proposals for more effective pesticides regulation. These include measures to assure adoption of less persistent or toxic materials, limit the availability of certain types of pesticides, and regulate disposal of unused pesticides."

In view of the foregoing, the Department of Agriculture recommends that consideration of S. 3866 including amendment No. 794 be deferred until the Administration has submitted its recommendations.

The Office of Management and Budget advises that there is no objection to the presentation of this report from the standpoint of the Administration's program.

Sincerely,

J. PHIL CAMPBELL,
Acting Secretary.

Senator HART. Our first witness today is Mr. Victor Lowe, the Associate Director of the General Accounting Office. I welcome you.

As we begin, let me explain as so often happens, today is one with other assignments that will require on occasion the interruption of these hearings. The full Committee on Commerce is meeting in the room to the rear as one can hear. It was anticipated that there would be votes in there that would require a recess perhaps during the testimony. Then, there is a meeting of the Appropriations Committee to which I must go sometime during this morning. We will have to anticipate recesses on occasions.

You may proceed, sir.

STATEMENT OF VICTOR L. LOWE, ASSOCIATE DIRECTOR, CIVIL DIVISION, U.S. GENERAL ACCOUNTING OFFICE; ACCOMPANIED BY OWEN A. KANE, LEGISLATIVE ATTORNEY, OFFICE OF LEGISLATIVE LIAISON, AND RICHARD E. CHERVENAK, SUPERVISORY AUDITOR, ASSIGNED TO AGRICULTURAL RESEARCH SERVICE, DEPARTMENT OF AGRICULTURE

Mr. LOWE. Mr. Chairman and members of the subcommittee, my name is Victor L. Lowe. I am an Associate Director in the Civil Division of the General Accounting Office. For the past 3 years I have been in charge of our work in the Department of Agriculture. With me is Mr. Owen A. Kane, Legislative Attorney, Office of Legisla-

tive Liaison, and Mr. Richard E. Chervenak, Supervisory Auditor, assigned to our work in the Agricultural Research Service (ARS) of the Department of Agriculture.

We are pleased to appear before this subcommitteee today. It is our understanding that we are not here to comment on the merits of subcommittee information on our work in the pesticides regulation activity of the Department of Agriculture.

As a result of a review we made of regulatory enforcement activities in the pesticides regulation division of the Agricultural Research Service, a rather critical report was issued to the Congress on September 10, 1968. This report is entitled "Need To Improve Regulatory Enforcement Procedures Involving Pesticides, Agricultural Research Service, Department of Agriculture, B–133192." Essentially this report contained three major points:

I. In taking action at locations against misbranded, adulterated, or unregistered products, ARS, with few possible exceptions, did not obtain quantity and shipping data to determine whether shipments of the same products were available to the public in other locations. As a result, the actions taken may not have removed from the market products which, in some instances, were potentially harmful.

II. ARS operating guidelines did not include procedures for determining when shippers who had apparently violated the law would be reported to the Department of Justice for prosecution. At the time of our report, there had been no action by ARS to report violators of the law for prosecution in 13 years. This was true even in instances where repeated major violations of the law were cited by ARS and when shippers did not take satisfactory action to correct violations or ignored ARS notifications that prosecution was being contemplated.

III. ARS was not publishing notices of judgment of the courts ordering products off the market as required by the law.

Subsequently, on February 20, 1969, we issued a related report to the Congress on the need to resolve questions of safety involving certain registered uses of Lindane pesticide pellets. Briefly, this report pointed out that ARS registered Lindane pellets for use in continuously vaporizing devices in commercial and industrial establishments—such as restaurants and other food handling businesses—even though the Public Health Service, Food and Drug Administration and other Federal, State, and private organizations had long opposed this use.

These organizations had questioned the adequacy of the scientific data available to prove that continuous vaporization of Lindane pellets was safe in certain commercial and industrial establishments. ARS had not resolved this question of safety as raised by these organizations. Nor had ARS taken action to restrict or disapprove the use of Lindane pellets in vaporizers in certain commercial and industrial establishments.

Summaries of our two reports are attached to this statement.

Shortly after our first report was issued, the Intergovernmental Relations Subcommittee of the House Committee on Government Operations initiated an investigation of the Pesticides Regulation Division of ARS. At the request of the chairman of the subcommittee, members of our staff assisted the subcommittee in its investigation. Rather extensive hearings were held in May and June of 1969; and,

on November 13, 1969, the committee issued its report. The committee's report was highly critical of the operations of the Pesticides Regulation Division and a number of recommendations were made for corrective action. Among other things, the committee recommended that the General Accounting Office maintain close surveillance over the future operations of the Pesticides Regulation Division. In accordance with this recommendation, we are currently in the process of reviewing the actions taken by the Department of Agriculture to comply with the committee's recommendations.

As a result of the two reports by our office and the report of the House Committee on Government Operations, a number of changes have been made, or are being made, in the Pesticides Regulation Division.

With respect to our first report which involved deficiencies in regulatory procedures:

Voluntary recall of products by manufacturers or shippers at the request of the Pesticides Regulation Division has substantially replaced the rather ineffective seizure of products at isolated locations.

Procedures have been established for referral of cases for prosecution. In February 1970 their first case in 15 years was successfully prosecuted; two additional cases are in the hands of the Justice Department; and several additional cases are being developed in the Department of Agriculture.

Publication of notices of judgments, as required by law, has been resumed.

With respect to our report dealing with registration of Lindane pesticide pellets:

In April 1969, the Department of Agriculture announced it was taking action to cancel registration of Lindane pesticide pellets for use in vaporizing devices. Four registrants of this product appealed the cancellation action; and, under the governing legislation, the matter has been referred to an advisory committee of the National Academy of Sciences. While the appeal is pending, of course, the products remain available to the public.

In addition to these actions:

A major reorganizational effort is underway in the Pesticides Regulation Division.

At the request of the Administrator of ARS the Department of Agriculture's Inspector General has conducted a comprehensive review of the operations of the Pesticides Regulation Division. We have monitored this review and believe it to be substantive and well done. The results of the review are now being incorporated into a report that will be sent to the Administrator of ARS and other department officials.

At the request of the Director, Pesticides Regulation Division, the management improvement staff of ARS is conducting a review in the Pesticides Regulation Division. This review was started after the Inspector General's staff completed its review.

In the fiscal year 1971 budget, the Department of Agriculture has requested an increase of $2.4 million for expanded registration and enforcement activities.

During the past year, additional badly needed staff have been assigned to the Pesticides Regulation Division.

Mr. Chairman, as previously mentioned, the essential point made in our report involving Lindane pesticide pellets was that the Pesticides Regulation Division had continued to register products containing the chemical Lindane for use in continuously vaporizing devices, even though the Public Health Service had long opposed this use.

In the hearings before the Intergovernmental Relations Subcommittee of the House Government Operations Committee, it was brought out that, over the years, a substantial number of pesticide registrations had been issued over Public Health Service objections and apparently in noncompliance with provisions of the 1964 interdepartmental agreement regarding pesticides. Although the interdepartmental agreement provided that—in the event agreement was not reached among the Department representatives within 2 weeks of the initial objection, the matter would then be referred directly to the Secretary of the Department responsible for final action—none of the objections made by the Public Health Service had been referred to the Secretary of Agriculture.

A new interdepartmental agreement was entered into on January 28, 1970. The new agreement sets forth specific procedures for resolving differences of opinion among the departments. If a department objects to a registration, the Department of Agriculture is to notify the applicant or registrant and offer him an opportunity to submit data, views, or arguments with respect to the objection.

After review of the additional data, any department may request the formation of a registration review panel, composed of two representatives from each of the three departments—Agriculture, HEW, Interior—to review the issues and report their findings. If significant differences remain unresolved, all information bearing on the matter is to be reviewed at the next monthly interdepartmental pesticide meeting.

In the event agreement is not reached at the monthly meeting, the Secretary of the objecting department may request that the matter be referred to the Cabinet Committee on Environmental Quality. Based on the consideration of the action of the Cabinet Committee, the Secretary of Agriculture is to make a decision as to the specific action to be taken with respect to the registration.

Our review work with respect to operations under the new interdepartmental agreement has been limited and is still in process. Officials of both the Pesticides Regulation Division and the Food and Drug Administration, which now performs the Department of Health, Education, and Welfare's review of pesticides registrations, informed us that there has been improvement in interagency relations at the operating level. Pesticides Regulation Division officials informed us that they have not registered a product over the objection of the Food and Drug Administration since December 1969 and that all outstanding objections are being or will be resolved.

Although the new interdepartmental agreement provides for monthly meetings of the representatives of the three departments, we understand that only one such meeting has been held to date.

Our review of information provided by the Pesticides Regulation Division indicated that during the period December 1, 1969, through April 24, 1970, the Food and Drug Administration objected to 136 registration applications. While we did not ascertain the number of

cases in which the Department of Agriculture has requested the registrant or applicant to submit additional data, we were told that neither the Department of Agriculture nor the Department of Health, Education, and Welfare has yet requested the formation of a registration review panel.

About 70 percent of the 136 objections related to applications for reregistration or amended registration of pesticide products. In such cases, the pesticide products remain available for sale to the public in the form objected to by the Food and Drug Administration.

Mr. Chairman, this concludes my prepared statement. We will be pleased to respond to any questions you and the members of the subcommittee might have.

Thank you very much.

Senator HART. Under your understanding of the interagency agreement now applicable, if there is a disagreement between the Department of Agriculture and Interior or HEW on an application for registration, who prevails?

Mr. LOWE. Mr. Chairman, my understanding of the agreement is that after all the steps have been gone through, the final decision is up to the Secretary of Agriculture.

Senator HART. Perhaps it is an unreasonable assumption, but your answer would suggest that if the Secretary of Agriculture simply disagrees completely with all of the prior contrary opinion, including a Cabinet agency, he can go ahead.

Mr. LOWE. This would be my understanding, yes, sir.

Senator HART. You say that Agricultural officials have told you that they have not registered a product over an FDA objection since December of 1969, if I understand your statement.

Mr. LOWE. Yes; that is correct.

Senator HART. Are there any products now being marketed to which HEW objects?

Mr. LOWE. I would have to answer that question this way, Mr. Chairman. I think I pointed out in my statement that 70 percent of the ones since December 1969 that HEW has objected to are reregistrations or changes in products that have already been registered, and as long as these products are not canceled, they are still available for sale in the form objected to by HEW.

Senator HART. Or any others?

Mr. LOWE. Yes, Mr. Chairman. As I pointed out in my statement here, in the hearings before the Intergovernmental Relations Subcommittee last year it was brought out there were quite a number of products on the market that had been registered over the objections of the Public Health Service, and since all of these have not yet been clarified and agreed to between the two agencies, I would have to assume that the majority of those products would still be on the market.

Senator HART. As far as you are able to understand, why has not action been taken against them under the tenth paragraph of this interagency agreement?

Let me order printed in the record at this point the language of the paragraph to which I have referred.

Mr. LOWE. Is that the one that starts "The departmental representative may review the existing pattern"?

Senator HART. Yes.

Mr. LOWE. May I read that to myself, please?

Senator HART. Fine.

Mr. LOWE. I think these are the ones that they advised us that they are working on at the staff level, and several of these products have been referred to advisory committees set up under the National Academy of Sciences as called for in the law. So, these products, while they are still available on the market, are under scrutiny at the working level between the two agencies, and several of them—and we do have some details on that—it looks like something in the neighborhood of about eight of these products have been referred to the advisory committees under the National Academy of Sciences, and another eight or so of the products have been taken up for public hearings which is also provided for in the law. I would say there is a backlog there that is being worked on. I do not want to characterize the progress.

Senator HART. You said the backlog is eight, plus eight are under the review category. How many others?

Mr. LOWE. I am not sure. These are the ones that have gone to formal review, formal hearings. There are a number of others that are being worked on at the staff level between HEW and the Agriculture people, but I could not say how many.

Senator HART. Whatever the procedure being followed and whatever the conclusions reached as a result of that procedure, is it correct that the Department of Agriculture will still make the ultimate decision?

Mr. LOWE. I believe that is correct.

Senator HART. Provision for the formation of a registration review panel is discussed in that 10th paragraph, and again I would make reference to it for the record, or I want to be sure it is incorporated in the record.

Mr. LOWE. I think I pointed out in my statement, Mr. Chairman, that to the best of the knowledge we have, to date there has not been a registration review panel set up. These cases are still being worked on at the staff level.

Senator HART. In my opening statement I made reference to hearings that this subcommittee recently held on the herbicide 2,4,5-T. On the second day of those hearings a partial suspension of that product was announced by the administration. Is there anything in the current law that would make illegal the purchase of that herbicide after it is relabeled to comply with the suspension and the use of the pesticide for one of the suspended uses? That is a pretty complicated question.

Mr. LOWE. It is, Mr. Chairman, and I am afraid I could not answer it even if you were to reword it. I am not an attorney.

Senator HART. Does either Mr. Kane or Mr. Chervenak want to answer that?

Mr. KANE. I am an attorney, Mr. Chairman, but frankly I have not studied that question. I would need to refer to the law on it.

Senator HART. Permit me to leave it this way. You have got the question. When you get back, hit the books, and we will accept your answer for the record.[1]

Mr. KANE. We will be happy to do that, Mr. Chairman.

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[1] See p. 73.

(The information was subsequently received for the record:)

COMPTROLLER GENERAL OF THE UNITED STATES,
Washington, D.C., June 17, 1970.

B–128552.
Hon. WARREN G. MAGNUSON,
Chairman, Committee on Commerce,
U.S. Senate.

DEAR MR. CHAIRMAN: Your letter of May 26, 1970, requests our comments on S. 3866, 91st Congress, entitled: "A bill to amend the Hazardous Substances Act to provide for more effective protection against the hazards caused by economic poisons."

We have no special information as to the advantages or disadvantages of the amendments proposed in S. 3866 and, therefore, make no recommendations on the merits of the bill.

Representatives of our Office, in testimony before the Subcommittee on Energy, Natural Resources, and the Environment of the Senate Committee on Commerce, on May 26, 1970, presented information on our work in the pesticides regulation activity of the Department of Agriculture, two prior audit reports we issued to the Congress relating to pesticides, and certain corrective actions being taken by the Department of Agriculture. We have no other comments to offer.

Sincerely yours,

R. F. KELLER,
Acting Comptroller General of the United States.

Senator HART. In that report that I think you referred to in your testimony, the House Intergovernmental Relations Subcommittee of November of 1969, several cases of conflict of interest within the Agriculture Department were cited. In your investigations, have you run across any other such cases?

Mr. LOWE. We have not.

Senator HART. Mr. Bickwit.

Mr. BICKWIT. I have just one question. You say that you have been told that neither USDA nor the Department of HEW has requested the formation of a registration review panel. Under the interagency agreement, if HEW objects to a registration, can it request a review panel until USDA offers the applicant an opportunity to submit data to answer HEW's objections?

Mr. LOWE. It is my understanding that the applicant should be asked to submit additional data before the registration review panel is formed.

Mr. BICKWIT. Do you have any data whatsoever on the number of cases in which USDA, following an HEW objection, has requested additional data and furnished it to HEW?

Mr. LOWE. I do not think we have any specific data on that. We do know from discussions with the people in Agriculture that they have requested additional data from some of the registrants, I am not sure how many.

Mr. BICKWIT. With regard to the others, you do not know that they have or that they have not?

Mr. LOWE. No, I do not.

Mr. BICKWIT. Are you planning to acquire data on this particular matter?

Mr. LOWE. We are in the process of following up on the recommendations made by the Intergovernmental Relations Subcommittee in that report, and I think that will require us to get the data on all these recommendations that they made.

Mr. BICKWIT. Could we have the data on this particular issue for the record when it is available?

Mr. LOWE. Yes, we will try to obtain that and submit it for the record.

(The information was subsequently received for the record:)

Sixty-eight of the 136 HEW objections to registration applications during the period December 1, 1969, through April 24, 1970, were made after January 28, 1970, the date of the new interdepartmental agreement. The new agreement provides that USDA will notify the applicant or registrant of an HEW objection and offer him an opportunity to submit any data, views, or arguments with respect to the proposed rejection.

In our review of agency records pertaining to 66 of the 68 applications (agency records were not readily available for two of the applications), we found no documentation to show that the Pesticides Regulation Division (PRD), USDA, had notified any of the applicants or registrants involved and offered them an opportunity to submit data, views, or arguments with respect to the proposed rejection.

With regard to 31 of the 66 applications, PRD had sent letters to the applicants or registrants, following HEW objections, generally to notify them of the HEW objections and of changes required in the products involved or their labeling before approval of the registration or continued registration. These letters, however, did not offer the applicant or registrant an opportunity to submit views or arguments with respect to the HEW objection.

PRD furnished us with a draft notice to manufacturers, formulators, distributers, and registrants concerning a proposed rejection of registration. This notice would specifically offer the applicant or registrant the opportunity to submit any data, views, or arguments with respect to the proposed rejection. A PRD official told us that issuance of the notice will be the first instance of adherence to the subject provision of the interdepartmental agreement, and that it is the intention of PRD to issue such notices in the future.

The PRD official also told us that PRD has requested additional data from applicants or registrants upon notification by HEW that additional information was needed to reach decisions on registration applications. These requests for data, however, were not made in connection with HEW objections.

Senator HART. Mr. Lowe and gentlemen, thank you very much for helping to give us the foundation for this hearing.

Our next testimony will come from Dr. Charles Wurster, who is Chairman of the Scientists Advisory Committee, Environmental Defense Fund, and will be accompanied by a distinguished Washingtonian, Edward Berlin, attorney at law.

STATEMENT OF CHARLES F. WURSTER, PH. D., ASSISTANT PROFESSOR OF BIOLOGICAL SCIENCES, STATE UNIVERSITY OF NEW YORK AT STONY BROOK AND CHAIRMAN, SCIENTISTS ADVISORY COMMITTEE, ENVIRONMENTAL DEFENSE FUND, STONY BROOK, N.Y.; ACCOMPANIED BY EDWARD BERLIN, OF BERLIN, ROISMAN & KESSLER, COUNSEL, WASHINGTON, D.C.

Dr. WURSTER. Mr. Chaiman and members of this committee, I am especially pleased to be invited by the committee to testify here today because I have long been concerned and involved with environmental pesticide problems, particularly that of DDT. As a university faculty member I have conducted research on the effects of chlorinated hydrocarbon insecticides on nontarget organisms, especially birds. My relationship with the Environmental Defense Fund—EDF—has involved the fitting of scientific information into the legal process in an attempt to eliminate the use of several exceptionally harmful

pesticides. EDF is a nationwide organization of scientists and other citizens that undertakes litigation as a mechanism for protecting the environment. Based on this experience, I would like to share my conclusions and suggestions with this committee.

In recent years I have become aware that our most serious pesticide problems require primarily political, rather than scientific solutions. That DDT, for example, is an enormous environmental problem—the greatest of our pesticide problems—has been known for years to many investigators within the scientific community. In spite of this knowledge the problem has continued to worsen for more than two decades, yet to this day almost no effective remedial action on DDT has been taken under existing Federal pesticide policies. The use of DDT continues. The DDT problem is not an isolated one but is a part of a pattern that implies serious deficiencies in the administration of pesticide policies at the Federal level.

I think many observers of Federal regulatory agencies will agree that with the passage of time some agencies become increasingly responsive to pressures and influences from the industries they are intended to regulate.

I am aware of no more obvious example of this than the relationship between the Pesticides Registration Division—PRD—of the U.S. Department of Agriculture—USDA—and the pesticide manufacturing industry. The recent report of the House Intergovernmental Relations Subcommittee, L. H. Fountain, chairman, House Report No. 91–637, November 13, 1969, entitled "Deficiencies in Administration of Federal Insecticide, Fungicide and Rodenticide Act," FIFRA, in outlining certain aspects of this relationship tells a shocking story of laxity, flagrant abuses, and conflicts of interest between employees of USDA and the pesticide industry, particularly the Shell Chemical Co.

One is virtually led to the conclusion that the administration of national pesticide policies has been largely determined by and for pesticide manufacturers.

USDA has a rather clearly defined, yet narrow mission. It is responsible for and responsive to agricultural interests and related industries, with the agricultural chemical industry playing an increasingly dominant role during recent years. Even though the biologically potent synthetic organic pesticides in use since World War II have important environmental and human health impact far removed from the farm, pesticide regulation is performed entirely by USDA in their administration of FIFRA.

Basically, we have a regulatory agency, USDA, administering the use of materials that affect interests well beyond their area of responsibility.

Simultaneously, we have two other Federal agencies, the U.S. Department of Interior, USDI, and the U.S. Department of Health, Education, and Welfare, HEW, that are charged with protecting environmental and human health interests that are affected by pesticides over which they have almost no jurisdiction or control. Under existing pesticide policies, USDI and HEW cannot adequately protect the environment or human health from pesticides. The environment and human health have been given inadequate protection by our Government.

FIFRA became law in 1947. It provides for the protection of man, other vertebrates, "useful" invertebrates, and vegetation from the damaging effects of pesticides when they are used as directed.

Adequate and reasonable administration and enforcement of FIFRA would appear to offer a considerable degree of protection for these nontarget organisms in the environment. Yet as it has been administered and enforced by PRD of USDA for the past 23 years, FIFRA might as well never have been in existence.

The above House reports detail some of the absurdities in the administration of FIFRA. By the public admission of a high officer of USDA, Dr. Theodore C. Byerly, Assistant Director of Science and Education for USDA, WNBC–TV, March 3, 1970, the environment, which includes those "protected" nontarget organisms, was not considered in determining pesticide regulations prior to October of 1969.

I have long favored a ban on the use of DDT and several other stable chlorinated hydrocarbons. They do great damage, and adequate or superior alternatives have been available for years. It is important to realize, however, that DDT, or any single pesticide problem, is merely a symptom of a much greater disease, and banning of individual pesticides merely provides symptomatic relief. The central problem with pesticides is that pesticide policy is administered exclusively by USDA, primarily for the benefit of pesticide manufacturers with minimal consideration of other interests. Until this central problem is understood and solved, we will continue to have nightmarish pesticide problems one after another.

I should add here that I have been greatly discouraged and disappointed by the attitudes and actions of certain manufacturers of pesticides, especially the Shell Chemical Co. and Montrose Chemical Co. and their trade association, the National Agricultural Chemicals Association, in their handling of these problems. Instead of helping to solve the problem, they deny its existence. Rather than recognizing incontrovertible scientific evidence, they attack those scientists who do the research. They treat serious pesticide problems as no more than problems in public relations, and assign public relations men to disseminate nonsensical propaganda that confuses the public.

I am prepared to submit some of this material for the inspection of the committee. It is sheer folly to expect the industry to police itself; the primary objective is to sell pesticides—as much as possible.

The complete and monopolistic control over administration of pesticide policy must no longer reside exclusively within a single-mission-oriented and industry-dominated USDA.

Environmental and human health interests must be represented by those agencies responsible for their protection, not by interagency agreements or in a consulting capacity, but by a statute regulating pesticides. The failure of past interagency consulting agreements is shown by the continued registration of pesticides over hundreds of HEW objections on public health grounds and in spite of great damage to fish and wildlife under the jurisdiction of USDI.

I would favor the simplest solution to the problem.

I believe that HEW and USDI should have veto power over any registration of any economic poison. Both agencies already have qualified staffs for the evaluation of pesticides. They have performed this

function for years, yet have had no statutory authority to implement their conclusions or protect their interests.

A veto power by HEW and USDI provides protection of public health and environmental values, yet leaves recommendation procedures, research and development, evaluation of effectiveness, and many other aspects of administering pesticide policy within USDA where it now properly resides.

I therefore recommend passage of the bill under consideration as a first essential step in solving this problem, but I urge that in the future the same veto power be extended to USDI for the protection of the environment.

Senator HART. Thank you, Doctor. I will have to recess the hearing for the moment. The first essential step in getting an additional $1.3 billion for urban renewal requires that I follow Senator Pastore, who has just left the room, over to his hearing.

We will recess to resume, I would think certainly within 30 minutes.

(Recess.)

Senator HART. The committee will be in order.

Before we go to questions, I think we should receive your testimony, Mr. Berlin.

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

Let me say initially that the comments that I do have to offer are on behalf of not only the Environmental Defense Fund but also the Consumer Federation of America which I do represent and which considers this legislation of vital importance.

It is my judgment, Mr. Chairman, that if the American citizen is really to obtain any meaningful protection from the ill-advised usage of economic poisons, enactment of this legislation is truly essential.

Those of us who have been forced to confront on a day-in, day-out basis various segments of the bureaucracy have reached the not very profound conclusion that there has got to be a reorganization of the executive branch to make it more responsive and to preclude the ease with which segments of the executive branch are able to avoid taking decisive actions by hiding behind claims of limited authority.

You have recognized in the bill before the committee one of the most serious sources of this kind of frustration. We recently—when I say "we," I have reference to the Environmental Defense Fund—experienced the workings of the administrative agency shell game when we tried to initiate responsible action directed at curbing the DDT menace. The Environmental Defense Fund has been on the forefront of the battle against DDT. It has been conscious, and I think we have all been conscious for some time, of the environmental degradation that DDT has been responsible for. We have either been made aware of the face that DDT is responsible for damage to the central nervous system and indeed to the liver.

Most recently, however, it became to my mind shockingly clear that DDT is a carcinogen, at least in test animals, and there is good probative evidence that that may well be true of man himself. Because of all these threats posed by DDT, EDF launched two actions.

First, it filed a petition with the Department of Health, Education, and Welfare, the Food and Drug Administration, asking that that agency take decisive action to lower the residue levels that are permitted on raw agricultural commodities.

Secondly, because of the interplay between HEW and Agriculture, we filed a separate action with the Department of Agriculture asking that it do two things, that it first suspend the registrations for DDT and second, that eventually it cancel those registrations.

After the usual delay which we have been accustomed to experience when trying to get decisive actions from administrative agencies these days, we decided it was necessary to go to court, and we filed two separate actions in the U.S. Court of Appeals for the District of Columbia. After the appropriate passage of time we received the brief of the Justice Department representing the HEW, and they said what do you want from HEW? Se can't do anything, even though we recognize and even though the Secretary's own expert commission on pesticides, the famous Mrak Commission, which had reported back to the Secretary only weeks before—even though we all recognized that DDT is truly a monumental environmental hazard, even though we recognize it may well have grave effects on human health, we cannot do anything. Our hands are tied; we cannot do anything so long as the registration remains in effect.

Therefore, you really should be seeking relief from the Department of Agriculture. That was HEW's response.

A day or two before we received HEW's brief, we received the Agriculture Department brief, which also was written by the Justice Department, but in fairness to their attorneys, it was by different officers.

One section of the Agricultural Department brief is labeled, and I am quoting now—I am sorry, I am not quoting, I don't have that brief in front of me—that the nonaction of the Department of Agriculture in response to our petition asking for the suspension and cancellation of DDT registrations was not reviewable in the courts, first, because they contended they had not issued a final order, and second, this to me is particularly shocking, because they took the position that unless you were a registrant, someone seeking to sell an economic poison, you had no standing to challenge a certification either before the Department or before the courts.

This then is the dilemma we now find ourselves in. When you try to move against the Department of HEW, they say, hold on a minute, we may agree with you from the environmental standpoint, we may agree with you from a human health standpoint, but we can't do anything about it; it requires Agriculture's turning off the tap.

When we go to the Agriculture Department, they say, I am sorry, you are not trying to sell poisons; therefore, you don't have standing to come before us and make that kind of request.

I think in my mind this one experience, which we are right now confronting ourselves with—and the agricultural case has yet to be argued before the court of appeals, the HEW case was argued before the court of appeals on April 10 but has not yet been decided—demonstrates the absolute necessity for the legislation which you have introduced. We will not have any meaningful action when it is clearly necessary in the protection of consumers of this country unless it is made abundantly clear that one agency, and it must be the agency with paramount responsibility for environmental protection and human health, has the definitive ability to take decisive action.

Thank you very much, Mr. Chairman.

Senator HART. Thank you, Mr. Berlin.

I am glad that you, among other things, got into the record the support for this legislation not alone from the environmental defense fund but the consumers federation.

The dilemma that you described is precisely what we are trying to resolve by this bill.

Doctor, what is your reaction to the Department of Agriculture's statement that they have demonstrated their independence from the economic interests that you say influence them by moving against DDT?

Dr. WURSTER. I think that is a clear example of their lack of independence; they have done effectively nothing with regard to DDT, and have been playing games with the wording of FIFRA.

On the one hand, they canceled registrations for certain uses which they claim amounts to 35 percent of total domestic usage. But cancellation merely opens the door to a lengthy appeal procedure, and, of course, the major manufacturers of DDT did make the appeal. The appeal eliminates the effect of the action until the appeal procedure is over, since prior usage continues during this period. The appeal procedure has never been pursued to its conclusion by USDA where there was an objection by the manufacturer. USDA has dropped the cancellation case in the past.

There is no way of knowing how long the appeal procedure would last after cancellation notices are issued. It probably would be several years. In other words, cancellation is a completely ineffective action. If USDA had been serious in its attempt to eliminate the use of DDT, they would have suspended registrations, thereby stopping usage overnight. There was clearly no serious attempt on the part of USDA to get rid of the DDT problem.

USDA even more flagrantly played into the hands of the pesticide industry when it initiated a 90-day commentary period on what it called "any other uses of DDT," that is, uses other than the four that they canceled. This commentary period is a procedure not authorized in the act and is merely another delaying tactic. The 90-day period ended about the first of March 1970.

USDA received comments on DDT from various people around the country, but nothing has happened there either. This 90-day period therefore precedes even the initiation of cancellation proceedings.

In other words, this is essentially an endless process, an endless game that USDA is playing in delaying effective action and manipulating the verbiage of FIFRA.

Senator HART. As a professor of biological sciences, what do you say in response to the broad generalization that I sometimes hear that in America, in this country, we just use pesticides in very great excess?

Dr. WURSTER. I think that is true. To answer you properly would take a lot of time, but I will try to do it very briefly.

If we consider a field of a certain crop, we have many, many species of insects in it, probably many hundreds. Usually only one, two, or three of them are pests in that there are large numbers of them, they are herbivorous, eat a certain amount of the crop. The rest of the insects are either beneficial or innocuous in one way or another.

Usually at least half of all those insects are entomophagous insects—the parasites and predators. These are the carnivorous insects that are working in our favor because they prey on or parasitize the pest, thereby maintaining a constant biotic pressure on the pests. If we then come in with a broad spectrum poison of one kind or another and kill all the insects, we leave an ecologically empty space. The empty space or niche has only one kind of food in it, the plant material that also happens to be our crop.

In other words, our use of a broad spectrum insecticide often favors the pest species. The pest species is the one whose population explodes into this vacuum, because only plant material is available as food. When we create an ecological vacuum, we always favor the herbivorous pest species. Then we have created the need for more pesticides. Pesticides in this respect are a little bit like drugs in that one becomes addicted to them. They are an ideal product for manufacturers in the sense that they create the need for themselves.

So the more pesticide you apply, the more you have to apply, and one application leads to another. Excessive use at one time often leads to excessive use continually. Pesticide manufacturers are often not the friends of the farmer that they are made out to be. They promote insecticides that he may not need, thereby destroying his natural stock of entomophagous insects, creating new and greater pest problems, the need for more insecticides, and ever higher pesticide bills.

That is what is going on in this country. Let me give an example that may make this clearer. Let's say we can apply a 10th of a pound per acre of a certain pesticide, that this amount will kill 80 percent of the pests, and that this would have eliminated significant economic damage. Instead, however, the procedure recommended by the manufacturer says to apply 1 pound to the acre. Now we get a 99-percent kill of the pest species. We have almost eliminated the pests, but we have now also eliminated the entomophagous species as well. We have eliminated the entomophagous insects not only by poisoning them, but by excessively suppressing the pest species, which is the food supply of the predators and parasites.

In a few weeks this process frequently leads to a greater explosion of the pests. Had we initially applied only a 10th of a pound per acre, we would have preserved a reservoir of parasites and predators, as well as a sufficient residual supply of the pest species to serve as hosts to the entomophagous species and then we wouldn't have needed the later applications. So 1 pound leads to another pound and still another pound, whereas a 10th of a pound may be enough for the whole season. You can see how applications may amount to a hundred times what is necessary.

Senator HART. The able Senator from Tennessee, Mr. Baker, who is a member of the Committee on Commerce, has asked that two questions be put to you. This I do.

Senator Baker's first question: What are the adequate or superior alternatives to DDT to which you make reference in your statement?

Dr. WURSTER. We have not one alternative but a whole complex of alternatives which are both chemical and biological. We should use them by a procedure commonly known as integrated control, where one process does not interfere with the other, where we take advantage of

those biotic agents already present and we supplement them when necessary with either a chemical or some other compatible procedure.

There are many alternative chemical pesticides. Methoxychlor is a chlorinated hydrocarbon that is unstable. Malathion is an organophoshate insecticide, and sevin is a carbamate. There are many others, very few of which present the great environmental hazards that DDT and a few of its close relatives do. Most pesticides don't begin to offer the problems of DDT, dieldrin, and a few other chlorinated hydrocarbons.

Senator HART. For the record and in recognition of Senator Baker's interest, I would ask that you later furnish for the record the names of additional pesticides[1] that may be appropriate, rather than DDT.

Dr. WURSTER. That I can do, but let me emphasize that the alternative is not always chemical. Sometimes it is chemical, sometimes it is biological, and usually it is both.

Senator HART. The second question for Senator Baker: Is it your testimony that there are hundreds of pesticide registrations to which Public Health objects?

Dr. WURSTER. The Fountain report mentions 1,633 objections between 1964 and 1969, and it indicates that many, probably most of them were overridden by USDA.

Senator HART. So that the documentation of this would be in the Fountain report?

Dr. WURSTER. That's right.

Senator HART. Mr. Bickwit.

Mr. BICKWIT. Mr. Berlin you have a petition, you say, in the court of appeals asking for the suspension, rather than the cancellation, of DDT. As a general matter, under what conditions do you think suspension, the more extreme form of regulation, ought to be applied?

Mr. BERLIN. The statute itself sets out the test that is appropriately applied, and I believe it is an imminent hazard. I think it is clear from the language surrounding the imminent hazard language in section 4 of FIFRA, that they are talking about imminent hazard to the environment generally and certainly imminent hazard to man.

We certainly think where there is a clear showing that a pesticide may well be a carcinogen to man, and when I say a clear showing, I mean a clear showing by the Secretary's own commission, notwithstanding outside literate and the scientific community, that certainly that is the kind of imminent hazard Congress contemplated.

All we ask is that the Secretary take the reasonable course of action of saying at least until it can be established that it is not a carcinogen, that it is not an imminent hazard, that further usage be suspended.

Dr. WURSTER. Let me add one thing about the word "carcinogen." DDT is a carcinogen in the normal context of the word. It has not been proven to be a carcinogen in humans, but we don't usually experiment with humans, so we can't answer the question. The normal way of testing for carcinogenesis is to use laboratory animals; in mice, trout, and rats, DDT has been shown to be carcinogenic, so we must properly speak of DDT as a carcinogen.

Mr. BICKWIT. Should the utility of a pesticide be relevant to the determination as to whether or not it ought to be suspended?

[1]The information could not be supplied.

Mr. BERLIN. I think clearly not. I think it is clear when Congress amended FIFRA to add the imminent hazard provision, it was concerned about the fact that the Secretary had no way of taking decisive action pending the outcome of a prolonged administrative proceeding and that the clear intention was to permit, if you will, the guilty until proven innocent kind of standard where there was an imminent hazard to health or the environment.

There is certainly no suggestion in the imminent hazard amendment that economic considerations were to be counterbalancing factors. With respect to DDT, the Mrak Commission in its voluminous report makes it very clear that as far as domestic usage, that is, use in this country, is concerned, DDT is neither necessary for the control of any disease vector, principally malaria, not is it necessary for food production.

Mr. BICKWIT. I should point out that the language in FIFRA says the Secretary "may" cancel or "may" suspend.

Mr. BERLIN. I think that is certainly as the literal language of the act. I think if that language is read with the urgency of the enactment and the legislative history which underlay the enactment, it would show Congress' frustration at the Secretary's inability to move decisively where there were real threats presented. It certainly indicates that the "may" qualifications, while calling for the exercise of some discretion, as perhaps whether or not DDT is carcinogen, whether or not DDT has human health implications, that once that finding is made, I think the permissive nature of the amendment no longer exists.

In the case of DDT there has been no dispute about its human health and environmental potentialities. So I think the "may" really has no proper application. We are not talking about discretion to invoke suspension once we find the existence of an eminent hazard, I think "may" goes to whether or not there is an eminent hazard and as I read Secretary Finch's pronouncements and the pronouncements of the Mrak Commission, everyone certainly agrees that DDT falls in that category.

Mr. BICKWIT. Thank you.

Senator HART. Gentlemen, thank you very much for your helpful testimony.

Our concluding witness today is from the Law School of the University of Washington, Mr. William Rodgers.

STATEMENT OF WILLIAM H. RODGERS, JR., UNIVERSITY OF WASHINGTON SCHOOL OF LAW

Mr. RODGERS. Good morning, Mr. Chairman. Like the other witnesses, I will try to confine myself to my written statement with some editorial comment.

My name is William H. Rodgers, Jr. I am an associate professor of law at the University of Washington School of Law.

I received my law degree from Columbia in 1965. At the outset I should confess to being a partisan on the pesticides issue. I am the petitioner in a legal action, which is presently pending before the Ninth Circuit Court of Appeals, against Secretary Finch seeking an order from the Food and Drug Administration establishing zero tolerance levels for DDT in raw agricultural commodities.

Bascially, this action is indistinguishable from the action described earlier by Mr. Berlin, initiated by EDF. My action has been stayed by order of the court dated April 1, 1970, pending the disposition of the EDF action.

My research includes an article, to be published shortly in the Columbia Law Review, discussing the recommendations of Secretary Finch's Commission on Pesticides and Their Relationship to Environmental Health—the so-called Mrak Commission.

You have convened this hearing to consider legislation that would authorize the Secretary of HEW to classify any "economic poison" as a "banned hazardous substance" upon a finding that current labeling precautions are inadequate to protect the public health and safety. I wholeheartedly support the bill because, as other witnesses already have mentioned, the administration of the existing legislative apparatus for protecting the public from the risks of pesticides poisoning has been scandalously deficient, and further that recent tack-on efforts to strengthen this apparatus by revising the interagency agreement have been incompatible with the recommendations of the Mrak Commission and clearly inadequate.

In the brief time available, I should like to comment on several behavioral patterns which have characterized efforts to strengthen controls over the use of chemical pesticides in the last several years.

PATTERN 1

For at least a decade distinguished panels repeatedly have issued insightful reports containing recommendations for reducing the hazards associated with the use of chemical pesticides. With rare exceptions, these recommendations, which sound a familiar refrain, have been ignored, obscured, or circumvented through some timid governmental response, only to be revived and repeated in the next major report examining the pesticides crisis.

I will provide further documentation. I will refer to several reports; these claims can be thoroughly documented. Ten years ago another commission chaired by Dr. Emil Mrak recommended to Governor Edmund Brown of California that—

> all users of pesticides, farmers, certainly, but home gardeners as well, should be encouraged through a continuous campaign of education, to follow directions explicitly * * *.

In 1963 the President's Science Advisory Committee declared that "elimination of the use of persistent toxic pesticides should be the goal," and stated unequivocally that "decisions on registrations, clearly related to health, should be the responsibility of (HEW)." That, of course, is the issue we are considering here today—7 years later.

In 1966 the Ribicoff committee of the U.S. Senate recommended legislation to prevent contamination of the environment through used containers, mislabeling, or faulty application; and further recommended legislative authority for the mission and activities of the Federal Committee on Pest Control, the body that I will discuss shortly.

In May of 1969 a report of the National Research Council of the National Academy of Sciences urged "that further and more effective steps be taken to reduce the needless or inadvertent release of persistent

pesticides into the environment." Most recently, of course, last November, the Mrak Commission released its report containing sweeping recommendations for reform and urging further drastic reductions in the use of the persistent pesticides.

PATTERN 2

As mentioned by Dr. Wurster, the chemical pesticides industry has compiled an unenviable record of irresponsible opposition to legitimate scientific concerns about the widespread and virtually uncontrolled use of chemical pesticides.

Opponents of DDT were pure food nuts, bug lovers, and rabble-rousers. In Seattle last October, less than a month before the release of the recommendations of the Mrak Commission, industry spokesmen were making preposterous assertions that the elimination of DDT would reduce by one-half food production in the United States; or that the movement to ban DDT was essentially an attack on the entire capitalistic profit system.

No reputable scientist would deny that persistent pesticides have been a factor of significance to the threatened extinction of the peregrine falcon. Industry representatives have denied this. An illustrative comment I think can be found in the March 1970, edition of the Top Operator, a farm journal publication, where Mr. K. R. Fitzsimmons, general manager of the agricultural chemicals division of Shell Chemical Co., gave this response to a question about Shell's intentions if aldrin is banned: "We intend to go on selling it. We feel it is necessary to food production. We have data from 17 years of experience both with employees in the plant and with use on the farm that aldrin is safe."

I think similar illustrations of these kinds of statements could be offered.

Let me put these remarks in perspective. No doubt the chemical pesticides industry when placed in an advocate's position, like any other advocate, is not the first to stretch a point in favor of a special economic interest. The assault against DDT undoubtedly on occasion has been characterized by sloppy science, misleading rhetoric, and outright emotionalism.

I think the chemical pesticides industry could cite to this committee instances of irresponsible statements attacking DDT. I think it nevertheless worthwhile to emphasize the irresponsibility of some of the industry advocacy because I believe this intransigence has contributed in no small measure to the current crisis in the pesticides area. False, commercial voices have been heeded in the highest policymaking circles of the Government. These voices too often have prevailed over reputable scientific views, with the consequence that governmental policy has lagged far behind current scientific thinking.

I think Dr. Wurster gave you some illustrations of that.

PATTERN 3

This is a point I will not dwell on. I think the Fountain committee report thoroughly documented that the U.S. Department of Agriculture, which has the sole legislative responsibility for the registration of chemical pesticides under FIFRA, has compiled a record of lawless

administration almost beyond belief. The particulars of the scandalous derelictions of the Pesticides Regulation Division have been thoroughly documented in the Fountain committee report which already has been mentioned, and I do not have to rehearse what is there so clearly established. Suffice it to say, that repeated and flagrant violations of the law have occurred with respect to labeling, the cancellation of registrations, and the removal of hazardous products from marketing channels.

For 13 years the Pesticides Regulation Division could not bestir itself to report to the Justice Department for prosecution a single one of the hundreds of criminal violations it had uncovered.

We have heard today that there has apparently been some modest improvement in these deficiencies.

I think the experience with DDT has demonstrated how ill equipped is USDA to handle a regulatory challenge. Under FIFRA an insecticide is misbranded if "when used as directed it shall be injurious to living man or other vertebrate animals," or if the label does not contain a warning or caution statement "adequate to prevent injury to living man and other vertebrate animals and useful invertebrate animals." It is a criminal offense to sell or distribute a misbranded pesticide. For many years, the sale and distribution of DDT products flatly have offended these misbranding provisions.

It would be an understatement to say that criminal prosecutions in this area initiated by USDA would be improbable.

The gathering storm over the use of DDT in this country in no way disturbed the complacency of USDA.

On April 30, 1969, after the appointment of the Mrak Commission by Secretary Finch in response to the coho salmon crisis in Lake Michigan, Dr. Harry Hays, Director of the Pesticides Regulation Division, testified in the Wisconsin DDT hearings that his division was not reviewing current DDT registrations.

On July 14, 1969, Dr. George W. Irving, Administrator of the Agricultural Research Service, was quoted in the Congressional Record as saying that he was unaware of any evidence indicating that DDT was unsafe.

In fact, the June 1969 issue of the Journal of the National Cancer Institute reported the results of extensive research implicating DDT and several other compounds as carcinogens in animal tests. The Mrak Commission later referred to this study as an "impressive" scientific work.

One point is indisputable: the impulse for the present reassessment of governmental policy pertaining to pesticides has not originated within USDA, which has central enforcement responsibilities under FIFRA. Instead, whatever action has been taken has occurred only upon the recommendations of a commission appointed by Secretary Finch of HEW and following disclosures that I think amount to a national scandal.

Against this background, I would like to speak for a moment about the "primary legal response"—if the revision of the interagency agreement can be dignified by that term—to the recommendations of the Mrak Commission.

I should at this point note that Secretary Finch, in a statement accompanying the release of the complete report of the Mrak Com-

mission on December 23, stated that HEW's "legislative authority should be strengthened"; and that HEW must have the "clearly defined authority" to intervene against registered uses of pesticides "deemed to be hazardous to the health of man or other living organisms upon which life depends." The Mrak Commission of course recommended that approval of HEW and Interior as well as Agriculture should be required for all pesticide registrations.

On this basis I would assume that HEW will be here before this committee enthusiastically supporting the bill.

The interagency agreement, as rewritten, does nothing to achieve the objective of giving HEW clearly defined authority to intervene. It is a legal and political insult to the impressive scientific work of the Mrak Commission.

It does not attempt—nor could it under existing law—to divest the Secretary of Agriculture of the sole responsibility for registration.

It is based, in large part, upon an earlier agreement the administration of which was characterized by immaturity, irresponsibility, and a wholesale circumvention of substantive responsibilities. It establishes an elaborate and highly artificial review procedure that will assure delays where speedy action is necessary. It does nothing to avoid the registration of new products over the objections of HEW and the virtual immunization of old products from effective review.

Under the old agreement unresolved HEW objections about proposed registrations and labeling were to be referred to the Secretary of Agriculture for decision.

Nothing has changed that basic premise. But, prior to this referral, HEW objections must be filtered through a three-staged review procedure which was described to you this morning. First, objections are to be considered by a Registration Review Panel made up of two representatives of each of the three interested departments, and second, in the event of continuing disagreement, objections are to be considered at the first monthly interdepartmental meeting.

I submit that these first two stages can be dismissed as hortatory reminders to the principals to talk about their differences a little bit longer.

I think it is significant that this morning we heard that, at least thus far, these first two stages have not yet been invoked.

Stage 3 calls for review by the Cabinet Committee on Environmental Quality, which is instructed to prepare a written recommendation for the Secretary of Agriculture.

The farce becomes apparent upon examination of the charter of the working group of the Subcommittee on Pesticides of this Cabinet Committee. The charter basically is indistinguishable in substance from the charter of the now defunct Federal Committee on Pest Control.

The revision thus amounts to inventing a new name for an old committee and authorizing it to make recommendations to the Secretary of Agriculture.

I think, Mr. Chairman, that it might be helpful to reproduce in the record side by side the old charter for the Federal Committee on Pest Control and the new charter for this working group of the Subcommittee on Pesticides.

At the conclusion of this prolonged rigmarole, the new agreement, like the old, vests sole responsibility for the decision in the Secretary of Agriculture. Noteworthy is the fact that not a single one of the

1,200 objections of HEW under the old agreement was referred to the Secretary for final decision—conduct patently in violation of the terms of the agreement.

The question is whether these objections will be referred to the Secretary under the new agreement. That this is at least doubtful is indicated by the practices described in the Fountain report.

Another crucial problem untouched by the revised agreement pertains to the burden of proof as to safety. The old agreement, in section 2(d), provided:

> If one department concludes that the proposal should be rejected in whole or in part, this view shall be expressed in writing and shall be supported by appropriate scientific evidence.

The Fountain committee strenuously objected to the practice within PRD to construe this language as meaning that HEW has the burden of proving hazard rather than that the registrant has the burden of proving safety. This administrative perversion of statutory purpose predictably will continue under the new agreement which, in section B(3), states:

> If a Department concludes that the registration should be rejected in whole or in part, this view shall be expressed in writing along with a statement of the reasons for the conclusion including the specific information, lack of information, or scientific judgment upon which these are based.

Already, to confirm the suspicions that the burden of proof problem will persist, Mr. Ned Bayley, USDA Director of Science and Education, in response to a question of whether a pesticide use will be canceled upon the recommendation of HEW, has stated publicly:

> From the standpoint of public health, we should lean on the expertise and medical responsibility of HEW. But this doesn't mean uses would be canceled in a sweeping manner. HEW will be expected to back its recommendations with facts * * * including backing them in any legal action that might develop. (Top Operator, March 1970, p. 30.)

The intractable problem—and I don't think it is solely a problem of administration in this connection—is that under FIFRA the USDA must supply a statement of reasons whenever registration of an economic poison is refused. The consequence is that today, as before, it will be necessary for HEW to prove to the satisfaction of PRD that a pesticides product creates a hazard before steps are taken to reduce the risk; that is, it must be said by PRD that these reasons are sufficient to support the defense of any legal action against it for a failure to register. I see no way to escape this burden of proof dilemma within the present legislative framework. I submit that it is unwise and unproductive to condition the power of HEW to move against a hazardous pesticide upon its ability to persuade another agency of the need.

Especially is this so when that other agency has compiled a dismal record of administration to the distinct detriment of the consuming public.

The bill before you would cure this irrationality by allowing the Secretary of HEW to move against hazardous pesticides when the protection of the public in his judgment could not be secured by precautionary labeling.

Of special significance is the subsection that would allow the Secretary, upon finding "that the use of any economic poison presents an imminent hazard to the public health," to adjudge the product a

"banned hazardous substance" pending the completion of the proceedings. This would allow immediate steps to seize the dangerous product, leaving the litigation to later.

In conclusion, I would like to devote a few comments to labeling. The fact that PRD never has secured the cancellation of a registration in a contested case indicates that great stress is placed upon labeling as a technique of legal control.

I think it is safe to say that the Department of Agriculture has devoted a great deal of effort urging pesticide users to read the label and read the instructions. Indeed, the Ribicoff committee was told by USDA that pesticide users have been receiving 3 million reminders a year to "Read the label and follow the instructions," a precaution of doubtful value if nobody reads the label or follows the instructions.

The empirical question is quite clear: in order to be an effective instrument of social control it is essential to have a label and instructions that are accurate and complete and a user who can understand and who has an inclination to obey what was understood.

Suffice it to say that the available empirical data indicates that this concurrence of circumstances is coincidental at best.

Illustrations of confusion, misrepresentation and fraud in labeling can be multiplied indefinitely. The Mrak Commission has made a series of recommendations calling for, among other things, readable printing, the identification of genuine names for all pesticides and "the conveying of clear directions for and information about proper use, dangers and first aid. This committee, during your hearings last year on the effects of pesticides on sports and commercial fisheries, was given an excellent clinical introduction to the liliputian print, contradictory instructions, and chemical doubletalk with which the retail consumer must come to grips.

Like my discussion of some of the statements of industry representatives, I would submit that it is difficult to discuss labeling without being anecdotal. Everybody has his favorite horror story. I will confine myself to mentioning one single label that I think is the epitome of irresponsibility, and that is the label of a common rose dust carrying this modest disclaimer: "This material is sold without warranty as to hazards or results."

I think what that indicates is that if the particular pesticide does not kill the bugs in the backyard, the manufacturer is saying "too bad, you lose," and if it kills everything else in the back yard, "too bad, again, you still lose."

Wholly apart from irresponsible labeling practices, I think the empirical data also gives us persuasive evidence of the inutility of even accurate labeling as an instrument of social control.

Most important is the fundamental issue of whether anybody would read the label even if it explained the risk.

PRD recently has invested $52,000 with the University of Illinois to test the empirical basis for the department's eternal assumption that labeling can bring about effective control.

We are spending a lot of money reminding users to read the label and follow the instructions, and the question is whether empirically that course makes any sense. Not surprisingly, a recent report by the project investigators indicates that a review of the literature confirmed "that most of the pesticide users do not read pesticide labels" and, moreover, "users find it difficult to understand pesticide labels when they read them."

What this does is tend to undercut completely the empirical basis for USDA's massive public education program.

In conclusion, I believe the sorry record on labeling confirms the wisdom of the provision in the bill before you granting HEW the statutory authority to give "prior approval" to a proposed label. This power should follow a fortiori from the proposed grant of authority to move against hazardous pesticides that should be withdrawn from interstate commerce when no label could supply sufficient protection.

I thank you, Mr. Chairman. That concludes my prepared statement and I would be delighted to answer any questions that you may have.

Senator HART. That is a statement comprehensive and understandable and one that hardly requires questions.

I appreciate the time it represents and the effort that was involved in preparing it and getting here to give it to us.

Mr. Bickwit.

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

Senator HART. I would like the staff to follow the suggestion that Professor Rodgers made to run in tabular form side by side the old charter of the Federal Committee on Pest Control and the new charter for the working group of the Subcommittee on Pesticides.

(The following information was subsequently received for the record:)

Federal Committee on Pest Control Charter

A. ESTABLISHMENT

The functions and procedures of the Federal Committee on Pest Control were published in the Federal Register on September 15, 1964. Like the Federal Pest Control Review Board before it, the Committee was established through the joint action of the Secretaries of Defense, the Interior, Agriculture, and Health, Education, and Welfare. The Committee objectives and procedures are hereby realigned in this revision of the Charter.

Germane to the establishment of the Federal Committee on Pest Control was recognition of the need for balance between man and his environment that will be consistent with his total aesthetic and economic necessities and his social values.

The Committee was established in recognition of the fact that the Federal Government both recommends and participates in pest control, regulatory, research, and information programs involving pesticides.

Proper usage of pesticide chemicals to destroy unwanted pests and disease organisms as they affect man, animals, and plants has an enormous potential for the public good. There must, at the same time, be a recognition that chemicals which will kill or control pests are, in many cases, capable of causing harm. It is therefore essential that any contemplated use of a pesticide chemical be first evaluated as to the good that its use is expected to achieve, the harm which may result, the precautions which should be taken to minimize harmful effects, and a decision made as to whether any risk that may be involved is warranted in the light of the benefits contemplated.

B. PURPOSE

This Committee is the primary coordinating mechanism for all Federal activities in the general field of pesticides, and pests and their control. The activities coordinated by this Committee include such things as the review of pest control programs in various parts of the world in which there is active participation on the part of the Federal Government either in funding or in supervision; research on pests and their control and effects of control procedures whether by chemical or other methods; monitoring of the environment for pesticides and their residues; public information on pest control and the use of pesticides; and evaluation of economic and social values and risks involved in the control of pests by various methods.

The Committee shall advise the appropriate Departments and agencies of government concerning matters of interest to more than one Department. This advice shall be offered in the light of the total interests of the citizens of this country and must take account of activities by other agencies and individuals. In no case, however, will the advice of this Committee supersede the responsibility of each Department and agency to carry out the function assigned to it by legislative and executive mandates.

The Committee will encourage exchange of information among International, Federal, and State agencies and, in the case of Federal multi-departmental effort, will review recommendations that may result.

(Continued on page 32)

Charter of the Working Group of the Subcommittee on Pesticides of the Cabinet Committee on the Environment

A. ESTABLISHMENT

A Working Group of the Subcommittee on Pesticides of the Cabinet Committee on the Environment (formerly Environmental Quality Council) is established pursuant to action of the Committee (Council) announced on November 20, and the Federal Committee on Pest Control is hereby abolished.

The Working Group will: (1) provide day-to-day coordination of Federal agency pesticide activities; and (2) develop program and policy proposals for consideration by the Subcommittee on Pesticides.

The following agencies will have membership on the Working Group:

Department of Agriculture.
Department of Health, Education, and Welfare.
Department of the Interior.
Department of Defense.
Department of Transportation.
Department of State.*

The Office of Science and Technology, the Bureau of the Budget, and the Office of Intergovernmental Relations will be invited to designate an observer at the meetings of the Working Group. Other agencies will be invited to participate in meetings when matters of significant concern to them are to be discussed.

The Working Group will consist of one principal authorized to commit his agency in routine coordination and on most issues and to make reservations on behalf of his agency on controversial issues. At the request of any principal, Departmental or agency issues will be referred to the Subcommittee on Pesticides for review prior to implementation.

Each member agency will name one or more alternates to speak for that agency in the absence of the principal. Other individuals, cognizant of the pesticide programs and responsibilities of their agencies, may attend meetings to provide technical support for the principal.

It is recognized that the use of pesticide chemicals is necessary to protect man, animals, plants, and the environment against harmful insects, rodents, other vertebrate pests, weeds, and diseases. It is further recognized that use of pesticide chemicals, especially careless and unauthorized use, is hazardous to nontarget man, plants, and animals, and the environment. It is, therefore, essential that any use of a pesticide chemical be evaluated as to the necessity for its use, the harm which may result, and the precautions which must be taken to minimize harmful effects.

B. PURPOSE

The Working Group is the primary staff level coordinating mechanism for Federal activities concerning pesticides, pests, and their control. The activities coordinated by the Working Group include, but are not limited to:

(1) Pest control programs in various parts of the world in which there is active participation on the part of the Federal government, either in funding or in supervision;

(2) Research on pests and their control and effects of control procedures, whether by chemical or other methods;

(3) Monitoring of the environment for pesticides and their residues;

(4) Establishment of pesticide investigation teams to conduct special investigations of pesticide problems which arise or which may be anticipated;

(5) Public information on pest control and the use of pesticides;

(6) Evaluation of economic and social values and risks involved in the control of pests by various methods; and

(7) Advice to the interdepartmental group on pesticide registration on problems that it believes should be considered by that group.

The Working Group shall advise the Subcommittee on Pesticides and the appropriate Federal departments and agencies concerning matters of common interest. In no case, however, will the Working Group supersede the responsibility of each department and agency to carry out the functions assigned to it by legislative and executive mandates. The Working Group will encourage exchange of information among international, Federal, state, and local agencies and may participate with them as appropriate.

*The intent is to assure adequate consideration of international concerns which are largely but not wholly represented within the Agency for International Development.

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C. PROCEDURES

1. Review of programs:

(a) The Committee may request any Federal agency to submit for review a detailed description of its proposed and current pest control programs, and monitoring, research, education and other programs pertaining to pest control.

(b) The Committee will identify those portions of such programs which have have some interaction with activities or interests of other Departments.

(c) The Committee will review such portions of programs from the standpoint of effectiveness, economic impact, and of hazards to human health, to livestock and crops, to fish or wildlife, and other elements of the environment.

(d) Based upon such review the Committee shall recommend to the heads of the Departments or agencies concerned, such modifications in the programs as the Committee feels will best serve the public interest.

2. Intergovernmental Cooperation:

(a) The Committee shall promote or encourage review of both Federal and non-Federal programs by State and local groups representing a broad spectrum of interests and responsibilities.

(b) The Committee may communicate with such State and local groups to receive their recommendations, and make recommendations to them, either directly or through member Departments, whichever seems most expeditious and effective.

(c) Subject to foreign policy guidance from the Department of State, the Committee may participate in joint activities with foreign or international groups having similar interests and will coordinate these activities among Federal and State agencies. Formal recommendations arising from such joint activities may be directed by the FCPC to any concerned Federal Department or agency. Such formal recommendations shall not be transmitted directly to any foreign government or international agency.

3. Stimulation of new activities:

(a) Whenever the Committee feels that the public interest will be served by the initiation of a new activity such as interdepartmental participation in integrating a variety of control methods or analyzing jointly the effects of such integrated control on all aspects of the environment, the Committee may recommend appropriate action to the heads of the concerned Departments or agencies and representatives of States.

4. Mechanisms available to the Committee:

(a) The Committee may establish subcommittees, *ad hoc* work groups, or panels of specialists to assist in discharging the Committee's responsibilities. Membership on such subcommittees, etc., need not be limited to representatives of Federal Departments.

(b) The Committee may request Departments or agencies to provide special services, consultation, staff, facilities, publications, conferences, etc., as may facilitate the work of the Committee. Expenditure of appropriated funds for such activities of the Committee must be within the authority and area of responsibility of the contributing Department or agency and must remain within their individual fiscal control, even though the technical supervision may be provided by the Committee.

D. MEMBERSHIP

Membership on the Committee is by appointment of two members by letter to the Chairman from the Secretaries of the primary pesticide-user Departments: Defense, the Interior, Agriculture, and Health, Education, and Welfare. Upon invitation of the committee, a liaison representative may be similarly appointed by other government agencies having an interest in interdepartmental, national, or international pest control and related problems. The Council of State Governments may also designate a representative to the Committee.

E. OFFICERS AND STAFF

1. The Officers of the Committee shall be: Chairman; Vice Chairman; and full-time Executive Secretary and professional staff as required.

(a) The Chairman and Vice Chairman shall be elected by the Committee from among its members. The Executive Secretary will be appointed by HEW from nominations submitted by the FCPC.

(b) The Chairman will be elected for a 1-year term (to be ineligible for more

(Continued on page 34)

C. PROCEDURES

1. Review of programs

(a) On request, any Federal agency shall submit to the Working Group for review a detailed description of its proposed and current pest control programs and monitoring, research, education, and other programs pertaining to pest control.

(b) The Working Group will review such programs from the standpoint of effectiveness, economic impact and hazards to human health, to livestock and crops, to fish or wildlife, and to other elements of the environment.

(c) Based on such review, the Working Group shall recommend to the heads of the departments or agencies concerned such modifications in the programs as the Working Group feels will best serve the public interest.

2. Intergovernmental Cooperation

(a) The Working Group shall promote or encourage review of both Federal and non-Federal programs by state and local groups representing a broad spectrum of interests and responsibilities.

(b) The Working Group may communicate with such state and local groups to receive their recommendations and to make recommendations to them, either directly or through member departments, whichever seems most expeditious and effective.

(c) Subject to foreign policy guidance from the Department of State, the Working Group may participate in joint activities with foreign or international groups having similar interests and will coordinate these activities among Federal and state agencies. Informal recommendations arising from such joint activities may be directed by the Working Group to the concerned Federal department or agency. No formal recommendations shall be transmitted directly to any foreign government or international agency.

3. Stimulation of new activities

(a) Whenever the Working Group feels that the public interest will be served by the initiation of new activity, such as interdepartmental participation in integrating a variety of control methods or in analyzing jointly the efforts of such integrated control on all aspects of the environment, the Working Group may recommend appropriate action to the Subcommittee on Pesticides and to the concerned departments or agencies and representatives of states.

4. Mechanisms available to the Working Group

(a) The Working Group may establish ad hoc groups or panels of specialists to assist in discharging the Working Group's responsibilities. Membership on such ad hoc groups need not be limited to respresentatives of Federal departments.

(b) The Working Group may request the appropriate agencies to provide special services, consultation, staff, facilities, publications, conferences, etc., as may facilitate the work of the Working Group. Expenditure of appropriated funds for such activities of the Working Group must be within the authority and area of responsibility of the contributing department or agency and must remain within its individual fiscal control, even though the technical supervision may be provided by the Working Group.

D. MEMBERSHIP

Membership and observer status on the Working Group is by appointment of principals and alternates by letter, to the Chairman of the Subcommittee on Pesticides, from the heads of agencies concerned. On invitation of the Working Group, a liaison representative may be similarly appointed by other government agencies having an interest in problems related to pest control.

E. OFFICERS AND STAFF

1. The officers of the Working Group shall be: Chairman; Vice Chairman; and Executive Secretary.

The Chairman and Vice Chairman shall be elected from among members of the Working Group.

2. The staff of the Working Group shall include such professional and other staff as may be required.

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than one additional successive term) and his successor will be elected from a different Department.

(c) The Vice Chairman will also be elected for a 1-year term but from a different Department than the Chairman (to be ineligible for more than one additional successive term).

2. It shall be the duty of the Chairman to preside at all meetings and assure compliance with the Charter of the Committee. He shall call meetings of the Committee when he deems it necessary or upon request of any member Department. The Chairman shall exercise leadership in seeking timely resolutions of interagency differences on items of concern to the Committee.

3. In the absence of the Chairman, the Vice Chairman will perform the functions of the Chairman. In the absence of both, the Chairman will furnish the Executive Secretary with the names of those individuals who can assume these duties.

4. By agreement of the signators, the Secretary of the Department of Health, Education, and Welfare will provide administrative support for the Executive Secretary and required professional and clerical staff. The Federal Committee on Pest Control will recommend staffing requirements and budgetary support to the Secretary of HEW consistent with workload requirements. The Secretariat will be responsible to the FCPC for functional and operational guidance.

5. The Executive Secretary will be responsible for:

(a) Preparation of agenda, notice of meetings, correspondence, subcommittee coordination, and representation of the Committee as requested by the Committee through the Chairman.

(b) Preparation and recommendation to the Committee of pertinent policies and plans to meet the Committee and subcommittee requirements and long-range objectives. To this end, the Executive Secretary may request the Chairman to appoint advisory planning work groups and *ad hoc* subcommittees as desired.

(c) Final review and consideration of publications or presentations authorized by the Committee through the Chairman.

(d) Maintenance of sufficient records and accounts to provide an annual report of the Committee's activities for such distribution as recommended by the Committee and acting as the Archivist of the Committee.

F. MEETINGS

1. Meetings shall be held at the call of the Chairman following coordination with members regarding time, place, and date.

2. Decisions of the Committe eshall be made normally at regular meetings where there is an opportunity for discussion, and not by correspondence or telephone calls except in rare cases of urgency.

3. Minutes of meetings shall consist of a record of important discussions and decisions of the Committee but need not be a verbatim record. Minutes shall be distributed to members and alternates.

G. QUORUM

A majority of the members of the Committee shall constitute a quorum authorized to transact any business duly presented at any meeting of the Committee.

Approved:

ROBERT S. MCNAMARA,
Secretary of Defense.
Date; June 19, 1967.

ORVILLE L. FREEMAN,
Secretary of Agriculture.
Date: May 25, 1967.

STEWART L. UDALL,
Secretary of the Interior.
Date: June 2, 1967.

JOHN W. GARDNER,
Secretary of Health, Education and Welfare.
Date: May 17, 1967.

3. It shall be the duty of the Chairman to preside at all meetings and to assure compliance with the Charter of the Working Group. He shall call meetings of the Working Group when he deems it necessary or on request of any member department. The Chairman shall exercise leadership in seeking timely interagency coordination on items of concern to the Working Group. The Chairman shall communicate directly with the Chairman of the Subcommittee on Pesticides as needed.

4. In the absence of the Chairman, the Vice Chairman will perform the functions of the Chairman.

5. The Executive Secretary will be responsible for:

(a) Preparation of agenda, notice of meetings, correspondence, coordination of administrative matters and representation of the Working Group as requested by the Chairman.

(b) Preparation and recommendation to the Working Group of pertinent policies and plans to meet the Working Group requirements. To this end, the Executive Secretary may request the Chairman to appoint advisory and other ad hoc groups as required.

(c) Maintenance of minutes, sufficient other records and accounts to provide an annual report of the Working Group activities for such distribution as recommended by the Working Group.

F. MEETINGS

1. Meetings shall be held at the call of the Chairman, following coordination with members regarding time, place, and date.

2. Decisions of the Working Group usually shall be made at regular meetings where there is an opportunity for discussion and not by correspondence or telephone calls, except in rare cases of urgency.

3. Minutes of meetings shall consist of a record of important discussions and decisions of the Working Group, but need not be a verbatim record. Minutes shall be distributed to principals, alternates and observers.

G. QUORUM

A majority of the members of the Working Group shall constitute a quorum authorized to transact any business duly presented at any meeting of the Working Group.

Approved

CLIFFORD M. HARDIN,
Secretary of Agriculture.

Mr. RODGERS. Thank you, Mr. Chairman.

Senator HART. Thank you very much.

This concludes the testimony scheduled to be received today.

We adjourn to resume tomorrow morning at 10 o'clock in room 1114.

(Whereupon, at 12:35 p.m., the hearing was adjourned, to reconvene at the call of the Chair.)

STATEMENT OF WILLIAM H. RODGERS, JR., UNIVERSITY OF WASHINGTON, SCHOOL OF LAW

Mr. Chairman, my name is William H. Rodgers, Jr. I am an Associate Professor of Law at the University of Washington, School of Law. I received my law degree from Columbia in 1965. At the outset I must confess to being a partisan on the pesticides issue. I am the petitioner in a legal action, which is presently pending in the Ninth Circuit Court of Appeals, against Secretary Finch seeking an order from the Food & Drug Administration establishing zero tolerance levels for DDT in raw agricultural commodities. My research includes an article, to be published shortly in the Columbia Law Review, discussing the recommendations of Secretary Finch's Commission on Pesticides and Their Relationship to Environmental Health (the Mrak Commission).

You have convened this hearing to consider legislation that would authorize the Secretary of HEW to classify any "economic poison" as a "banned hazardous substance" upon a finding that current labeling precautions are inadequate to protect the public health and safety. I wholeheartedly support the bill because I believe the administration of the existing legislative apparatus for protecting the public from the risks of pesticides poisoning has been scandalously deficient and that recent tack-on efforts to strengthen this apparatus by revising the interagency agreement have been incompatible with the recommendations of the Mrak Commission and demonstrably inadequate given the present dimension of our pesticides crisis.

In the brief time available, I should like to comment on several behavioral patterns which have characterized efforts to strengthen controls over the use of chemical pesticides in the last several years.

PATTERN NO. 1

For at least a decade distinguished panels repeatedly have issued insightful reports containing recommendations for reducing the hazards associated with the use of chemical pesticides. With rare exceptions, these recommendations, which sound a familiar refrain, have been ignored, swept under the rug or circumvented through some timid governmental response, only to be revived and repeated in the next major report examining the pesticides crisis.

Ten years ago another commission chaired by Dr. Emil Mrak recommended to Governor Edmund Brown of California that "all users of pesticides, farmers, certainly, but home gardeners as well, should be encouraged through a continuous campaign of education, to follow directions explicitely . . . ." [1]

In 1963 the President's Science Advisory Committee declared that "elimination of the use of persistent toxic pesticides should be the goal," and stated unequivocally that "decisions on registrations, clearly related to health, should be the responsibility of [HEW]." [2] In 1965 the same group recommended that "unnecessary use of pesticides should be avoided wherever possible." [3] A sub-panel report noted emphatically that, "Substantial reduction in insecticide use, in specific cases as much as 50%, can be made by applying our present knowledge of pests and their control." [4] In 1966 the Ribicoff Committee of the United States Senate recommended legislation to prevent contamination of the environment through used containers, mislabeling or faulty application; and further recommended legislative authority for the mission and activities of the Federal Committee on Pest Control. In May of 1969 a report of the National Research Council of the

[1] Report of Governor Edmund G. Brown's Special Committee on Public Policy Regarding Agricultural Chemicals (1960).
[2] Use of Pesticides 17.
[3] Report of the Environmental Pollution Panel, Restoring the Quality of Our Environment 17 (1965).
[4] *Id.* at 291.

National Academy of Sciences urged "that further and more effective steps be taken to reduce the needless or inadvertent release of persistent pesticides into the environment." [5] In November, 1969, the Mrak Commission released its report containing sweeping recommendations for reform and urging further drastic reductions in the use of the persistent pesticides.

PATTERN NO. 2

The chemical pesticides industry has compiled an unenviable record of irresponsible opposition to legitimate scientific concern about the widespread and virtually uncontrolled use of chemical pesticides. Opponents of DDT were pure food nuts, bug lovers and rabble-rousers. In Seattle last October, less than a month before the release of the recommendations of the Mrak Commission, industry spokesmen were making preposterous assertions that the elimination of DDT would reduce by one-half food production in the United States; or that the movement to ban DDT was essentially an attack on the entire capitalistic profit system. No reputable scientist would deny that persistent pesticides have been a factor of significance to the threatened extinction of the peregrine falcon. Industry representatives did. An illustrative comment can be found in the March, 1970 edition of the Top Operator, a Farm Journal Publication, where Mr. K. R. Fitzsimmons, General Manager of the Agricultural Chemicals Div. of Shell Chemical Co. gave this response to a question about Shell's intentions if aldrin is banned: "We intend to go on selling it. We feel it is necessary to food production. We have data from 17 years of experience both with employees in the plant and with use on the farm that aldrin is safe." [6] Similar illustrations could be offered.

Let me put these remarks in perspective. No doubt the chemical pesticides industry is not the first to stretch a point in favor of a special economic interest. The assault against DDT undoubtedly on occasion has been characterized by sloppy science, misleading rhetoric and outright emotionalism. I think it nevertheless worth while to emphasize the irresponsibility of some of the industry advocacy because I believe this intransigence has contributed in no small measure to the current crisis. False, commercial voices have been heeded in the highest policymaking circles of the government. These voices too often have prevailed over reputable scientific views, with the consequence that government policy has lagged far behind current scientific thinking.

PATTERN NO. 3

The United States Department of Agriculture (USDA), which has the sole legislative responsibility for the registration of chemical pesticides under the Federal Insecticide, Fungicide & Rodenticide Act (FIFRA), has compiled a record of lawless administration almost beyond belief. The particulars of the scandalous derelictions of the Pesticides Regulation Division (PRD) have been thoroughly documented in the Eleventh Report by the House Committee on Government Operations, "Deficiencies in Administration of Federal Insecticide, Fungicide and Rodenticide Act," November 1969 (the Fountain Committee).

Let me summarize what was there so persuasively documented: Pesticide products have been approved for use without compliance with established interdepartmental procedures for resolving safety questions. Products have been approved for uses that were practically certain to result in the illegal adulteration of food. Repeated and flagrant violations of the law have occurred with respect to labeling; the cancellation of registrations; and the removal of hazardous products from marketing channels. For thirteen years the Pesticides Regulation Division (PRD) could not bestir itself to report to the Justice Department for prosecution a single one of the hundreds of criminal violations i had uncovered. And the Fountain Committee reported instances where PRD officials have appointed consultants to positions in which their duties presented a clear conflict of interest with their private employers in the pesticides industry.

The experience with DDT has demonstrated how ill-equipped is USDA to handle a regulatory challenge. Under FIFRA an insecticide is misbranded if "when used as directed it shall be injurious to living man or other vertebrate

[5] Report of the Committee on Persistent Pesticides, Division of Biology and Agriculture, p. 29.
[6] P. 31.

animals;" or if the label does not contain a warning or caution statement "adequate to prevent injury to living man and other vertebrate animals . . . and useful invertebrate animals." [7] It is a criminal offense to sell or distribute a misbranded pesticide. For many years, the sale and distribution of DDT products flatly have offended these misbranding provisions. It would be an understatement to say that criminal prosecutions, initiated by USDA, would be improbable.

The gathering storm over the use of DDT in this country in no way disturbed the complacency of USDA. On April 30, 1969, after the appointment of the Mrak Commission in response to the coho salmon crisis in Lake Michigan, Dr. Harry Hays, Director of the Pesticides Regulation Division testified in the Wisconsin DDT hearing that his division was not reviewing current DDT registrations.[8] On July 14, 1969, Dr. George W. Irving, administrator of the Agricultural Research Service, was quoted in the Congressional Record as saying that he was aware of no evidence indicating that DDT was unsafe.[9] In fact, the June 1969 issue of the Journal of the National Cancer Institute reported the results of extensive research implicating DDT and several other compounds as carcinogens in animal tests. This study was termed "impressive" by the Mrak Commission.

One point is indisputable: the impulse for the present reassessment of governmental policy pertaining to pesticides has not originated within USDA, which has central enforcement responsibilities under FIFRA. Instead, whatever action has been taken has occurred only upon the recommendations of a commission appointed by Secretary Finch of HEW and following disclosures that amount to a national scandal.

Against this background, I would like to speak for a moment about the primary legal response—if the revision of the interagency agreement can be dignified by that term—to the recommendations of the Mrak Commission. It should be noted that Secretary Finch, in a statement accompanying the release of the complete report of the Mrak Commission on December 23, stated that HEW's "legislative authority should be strengthened"; and that HEW must have the "clearly defined authority" to intervene against registered uses of pesticides "deemed to be hazardous to the health of man or other living organisms upon which life depends." The Mrak Commission of course recommended that approval of HEW and Interior as well as Agriculture should be required for all pesticide registrations. On this basis, I would assume that HEW will be enthusiastically supporting this bill.

The interagency agreement, as rewritten, does nothing to achieve these ends. It is a legal and political insult to the impressive scientific work of the Mrak Commission. It does not attempt—nor could it under existing law—to divest the Secretary of Agriculture of the sole responsibility for registration. It is based, in large part, upon an earlier agreement the administration of which was characterized by immaturity, irresponsibility and a wholesale circumvention of substantive responsibilities. It establishes an elaborate and highly artificial review procedure that will assure delays where speedy action is necessary. It does nothing to avoid the registration of new products over the objections of HEW and the virtual immunization of old products from effective review.

More particularly, under the old agreement unresolved HEW objections about proposed registrations and labeling were to be referred to the Secretary of Agriculture for decision. Now, prior to this referral HEW objections must be filtered through a three-staged review procedure. First, objections are to be considered by a Registration Review Panel made up of two representatives of each of the three interested departments, and second, in the event of continuing disagreement, objections are to be considered at the first monthly Interdepartmental Meeting. I submit that these two stages can be dismissed as hortatory reminders to the principals to talk about their differences a little while longer.

Stage three calls for review by the Cabinet Committee on Environmental Quality, which is instructed to prepare a written recommendation for the Secretary of Agriculture. The farce becomes apparent upon examination of the Charter of the Working Group of the Subcommittee on Pesticides of this Cabinet Committee, which basically is indistinguishable in substance from the charter of the now defunct Federal Committee on Pest Control. The revision thus amounts to inventing a new name for an old committee and authorizing it to make *recommendations* to the Secretary of Agriculture. At the conclusion of this prolonged rigmarole, the new agreement, like the old, vests sole responsibility

[7] 7 U.S.C. § 135 (z)(2)(g), (d).
[8] Transcript, vol. XVI, pp. 1541–42.
[9] See 115 Cong. Rec. E5889 (daily ed. July 14, 1969).

for the decision in the Secretary of Agriculture. Noteworthy is the fact that not a single one of the 1200 objections of HEW under the old agreement was referred to the Secretary for final decision—conduct patently in violation of the terms of the agreement.

Another crucial problem untouched by the revised agreement pertains to the burden of proof as to safety. The old agreement, in section 2(d), provided "If one Department concludes that the proposal should be rejected in whole or in part, this view shall be expressed in writing and shall be supported by appropriate scientific evidence." The Fountain Committee strenuously objected to the practice within PRD to construe this language as meaning that the Public Health Service has the burden of proving hazard instead of that the registrant has the burden of proving safety. This administrative perversion of statutory purpose predictably will continue under the new agreement which, in section B(3), states: "If a Department concludes that the registration should be rejected in whole or in part, this view shall be expressed in writing along with a statement of the reasons for the conclusion including the specific information, lack of information, or scientific judgment upon which these are based." Already, Mr. Ned Bayley, USDA Director of Science and Education, in response to a question of whether a pesticide use will be canceled upon the recommendation of HEW, has stated publicly: "From the standpoint of public health, we should lean on the expertise and medical responsibility of HEW. But this doesn't mean uses would be canceled in a sweeping manner. HEW will be expected to back its recommendations with facts . . . including backing them in any legal action that might develop." [10]

The intractable problem is that under FIFRA the USDA must supply a statement of reasons whenever registration of an economic poison is refused. The consequence is that today, as before, it will be necessary for the Public Health Service to prove to the satisfaction of PRD that a pesticides product creates a hazard before steps are taken to reduce the risk. I see no way to escape this burden of proof dilemma within the present legislative framework.

I submit that it is unwise and unproductive to condition the power of HEW to move against a hazardous pesticide upon its ability to persuade another agency of the need. Especially is this so when that other agency has compiled a dismal record of administration to the distinct detriment of the consuming public.

The bill before this body would cure this irrationality by allowing the Secretary of HEW to move against hazardous pesticides when the protection of the public in his judgment could not be secured by precautionary labeling. Of special significance is the subsection that would allow the Secretary, upon a finding "that the use of any economic poison presents an imminent hazard to the public health", to adjudge the product a "banned hazardous substance" pending the completion of the proceedings. This would allow immediate steps to seize the dangerous product, leaving the litigation to later.

In conclusion, I would like to devote a few comments to labeling. The fact that PRD never has secured the cancellation of a registration in a contested case indicates that great stress is placed upon labeling as a technique of legal control. Indeed, the Ribicoff Committee was told by USDA that pesticide users have been receiving 3 million reminders a year to "Read the label and follow the instructions," [11] a precaution of doubtful value if nobody reads the label or follows the instructions.

In order to be an effective instrument of social control, it is essential to have a label and instructions that are accurate and complete and a user who can understand and has an inclination to obey what was understood. Suffice it to say that the available empirical data indicates that this concurrence of circumstances is coincidental at best. Illustrations of confusion, misrepresentation and fraud in labeling can be multiplied indefinitely. The Mrak Commission made a series of recommendations calling for, among other things, readable printing, the identification of genuine names for all pesticides and "the conveying of clear directions for and information about proper use, dangers and first aid." This committee, during your hearings last year on the Effects of Pesticides on Sports and Commercial Fisheries, was given an excellent clinical introduction to the liliputian print, contradictory instructions and chemical doubletalk with which the retail consumer must come to grips.

[10] Top Operator, March 1970, p. 30.

[11] Hearings Before the Subcommittee on Reorganization and International Organizations of the Senate Committee on Government Operations, 88th Cong., 1st Sess., pt. 3 at 723 (1966).

It is difficult to discuss labeling without being anecdotal. I will confine myself to a single story about a common rose dust carrying this modest disclaimer: "This material is sold without warranty as to hazards or results"! This definitive disclaimer of responsibility is a typical indication of why efforts to impose a rule of law on the use of chemical pesticides have been frustrated for so long.

More important than the accuracy of the label, of course, is the fundamental empirical question of whether anybody would read it even if it fairly explained the risk. PRD recently has invested $52,000 with the University of Illinois to test the empirical basis for the department's eternal assumption that labeling can bring about effective control. Not surprisingly, a recent report by the project investigators indicates that a review of the literature confirmed "that most of the pesticide users do not read pesticide labels" and. moreover, "users find it difficult to understand pesticide labels when they read them."

In conclusion, I believe the sorry record on labeling confirms the wisdom of the provision in the bill before you granting HEW the statutory authority to give "prior approval" to a proposed label. This power should follow *a fortiori* from the proposed grant of authority to move against hazardous pesticides that should be withdrawn from interstate commerce under all circumstances.

I thank you Mr. Chairman for this opportunity to place before your committee my views on the legal aspects of your proposal to strengthen protections against the hazards of economic poisons.

[From the Federal Register, vol. 35, No. 42, Mar. 3, 1970]

OFFICE OF THE SECRETARY

Pesticides

Interdepartmental Agreement for Protection of Public Health and Quality of Environment

Purpose. Coordination of the activities of the three Departments pertaining to economic poisons as defined in section 2 of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 135), hereinafter referred to as pesticides, with reference to the review of current or proposed registrations to assure maximum protection of the public health, the well being of man, and the quality of the environment.

Existing departmental responsibilities. Each of the three Departments has certain statutory authority and responsibility relating to pesticides in the environment, as set forth below:

Department of Agriculture

1. Statutory authority under the Federal Insecticide, Fungicide, and Rodenticide Act for registration of pesticides.

2. Responsibility for research, education, information, regulatory, and action programs designed to protect the well being of man, crops, livestock, forests, ranges, habitats, products, structures, and premises against arthropod and other invertebrate pests, weeds, and fungi with equal concern for the protection of beneficial nontarget organisms and the quality of the environment.

Department of Health, Education, and Welfare

DHEW has the statutory authority and responsibility under the Federal Food, Drug, and Cosmetic Act for establishing safe tolerances for pesticides in or on raw agricultural commodities, processed food and potable water. The Department also has responsibilities for protecting the public from health, occupational, and environmental hazards related to the use and disposal of pesticides, and for other public health aspects such as the control of diseases and their vectors.

DEPARTMENT OF INTERIOR

USDI has statutory authority and responsibility under the Federal Water Pollution Control Act to carry out programs, to protect and enhance the quality of the Nation's waters including determining the effects of pesticides in water on health, welfare, and aquatic life. These responsibilities include establishing water quality standards for interstate waters. The Department also has statutory authority for the conservation of wild birds, fish, mammals, their food organisms and their environment as affected by pesticides and the appraisal of effects of pesticides on fish and wildlife.

Information. Each Department will keep each of the other Departments fully informed of developments in knowledge from research or other sources which may come into its possession in connection with matters referred to in this agreement. High priority shall be placed by each Department representative to respond to each of the other Departments' requests, whether written or oral, for any and all information concerning action pending or taken on pesticide matters.

Procedures—A. *General.* 1. Each Department will designate a qualified representative to act on behalf of such Department in carrying out the terms of this agreement. All communications from USDA, DHEW, and USDI will be directed to these representatives.

2. USDA shall furnish to the other Departments copies of each proposal received for registration or reregistration with the accompanying safety data (if any) and a request for an opinion from DHEW and USDI on the requested action in their areas of responsibility.

3. Within 15 working days, DHEW and USDI shall evaluate each registration or reregistration proposal in light of the data supplied and offer an opinion or provide a status report as to whether or not the registration should be granted or specify the additional data deemed necessary before such evaluation can be made. When either is unable to assess the public health or environmental risk without additional data, USDA shall advise the registrant of its inability to consider registration of the pesticide until the additional data requested have been received and reviewed by the respective Departments according to the following procedures described below.

B. *Specific.* 1. The Departmental Representative will accomplish review by his agency of each proposal and report results of such review to each of the other agencies within 15 working days of the receipt of the proposal. If there is insufficient information to reach a decision on the proposal, USDA will be contacted within such period of 15 working days and advised with particularity what additional information is needed for the necessary evaluation. Applicants for registration should not be discouraged from communicating with DHEW or USDI on registration matters of mutual interest, so long as the other representatives are informed of the details of such contact by memorandum thereof.

2. Upon receipt of such a request for further information, USDA will make arrangements to obtain the additional information, if available, and furnish it to the Department making the request. USDA will withhold final action on the matter for 15 working days, from the date of furnishing the requested information or advice that such information is not available, pending receipt of the report of the other Department of the results of further review.

3. If a Department concludes that the registration should be rejected in whole or in part, this view shall be expressed in writing along with a statement of the reasons for the conclusion including the specific information, lack of information, or scientific judgment upon which these are based.

Upon being so notified, USDA will notify the party involved, i.e., the applicant or registrant, and offer him an opportunity to submit any data, views, or arguments with respect to the proposed rejection and any such submission shall be promptly referred to the other Department representatives who shall report to USDA the results of their review of the submission.

4. In the event that after the review of the additional data the Departments cannot agree on the approval of the proposal, any Department may request the formation of a Registration Review Panel for the purpose of making a complete

review of the issues and related information or lack thereof and submit a detailed report of their findings. Each Registration Review Panel shall be composed of two representatives from each of the three Departments with the chairman to be selected from the representatives of the Department from which the objections have come.

The Registration Review Panel shall prepare its report within 20 working days, including any minority opinions, and submit it to each of the three departments.

5. The report(s) of the Registration Review Panel shall be reviewed by each Department within 15 working days of its receipt.

6. If significant differences between the Departments remain still unresolved, all data and information submitted by all parties shall be reviewed at the first monthly Interdepartment Pesticide Meeting after the reviews of the Registration Review Panel reports have been made.

7. In the event agreement is not reached among the Department representatives at the monthly Interdepartment Pesticide Meeting, a submission of the reports of the reviews referred to in paragraphs B–1 through B–6 above, will be referred at the request of the Secretary of the objecting Department to the Cabinet Committee on Environmental Quality. The referral shall be accompanied by a statement prepared by each Department analyzing the issues involved and setting forth the decision it recommends. The Cabinet Committee on Environmental Quality will consider such recommendations and make a written report, either accepting, rejecting, or modifying them.

8. Based upon consideration of the action of the Cabinet Committee, the Secretary of Agriculture will make the decision as to the specific action to be taken with respect to the matter on which the Department representatives were not in agreement, and will thereupon notify the other two Secretaries in writing in advance of the publication of the final determination if he has not followed the recommendations made by the objecting Department(s), specifically stating his reasons for such action.

9. When registration is granted, USDA shall supply to DHEW and USDI final printed labeling at the time of registration with a copy of the final letter to the registrant.

10. The Departmental representatives may review existing patterns of usage and registrations for particular pesticides. A conclusion by USDA, DHEW, or USDI that an existing pesticide use or registration may be detrimental to the public health or to the quality of the environment shall be transmitted to the other two Departments together with the supporting reasoning and information, with a recommendation for corrective action. Written information from all sources on the health or environmental aspects of such pesticides shall be submitted to a Registration Review Panel for review and recommendations. If USDA, DHEW, or USDI disagrees with the recommendations of the Registration Review Panel, that Department can initiate further review by the procedural steps described in paragraphs B–6 through B–8 above.

Interdepartment pesticide meetings and conferences. The Department representatives will meet jointly at an Interdepartment Pesticide Meeting once a month to provide a continuous dialogue concerning all aspects of their current activities and to promote cooperation and understanding among the Departments. Monthly reports concerning their activities will be made to the Secretaries of the three Departments, according to a mutually agreed upon format.

The Departmental representatives will arrange a general conference at least once each year to discuss research needs, research program and policy, and the application of research findings in action programs, including public information relating to pesticides. The Interdepartment Pesticide Conference will consider broad questions on policies relating to pesticides involving the interrelationships of control programs, research, registration, tolerances, the public health, and general departmental recommendations to the public.

In order to promote free interchange of information among the Departments involved under this agreement, each Department representative should be invited and encouraged to participate in conferences, meetings, and various symposiums with Federal, State, university, or industry people on possible matters of mutual interest.

Effective date and supersedure. This agreement shall become effective upon signature by the Secretaries of USDA, USDI, and DHEW, and shall supersede

the agreement entitled "Interdepartmental Coordination of Activities Relating to Pesticides by the Department of Agriculture, the Department of Health, Education, and Welfare, and the Department of the Interior", published in the FEDERAL REGISTER on May 1, 1964 (29 F.R. 5808).

Dated January 28, 1970.

CLIFFORD M. HARDIN,
Secretary of Agriculture.
ROBERT H. FINCH,
Secretary of Health, Education, and Welfare.
WALTER J. HICKEL,
Secretary of the Interior.

[F.R. Doc. 70-2568; Filed, Mar. 2, 1970; 8:49 a.m.]

PESTICIDES AMENDMENTS TO HAZARDOUS SUBSTANCES ACT

TUESDAY, SEPTEMBER 29, 1970

U.S. SENATE,
COMMITTEE ON COMMERCE,
SUBCOMMITTEE ON ENERGY, NATURAL
RESOURCES AND THE ENVIRONMENT,
Washington, D.C.

The subcommittee met at 10 a.m., in room 1218, New Senate Office Building, Hon. Philip A. Hart (chairman of the subcommittee), presiding.

Present: Senator Hart, Mr. Bickwit.

Senator HART. The committee will be in order.

Today we are resuming hearings on S. 3866. This is a bill to strengthen Federal control over harmful pesticides. I introduced it in May and later filed an amendment to it. The bill is intended to remedy what I think are glaring deficiencies in the existing pesticide law.

A fair summary of its purpose, I think, is that it is intended to set legislative requirements as to when a pesticide must be removed from the market and to make criminal the misuse and sale of banned pesticides; and finally, to define the previously undefined statutory phrase "imminent hazard" which has traditionally denoted those situations where immediate suspension of a pesticide is appropriate.

I had hoped that an administration bill giving support to some of these proposals would have been sent up to the Hill by this time. Almost 3½ months ago Dr. Ned Bayley, speaking for the Department of Agriculture, told this committee that he did not believe the law as presently written was adequate to carry out the responsibility to protect the public. He then proceeded to list several amendments to existing law which the Department had developed and which he explained were then under review among the various Federal agencies. Certainly all of us here this morning understand the problem of obtaining approval from numerous disparate interests. I think it not unfair to ask why after almost 3½ months we are still without any administration bill.

For a good many years we tolerated—and all of us can share the blame for this one—pesticide laws which are clearly deficient. Yet the mere fact that we have done so for a long time should not dull our realization that there is urgency of the need to remedy the situation. If, as Dr. Bayley says, we cannot protect the public under existing law, we must act as rapidly as possible to insure that we will soon be able to.

To help us with our efforts in this regard, I hope the administration, although without a legislative proposal as yet of its own, will give us its reactions and suggestions to the bill that I have offered. We have

invited the Departments of Health, Education, and Welfare and of Agriculture with that purpose in mind, and we welcome them back.

Our first witness is Dr. George Irving, the Administrator of the Agricultural Research Service of the Department of Agriculture.

STATEMENT OF DR. GEORGE W. IRVING, JR., ADMINISTRATOR, AGRICULTURAL RESEARCH SERVICE, DEPARTMENT OF AGRICULTURE

Dr. IRVING. Mr. Chairman, I appreciate the opportunity to appear before your committee to discuss the provisions of S. 3866, including the proposed amendment No. 794, concerning the regulation of pesticides. I am accompanied by Dr. Francis J. Mulhern, Associate Administrator, regulatory and control programs of ARS, and Mr. Charles W. Bucy, Assistant General Counsel.

On July 9, 1970, the President submitted to the Congress, Reorganization Plan No. 3 of 1970, which provides for establishing the Environmental Protection Agency. This Agency will be the focal point for Federal activities to insure further environmental protection and will have full responsibility for pesticides regulation. The statutory period for the plan becoming law, absent of congressional action, will expire in a few days.

The legislative report by the Department of Agriculture on S. 3866 recommends that consideration of the bill now before your committee be deferred until the legislative recommendations by the executive branch are submitted to the Congress. Without a doubt, there is a need for legislation to strengthen and extend Federal regulation over pesticides.

On August 10, 1970, the Council on Environmental Quality submitted to the Congress its first annual report. On page 140, the report states that:

> The administration is considering a broad range of legislative and administrative proposals for more effective pesticides regulation. These include measures to assure adoption of less persistent or toxic materials, limit the availability of certain types of pesticides and regulate disposal of unused pesticides.

These and others are forthcoming.

We know that intensive consideration is being given to a package of legislative recommendations that will be far reaching in extending Federal control over the use of pesticides. The Administrator of the Environmental Protection Agency will have full responsibility for effective enforcement of pesticides regulation and it would appear that he would desire to be heard with regard to what specific legislation is needed.

Mr. Chairman, the Department of Agriculture has recognized, for some time, the necessity to strengthen the regulation of pesticides. In the 90th Congress, for example, we supported S. 2057 and H.R. 11846, which were the proposed "Federal Pesticide Control Act." These bills were the result of a legislative recommendation submitted by the Secretary of Agriculture to the President of the Senate and the Speaker of the House on June 9, 1967.

These bills would have strengthened the enforcement of the Federal Insecticide, Fungicide, and Rodenticide Act by authorizing establishment registrations, inspection of plants, a system of quality controls

over pesticide production operations, civil penalties for violations, and the authority to issue injunctions.

In addition to supporting legislation to strengthen existing laws, I would like to describe very briefly, an example of what we are doing, without new legislation, to bring about better management in the use of pesticides. The misuse of pesticides is the major factor in the public health and environmental problems associated with pesticide use. Improper usage results from failure to follow the directions for use and precautionary statements on the label or from applications made for pest control which are not needed.

We are taking steps to develop a cooperative Federal-State program that would insure safe and effective use of pesticides by all users. Under this program, there would be supervision and monitoring of pest control work where intensive pesticide use is involved as well as furnish technical advice on pest control needs; and a voluntary system developed under which certain pesticides would be handled on a restricted basis to insure that only qualified persons would use them.

This program will have a direct and immediate impact upon pesticide use patterns. It will result in reducing the amount of pesticides used by eliminating any unnecessary treatments. This will allow for greater use of biological control agents and lower environmental pollution; improved safety of use by restricting the availability of hazardous chemicals to the general public; and allow the collection of necessary data for an ecological systems approach to pest management.

Mr. Chairman, this concludes my statement. My associates and I will be happy to respond to any questions you or members of the committee may have.

Senator HART. Well, as so often happens probably the fellows that are here are the least responsible for what, no matter how you couch it, is a critical reaction. So I communicate to the administration through you, this reaction. You may be right that the Congress was at fault in not moving on those bills that were sent up in the 90th Congress; but assuming that was wrong, I apply the maxim two wrongs don't make a right, and this administration is wrong in not having sent anything of significance to the 91st, because time runs out on the public we are supposed to be protecting.

I think the fact that you prefer not to comment on the bill that is here would indicate that you are suggesting that until the administration gives us its proposals we ought to sit in dead center. I said 3½ months ago that Dr. Bayley indicated that the Department, his associates, recognized that we needed to move, that there was inadequacy in the existing law. He had some rather specific objections. But it really goes back as far as 1967 when the Department was aware of the need to strengthen the controls. We spent in this subcommittee the time and effort to move on the matter of 2,4,5–T. The Department did suspend 2,4,5–T, and here is a product that was purchased at retail just yesterday by our staff that shows what under existing law suspension of a product like this means.

You can't see it from out there, but there are two or three words on this labeling that have been blanked out. Somebody took one of those brush pens and simply lined out the use that this thing was

suspended for. Now that line out is made with a magic marker, I suppose, but I am sure that is no magic in terms of protecting the public. And yet I take it that the law that is on the books allows the manufacturer to discharge his obligation to produce a safe product by scratching a line out on the can.

As I say, that is a message through you, not to you, because I sense that you may share my own feeling, and I shall not ask you to comment on that.

Staff has prepared some questions, and we would welcome your response.

Mr. BICKWIT. If you would prefer not to comment about the bill perhaps we can talk to some extent about the need for the bill. One of the needs we felt was that of defining the term "imminent hazard." Some were disturbed by the definition the Department offered when it last appeared before us, that is, that an imminent hazard was "one threatening to happen now." This definition, it was agreed by the Department representatives and by us, would greatly inhibit, if not destroy, the Department's power to suspend use of pesticides on food crops; and it was for this reason, among others, that we decided to reject that definition in S. 3866.

What I am interested in knowing now, without regard to whether you approve of our definition, is whether you still adhere to the definition offered by departmental representatives three and a half months ago.

Dr. IRVING. We would prefer now to adhere to a statement which Mr. Bucy will provide as to what we regard as a better working definition of imminent hazard. May I ask Mr. Bucy to respond to that?

Mr. BUCY. We have, as you know, had litigation. In this connection, the court requested the Department to submit an answer to the question of what the criteria is for determining an imminent hazard. I have here the prepared answer to that question. It is rather lengthy, about three pages. If you prefer, I can submit it to the committee for the record. I think this is better in view of the fact that the matter is still in litigation.

Senator HART. Asking a lawyer to summarize a definition that takes three pages would be unfair, and I won't. Why don't you read it, unless you think you can summarize it.

Mr. BUCY. This is the prepared answer that was filed in court, Mr. Chairman.

The criteria that have long been applied when determining whether a hazard is "imminent" have been set forth by the Secretary in the statement of reasons filed with this court on August 31, 1970, in the case of *Harrison Wellford, et al.* v. *Clifford M. Hardin, Secretary of Agriculture,* No. 24,434. Specifically, the Secretary said in his statement:

> The FIFRA authorizes the Secretary to suspend the registration of an economic poison immediately "when he finds that such action is necessary to prevent an imminent hazard to the public." 7 U.S.C. 135b(c). Congress did not define the term "imminent hazard" in the 1964 amendment which created the suspension authority, and the legislative history of the amendment is silent with respect to definement of the term. While the Government does not agree with the result reached in *Nor-Am Agricultural Products, Inc.* v. *Hardin* (No. 18,478, decided July 15, 1970), where a divided Seventh Circuit panel concluded that there is judicial review in a district court of an order of the Secretary which suspends the

registration of an economic poison, the Secretary does concur with the majority's exposition of the term "imminent hazard." Specifically, the Seventh Circuit majority said:

"* * * The term [viz., "imminent hazard to the public"] appeared in federal legislation in "The Drug Amendments of 1962," an act amending the Federal Food, Drug and Cosmetic Act. Under that statute the "imminent hazard" finding is required for the summary suspension of a license to market drugs, if the suspension is to be effective prior to hearing. While the legislative histroy of the 1964 amendment to the Federal Insecticide, Fungicide, and Rodenticide Act, giving the Secretary of Agriculture similar summary authority, does not seem specifically to contain a discussion of the concept of "imminent hazard" it does refer to the fact that the new procedure is modeled after that contained in the Federal Food, Drug, and Cosmetic Act. Viewing the similarity of the language utilized and the purposes for which it was intended, it seems clear that the language in both acts should be similarly interpreted.

The Senate report on the "Drug Amendments of 1962" reflected that an imminent hazard to the public health would exist when the evidence before the Secretary showed that a drug was so unsafe as to create a public health situation "which must be corrected immediately, and cannot be permitted to continue while a hearing is being held." The Committee contemplated that the power would be exercised only in the exceptional case of an emergency which did not permit the Secretary to correct it by other means. S. Rep. No. 1744 (pt. 2), 87th Cong., 2d Sess. 7 (1962). As Senator Eastland elaborated in his prepared report on the Senate floor:

"The committee believes that this authority, which could have grave effects upon a manufacturer and upon the confidence of the public in a drug which might later be found appropriate for continued availability to physicians, should only be exercised under the most extreme conditions and with the utmost care." 108 Cong. Rec. 17366 (1962).

Similarly, the House of Representatives Report on the same provisions stated in part that it would be expected that in exercising the imminent hazard authority the Department would make every effort, within the limits of its public responsibility, to notify the applicant and allow him to advance arguments why summary suspension was not required, or after suspension has been invoked, why it might safely be withdrawn pending the hearing. H.R. Rep. No. 2464, 87th Cong. 2d Sess. 8–9 (1962).

While it is apparent that the Department has been concerned with the environmental impact of the use of mercury products, it is certainly much less clear that the data available to the Department, at least insofar as our record is concerned, indicated the necessity for emergency action as opposed to continued and in-depth analysis study. Slip op., pp. 17–19.

The Secretary agrees that an imminent hazard exists when an economic poison presents a public health situation which must be corrected immediately and cannot be permitted to continue while a hearing is being held and that the suspension authority must be exercised sparingly, i.e., only when a serious emergency exists.

Effect and time, not time alone, are the determinatives of the Secretary's authority to suspend a registration, particularly in light of the fact that the FIFRA authorized suspension "to *prevent* an imminent hazard to the public [emphasis supplied.]." In this connection the Secretary concurs with Surgeon General Jesse Steinfeld's statement that "if an individual or an animal were exposed to a carcinogen, and developed a cancer 20 years later, this is nonetheless as far as I am concerned, an imminent hazard and we should remove it."

Senator HART. Well, I am glad we have got a record; we can all read that. Assuming I absorbed most of it, I would tend to think it is more satisfactory in terms of protection of the public than the definition we had earlier which, as I recall it, seemed to say that application of the pesticides could go forward unless as of the moment it could be found to be threatening to health.

Mr. BUCY. I think, possibly, that was not intended to fully convey the Department's position. Where there is a general discussion, one might get the impression that it was limited to that degree. With respect to agricultural commodities, you may put some chemicals on

them which will dissipate at a very early stage in the growth and will not be present in the end product. On the other hand, other applications may be present in the food item that resulted from the earlier application. In that instance, you have the hazard being initiated at the time you apply it and the result coming when the crop is harvested, and there you have to consider both effect and time as indicated in the statement on imminent hazard.

Senator HART. You stated it much more clearly than I can. That is the reason I think this is an improvement, assuming that the earlier statement was just a casual comment.

No matter how you handle the legislative history or the statutory language or our exchanges here, I would hope now there is general agreement that whether it is a drug that comes under the Food and Drug Act or a pesticide which has primary agricultural application but potential physical human damage—I hope there would be general agreement that the burden of proof is on those who would propose to introduce such an element to establish that it is safe rather than take the other approach, go ahead and we will find out.

Mr. BUCY. We are taking the position that the burden of proof is on the party that is introducitng this to the public and the environment. We are litigating that question in a case in Chicago, and it is before the court presently as to whether that is a proper interpretation.

Senator HART. Exactly. I remember our visit on that.

Mr. BICKWIT. That earlier statement arose at a hearing before the subcommittee on 2,4,5–T herbicides. As you know, we in this subcommittee have been very concerned with the use of these particular herbicides. Where do we stand on research on the phenoxy herbicides and the dioxins? Last time Dr. Byerly told us it would take 3 months to find out whether 17 other pesticides contained dioxins. Have you any results of that research at this point?

Dr. IRVING. Yes, sir, we do. The work is proceeding intensively in a laboratory designated for that purpose at Beltsville. On the point that you raised and which Dr. Byerly referred to earlier, we have now collected some 110 commercial samples of herbicides. Included are many of the phenoxys and samples of all of those that are used in substantial quantities in the United States. These are certain chlorinated phenols and others such as 2,4–D; 2,4,5–T; 2,4,5–TP; 2,4,5–DB.

Of these 110 samples, we have completed the analysis of 60. We found the vast majority of these samples contained less than one-tenth of a part per million of dioxins. This is the contaminant that was discussed rather thoroughly with the committee at the previous hearings. Five of the 60 samples contained amounts ranging from two to 22 parts per million of dioxin.

We issued a press release yesterday announcing that these high analysis samples were those of one manufacturer only and some samples were from materials manufactured in prior years. In the case of this one manufacturer, the contamination levels of dioxins in his preparations of 2,4,5–T have gone steadily downward. Currently, they are much less than the extreme upper limit that I have mentioned in these analyses.

Moreover, the company has ceased to manufacture 2,4,5–T and has volunteered to recall all stocks of 2,4,5–T of their manufacture and reprocess them to purify them with respect to dioxins.

We are still working to complete the analysis of the remaining samples that we have collected. But, I would emphasize the point, that with half of the samples analyzed, representing a good spectrum of the types of products on the market, that we are finding the vast majority to contain less than one-tenth of a part per million of dioxins. To make sure, we issued an order yesterday that dioxin is considered a contaminant and legal actions will be taken if this contaminant appears in products henceforth in the market.

There are two other aspects of our research that I will mention because of your interest in the effects of some phenoxy herbicides and possible dioxins contaminants on the public health. The first thing that I want to speak about briefly, concerns the degree of uptake by the plant.

Senator HART. The degree of what?

Dr. IRVING. The degree of uptake by plants of dioxins. I don't need to remind the committee that we are focusing on dioxins because they have been found to be most toxic substances. We have grown soybeans and oats experimentally in nutrient solutions containing measured amounts of several of the dioxins. After a suitable period of time—in this case 14 days—we have measured the amounts taken up by the plant. They do take up dioxin. Oats, in the two plants tested, take up more, relatively, than soybeans. But the total amount taken up is considerably less than 1 percent of the amount in the nutrient solution. The uptake is confined to the first several days in the growth period of plants in these nutrient solutions.

We have repeated these same experiments using a sandy loam soil where there would be the maximum opportunity for plants to absorb dioxins when added to soil. The dioxins were intimately mixed with the soil and the oats and soybeans grown in it. After a period of 4 weeks, the plants were harvested and analyzed. Again, oats seemed to have the capacity to pick up more dioxin than the soybeans. In this case, there was even less absorption than in the experiments using the nutrient solution. The uptake figures run from a low of 0.008 to a high of 0.37 percent of the dioxin absorbed.

We conclude, tentatively, from this—and I think these conclusions are justified—that under these extreme conditions with maximum opportunity for absorption of dioxins, so little is absorbed that, under field conditions, it would be very doubtful if we would ever be able to detect dioxin in field grown plants. The amounts present in the plants are infinitesimally small, perhaps beneath our capacity to detect them by present analytical methods.

The second point that was of interest to the committee in the earlier hearings concerned the fate of chlorinated phenols in or on soil when exposed to sunlight. We have done direct experiments irradiating 2,4-dichlor-phenol, with long wavelength, low energy radiation simulating sunlight with the added color sensitizer riboflavin. This was done to maximize the effect of the radiation on the possible precursors of the dioxins. We find that dioxins under these circumstances are not a major product of photolysis, that is, of sunlight radiation.

We are continuing these experiments because there is a possibility that one of the photolytic products might subsequently be transformed by heat into a dioxin. Theoretically a trichlor-dioxin

could be produced. We don't know yet whether this is the case. Our continuing experiments may provide additional data.

This is a brief summary of the nature of our research and the current status of it.

Mr. BICKWIT. You say that the dioxin you examined is not likely to be taken up in large percentages from the roots to the leaves of the plant?

Dr. IRVING. Yes, sir.

Mr. BICKWIT. Which dioxin did you test?

Dr. IRVING. We tested TCDD. This is the tetrachloro dibenzo para dioxin; the dichloro-dioxin, and dichloro-phenol itself. Of the three, the one absorbed in least amount in our experiments is the one that has received the most attention. This is TCDD. It is taken up in the least amount, but none of them were taken up in amounts that are of any practical significance.

Mr. BICKWIT. Did you have any results on the adherence of these dioxins to the roots prior to the time you tested for uptake?

Dr. IRVING. We have no final results. Our testing experience has indicated that a good bit of the dioxin measured in the plant is present as adsorbed rather than as absorbed dioxin. In other words, it is adhering to the roots and is measured when we harvest the plants and analyze them. Adsorption quite likely accounts for some of the dioxin in our analyses, but even including this, the total amount in the plant and on the plant is relatively insignificant.

Mr. BICKWIT. I am not sure I understood that last part. You said a large part of the dioxin does adhere to the roots?

Dr. IRVING. Our estimates are that a part adheres. Whether this is 10, 20, or 30 percent, I can't tell you now. But, we know a significant part is present as adsorbed dioxin on the outside of the root.

Mr. BICKWIT. Do we eat any roots that are treated with any of these herbicides?

Dr. IRVING. Offhand, I can't think of any.

Mr. BICKWIT. Could you check that for the record?

Dr. IRVING. I will.

(The information requested follows:)

U.S. DEPARTMENT OF AGRICULTURE, AGRICULTURAL RESEARCH SERVICE

The possibility of consuming 2,4,5–T and any dioxin impurity as a result of the adsorption or absorbtion of the chemical by root food crops is extremely remote. The phenoxy herbicides are generally phytotoxic toward vegetable crops. They are seldom, if ever, used in crop rotations with vegetables. Consequently, the adsorption or absorption of dioxin residues onto root food crops is highly unlikely from current usage patterns of the phenoxy herbicides or from residual contaminating dioxin resulting from previous application in any rotational system.

Mr. BICKWIT. This may be a naive question, but if dioxin does adhere to the roots of certain plants—and Dr. Byerly told us last time that it adheres or forms a bond with soil and does not disintegrate under those conditions rapidly—isn't it possible that dioxins sprayed directly on plants would adhere to the leaves of those plants?

Dr. IRVING. I think that is a fair hypothesis. I would like to see it done. However, a stem or a leaf is different from a root. The physical properties—adsorption properties—are different.

Mr. BICKWIT. Have you run any tests on that?

Dr. IRVING. Not that I know of.

Mr. BICKWIT. Do you plan to?

Dr. IRVING. We could include them.

Mr. BICKWIT. Your last remark suggests that you have doubts as to the relevance of those tests.

Dr. IRVING. I think that the levels we are talking about here are almost at the limits of our analytical methods to detect. The amounts likely to be absorbed by plants treated with low level of contamination would be insignificant so far as toxicity is concerned.

Mr. BICKWIT. Well, we know that the dioxin when sprayed could be present in sufficient amounts that we would say it was toxic, and if it did not disintegrate I assume it would remain toxic. In that case——

Dr. IRVING. I'm sorry, I missed your point. We were talking about uptake of dioxin by plants through the roots. You are postulating here what happens when the material is applied to the aboveground portion of the plant. I believe we plan studies to determine the persistence of the dioxins in the aboveground portion of the plat.

Mr. BICKWIT. But you have no doubts as to the relevance of——

Dr. IRVING. Yes, that's right.

Mr. BICKWIT. Of those kind of tests.

This is a simple point, but I feel it should be made. If dioxin can adhere to roots and can adhere to soil it seems possible that it can adhere to plants or for example, to blueberries when used on blueberries. The fact that the plants didn't take it up from the roots would be mild consolation if the dioxin, when sprayed directly on the plants, remained on the plants.

Now about the company that has produced 2,4,5-T with percentage of the dioxins ranging up to 22 parts per million. Is it in fact likely that this stuff is floating around and that cans of 2,4,5-T containing 22 parts per million are currently on shelves?

Dr. IRVING. Well, I think there is likelihood that some could be found. But, the intent is to recall any dioxin contaminated, unformulated 2,4,5-T. If that is successful, the only contaminated products that would remain available for use would be those already formulated. In formulated products the contaminated raw material is diluted quite a bit during the formulation process so that the formulated products would not contain anywhere near the 22 parts per million present in the raw material. The actual concentration of dioxin would depend on how much it has been diluted in the formulation process. We will continue to be on the lookout for any identifiable formulated, contaminated material that needs to be recalled. So far we have found none.

Mr. BICKWIT. If the voluntary recall procedure does not work, is it now illegal to sell 2,4,5-T containing 22 parts per million dioxin for use on food crops? Is it now illegal to sell 2,4,5-T containing 22 parts per million dioxin at the retail level?

Dr. IRVING. We have a cancellation order on 2,4,5-T for use on food crops. So far as the exercise of our authority under the Federal Insecticide, Fungicide, and Rodenticide Act is concerned such products are illegal and subject to all procedures under the act.

Mr. BICKWIT. In cancellation procedures it is my understanding that this material can continue to be shipped in interstate commerce and can be sold. Is that not your understanding?

Mr. BUCY. If they have requested a review under section 4(c) of the act; yes. Until the cancellation becomes final, they can continue to move it in interstate commerce.

Mr. BICKWIT. After the cancellation becomes final it may be a somewhat different story. But my understanding is that it still would not be illegal to sell that which remains on the shelves at the time the cancellation becomes final.

Mr. BUCY. We would be in a position where seizure authority is available, but it would not be a crime within the States.

Mr. BICKWIT. And it would not be a crime to misuse that pesticide in a way which might hurt——

Mr. BUCY. There is no provision in the law controlling the use of the pesticide by the buyer of the pesticide.

Mr. BICKWIT. We feel there should be.

Thank you very much.

Senator HART. Gentlemen, thank you very much.

Our next witness is the Director of the Bureau of Foods, Pesticides, and Product Safety of the Food and Drug Administration, Dr. Virgil Wodicka.

Dr. WODICKA. With your permission, Mr. Chairman, I would like to be supported by Dr. Ramsey, the Acting Associate Director of the Office of Compliance of the Bureau, and Mr. J. W. Cooke, Director of our Division of Pesticides.

Senator HART. You may proceed.

STATEMENT BY DR. VIRGIL O. WODICKA, DIRECTOR, BUREAU OF FOODS, PESTICIDES, AND PRODUCT SAFETY, FOOD AND DRUG ADMINISTRATION; ACCOMPANIED BY DR. RAMSEY, ACTING ASSOCIATE DIRECTOR, OFFICE OF COMPLIANCE, AND J. W. COOKE, DIRECTOR, DIVISION OF PESTICIDES

Dr. WODICKA. Thank you for this opportunity to appear to discuss S. 3866, a bill to amend the Federal Hazardous Substances Act which is administerd in this Department. This bill would remove the exemption for economic poisons which is presently embodied in that law. Under the proposal, an economic poison would be a banned hazardous substance if there is a reasonable doubt as to the safety of the poison for man or the environment and there is a less serious doubt about an alternative posion; or if the protection of man or the environment requires banning. If the hazardous effect of the poison is likely to occur before the usual procedures for banning the poison could be carried out, the hazard would be considered an imminent hazard and the poison could be summarily banned pending completion of the procedures.

The labeling of economic poisons could not be registered with the USDA without first securing the approval of the Department of Health, Education, and Welfare and use of pesticides in contravention of the labeling would be a criminal offense.

Economic poisons are presently exempted from the provisions of the Federal Hazardous Substances Act because they are subject to the Federal Insecticide, Fungicide, and Rodenticide Act, administered by USDA. The U.S. Department of Agriculture has statutory authority under the act for the registration of pesticides. As part of this

function, USDA is charged with determining whether a pesticide serves a useful purpose and reviews the labeling for such substances.

The Department of Health, Education, and Welfare has two responsibilities related to this scheme of pesticide control. First, this Department has the statutory authority and responsibility under the Federal Food, Drug, and Cosmetic Act for establishing safe tolerances for pesticide residues in or on raw agricultural commodities, processed food, and potable water. Before a tolerance is set, the Department of Agriculture must provide us with a certificate of usefulness and the registrant must petition this Department for the establishment of a safe-residue tolerance if the use of the economic poison is likely to result in a pesticide residue on a raw agricultural commodity. No tolerance is established without sufficient data to assure the safety of the consuming public. Second, this Department reviews labels from a health standpoint prior to registration by USDA, advising USDA on cautionary labeling for the protection of individuals using economic poisons. This role is purely an advisory one and is carried out through the mechanism of an interdepartmental agreement. The U.S. Department of Interior exercises a similar function with respect to the protection of fish and wildlife.

As one can observe, the jurisdiction over pesticides is splintered among several departments and agencies. Obviously this presents problems of coordination and proper utilization of resources. The need for concerted action in this area was recognized in 1964 when the Department of Agriculture, the Department of Interior, and this Department entered into an interdepartmental agreement, in order to effectively coordinate the functions of the three departments. Unfortunately, this agreement failed to achieve its intended purpose. Therefore, earlier this year a new agreement was executed which provided a more clearly defined mechanism for achieving the coordination necessary to protect man and his environment. The Council on Domestic Affairs was given the role of resolving conflicts when agreement could not be reached between the participant agencies.

Much public attention has been focused recently upon the problem of controlling the use of pesticides. The effectiveness of the present system has come into serious question in terms of the ever-increasing complexity of the impact of economic poisons upon man and his environment.

Legitimately, one may ask if merely an interdepartmental agreement without a statutory base is sufficient when several agencies have important and differing responsibilities in the overall objectives of pesticide control. True coordination might never be achieved.

Other means of accomplishing these objectives have been suggested.

One alternative would be to create a legal base which gives each agency independent authority to implement its responsibilities. Regulatory actions could be instituted without consultation with or the approval of the other agencies. This would provide each agency with the authority to fulfill its obligation without any outside encumbrances.

The other mechanism would be to combine the differing functions of each Department into one unit which could provide direction toward the common objective of environmental protection. This course would necessitate a unified approach which would avoid many of the pitfalls of the current system.

The first approach could lead to serious conflicts and duplication. For example, under S. 3866, both USDA and HEW would be empowered to seek the removal of a pesticide from the market.

It would also perpetuate the cumbersome jurisdictional lines of today's pesticide regulatory activities. Many inconsistencies would be created with the enactment of S. 3866. Different penalties would apply depending upon which agency sought enforcement. The penalties imposed under the Federal Insecticide, Fungicide, and Rodenticide Act are more stringent than under the Federal Hazardous Substances Act and USDA does not have authority to institute injunction proceedings. If FDA proceeded against a pesticide as a banned hazardous substance, it could require repurchase whereas USDA would be unable to do so.

The Food and Drug Administration would be required to administer the provisions without access to formula data which would be available to USDA. Declaring an economic poison a banned hazardous substance would be done pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act procedures rather than the procedures for declaring other substances to be banned under the act administered by the Department of Health, Education, and Welfare.

The second approach, namely, combining the statutory pesticide control responsibilities now found in three departments, HEW, USDA, and DOI, is the one which has been proposed by the administration. President Nixon, in his message to Congress of July 9, 1970, recognized the difficulties of the present arrangement and recommended the establishment of a new Environmental Protection Agency. In his message, he stated:

> Our national government today is not structured to make a coordinated attack on the pollutants which debase the air we breathe, the water we drink, and the land that grows our food. Indeed, the present governmental structure for dealing with environmental pollution often defies effective and concerted action.
>
> Despite its complexity, for pollution control purposes the environment must be perceived as a single, interrelated system. Present assignments of departmental responsibilities do not reflect this interrelatedness.

Under the EPA proposal, the several statutory authorities relating to pesticide control would be vested in a single agency. The proposed plan would eliminate many of the problems which S. 3866 seeks to remedy. It now seems very likely that within a few days the President's proposal to establish EPA will go into effect.

Beyond the need for centralizing control over pesticides in a single agency, there is a need for substantive improvement in the present legislative and administrative scheme for control of pesticides. In its recent first annual report to the Congress, the Council on Environmental Quality stated:

> The Administration is considering a broad range of legislative and administrative proposals for more effective pesticide regulation. These include measures to assure adoption of less persistent or toxic materials, limit the availability of certain types of pesticides, and regulate disposal of unused pesticides.

Accordingly, we would recommend deferring action on S. 3866 until the administration has submitted its comprehensive recommendations.

Although we believe this is not the propitious time for consideration of S. 3866, we would like to make several general comments about the bill in addition to those already mentioned.

The criteria for banning economic poisons would be difficult to administer. Determining whether there are less serious doubts as to the safety of reasonable alternatives to such poisons would be particularly difficult under the procedures which provide for advisory committees and public hearings if requested.

The proposed amendment to section 4 of the Federal Hazardous Substances Act would make the use by any person of an economic poison in a manner that is prohibited by the express terms on the label of such poison a prohibited act. We question whether this provision, as a practical matter, could be enforced. For example, a substantial number of the households in the United States each year utilize one or more economic poisons. To maintain any significant degree of surveillance over household, and many other, uses of these products would be extremely difficult.

In conclusion, we believe the establishment of EPA as the Federal Government's single pesticide regulation agency will resolve the multi-agency relationship problems addressed in S. 3866, and that action to remedy substantive deficiencies of present law should be deferred until the administration submits its comprehensive recommendations.

Thank you, Mr. Chairman.

Senator HART. Thank you, Doctor, very much. On that last point I agree with your comment that—rather than paraphrasing, I will read it:

> The proposed amendment to the bill pending here would make use by any person of an economic poison in a manner that is prohibited by the express terms on the label a prohibited act.

You go on the question whether this provision as a practical matter could be enforced, citing the number of households and how you ride herd on that. Your point is well taken. But the danger that we seek to respond to is there also. Do you have any suggestions as to how we should proceed?

Dr. WODICKA. I would have nothing substantive to offer on immediate thought.

Senator HART. So we have a danger and we have an obligation to attempt to come up with some answers.

Dr. WODICKA. That is correct.

Senator HART. I filed mine. We will wait for yours. Not too long, I hope.

Mr. BICKWIT. I take it from your statement and your last response that you would not care to comment further on the bill. If that is so, perhaps it would be beneficial to resume our discussion of last month on the problem of mercury and other toxic metals. At that hearing, as I understood you, you appeared to rely on the findings of the market basket study to justify the Department's failure to conduct a routine surveillance program to check for the presence of mercury in food other than fish. When were your last results on mercury in the market basket study?[1]

Dr. WODICKA. On the basis of a faulty memory I would hazard a guess 1967, but I would have to check the record to be sure of this.

Mr. BICKWIT. Do you remember what the data showed?

Dr. WODICKA. Not in detail. The data showed low levels, of course, because there wasn't any followup as a consequence of our analysis.

[1] See p. 74.

Mr. BICKWIT. Well, I have to admit to some skepticism with respect to that study since it did not suggest the mercury crisis that we are experiencing now in fish. Why do you think it completely missed that?

Dr. WODICKA. The market basket study depends largely on composite samples of commodity groups, as a matter of analytical feasibility. If there were, for instance, high individual samples of fish—and, of course, there is no assurance that there were—these would tend to be leveled out by dilution with other substances of the same analytical composite so that the overall level, which is a mesasure of average exposure, would not necessarily reflect the presence of an extreme sample in that composite. Now, of course, if the extremes were high enough to bias the average they would be picked up. I don't recall the specifics of the sampling procedure, but I think that meats and fish are combined.

Dr. RAMSEY. That's right.

Dr. WODICKA. So that in view of the fact that the level of exposure of meat animals and fish is quite different from what we now know of the environmental hazard, the composite sample would tend to dilute out whatever might be present in terms of the fish. And, of course, as you are aware, the mercury hazard to the extent it exists in fish is not in all fish, so that whether in fact samples with elevated mercury levels were picked up at that time is unknown.

Mr. BICKWIT. I have to say that I wonder whether it is worth relying on samples like that if either they don't include extremes or if the extremes are in there but are averaged out so that we don't worry about them until someone up in Canada tests a pickerel and finds mercury.

Dr. WODICKA. The statistical criteria for further action are more stringent on the pooled samples than they are for individual samples, so that it seems almost the only practical approach to the identification of areas for further concern in terms of the broad and varied nature of the American diet. The many hundreds of materials that are normally consumed would be as a practical matter unfeasible to sample individually. About the only practical approach is to form some sort of grouping to get some sort of feel for the problem area and then follow through in detail if any indication for concern is found.

Mr. BICKWIT. But the indications aren't found.

Dr. WODICKA. Let me respond to that in this way: The hazard presented by a food borne material is necessarily assessed in terms of the total intake of whatever hazardous material may be present. [and] The market basket survey is a reasonable approximation of total intake not only of total diet, but also of various commodities within that diet. So that if there are extreme samples, they would be diluted in the actual diet of people as they are in the sampling plan. So that this is a reasonable approximation of what people actually eat. In other words, they don't eat extremes all the time any more than the samples would reflect extremes all the time. On the other hand, when on the basis of any evidence extreme samples are present, action is taken to limit the exposure of man.

Mr. BICKWIT. How many samples do you look at under the study?

Dr. WODICKA. Thirty samplings per year of the selected American diet.

Mr. BICKWIT. That strikes me as pitifully small. You are looking at 30 samples bought from how many grocery stores, 30 grocery stores? Is this what we are dealing with as a representative sample of the total number of grocery stores?

Dr. WODICKA. Let me ask Mr. Ramsey if he can be more responsive to the details of the study.

Dr. RAMSEY. The samples are from 30 market baskets which represent, that is, each basket represents a 2-week food supply for the heaviest eater in the American population, who is the 18- to 19-year-old boy. So we do think that this does give us a representative value for the daily intake. We analyze these samples for a variety of pesticides that respond to our multiple detection methods. These studies were designed primarily to give us an idea of what the exposure of the American consumer is to pesticides.

Mr. BICKWIT. Well, the fact that it missed the mercury crisis suggests to me at least that it may not give us that idea.

Another reason for skepticism, it would appear, is a recent study conducted in Canada by the University of Toronto. That revealed considerably higher levels of mercury in virtually all the food examined. I am told that levels up to 0.4 parts per million in unclean wheat, 0.38 in flour, 0.23 in white bread, 0.31 in hamburger, 1.54 in walleye, 0.66 in yellow pickerel, 0.63 in northern pike, 1.68 in dill, 0.37 in walnuts, 0.37 in cocoa, 0.43 in sage, and 0.46 in pheasants, were found. I am also told that more than half of these samples exceeded 0.05 parts per million. Why do you think the difference between these results and the results you got in 1967 in your market basket study are so great?

Dr. WODICKA. There is probably some vulnerability to the earlier results on mercury, ours and substantially everybody else's, because we now know, which we as a scientific community did not know so well at an earlier date, that much of the mercury of concern is in the form of methyl mercury rather than inorganic form. Methyl mercury is quite volatile and can be lost in the preparatory procedure in getting a sample ready for the final determination of concentration. So it is possible that that last series of samples was biased on the low side.

However, I would point out that the results that you have just presented except for the fish items and I believe the dill, which is obviously consumed in trivial quantities, were all below our guideline level.

Mr. BICKWIT. On the matter of that guideline, at our last hearing we discussed that there had been some criticism of it. When Dr. Steinfeld was asked at that time why that guideline was based on tests using a safety factor of 10, he replied that the Department uses a factor of 10 when it has human data. Yet your deputy, Dr. Kolbye, told us at Mount Clemens that a hundredfold safety factor is desirable across the board. At least that was what I understood him to say. How do you reconcile these apparently differing views?

Dr. WODICKA. The most definitive document now in circulation on toxicology is the World Health Organization document, and it discusses ratios varying from 10 to 500 depending on a number of factors which really resolve down to the judgment of the people charged with decision. General criteria, to the extent that any can be given in the selection of safety factors, would hinge on the reliability and the relevance of the data involved. The higher ratios would apply to meager and

questionable data, whereas the lower ratios would apply to highly relevant and highly reliable data. This underlies the convention—and it is only that—of applying the factor of 10 to data of relevance obtained directly on man and taking the 10 factor and making it 100 when the data are obtained primarily on laboratory animals where the inferences with respect to human exposure are less certain.

Mr. BICKWIT. With regard to that World Health Organization paper I have been told, although I haven't seen the paper, that they recognize a tenfold factor as valid to compensate only for intraspecific differences, i.e., differences in makeup of members of the same species, and that the paper suggests that it should be used—the tenfold safety factor should be used—only with regard to a non-effect level which includes subclinical or unobservable effects. Is that true?

Dr. WODICKA. When we talk about safety factors we are almost always applying them to the maximum no effect level, whether the no effect level is established in man or in test animals. In other words, this is the base to which the safety ratio is applied.

Mr. BICKWIT. But does that in effect mean no effect at all or no observable effect?

Dr. WODICKA. How do you distinguish?

Mr. BICKWIT. I have read studies which have distinguished and which have taken a factor to compensate for the fact that there may be unobservable effects which in fact are quite toxic.

Dr. WODICKA. Well, what I am trying to suggest is that it is extremely difficult experimentally to establish an effect which you would define as unobservable. In other words, when you are talking about a maximum no effect level you are talking about the highest level that has been tested, in which such tests as anybody can think of that are applied to the test subject, be it animal or man, disclose no result.

Mr. BICKWIT. My understanding is that WHO is saying you are not supposed to use that tenfold safety factor unless you have already used some factor to allow for subclinical effects in determining a no effect level.

Dr. WODICKA. Well, this is really implied in the safety factor. In other words, the safety factor does indeed take care of interindividual differences——

Mr. BICKWIT. But not only that?

Dr. WODICKA. Not only that, that's right. It also has to take care of such interactions as may exist with other stimuli, other materials present simultaneously.

Mr. BICKWIT. But does it also account for the fact that "no observable effect" may not be the same as "no effect"? Is that one of the reasons you apply——

Dr. WODICKA. Necessarily, yes.

Mr. BICKWIT. Well, I understood that the WHO report says that a safety factor of ten is not to be used for that purpose, or, put another way, that if a safety factor is to be used for that purpose it ought to be greater than ten. I reserve judgment on whether it does say that until I read it, unless you can tell me that it definitely does not.

Dr. WODICKA. I have it with me, but I don't know whether you want to take the time to dig it out or not.

Mr. BICKWIT. Can we have it for our files.

Dr. WODICKA. Yes.[2]

[2] See p. 74.

Mr. BICKWIT. I do want to point out before concluding that if the paper does say what my present understanding of it is, then a tenfold safety factor might not be proper in this case. Moreover, as you yourself point out, the tenfold safety factor is just a convention anyway. Therefore, we really can't ignore the results of that Canadian study merely because they do not exceed the present guideline which is based on a tenfold safety factor.

Dr. WODICKA. I might point out in that same connection that I have another document that indicates undesirable manifestations on the consumption of some vitamins at ratios of 25 or 50 times the recommended dietary allowance. So this would suggest that a safety factor of 100 is certainly a very conservative one.

Mr. BICKWIT. And yet your deputy did tell us that guideline was desirable.

Dr. WODICKA. Yes, unquestionably, and we do use it particularly as applied to animal observations in most instances because most of our conclusions are derived from animal data.

Mr. BICKWIT. Thank you very much.

Senator HART. Thank you, Doctor. Was there anything else you would like to add in view of this exchange?

Dr. WODICKA. I don't know of anything.

Senator HART. Thank you very much.

Our concluding witness is a member of the District Bar, Mr. William Dobrovir.

STATEMENT OF WILLIAM DOBROVIR, PUBLIC INTEREST LAWYER

Mr. DOBROVIR. Thank you, Mr. Chairman.

I filed a rather lengthy statement which I will not read in order to not take any more time than is necessary. I would like to touch on some of the high points in the statement.

Senator HART. Let me then order the statement printed in full after your oral summizeration.

Mr. DOBROVIR. Thank you very much.

First of all, let me say that I support the legislation which the chairman has introduced. Indeed, I and people with whom I work in the environment area specifically in connection with pexticides, as the paper makes clear and as I will mention, would rather indeed suggest additional amendments to the regulatory structure.

I must take issue with those who indicate that the reorganization plan establishing the Environmental Protection Administration is going to solve the problem. The Environmental Protection Administration, as with all reorganizations, will do nothing but administer the same patchwork legislative structure which is now divided among the various agencies. I think it is an improvement to put it under one roof, and particularly under a roof which is going to be concerned specifically with environmental problems, but I think it is most important that the people operating in that house have a better legislative scheme to enforce.

In this connection we support a definition of imminent hazard such as that which is included in S. 3866. We support the provision of S. 3866 which would provide for use of the less dangerous pesticide where two pesticides are effective for a particular use, and we support the provision which would make it a prohibited act to misuse a pesticide.

To say that it would be difficult to police prohibited uses on a home-to-home basis misstates the problem. We are concerned about misuse of pesticides on an industrial level by the farming industry in this country for example. An incident came to my attention recently of somebody spraying 2,4,5-T on brush on his property in such a way that most of the 2,4,5-T blew onto somebody else's farm in 1969. The damage to the crops has continued into the 1970 season. So I wonder if that kind of thing should not be made a prohibited act. And I think it can be policed, because the damage is such that the people affected will bring it to the attention of the policing authorities.

We also suggest giving to the enforcers, be they the Environmental Protection Administration or whoever is going to have this authority, power to issue stop sale orders.

There was considerable discussion today about the discovery that a particular manufacturer of 2,4,5-T has extremely high levels of dioxin, up to 22 parts per million in his product. Dioxin is one of the most highly toxic of substances and there has been evidence of teratogenic effect in test animals at levels of three parts per trillion. Now when we are talking about 22 parts per million the order of magnitude is obvious.

It was a bit like sitting in wonderland to listen to the discussion of this problem and to hear absolutely no mention of the name of this manufacturer or the name of the products, which apparently are currently reposing on the shelves of agricultural suppliers, and perhaps if this particular manufacturer's product is formulated into 2,4,5-T products for home use, sitting also on your hardware store shelf. It is rather strange that the Department of Agriculture is so careful not to make known to the public whom it is supposed to protect what are the products the public should avoid; and in view of what we know about the ineffectiveness of recall procedures I would urge the Department of Agriculture to change its policy.

It would be recalled that in June before this committee one of the witnesses testified that he had the day before picked up in eight or nine hardware stores in the District of Columbia 2,4,5-T products, the use of which had been suspended in April, and they still had not been recalled.

The Senator today showed us a can of a household weed killer with the offending use marked out in black pencil. It is astonishing that this kind of relabeling is considered compliance with the law. There would hardly seem to be any reason for anybody to buy the stuff in his hardware store except to use; as a household weed killer. If it isn't taken off the shelf, and is sold, it is probably going to be used for that purpose. Some kind of direct authority to order sales of these products stopped is imperative.

As our statement points out, relabeling is virtually ineffective, and this is an obvious example of that ineffectiveness. It isn't a relabeling; it was a marking out with a black pencil.

We are dealing with substances here that have been demonstrated to have long term serious effects and effects which we are not really sure about yet, and experimentation is obviously continuing. The whole focus heretofore seems to have been on the acute toxic effects on an individual person practically dumped in a barrel of pesticide. This rarely happens. But this has been the focus of the regulators,

and I got that impression from what was said by the two earlier withnesses about what they are concerned with in connection with pesticides.

Mercury, for example, is not only a poison to an individual if taken in sufficiently large amounts, it is also a demonstrated teratogen and demonstrated to be a human teratogen. A teratogen is a substance which causes fetal damage to the unborn child. Other substances like 2,4,5-T have been demonstrated to be teratogenic in test animals. Other pesticides like DDT have been shown to be mutagenic, cause long term genetic damage, particularly to wildlife. We do not know what the effects are likely to be in the long term on human genetics. Other substances have been indicated to be carcinogenic. We are talking about effects which are extremely serious, but in long term. And it is time, I think, that we focused on these effects in terms of what are we going to do about pesticides and about economic poisons which include pesticides, herbicides and fungicides, and the lot.

The Department of Agriculture, I think, has demonstrated that it is not the agency to continue regulating pesticides. For that reason we are cautiously optimistic about the transfer of its functions to the Environmental Protection Administration. The Department of Agriculture naturally tends to serve its major constituent, the farming industry.

Some of the testimony before the Fountain committee a couple of years ago indicated that there were strong links between the regulators of the Pesticide Regulation Division and various of the chemical manufacturers of pesticides, including the astonishing instance of one of the personnel going to work immediately afterward for a chemical manufacturer and working on some of the same problems that that chemical manufacturer had had before his agency. We were presented with the spectacle of the Department of Justice saying that they were not interested in indicting this individual for violation of the conflict-of-interest laws.

The Department of Agriculture has brought several suspension and cancellation proceedings in the recent past now that there is a focus on its activities and now that the public is beginning to see that economic poisons can be dangerous to human health in the long term, to our children and to our grandchildren. But the action taken has been insufficient or ineffective. Even the Department would admit, I think, that its order on mercury failed to be based upon most of the important evidence about the dangers of mercury which was becoming available and which is now available. They are still trying to defend a suspension order based on a very flimsy record and which perhaps may well have been issued in a panic over the publicity concerning the incident in Alamogordo, where the farmer fed grain treated with a mercury fungicide to a hog, killed the hog, fed the pork to his children and caused serious injury to the children, two of whom apparently are never going to recover.

In another case involving arsenicals, indicated to be a cause of skin cancer, the Department pussyfooted around for several years with cancellation procedures and finally issued a cancellation notice. One of the manufacturers of this product demanded appointment of an advisory committee and asked for a waiver of fees which the pesticide manufacturer is supposed to pay. The Department declined, and

a district court in Utah issued a preliminary injunction against the cancellation proceedings going forward any further on the ground this particular manufacturer is in financial difficulty, is entitled to an advisory committee, can't afford it, and therefore he should be allowed to have an advisory committee paid for by the Department. I don't know what action the Department is going to take in response to this preliminary injunction. But warnings about arsenicals went out in 1967 and there still seems to be no future date in sight when these products are going to be taken off the market.

So you have a record of ineptness by the Department of Agriculture in its enforcement of the FIFRA.

Now as far as HEW is concerned, again I was amazed to hear the testimony with respect to the market basket sampling and the phrase used that the market basket sampling is a composite sampling of commodity groups. My immediate reaction is to say people don't eat composite samples. People eat meat, fish, or other agricultural products, some of which may be contaminated, some of which may not. Someone who eats a contaminated fish is going to get sick even though only a little bit of that fish is mixed up with 2 weeks worth of food and sampled as a composite sample. I find this method, as did the committee counsel, quite inadequate to determine whether or not people are going to be eating mercury in their food supply.

The answer I think is not only to approve the reorganization plan creating the Environmental Protection Administration; I think the answer is further to press forward with legislation like the legislation which the chairman has introduced, to press forward with additional legislation to put teeth into the enforcement powers of the new agency, some suggestions of which we have made; and most important, to bring constantly to the attention of the public what this agency is doing and what the manufacturers of pesticides are doing or are not doing in order to improve the qualities of their products and to specifically improve the safety of their products.

Thank you.

Senator HART. Thank you very much. I have had opportunity to read much of your prepared statement. I urge all who are interested to read that statement. And in that prepared statement you sort of make the case for prohibiting the knowing misuse of pesticides. Now the bill does not require that the misuse be with knowledge in order to be prohibited. The HEW testimony made comment on the difficulty of enforcement of such a thing. You responded in your informal remarks to that earlier testimony. The reason that we drafted the bill in the form it was introduced; namely, not requiring knowledge, was to eliminate the very difficult proof work that we would have if it was required that we prove knowledge of the improper use. And we thought also that prohibition against any misuse would be likely to persuade the public to read the darn label and hopefully use it within the limits that the label directed.

Now there is a third suggestion we have heard, yours with knowledge, ours without—in the earlier hearings Dr. Bayley speaking for the Department said he thought that we should classify pesticides as to their hazards and require that the most hazardous be applied only by licensed applicators who would be responsible for misuse. Now there are three suggestions. Do you stick with yours or see any value in either of these others, or does a combination suggest a fourth one perhaps more effective?

Mr. DOBROVIR. Well, I wonder if perhaps all industrial applicators of pesticides shouldn't be licensed whether they are going to use hazardous pesticides or not. I must say perhaps a pesticide which is sufficiently hazardous for Dr. Bayley to think that the applicator ought to be licensed is probably too hazardous to be used at all. After all, it was Dr. Bayley who indicated that even though a product would be eaten within 3 months that that did not create any hazard.

Senator HART. Well, in fairness to Dr. Bayley he didn't say he thought that wouldn't be hazardous. His said——

Mr. DOBROVIR. Excuse me. I withdraw the remarks, but I think perhaps a licensing scheme which would require responsibility for all industrial users of economic poisons would be a good idea.

As to the difference between knowing and unknowing misuse, I suppose that I may have been a little bit too legalistic in using that phrase. It may be there really won't be any difference, because to impose a criminal penalty legal knowledge would be required in any event. That is, there would have to be reason to know, meaning that if the information is on the label and someone simply does not read the label they nevertheless would be considered to have reason to know and would be criminally liable. So I have no difficulty at all with accepting the phraseology in your bill.

Mr. BICKWIT. In your statement you cite the need for the Department of Agriculture to have the authority to issue a stop sale order to prevent the sale of a banned pesticide at the retail level. Under our approach the Hazardous Substances Act would be amended to prohibit "the sale or offer for sale of any economic poison which has been designated a banned hazardous substance and which has moved in interstate commerce." Do you see a distinction between your proposed stop sale authority and merely prohibiting the sale of a banned pesticide?

Mr. DOBROVIR. I think perhaps not in substance, but in administration. What I would envision as part of the stop sale provision would be provision for immediate notification to be made to every retail seller. The burden of making that notification should be put upon those who know who are the people they have sold the products to, to wit, the manufacturer, wholesaler, jobber, and retailer. The notification would state, "if you continue to sell this pesticide you will be guilty of violation of the act and subject to the following penalty." I think that this is necessary, that merely making it a criminal penalty without any provision for getting the information down to the possible violator would not be enough.

Mr. BICKWIT. Thank you very much.

Senator HART. Thank you. Again I repeat that your statement is worth reading.

Mr. DOBROVIR. Thank you, sir.

(The statement follows:)

STATEMENT OF WILLIAM A. DOBROVIR

Mr. Chairman, I appreciate the invitation to appear before your subcommittee. My name is William A. Dobrovir, and I am an attorney specializing in public interest matters including protection of the environment. The following statement was prepared with the cooperation of Harrison Wellford of the Center for Study of Responsive Law, who is preparing a study of the Department of Agriculture's regulation of pesticides. He is also a petitioner in the legal action respecting the herbicide 2,4,5-T, discussed below, in which I am counsel.

SUMMARY

The Department of Agriculture has failed to perform its duty to prevent damage to the environment and to people from harmful pesticides. It has too often regarded the farming and chemical industries as its primary constituency and approved for general use pesticides which create unnecessary risks for human and environmental health. It is, however, a mistake to make the Department a scapegoat for all pesticide problems.

Not only must it exercise its vast responsibility with an absurdly over extended staff, but it lacks the teeth to enforce the statutory power it does have. Remarkably federal pesticide officials lack the power to order a general "stop sale" of illegal pesticides. Their efforts are further hamstrung by the lack of criminal penalties for those individuals who misuse pesticides. These powers are strongly needed to make pesticide regulation effective.

In addition, the USDA has added to its own burdens by its clumsy use of the powers which it does have. Its narrow interpretation of its power to order immediate suspension of a pesticide has placed a major hurdle in the path of government's ability to respond swiftly to a pesticide hazard. Legislation including the legislation introduced by Senator Hart, Chairman of this Subcommittee, is needed to clarify the regulatory authority and to promote its vigorous and intelligent implementation.

INTRODUCTION

In recent years there has been a great improvement in our understanding of ecological systems and specifically in our knowledge of the effects on the environment and on the chain of life of pesticides and herbicides. The public at large, and certainly this subcommittee, has become concerned with these effects. There seems to be a general public consensus that pesticides and herbicides need to be much more carefully controlled than they have in the past. Control is needed in order to limit and, where possible, prevent the dangers to the living environment caused by the heretofore largely uncontrolled use of economic poisons. Of course, this responsibility must be shared with the men who set budgetary priorities for the Federal government. There is a limit to how much competence one can expect from a pesticide control agency when it has less than 200 professionals to supervise a two billion dollar pesticide industry with more than 50,000 separately labeled products on the market.

Regulation of pesticides is presently divided among the Department of Agriculture, the Department of Health, Education and Welfare, and the Department of the Interior. An interdepartmental committee on pesticides has been established, which is supposed to reach joint determinations in connection with the regulation of pesticides. As this subcommittee has been informed by Dr. Jesse Steinfeld, Assistant Secretary of HEW and that Department's representative on the Interdepartmental Committee, the committee is really controlled by Agriculture. HEW, through the Food and Drug Administration, has authority to set standards for allowable tolerances on food crops of residues of pesticides on public lands.

But USDA's role is the most important. USDA controls the registration of pesticides and the suspension and cancellation of registration of pesticides under the Federal Insecticide, Fungicide and Rodenticide Act.

Unfortunately, the Department of Agriculture has often failed in its duty to control and prevent these dangers. The report of the Fountain Subcommittee on the House of Representatives' Committee on Government Operations in 1969 relates an astonishing history of maladministration of the Federal Insecticide, Fungicide and Rodenticide Act by the Department of Agriculture.

Agriculture's opposition to efforts to force improvement in its regulatory activities has extended even to last ditch resistance to allowing those who wish to study its performance access to the records of the Pesticide Regulation Division. That resistance is now subject of a challenge in a suit under the Freedom of Information Act now pending in the U.S. District Court for the District of Columbia. The court has already ordered a partial opening of the files, to allow the students to examine the indexes Agriculture maintains. Agriculture had claimed that even its indexes were exempt from disclosure under the Freedom of Information Act. The issue of access to the substantive records of the Division's regulatory activities is next to be argued. For these reasons, the removal from Agriculture of authority to regulate the registration and use of pesticides, and its transfer to the new Environmental Protection Administration, is ground for cautious optimism.

Executive reorganizations, however, are frequently triumphs of form over substance. The appearance of action is striking but new titles and new offices

alone are often feeble supports of change. Without basic changes in the enforcement powers available to federal pesticides officials, the change may mean very little.

REGISTRATION AND ENFORCEMENT

This power to register or refuse to register pesticides before they are released in the market place is considered to be the public's shield against pesticide hazards. Registration, however, amounts to no more than a paper review of documents submitted by the company in support of the claims it makes for safety and effectiveness on a pesticide label. Ordinarily USDA does not make its own laboratory tests before it approves the registration.

Once a pesticide is on the market, the enforcement branch of the Pesticide Regulation Division of USDA sends out inspectors periodically to pick up retail samples. These are then laboratory analyzed to see if the products conform to the approved labels. If the pesticide proves to be ineffective or hazardous, PRD may ask a federal court for an order permitting it to seize all of that product at the store where the sample was found. But a separate court order must be obtained for every single retail outlet.

For example, in August 1967, PRD inspectors picked up a sample of the pesticide toxaphene in a formulation produced by the Agricultural Chemical Service Company in Montgomery, Alabama. Lab tests revealed that the product contained not only toxaphene but a deadly additional ingredient not on the label: methyl parathion. (USDA, ARS, PRD, Notices of Judgment under the FIFRA, Notice Number 755). The sample was then destroyed. But what happened to the misbranded toxaphene at other retail outlets PRD did not visit?

NEED FOR STOP SALE AUTHORITY

Here is the rub. PRD does not have authority to issue stop sale orders to the hundreds and perhaps thousands of other retail outlets selling this illegal and deadly product. This gap in enforcement powers was acknowledged by PRD officials last year in testimony before the House Subcommittee on Intergovernmental Operations:

"Mr. NAUGHTON (committee counsel). In 1966 and prior thereto, is it correct that your normal procedure when your inspectors found a sample of a product which was in violation of the act and which might be dangerous and potentially harmful in a retail establishment, the procedure followed was to seize the product in that particular retail establishment and if this was one of 50,000 retail establishments which had received that potentially harmful product it would be seized at one establishment and remain for sale without interference by ARS at 49,999 other establishments?

"My question is, can any of you at this table recall a single instance in 20 years where you went to the records of the manufacturer (of a dangerous product) to find out where additional supplies of that product were located for sale so that you could take it off the market completely?

Dr. ANDERSON. We do not recall any instance where we went directly to the records of the company.

In an attempt to remedy this, PRD in 1967 instituted a procedure for voluntary recall. Under this procedure, PRD writes to the maker of the pesticide it wants banned and requests that the company write a letter to its retail outlets asking them to stop selling the product. This is better than doing nothing at all but it has serious limitations. First, there is delay of weeks while USDA notifies the company and the company notifies the retailer. Second, the pesticide maker may be very vague about where all of its products are being sold. Third, the retailer may with impunity refuse to comply with the comapny's request and continue to sell the banned product as long as he can get it.

2,4,5-T products for home use were suspended by USDA in April of this year, yet it is still possible to find a few stores selling the banned products in the Washington area. When the retailers are questionsed, they claim they never got the word from the company to stop selling.

Enforcement officials need a new power, to issue an effective stop sale order to all sellers of an illegal pesticide—with civil and perhaps criminal penalties for violation to put teeth behind the order.

NEED FOR PENALTIES FOR MISUSE

One of the major sources of the credibility gap in pesticide control is that a pesticide itself is never banned—only certain uses are banned. When the public hears that DDT has been banned for use on tobacco and shade trees it may be surprised to see it still in its accustomed place on the retailer's shelf.

When a specific use of a pesticide is banned, it may remain on the shelf for sale in its original container. *Only the label is changed, to delete the prohibited use.* There is no reason to expect that a person accustomed to using a pesticide in container X to spray his elm tree will cease because container X has a few lines changed in its label to forbid its use on shade trees. Similarly, homeowners will probably continue to use DDT inside the house unless the manufacturers abandon home use packaging, which for obvious reasons they may be reluctant to do.

Even if the homeowner reads the label, there are no sanctions whatever to require him to follow it. The farmer may be reluctant to use DDT on tobacco out of fear that his tobacco might be condemned if FDA inspectors should happen to sample it and discover DDT residues. He can spray it in his home, his trees and ponds and lakes with absolute impunity.

Amazingly, *it is not against the law for an individual to misuse a pesticide.* As long as DDT remains on the market for any approved use, buyers out of force of habit, convenience or economy will continue to use it in many of the prohibited ways. Consider the plight of the citizen whose property adjoins land owned by a misuser of a pesticide. There are a number of instances of complaints from homeowners who felt powerless to stop a neighbor from using 2,4,5–T on his lawn months after it had been banned for such use.

Shell Chemical Company has now agreed to relabel its No-Pest Strip to warn against kitchen use. But there is no penalty for the restaurant owner who continues to use it and endanger the health of his employees and customers. Penalties for knowingly misusing a pesticide will allow the individual citizen to aid the federal government in enforcing a pesticide ban. Such a provision would be a giant step toward responsible pesticide use in this country.

THE STATUTORY SCHEME—SUSPENSION VERSUS CANCELLATION—USDA'S INTERPRETATION

The major responsibility for pesticide regulation is as we have seen, USDA's. We have seen that USDA has not had effective enforcement tools. Nor has it been inclined to use the tools and procedures that it does have.

Even if Interior determines that pesticides should no longer be used on public lands, and even if HEW determines that a pesticide is so dangerous to humans that no residue may be allowed on food, USDA can refuse to take action to cancel or suspend the pesticide's registration, allowing it to continue to be used with impunity by the farm industry or by anyone else. Indeed, Interior has banned two of the most dangerous pesticides (which are discussed in detail below) for use on public lands. They are DDT and 2,4,5-T. HEW has refused to set a tolerance for 2,4,5-T residues on foods. USDA nevertheless has refused to suspend the use of DDT by cotton farmers and has commended the long and cumbersome cancellation proceedings only with respect to some DDT uses. USDA also has refused to suspend the use of 2,4,5-T on food crops, even though it has suspended the use of 2,4,5-T as a household weed killer.

The difference between suspension and cancellation is crucial to the protection of the environment, the food chain, and human life. A valid suspension order requires removal of the pesticide or herbicide from the market immediately. Cancellation merely begins proceedings to determine whether or not a pesticide is safe. These proceedings may take many months, often years, before all judicial review proceedings, for example, would be concluded. The issue of when use of a pesticide ought to be suspended immediately is the issue dealt with in the amendments proposed by Senator Hart to the Federal Hazardous Substances Act, which are the subject matter of this Subcommittee's consideration. The question of suspension is also the subject matter of the three major legal actions pending in the Courts of Appeals which are discussed below.

Briefly, the FIFRA provides that the Secretary of Agriculture has authority to suspend the use of pesticides where "he finds that such action is necessary to prevent an imminent hazard to the public." What is an "imminent hazard" is nowhere defined in the act.

The three legal actions pending in the courts involve mercurial fungicides, DDT, and 2,4,5-T. We are all now aware of the tremendous hazard presented by the introduction of mercury into the environment, particularly into water courses. The Department of the Interior and the Department of Justice have, after considerable delay finally now begun to take action against industrial producers of mercury pollution. Mercury, very simple, is a deadly poison. In water, it contaminates fish and makes them unfit for human consumption. Used as a fungicide on animal feed, for example, it can poison the flesh and milk of the

animals and make them unfit for human consumption. It is also teratogenic—causing damage to the unborn child. DDT is a biocide, a life-killer, which accumulates and concentrates in the bodies of animals and human beings and which rises in the food chain, as one animal eats another. It is persistent and harmful, and is concentrated in the milk of nursing mothers at higher levels than FDA allows it in food. 2,4,5-T, a herbicide, with its highly toxic contaminant, dioxin, which cannot be entirely eliminated from it, is used as a weedkiller domestically and as a defoliant militarily. It has been demonstrated to be a teratogen—to cause birth defects in the foetus of test animals when ingested by the carrying mother.

MERCURY

Mercury used as a pesticide is the subject of an appeal now pending before the U.S. Court of Appeals for the Seventh Circuit. On February 18, 1970, the Secretary found "imminent hazard" in the continued use of mercury fungicides and invoked Section 4c of FIFRA to suspend their use immediately.

The suspension was triggered by an incident in August of 1969. A farmer in Alamogordo, New Mexico fed waste grain to his hogs. The grain had been treated with an organic mercury fungicide. In mid-September one of the hogs which had been fed the grain was slaughtered for food for the family. The pork was eaten for about three and one-half months. Then in December and January the farmer's children began to fall sick; today two of the children remain comatose and the other is making only slow progress towards recovery.

Then USDA acted. But Nor-Am, a fungicide producer, obtained a District Court preliminary injunction against the suspension, and on appeal, the Court of Appeals affirmed the preliminary injunction. It rejected arguments that its order suspending the registration of mercury fungicides was not reviewable and that the suspension action was justified. The Court ruled that USDA had not made out a sufficient action. In effect, USDA had acted prematurely, ineptly, and without sufficient preparation. The Court held, therefore, that the suspension was "arbitrary and capricious" and charged USDA with reacting to the New Mexico incident with "emotionalism".

The Department has been granted a review of the decision by the full Court of Appeals, *en banc*. We also understand that the Department is now busy compiling a comprehensive factual record. In view of the demonstrated dangers of mercury in the environment, we assume that there should be little difficulty in completing that compilation promptly.

DDT

DDT was the subject of a two-pronged attack by various environmental groups, led by the Environmental Defense Fund. EDF petitioned HEW to set a zero tolerance for DDT residues on food, and petitioned USDA for the institution of cancellation proceedings and immediate suspension of DDT for all uses. Both agencies refused to take any action at all; HEW refused to publish the petition in the Federal Register; Agriculture simply declined to take any action. EDF appealed both agencies' inaction to the Court of Appeals. The Court found that the inaction by USDA in effect amounted to denial of the petition and ordered the Department to file a statement of reasons and supporting data for its refusal to take action. The Court ordered HEW to publish the petition in the Federal Register and commence proceedings pursuant to the petition that under the Federal Food, Drug and Cosmetic Act would be triggered by publication.

In its statement of reasons, filed in the court, Agriculture argued that the evidence of the dangers, of DDT, particularly its cancer-causing capacity and its effects on wildlife, were insufficient to constitute DDT an "imminent hazard". Agriculture emphasized the need to use DDT in order to control agricultural pests. It also argued that DDT was needed to control insects which carried human disease. Agriculture's conclusions seem clearly against the overwhelming weight of the evidence submitted to the Department by EDF. The evidence proves that DDT is mobile, persistent, soluble in fatty tissues, is broadly toxic to animals and concentrates biologically as it passes up the food chain. The evidence also demonstrates that some species of wildlife are now in danger of extinction because of DDT, and that DDT has caused cancer in animals and has caused genetic damage in animals. There is a demonstrated relationship between substances causing cancer in animals and causing cancer in humans. Agriculture has now finally begun cancellation proceedings in respect of certain uses of DDT. It has continued, however, to refuse to issue suspension orders.

2,4,5-T

2,4,5-T is the subject of an attack instituted by a group of individuals and organizations headed by Harrison Wellford of the Center for Study of Responsive Law. They petitioned the Department of Agriculture to issue suspension orders for uses of 2,4,5-T as a household weedkiller, in water courses and on food crops, and petitioned for the institution of cancellation proceedings in respect of all uses of 2,4,5-T. USDA refused to suspend 2,4,5-T for use on food crops and for use around the home in non-liquid formulations. It also refused to issue Notices of Cancellation for uses of 2,4,5-T except for home use and for use on food crops. This order has also been appealed to the Court of Appeals. The main issue is the Department's refusal to issue an immediate suspension order for use of 2,4,5-T on food crops. In this case, HEW refused to establish any tolerance for 2,4,5-T in response to a petition to establish such a tolerance. This amounts to a judgment by HEW that no amount of 2,4,5-T can be considered safe for human ingestion.

The reason given by Agriculture for its refusal is that, as stated by their witnesses before this subcommittee in June, they do not consider a hazard to be "imminent" when the food on which the pesticide is sprayed may not be eaten until after it is harvested, weeks or months later—no matter how dangerous the substance may be when eaten. In its statement of reasons filed in the court, however, Agriculture attempted to minimize the evidence of foetal damage caused by 2,4,5-T and emphasized the importance of 2,4,5-T as an agricultural weedkiller. Agriculture also ignored its earlier interpretation of "imminent hazard" and instead claimed that it had adopted the definition of "imminent hazard" suggested by the Seventh Circuit Court of Appeals in the mercury decision. The court, referring to the legislative history of the similar "imminent hazard" language in the drug amendments of 1962 to the Federal Food, Drug, and Cosmetic Act suggested:

"* * * than an imminent hazard to the public health would exist when the evidence before the Secretary showed that a drug was so unsafe as to create a public health situation 'which must be corrected immediately, and cannot be permitted to continue while a hearing is being held'."

The Court cited the Congress as having contemplated that the power would be exercised only in the exceptional case of an emergency which did not permit the Secretary to correct by other means.

Unfortunately, Agriculture applied this standard—which is dangerously restrictive—inconsistently. It suspended use of 2,4,5-T in the home, throwing a bone, as it were, to the overwhelming evidence of the danger of 2,4,5-T and its contaminant, dioxin. But it declined to offend both the farming industry, by refusing to suspend for use on food crops, and the chemical industry, by refusing even to begin cancellation proceedings for use for bush control. The Court of Appeals will decide whether it is rational to rule that this substance is imminently hazardous when inhaled, but not when eaten.

The history of these legal disputes demonstrates clearly the need for legislation like that proposed by Senator Hart in S. 3866 and the amendments to that bill to clarify the definition of imminent hazard. There is also need, as reflected in the amendments, to provide for choice of the pesticide that appears to be safest where there is more than one pesticide that will do the job. This provision will furnish a much-needed incentive to the chemical industry to develop poisons that do the job and are not harmful to humans and other animals.

As for imminent hazard: it is well to define the term as the bill defines it. But this is surely not enough. The delay in prosecution of cancellation proceedings is a scandal. USDA began consideration of arsenic herbicide compounds in 1967. They are still on the market. Indeed, one small company (USDA rarely tackles the big companies like Dow Chemical, chief producer of 2,4,5–T) has just obtained a preliminary injunction against proceedings going forward before an advisory committee appointed by USDA under section 4c of FIFRA.

Moreover, it must be made clear that the burden of proof of safety must remain always with the manufacturer. While FIFRA seems to so provide, USDA and some courts shift the burden after a pesticide has been registered. Where human health and the environment are in increasing jeopardy from useful but dangerous substances, those who market and profit from them should be continuously required to demonstrate that the products are safe.

Senator HART. This completes the list of scheduled witnesses. Whether the hearing will encourage the administration to file its recommendations more promptly than it might otherwise remains to be seen, but in any event, I hope that it will, among other things, have that effect.

We are adjourned subject to the call of the Chair.

(Whereupon, at 11:45 a.m., the subcommittee adjourned.)

ADDITIONAL ARTICLES, LETTERS, AND STATEMENTS

U.S. SENATE,
COMMITTEE ON COMMERCE,
Washington, D.C., June 8, 1970.

Hon. PHILIP A. HART,
Chairman, Subcommittee on Energy, Natural Resources and the Environment, Washington, D.C.

DEAR PHIL: I am writing to indicate my support for S. 3866, your bill to include pesticides among the substances regulated by the Federal Hazardous Substances Act.

Pesticides are poisons. They are designed to kill or metabolically upset target organisms. While pesticides have made a significant contribution to agricultural productivity, their indiscriminate use has over a long period of time contributed substantially to the decline in the quality of our environment. Pesticide residues are now commonly found throughout our land and water resources. The AMA Committee on Occupational Toxicology recently stated that "the indiscriminate use of DDT and other toxic materials is to be deplored and should be stopped."

I am particularly concerned over the danger pesticides pollution poses to our coastal seafood resources. Evidence now suggests that fish and shrimp must, in some instances, be considered endangered species in some of our estuaries. Marine life is particularly sensitive to pesticides. A small amount can kill, while many living organisms concentrate the poisons and pass them up the food chain to higher animals.

The failure of the Agriculture Department to regulate effectively the production and use of pesticides is deeply disturbing. USDA has failed to keep harmful pesticides off the market and apparently abdicated its responsibility for protecting our resources. The Department has relied too heavily on the date supplied by manufacturers for the registration and labeling of pesticides and, according to a GAO report, failed to take appropriate action when violations occurred. In addition, after the Mrak Commission report verified the harm done by pesticides the Department moved only haltingly to ban nonessential uses of DDT and other persistent pesticides.

The lax position of the Department of Agriculture is not surprising. USDA has a vested interest in pesticides since they contribute to the production of food, the Department's basic mission. USDA is oriented to the farmer. It is not attuned toward restricting a tool highly valued by the constituency it serves. It has not been as sensitive as it should be to disturbances in our ecological system.

Last July I introduced legislation, S. 2747, to transfer the pesticide regulatory function of USDA to HEW. The latter should be more responsive to environmental degradation by pesticides. The bill thus removes the conflict of interest inherent when an agency polices a program it promotes. Regrettably S. 2747 is still pending before the Agriculture Committee.

S. 3866 seeks to achieve the same end by a different approach. As a member of the Energy, Natural Resources and Environment Subcommittee, it has my full support.

Sincerely,

JOSEPH D. TYDINGS.

COMPTROLLER GENERAL OF THE UNITED STATES,
Washington, D.C. June 17, 1970.

Hon. PHILIP A. HART,
B–128552.

Chairman, Subcommittee on Energy, Natural Resources, and the Environment, Committee on Commerce, U.S. Senate.

DEAR MR. CHAIRMAN: At the recent hearings on S. 3866, a bill to amend the Hazardous Substances Act to provide more effective protection against the hazards of economic poisons, you inquired of attending members of our staff,

with reference to the partial suspension by the Department of Agriculture of herbicide 2,4,5-T, whether there is anything in the current law that would make illegal the utilization by a purchaser of the relabeled herbicide for one of the suspended uses.

The misuse of a herbicide or other economic poison by a purchaser, sought to be prevented by the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 135–135k), is not prohibited by that act. Nor do we find the mere misuse of an economic poison to be per se a violation of current Federal law. However, the misuse of an economic poison may result in commodities being "adulterated" within the meaning of the Food, Drug, and Cosmetic Act (21 U.S.C. 301, 331, 342) so as to preclude their introduction into interstate commerce.

Sincerely yours,

R. F. KELLER,
Acting Comptroller General of the United States.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
PUBLIC HEALTH SERVICE,
FOOD AND DRUG ADMINISTRATION,
Rockville, Md., October 26, 1970.

Hon. PHILIP A. HART,
Chairman, Subcommittee on Energy, Natural Resources, and the Environment, Committee on Commerce, U.S. Senate, Washington, D.C.

DEAR SENATOR HART: We are submitting herewith the information requested for the record during the testimony of Dr. Virgil Wodicka, Director, Bureau of Foods, Pesticides, and Product Safety of the Food and Drug Administration on September 29, 1970, regarding S. 3866.

We have confirmed the accuracy of Dr. Wodicka's response to the question: "When were your last results on mercury obtained in the market basket survey?" (Page 35 of hearing transcript). The last of these findings were in 1967.

It was also requested that a copy of the World Health Organization (WHO) report on "Procedures for Investigating Intentional and Unintentional Food Additives" be submitted. A copy of that publication is enclosed.

If we can be of any further assistance please let us know.

Sincerely yours,

M. J. RYAN,
Director, Office of Legislative Services.

This report contains the collective views of an international group of experts and does not necessarily represent the decisions or the stated policy of the World Health Organization.

World Health Organization Technical Report Series No. 348

PROCEDURES FOR INVESTIGATING INTENTIONAL AND UNINTENTIONAL FOOD ADDITIVES

Report of a WHO Scientific Group

WHO SCIENTIFIC GROUP ON PROCEDURES FOR INVESTIGATING INTENTIONAL AND UNINTENTIONAL FOOD ADDITIVES

Geneva, 12–18 July 1966

Members:

Dr M. G. Allmark, Assistant Director-General (Drugs), Food and Drug Directorate, Department of National Health and Welfare, Ottawa, Canada (*Rapporteur*)

Dr V. Benes, Head of the Department of Toxicology, Institute of Hygiene, Prague, Czechoslovakia
Dr F. Coulston, Professor and Director, Institute of Experimental Pathology and Toxicology, The Albany Medical College, Albany, N.Y., USA
Dr G. J. van Esch, Head of the Laboratory for Toxicology, National Institute of Public Health, Utrecht, Netherlands
Dr L. Golberg, Director, The British Industrial Biological Research Association, Carshalton, Surrey, England (*Chairman*)
Dr P. Shubik, Professor of Oncology, Chicago Medical School, Chicago, Illinois, USA
Dr R. Truhaut, Professor of Toxicology, Director, Toxicological Research Centre, Faculty of Pharmacy, University of Paris, France (*Vice-Chairman*)
Dr R. T. Williams, Professor of Biochemistry, St. Mary's Hospital Medical School, University of London, England

Representative of the Food and Agriculture Organization of the United Nations:
Dr D. M. Smith, Food Science and Technology Branch, Nutrition Division, Rome, Italy

Secretariat:
Dr F. C. Lu, Senior Scientist (Food Additives), Nutrition, WHO (*Secretary*)
Dr A. C. Frazer, Professor, Head of Department of Medical Biochemistry and Pharmacology, The University of Birmingham, England (*Consultant*)
Dr L. W. Hazleton, President, Hazleton Laboratories Incorporated, Falls Church, Virginia, USA (*Consultant*)

PRINTED IN FRANCE

Procedures for Investigating Intentional and Unintentional Food Additives

Report of a WHO Scientific Group

The WHO Scientific Group on Procedures for Investigating Intentional and Unintentional Food Additives met in Geneva from 12 to 18 July 1966. The meeting was opened by Dr. J. Karefa-Smart, Assistant Director-General. Dr. L. Golberg was unanimously elected Chairman of the Group and Professor R. Truhaut Vice-Chairman. Dr. M. G. Allmark agreed to act as Rapporteur.

INTRODUCTION

The Scientific Group was convened on the recommendations made in the eighth [1] and ninth [2] reports of the Joint FAO/WHO Expert Committee on Food Additives. Its terms of reference were:

(1) to review, in the light of new scientific knowledge, the criteria used in establishing acceptable daily intakes, with the object of providing guidance to future Joint FAO/WHO Expert Committees on Food Additives and Joint Meetings of the FAO Working Party on Pesticide Residues and the WHO Expert Committee on Pesticide Residues;

(2) to suggest further studies on toxicological procedures used for the evaluation of intentional and unintentional food additives in order to establish their safety to the consumer.

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[1] *Wld Hlth Org. techn. Rep. Ser.*, 1965, 309; *FAO Nutrition Meetings Report Series*, 1965, No. 38.
[2] *Wld Hlth Org. techn. Rep. Ser.*, 1966, 339; *FAO Nutrition Meetings Report Series*, 1966, No. 40.

1. SCIENTIFIC BACKGROUND

During the last eleven years the Joint FAO/WHO Expert Committee on Food Additives [1] has prepared nine reports [2–10] and three reports have resulted from the Joint FAO/WHO meetings on pesticide residues,[11–13] all of which are concerned with various aspects of the toxicology and the safety evaluation of chemicals that may be intentionally or unintentionally incorporated into food. A number of problems have been encountered in the course of the discussions that led to these reports. Furthermore, over the same period, significant advances have been made in many fields relevant to these problems.

Thus, many new and more sensitive methods of analysis have been devised and applied to the detection of minute amounts of chemicals in the environment. The detailed study of metabolism at the molecular level has been applied to many problems and this has special relevance to toxicology. Modification of substances in the course of their metabolism may significantly affect their toxicity; chemicals may alter enzyme activity and some substances may stimulate the production of metabolizing enzymes. Hence, for a full understanding of the effects of a chemical on biological systems it is necessary to have as much knowledge as possible about the relationships between the chemical (and its derivatives) and the complex pattern of enzymes in living organisms.

Considerable advances have also been made in molecular biology, coupled with more detailed information on the structure and ultrastructure of cells and tissues; their relationship to function may now be interpreted in molecular terms. Various isolated fractions derived from cells and tissues can be subjected to detailed investigation. Electron microscopy and histochemistry are now commonly used in pathological and toxicological laboratories.

Important developments have occurred in the availability and quality of laboratory animals. Better genetic control, a wider range of species and the provision of animals in which common pathogens are controlled, or from which micro-organisms are completely eliminated, are also important to toxicologists.

These and other advances have resulted in the development of better methods of investigation in toxicology. It is now generally possible to study more precisely, or to follow in greater detail, the absorption, distribution, metabolism and elimination of a substance, to discover the modifications that may occur in the course of its passage through living systems, to investigate its effects on enzymes or morphology and to relate these observations to alterations in structure and function and to the signs and symptoms of toxicity. Thus, with increasing frequency, it should be possible to explain many toxicological phenomena in chemical and biochemical terms.

As the methods for the detection of changes in biological systems become more sensitive, the investigator needs to become more critical in his interpretation of the significance of the effects he observes. New approaches and new techniques make it possible to probe in depth into the nature of the earliest response of the organism to exposure to a chemical. The interpretation of observations is often difficult and is not made easier by the administration of high doses in studies on substances of relatively low toxic potential. There are also instances where adaptive changes occur. Since many toxicological decisions are based on the assessment of the highest dose level that causes no deleterious effect, the differentiation of adverse effects from other changes is crucial. Several examples of problems of this nature are mentioned elsewhere in this report.

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[1] The general term "food additives", as used in this report, is intended to apply to substances incorporated directly into foods, those arising indirectly from migration out of food-packaging materials, those present as pesticide residues, and any others resulting from the intentional or unintentional incorporation of chemicals into food.

[2] *Wld Hlth Org. techn. Rep. Ser.*, 1957, 129; *FAO Nutrition Meetings Report Series*, 1957, No. 15.

[3] *Wld Hlth Org. techn. Rep. Ser.*, 1958, 144; *FAO Nutrition Meetings Report Series*, 1958, No. 17.

[4] *Specifications for identity and purity of food additives. Vol. I Antimicrobial preservatives and antioxidants*, Rome, Food and Agriculture Organization of the United Nations, 1962.

[5] *Specifications for identity and purity of food additives. Vol. II Food Colors*, Rome, Food and Agriculture Organization of the United Nations, 1963.

[6] *Wld Hlth Org. techn. Rep. Ser.*, 1961, 220; *FAO Nutrition Meetings Report Series*, 1961, No. 29.

[7] *Wld Hlth Org. techn. Rep. Ser.*, 1962, 228; *FAO Nutrition Meetings Report Series*, 1962, No. 31.

[8] *Wld Hlth Org. techn. Rep. Ser.*, 1964, 281; *FAO Nutrition Meetings Report Series*, 1964, No. 35.

[9] *Wld Hlth Org. techn. Rept. Ser.*, 1965, 309; *FAO Nutrition Meetings Report Series*, 1965, No. 38.

[10] *Wld Hlth Org. techn. Rep. Ser.*, 1966, 339; *FAO Nutrition Meetings Report Series*, 1966, No. 40.

[11] *Wld Hlth Org. techn. Rep. Ser.*, 1962, 240; *FAO Plant Production and Protection Division Report* No. PL/1961/11.

[12] *WHO/Food Add.*/23 (1964); *FAO Meeting Report* No. PL/1963/13.

[13] *WHO/Food Add.*/26.65; *FAO Meeting Report* No. PL/1965/10.

Since these advances in scientific knowledge are being applied in the evaluation of safety, it is necessary to bring up to date the guidance given to all concerned in this field. It is equally essential that regulatory agencies should be aware of the importance and significance of such progress and should take appropriate action for the protection of the community.

The Group has given detailed consideration to a limited number of special procedures among the many involved in toxicology. Its general conclusions are set out below. The remainder of this extensive field awaits future consideration.

2. GENERAL CONSIDERATIONS

The Group is in agreement with the general principles and approaches set out in the earlier reports. There are, however, a few points of interpretation that call for comment.

In the first report of the Joint FAO/WHO Expert Committee on Food Additives[1] it was suggested that "provision must be made for the admission with a minimum delay of properly tested food additives which are considered desirable". The Group feels that the permitted list should always remain open for additions resulting from technological development or changes depending on the progress of scientific knowledge.

The report stressed that "it would not be practicable for the responsible authorities to limit any group (of food additives) to a specific number, i.e., to insist that the inclusion in the list of a new additive requires the elimination of one already permitted". The Group is of the opinion than an increase in the number of food additives on a permitted list does not necessarily imply any over-all increase in additives used; the different additives are largely used as alternatives. From the point of view of food technology, the chemistry of food is highly complex and many different direct additives with generally similar actions may be needed to cope with a wide range of problems. From the toxicological point of view, there is less likelihood of long exposure to one chemical, or of high or cumulative dose levels being attained, if a wide range of substances is available for use. Similar considerations apply to pesticide residues.

It is desirable that national governments should maintain a check on the total intake of each food additive, based on national dietary surveys, to determine whether the total load in the diet approaches the acceptable daily taken. The Group was informed that the FAO/WHO Codex Alimentarius Commission will be using the data from such surveys to carry out this study on an international basis.

Toxicologically, it generally makes no difference how a chemical is distributed in the diet provided that the over-all content does not exceed the acceptable daily intake (ADI). In some instances, regulatory bodies may decide to recommend the use of a particular chemical in certain specified foods. If the levels proposed are likely to result in over-all amounts in the diet equal to the ADI, difficulties might arise from the presence of this chemical in other foods. A problem of this sort might arise from background levels, spray drift or other causes; the Group considers it advisable to reserve some small proportion of the ADI to cover this.

It is well established that many food additives are altered by plants or animals or by reaction with foodstuffs, and that the products of such reactions are consumed. Efforts should be made to determine the ultimate fate of each such chemical. Safety-evaluation studies should take into account the safety of each compound formed, since in some cases the metabolites or degradation products may be more toxic than the original material. On the other hand, it may happen that these materials, as well as the original substance, are destroyed or eliminated during processing or cooking.

It has been stated that all intentional food additives should be subjected to individual toxicological investigation. This generalization needs modification along the following lines:

(*a*) Many additives may already be present in food or elsewhere in the environment. The background occurrence of the chemical must be taken into account in the evaluation of its safety.

(*b*) Some additives give rise to molecules already present in food in much greater amounts. If the biochemical evidence shows that the additive makes only a small contribution to existing metabolic pools from food components or in the tissues, there may be no need for detailed toxicological studies on it, pro-

[1] *Wld Hlth Org. techn. Rep. Ser.*, 1957, 129; *FAO Nutrition Meetings Report Series* 1957, No. 15.

vided that it conforms to adequate specifications. An example of a substance of this kind would be an ester of a sugar and a fatty acid that is completely hydrolysed in the intestinal lumen with the formation of two substances already present in the diet in much greater quantities.

(*c*) If a series of chemical analogues can be shown to give rise to the same main metabolic product and other compounds that are already present in the organism in greater quantities or that can be readily and safely metabolized, it may be sufficient to carry out toxicological studies on a suitable representative of the series.

(*d*) Toxicological information for the evaluation of safety is not always fully adequate and it is suggested that some substances, especially those that are urgently needed or are present in relatively minute amounts, might be given at least temporary clearance. Thus, the establishment of "temporary acceptable daily intakes" is recommended in situations in which a particular food additive would be useful, or may already be in use, and for which toxicological or other data are not fully adequate to permit an acceptable daily intake to be set by the normal procedure. The conditions that need to be satisfied before such a "temporary acceptable daily intake" is established are discussed later in this report (section 3.4.2). In the case of substances that occur in minute quantities, a procedure for the establishment of an "administrative acceptable daily intake" is also discussed (section 3.4.3).

3. SPECIFIC PROBLEMS

3.1 Specifications

Adequate specifications for identity and purity should be available before toxicological work is initiated. Toxicologists and regulatory bodies need assurance that the material to be tested corresponds to that to be used in practice. Ideally, the specifications should be such as to define a material that will give reproducible biological results.

Specifications for food additives produced commercially should be broad enough to include all the variations in the composition of these additives that, according to current knowledge, do not significantly affect their biological properties. As an example, mono- and di-glycerides of edible fatty acids [1] were considered as coming under one specification for the purpose of toxicological evaluation. In any case, each such group of additives will have to be judged individually with respect to the limits of composition set out in the specifications.

The levels of impurities that, according to current knowledge, are considered to be toxicologically significant and the methods for their determination must appear in the specifications. Tests for impurities such as lead, arsenic and heavy metals as a measure of good manufacturing practice should be maintained, unless and until a better measure becomes available. These tests are needed, irrespective of the high standards usually maintained in manufacture, in cases where inexperienced and less well-equipped manufacturers may produce food additives.

The Group was informed that in the eventual publication of the work on food additives and pesticide residues in the *Codex Alimentarius*, the foods in which these materials will be used and the levels of use will be indicated. Changes in usage of these materials will also be noted under the system of continuous revision that the *Codex Alimentarius* will undergo.

3.2 Methodology

3.2.1 *Appropriate species of test animals*

It is often stated that results obtained in the most sensitive species should take precedence in toxicological evaluation. The Group recommends that, wherever possible, the most appropriate species should be chosen for this purpose; this would be the species most similar to man with regard to its metabolic, biochemical and toxicological characteristics in relation to the substance under test.

3.2.2 *Investigation in human subjects*

Studies in experimental animals on the biological effects of chemicals that may be introduced into the environment have as one of their major objectives the prediction of any possible hazard to man. One of the greatest problems that arises in these studies is in the extrapolation of the data obtained from investigations in

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[1] *Wld Hlth Org. techn. Rep. Ser.*, 1964, 281; *FAO Nutrition Meetings Report Series*, 1964, No. 35.

animals to the definition of safe levels of exposure in man. The purpose for which the chemical may eventually be used does not necessarily affect the nature of the investigational problems involved.

The prediction and prevention of possible toxic hazards to the community that might arise from the introduction of a chemical into the environment can be made more certain if information from meaningful studies in human subjects is available. Three particular aspects of toxicology require consideration in this connexion: first, the choice of the most appropriate animal species for investigations that aim at the prediction of human responses; secondly, the investigation of a reversible specific effect observed in the most sensitive animal species to determine whether it represents a significant hazard to man; thirdly, the study of effects specific to man.

Metabolic studies. There is a need at a relatively early stage to obtain information on the absorption, distribution, metabolism and elimination of the chemical in human subjects, since this makes it possible to compare this information with that obtained in various animal species and to choose the species that are most likely to have a high predictive value for human responses.

The problems that arise in connexion with such early human studies in the investigation of drug toxicity have been discussed in a recent report of a WHO Scientific Group.[1] The sooner, in the course of toxicological investigation, these studies at a low dosage level can be undertaken, the better; however, it is necessary to have adequate short-term toxicological information in several species before even low doses of a new chemical are administered to human subjects.[1 2 3]

Confirmation of predicted safety margin. Chemicals intended for use as drugs are subjected to human pharmacological investigations and to clinical trials that must, of necessity, involve the use of biologically effective dosage levels. In the examination of other chemicals from a toxicological point of view, it is sometimes necessary to ascertain whether the safety margin predicted from animal data is valid. For this purpose it may be helpful to administer the chemical to human volunteers. It is emphasized that the following conditions should be fulfilled with regard to such a study:

(*a*) The chemical should have been fully studied in a range of experimental animals.

(*b*) There should be a clear need, in the public interest, for the study of some effect or effects in the human subject.

(*c*) The effect or effects studied should be reversible.

(*d*) The dose levels used should be based on full information of the toxicological properties of the substance in animals.

(*e*) The investigation should be terminated immediately the effect has been unequivocally demonstrated.

Effects specific to man. The Group considered the fact that, in the case of drugs, effects specific to man may be revealed during clinical trials or as a result of the reporting of adverse reactions after the drug is placed on the market.

In the case of other chemicals, it is not acceptable to study such effects by the use of volunteers. Toxicological studies can be made in those who are occupationally exposed to the chemical or in patients suffering from accidental poisoning. There is a need for more critical epidemiological and toxicological investigations in such situations. If unexpected effects apparently specific to man are observed, it is advisable to re-examine the evidence obtained earlier from animal studies to determine whether useful information in those investigations was missed or whether some different method of study might have been of greater predictive value.

Human volunteers. Ethical and legal problems may arise in connexion with the provision of volunteers for these investigations. Since the situation differs greatly from country to country, it should be left to the appropriate authorities in each country to decide any issues involved.

3.2.3 *Effect of age on toxicity*

The response of an animal to a particular substance may vary with age. In general, but not invariably, the young animal is more sensitive to the toxic effects of exposure to chemicals. The difference may arise from the presence of distinctive

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[1] *Wld Hlth Org. techn. Rep. Ser.*, 1966, 341.

[2] Hayes, W. J., jr (1965) *Research in pesticides*, New York, Academic Press.

[3] Ad Hoc Subcommittee on Use of Human Subjects in Safety Evaluation, Food Protection Committee, Food and Nutrition Board (1965) *Some considerations in the use of human subjects in safety evaluation of pesticides and food chemicals*, Washington D.C., National Academy of Sciences—National Research Council (Publication 1270)

flora in the upper part of the bowel, a factor that accounts for the susceptibility of human babies to poisoning by nitrates. In most cases, however, there exists an enzymic basis for the age difference in response to foreign compounds.

Many foreign substances are metabolized in the body by enzymes that occur in the endoplasmic reticulum of the liver cells. There is evidence that these enzymes may be poorly developed in newborn animals, [4] [5] possibly owing to lack of inducers.[6] Here also there may be significant species differences. In the rat the activity of the group of enzymes commonly called "drug-metabolizing enzymes" and mainly studied in the liver is maximal at the age of about 30 days and thereafter declines to some extent. Glucuronyl tsansferase is deficient in many newborn animals, including man, but not in the rat.

Thus, the enzymes that metabolize foreign substances may be at a low level in newborn animals, but develop later. Occasionally, they may be found in the newborn of some species, but not of others. A few metabolizing enzymes may be present in the newborn of some species although enzyme activity is no longer manifest in the adult animal of the same species. In any case, the metabolizing enzymes may either enhance or diminish toxicity, depending upon the biological properties of the substrate and the various products, although in the main these enzymes act beneficially.

These considerations must now be applied to the question of the possible presence of additives or trace contaminants in the diets of babies. It should be stressed that, in spite of the often considerable efforts made by manufacturers to avoid the presence of such contaminants in baby foods, the diet of babies is likely under present-day conditions to contain traces of pesticide and other residues. In addition, there are circumstances in which the benefit to the baby arising from the inclusion of some additives, for example a preservative, in its diet may greatly outweigh any possible hazard. Nevertheless, it is necessary to exercise great care in making such additions, keeping in mind the possible long duration of exposure.

The discussion presented above of species differences in response to the toxic effects of chemical compounds underlies the fact that data derived from such studies, or from other experiments with newborn or young animals, cannot be regarded as sufficient in themselves to permit the assessment of safety. It is particularly important to have a knowledge of the metabolism of the compound and to carry out other biochemical and toxicological studies in the most appropriate species in order to provide a firm basis for the evaluation of safety. However, pertinent information derived from reproduction (multigeneration) studies provides some assurance on the safety of compounds that might be present in the diet of babies.

Since babies constitute a special population, close observation of epidemiology in this group is an important practical aspect of the evaluation of the effects of exposure. The need exists for further information on the development of enzyme systems in the human young, with particular emphasis on those enzymes responsible for dealing with foreign compounds.

Further problems may arise when aged animals are used for the evaluation of safety. It is better to carry out toxicity studies before the complications of senescence arise. It is clearly essential in all such investigations to record the age of the animals as one of the factors of major importance in the experimental design. More basic information is required on toxicity in aged as well as in young animals.

3.2.4 *Effect of nutritional state on toxicity*

Nutritional state can influence toxicity. The effects of starvation or more specific nutritional deficiencies on the biological response to different substances will vary widely. It has been shown, for example, that glycogen depletion in the liver may interfere with the production of metabolizing enzymes in mice and in guinea-pigs.[1] [2] Poor nutritional status does not necessarily increase susceptibility to toxic effects; for example, depression of metabolizing enzymes that give rise to toxic products may diminish susceptibility. The general effects of reduced food intake on biological responses have been reviewed by Friedman,[3] and the effects

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[4] Hart, L. G., Adamson, R. H., Dixon, R. L. & Fouts, J. R. (1962) *J. Pharmacol. exp. Ther.*, 137, 103.
[5] Kato, R., Vassanelli, P., Frontina, G. & Chiesara, E. (1964) *Biochem. Pharmacol.*, 13, 1037.
[6] Fouts, J. R. (1965) In: Robson, J. M., Sullivan, F. & Smith, R. L., ed., *Embryopathic activity of drugs*, London, Churchill.
[1] Dixon, R. L., Shultice, R.W. & Fouts, J. R. (1960) *Proc. Soc. exp. Biol. (N.Y.)*, 103, 333.
[2] Kato, R. & Gillette, J. R. (1965) *J. Pharmacol. exp. Ther.*, 150, 279.
[3] Friedman, L. (1966) *Fed. Proc.*, 25, 137.

of specific nutritional deficiencies on toxicity have been fully discussed by Hötzel.[4] The relationship between nutritional status and carcinogenesis has been reviewed by Tannenbaum[5] and discussed in the fifth report of the Joint FAO/WHO Expert Committee on Food Additives.[6] Carcinogenic action tends to be diminished by calorie restriction and protein deficiency and in certain cases by specific nutritional deficiencies. The composition of the intestinal flora and such practices as coprophagy have an important influence on the nutritional status of experimental animals.

So far as toxicity studies are concerned, it is wise to maintain all the animals on a diet that is nutritionally adequate in every way, unless there is some specific reason for doing otherwise. It follows from the complexity of the effects of starvation or specific nutritional deficiencies in different species of animals that the indiscriminate use of undernutrition or dietary deficiencies might give rise to misleading results. A clear distinction must be drawn between investigations forming part of research projects and toxicological studies intended for safety evaluation. In applying the results of such safety tests, the sate of nutrition of the individuals exposed is taken into account by means of appropriate adjustments in the margin of safety used in specific instances. Equally, such adjustments must make allowance for other relevant factors in the chemical environment to which the population under consideration is exposed.

Food additives may be used, or contamination of food with chemicals may occur, in countries in which malnutrition is widespread. The Group considers that further work is needed on the effects of various states of malnutrition or undernutrition on the toxicity manifested by chemical compounds.

Manipulation of the composition of the diet of experimental animals, either in an effort to simulate conditions of malnutrition in man or in the belief that such dietary modifications help to elicit latent toxic effects of the material under study, is not considered advisable in routine toxicological investigations intended for the evaluation of safety.

3.2.5 *Duration of toxicity tests in experimental animals*

For adequate interchange of information a precise description is more meaningful than such terms as "acute", "subacute", "shortterm" and "chronic". Each report of an experiment should state in precise terms, in respect of both control and test animals, the species, sex, diet, route of administration and duration. The objective should be to define clearly all the known variables.

Scientific judgement is necessary in determing the duration of animal studies for the evaluation of an individual food additive. Where adequate biochemical and toxicological data on closely related chemicals are available, the objective becomes the detection of any deviation from the established pattern. This can usually be determined by intensive studies of a few months' duration when these are adequately designed and evaluated. Appropriate studies in humans add significantly to the adequacy of the data.

In the absence of such definitive data, or if there are reasons to suspect carcinogenic potential, longer-term studies must still be relied upon for reassurance. Recent advances in the quality of research animals, and particularly in the control of pathogens, have increased the life-span of some strains of animals. In spite of this, feeding studies adequately designed and evaluated extending up to eighteen months in mice and two years in rats are still considered adequate to ensure a minimum safeguard in evaluating the carcinogenic potential of a chemical additive. In special cases it may be desirable to prolong the observations in these species.

If there are good reasons to doubt the relevance to man of the data obtained in rodent species—for example, if the metabolism of the additive in man is found to be significantly different from that in rodents—it may be desirable to carry out investigations of longer duration in other species. The design and conduct of reproduction and teratogenic studies should take into account placental and mammary transmission. In addition, the investigation of some potential toxic effects, particularly carcinogenicity, requires careful prolonged observation of the offspring.[1] [2] Detailed study of general appearance and behaviour, biochemical effects,

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[4] Hötzel, D. (1964) *D sch. med. Forsch.*, 2, 105.

[5] Tannenbaum, A. (1959) *Nutrition and cancer.* In: Homburger, F., ed., *The physiopathology of cancer*, 2nd ed., New York, Hoeber-Har ber, p. 517.

[6] *Wld Hlth Org. techn. Rep. Ser.*, 1961, 220; *FAO Nutrition Meetings Report Series*, 1961, No. 29.

[1] Druckrey, H., Ivanovic, S. & Preussmann, R. (1966) *Nature (Lond.)*, 210, 1378.

[2] Druckrey, H., Ivanovic, S. & Preussmann, R. (1967) *Naturwissenschaften* (in press).

metabolism and histopathology should be included and fully reported, both qualitatively and quantitatively.

Further research in these important areas should be encouraged.

3.2.6 *Enzyme studies*

The study of enzymes in relation to pharmacological and toxicological action has developed considerably in recent years. Increases or decreases in enzyme levels caused by foreign chemicals may be studied either in the blood or in the tissues. It has become more and more apparent that, among the mechanisms of action of toxic substances, those of a biochemical nature are of prime importance. In this connexion, the basic enzyme systems are certainly among the first sites of action to merit careful study, since their inhibition often constitutes the causal biochemical lesion that determines, at least in part, the nature of toxic effects. It is enough to recall, among other classical examples, the inhibiting effect of cyanides and sulfides on cytochrome oxidases, of the fluoride anion on phosphoenolpyruvase, of fluoroacetates on aconitase and of novobiocin on glucuronyltransferase to realize the importance of this approach to toxicological evaluation. Enzyme inhibition may explain the toxic phenomena found in routine tests in laboratory animals or in observations in man. It may also provide a basis for forecasting toxic effects by indicating the first steps in the process.

The difficulties are to select the right enzymes for study and the most significant sites (body fluids, tissues, cells or subcellular fractions) for the measurement of changes in enzyme activity brought about by the substance under test. This is probably why, in the field of food additives, this approach has been so little used.

Enzymes in blood. The part of this subject relating to decreased levels of cholinesterases in the blood is dealt with elsewhere in this report (section 3.3.2).

An increase in the level of certain enzymes in the blood may be indicative of tissue damage; from this point of view, transaminases and other intracellular enzymes have been studied. When tissue damage occurs, these enzymes may leak out of the cells and cause a significant increase in blood enzyme levels. Such changes have been extensively studied in clinical biochemical laboratories in relation to myocardial damage following infarction and, in this instance, the time relationships between the occurrence of myocardial damage and alterations in the blood enzyme levels are important. Alterations in glutamic-pyruvic transaminase and glutamic-oxaloacetic transaminase have been observed to follow liver damage. Damage to a number of other organs has also been associated with various changes in blood enzyme levels.[1-4] Changes of this sort may be useful in indicating that tissue damage has occurred without the need to sacrifice the animal. However, if the damage is caused gradually, enzymes may be lost from the tissue cells without causing a demonstrable change in blood enzyme levels.

Enzymes in the tissues. Some food additives produce their effects by enzyme inhibition. Thus, in moulds, sorbic acid inhibits a number of enzymes, including catalase and alcohol dehydrogenase and its fungistatic properties are probably related to this effect. However, in the animal body, metabolic degradation makes it impossible to administer enough sorbic acid by mouth to cause significant inhibition of dehydrogenase systems.[5] Study of the effect of food additives on enzymes should be encouraged.

Apart from enzyme inhibition, the level of tissue enzymes may also give some indication of toxicity. As already mentioned, when cells are damaged, intracellular enzymes may enter the blood. The level of these released enzymes in the blood depends on the relative rates at which the enzymes leave the cell and are inactivated or otherwise eliminated. The acuteness and severity of the damage and the timing of changes in relation to damage are significant factors in determining the blood level. Loss from the tissues will lead to a diminished enzyme concentration in the cell, unless regeneration keeps pace with the rate of loss. Thus, the cell lar enzymes may indicate either acute or chronic damage and measurement of these levels might prove useful in the differentiation of toxic and toxicologically irrelevant changes in cells and organs.

Another aspect of enzyme changes of toxicological interest is the induction of so called drug-metabolizing enzymes, especially in the liver. Some substances cause a considerable increase in many of these enzymes, which are found in the

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[1] Chirskey, M., Wolff, R. J. & Sherry, S. (1957) *Amer. J. med. Sci.*, 233, 400.
[2] Koide, H. & Oda, T. (1959) *Clin. chim. Acta*, 4, 554.
[3] Somerville, R. L., Fleisher, G. A. & Dearing, W. M. (1960) *Gastroenterology*, 39, 574.
[4] Wroblewski, F. & La Due, J. S. (1956) *Ann. intern. Med.*, 45, 801.
[5] Melnick, D., Luckmann, F. H. & Gooding, C. M. (1954) *Food Res.*, 19, 44.

microsomal fraction of liver cells. This increase enables the animal to metabolize greater amounts of the substrate and other substances. The products of metabolism may be more or less toxic than the original substance. If the products are less toxic, the tolerance of the animal to the original substance may greatly increase. However, not all substances induce metabolizing enzymes, and some may take several weeks before causing significant induction. Examples of the former are parathion and isopropanol and of the latter are carbaryl and, to a lesser extent, methoxychlor and TDE. [1] These biochemical changes may or may not be related to ultrastructural changes in hepatic cells, they are often quickly reversible and may represent adaptation of the cell to the administered chemical.

Investigation of these phenomena as a part of the biochemical and metabolic studies may be expected to contribute significantly to the understanding of the inter-relationships between the additive and other chemicals in the environment.

3.2.7 *Special studies*

3.2.7.1 *Mutagenicity.* Mutagenic action of chemical agents represents a problem since, although exposure to chemicals in the external environment is increasing, there is little information on their possible mutagenic action. Attention has been drawn to the genetic effect of chemicals in connexion with radiation hazards.[2]

This problem cannot be ignored, since it represents one of the potential risks from chemical exposure. However, insofar as food additives are concerned, this possible risk must always be considered in the context of toxicological hazards in general, including the possible mutagenic effects of food themselves. The Group stresses the difficulties of extrapolating experimental data on mutagencity of chemicals obtained in bacterial systems, yeasts, or *Drosophila* to possible hazards of food additives in man; these special procedures commonly used to detect mutagenic activity cannot be recommended as part of the routine investigation of a food additive.

Further research in this field is needed.

3.2.7.2 *Teratogenicity.* By teratogenicity is meant a toxic effect on the embryo or foetus resulting in a congenital abnormality. The Group feels at present unable to recommend a specific test for the detection of teratogens, but reproduction studies currently recommended as part of routine investigations of food additives should reveal some teratogens. It is recognized that improved tests are required to provide additional safeguards. However, further research is needed to design such tests. Since much research in teratology is under way, it is important that investigators concerned with food additives should keep in close touch with advancing knowledge in this field.

3.3 Interpretation of findings

3.3.1 *Decrease in rate of body-weight gain*

This effect may be brought about by many factors, such as an alteration of water intake, increased water loss, an alteration of food or calorie intake or faulty utilization of absorbed nutrients. These various effects may be due to a toxic action of the substance under investigation or to causes that are not relevant to the assessment of toxic potential, as, for example, diarrhea due to an osmotic effect at high dosage levels of the test substance or interference with the palatability of the diet by the presence of the test substance. The effects that are irrelevant to toxicity should be differentiated from true toxic effects by appropriate studies. A decrease in the rate of body-weight gain, accompanied by a corresponding reduction of food intake, should not be assumed to be caused by a palatability defect, since the reduction of food intake may be due to toxic anorexia. If a palatability defect is present, this may be disclosed by a preference test in which the diets fed to the control and experimental groups are compared.[3]

3.3.2 *Inhibition of cholinesterases*

Cholinesterases in both plasma and erythrocytes are markedly reduced by a number of substances, including many organophosphorus compounds used as pesticides. There is, however, poor correlation between the cholinesterase levels

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[1] Stein, W. H., Serrone, D.M. & Coulston, F. (1965) *Toxicol. appl. Pharmacol.*, 7,499.

[2] *Wld Hlth Org. techn. Rep. Ser.*, 1962, 248.

[3] Sharratt, M., Frazer, A. C. & Cutler, M. (1964) *Methodological studies in the assessment of the acceptability of a food additive.* In: *Proceedings of the First International Congress of Food Science and Technology*, New York, Gordon & Breach, p. 583.

and the signs and symptoms of toxicity. Blood cholinesterase levels may be useful as an indication of exposure to a substance with anticholinesterase activity, but not as an invariable guide to the degree of intoxication present or predicted. In general, lack of correlation between the activity of a particular enzyme, or the level of a chemical of one of its metabolites, at some specified site (for example, in blood) and the occurrence of toxic signs or symptoms may be due to the fact that the more significant change in activity or concentration is occurring at some other site (for example, at nerve endings). Thus, the changes being measured may correlate with changes at the more significant site only over a small part of the range. Alternatively, some other enzyme, chemical or metabolite may be more closely related to the toxic mechanism. Although changes in blood cholinesterase levels may be helpful in toxicological studies, it is important that further research should be done to relate the indices used as closely as possible to the biochemical changes concerned in bringing about the toxic effects. In this context, special attention should be paid to the method of estimating cholinesterases.

3.3.3 *Liver enlargement*

The occurrence of enlargement of the liver in the absence of other apparent changes in this organ has often been reported in toxicological studies. Customarily, hepatomegaly has been considered to indicate a pathological change, and this interpretation has been applied in establishing "no-effect" levels. It is reasonable to believe that this alteration may not always represent a pathological change and in some instances may, on investigation, be revealed to be a normal response to an increased work load. This seemingly logical contention requires substantiation. It is recommended that a detailed investigation of liver enlargement in toxicity tests be carried out (as set out below), including a study not only of the absolute weight of the liver (measured under standard conditions) but also of the relationship of the weight of the liver to body-weight, provided that the growth and condition of the animals justifies the calculation of the relative liver weight on this basis. If this is not the case, for example because of emaciation, liver weight may be related to the weight of the heart or brain for purposes of comparison with control groups.

In studies on food additives it is usual to administer the substance under investigation at several dose levels; some at least of these are far in excess of those that are ever likely to be administered to man. Such high dose levels of a metabolizable chemical substance must inevitably increase the load on the liver, if this organ plays any part in its metabolism. It is known that under these circumstances the endoplasmic reticulum in the liver cells frequently proliferates, elaborating more enzymes and thereby facilitating the metabolism of the compound. It is likely, therefore, that liver enlargement will often be observed in animal studies on the biological effects of new substances proposed for use as food additives. To evaluate fully the significance of such findings the following studies are recommended:

(1) Liver morphology; ultrastructural studies.

(2) Detailed investigation of the relationship to the dose and to the time of development of hepatomegaly during feeding experiments.

(3) Reversibility of liver enlargement on continuing dosage and on cessation of administration of the compound.

(4) Additional criteria of liver response and the relationship of these to dose and liver enlargement. Such criteria may include the activities of microsomal-processing (drug-metabolizing) enzymes in the liver and of glucose-6-phosphatase or other indicators of changes taking place within the liver in response to exposure of the test compound.[1]

3.3.4 *Local sarcomas*

The significance of the occurrence of sarcomas following subcutaneous injection has been discussed in the fifth report of the Joint FAO/WHO Expert Committee on Food Additives.[2] In that report it was concluded that in certain experiments sarcomas were a result of the physical characteristics of the test material. Further research was recommended. As a result of developments since that time it is now recommended:

(*a*) that for the *routine* testing of food additives and contaminants, the subcutaneous injection test should be considered inappropriate unless special condi-

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[1] Golberg, L. (1966) *Proc. Europ. Soc. Study Drug Tox.*, 7, 171.

[2] *Wld Hlth Org. techn. Rep. Ser.*, 1961, 220; *FAO Nutrition Meetings Report Series*, 1961, No. 29.

tions, such as lack of absorption from the gastrointestinal tract under conditions of routine feeding to experimental animals, demand additional studies;

(*b*) that the occurrence of a local sarcoma following subcutaneous injection of food additives or contaminants should not, alone, be considered significant evidence of a carcinogenic hazard; such a finding, however, indicates the desirability of a thorough study for systemic manifestations of carcinogenicity by other parenteral or further specific oral investigations.

3.4 Decision and regulation

3.4.1 *Margin of safety*

Some margin of safety is necessary for the extrapolation of the maximum dietary level causing no effect in experimental animals to the acceptable dietary intake in man. An arbitrary factor of 100 has been widely accepted and this figure was recommended by the Joint FAO/WHO Expert Committee on Food Additives in its second report.[1] In practice the margin of safety has varied from 10-fold to 500-fold, based on the scope and comprehensiveness of the data available. The following points are relevant to the establishment of this margin of safety:

(1) *The "no-effect" level.* There would appear to be a need to consider more closely what "no-effect" means. The obvious intention is that the maximum dietary level that causes no *deleterious* effect should be taken for extrapolation to give the acceptable dietary intake in man. It may be difficult, however, to know whether an effect observed is deleterious or not. For example, diarrhea may be a toxic effect, or it may be due to the osmotic effect often associated with a high dose level of the test substance; decrease of weight gain may be due to toxic anorexia or to a loss of palatability of the diet. If effects of a physical nature (such as osmosis) or other effects (such as a palatability defect or stimulation of the metabolizing enzymes in the liver) resulting from a high dose level of the test substance, but unrelated to its toxic action, are included with toxic effects in selecting the "no-effect" level, it is reasonable to apply a lower margin of safety than that required for an unequivocal toxic effect.

In the absence of adequate evidence to the contrary, it should be assumed that any effect observed is a toxic effect. The onus for establishing that an effect observed is not a toxic one must rest on the investigator. Such features as reversibility and the differentiation of effects at lower dose levels may assist in distinguishing between physiological and pathological phenomena; research aimed at elucidating problems of this nature should be encouraged.

(2) *Variation of margin of safety.* It is not necessary to demand the rigid application of an arbitrary figure. The grounds upon which a different figure might be applied can be considered as follows:

(*a*) *Possible grounds for increasing the margin of safety*

The Joint FAO/SHO Expert Committee in its sixth report [2] provided a greater margin of safety for any country that did not have expert advice on food technology and food standards. What was considered as an unconditional acceptance zone was usually based on a safety margin of 100; in many instances a margin of 200 was used.

There may be other reasons for using a greater margin of safety; a case in point is an additive for which an adequate amount of toxicological data is not available. The Group have taken cognizance of the situation and have recommended the establishment of temporary acceptable daily intakes (section 3.4.2). In these cases a larger margin of safety should be employed and all such temporary acceptable daily intakes should be considered as conditional.

Another example that may be cited is when the food additive is proposed for use in food items that show wide variations in daily intake, perhaps for climatic reasons, such as ice cream or soft drinks. Again, some foods may be particularly popular with children and this may be though to justify an increase in the safety margin.

(*b*) *Possible grounds for decreasing the margin of safety*

The magnitude of the margin of safety to be applied is technically a factor of the adequacy of available toxicological data. If an intentional food additive is a beneficial constituent of the diet or is a normal body constituent, this may provide grounds for a lower safety margin. It would not be feasible to apply a 100-times

[1] *Wld Hlth Org. techn. Rep. Ser.*, 1958, 144; *FAO Nutrition Meetings Report Series*, 1958, No. 17.
[2] *Wld Hlth Org. techn. Rep. Ser.*, 1962, 228; *FAO Nutrition Meetings Report Series*, 1962, No. 31.

safety margin to many common food additives, e.g., sodium chloride. There are also many substances, some of which may be used as food additives, that are known to be well tolerated by man at certain dose levels. The relevance of human data is discussed elsewhere in this report (section 3.2.2). Valid human data should take precedence over predictions arrived at by extrapolation from animal studies and may make it possible to apply a lower margin of safety.

When pertinent biological data (such as acute and long-term toxicity, biochemical reactions and histopathology) reveal a uniform species response, and when the most sensitive criterion of effect is clear-cut and the effect is reversible, then a materially reduced margin of safety can and should be applied to the "no-effect" level. Another example is the situation where the "no-effect" level of a product is based on cholinesterase inhibition or adaptive liver enlargement. In these cases the margin of safety may be reduced substantially below the usual 100-fold margin of safety, provided that the additional biological data are satisfactory. In no case, however, should this factor be employed to justify the use of amounts of the additive in excess of that required for the indicated purpose.

The margin of safety to be applied to the "no toxic effect" level in the process of extrapolation from animal data to human exposure to fundamantal for deriving values such as the acceptable daily intake and tolerances. It is important, therefore, that all details of the animal data and probable exposure to be carefully evaluated. Continued research in this area is to be encouraged. Exploratory research in additional animal species, new techniques and new biological systems may yield data unique in character that are of research value but that should not necessarily be used to determine the "no toxic effect" level. Only when such data become recognized as significant should they be prime factors of evaluation.

It may be concluded that the 100-fold margin of safety is a useful general guide; it should not be applied rigidly. If, however, a different margin of safety is used, the basis for changing the 100-fold margin should conform to the principles outlined above.

3.4.2 *Establishment of temporary acceptable daily intakes*

The Group approves in principle the establishment of temporary ADIs for those food additives that would be useful and those that are already in use but for which data may not be fully adequate by current standards. It is recommended that such temporary ADIs be used as a basis for the establishment of temporary tolerances only if the following specific conditions are rigidly adhered to:

(1) Each chemical additive must be considered on its merits.

(2) The temporary ADI must be established only for a specific and definite period, namely, 3–5 years.

(3) In setting a temporary ADI, the additional biochemical and toxicological data required for the eventual establishment of an ADI must be clearly stated. The additional requirements must be justified as being essential for the protection of the consumer.

(4) A review of the original and new data must be carried out before the expiration of the provisional period.

3.4.3 *Establishment of administrative acceptable daily intakes for pesticide residues*

The Group discussed various classes of food additives and concluded that in the case of some pesticides it may be advisable to allocate an "administrative ADI". This figure is intended to enable those concerned to establish a finite tolerance or "negligible level" in each case. The folllowing factors especially should be taken into consideration:

(1) The nature of the substance.

(2) The magnitude of the residue and the availability of suitable analytical methods for control purposes.

(3) The adequacy of toxicological and biochemical data for the purpose of establishing an administrative ADI.

(4) The absence of specific justification requiring additional data.

4. SUMMARY AND CONCLUSIONS

Specifications.—Adequate specifications for identity and purity should be available before toxicological work is undertaken. They should be broad enough to include all the variations in composition that do not significantly affect the biological properties of the additives and they should include methods for the determination of toxicologically significant impurities; tests for "good manufacturing practice" be maintained.

Test animals.—Data from the most appropriate, rather than the most sensitive, species should take precedence for toxicological evaluation.

Investigation in human subjects.—It is desirable and in many cases necessary to study the metabolic fate and effects of food additives in man. Such investigations, which should be carefully planned and controlled, form a valuable part of the evaluation of safety.

Effect of age on toxicity.—In general, the young animal is more sensitive to the toxic effects of exposure to chemicals, but this is not invariably so. Useful information may be obtained from studies in newborn or young animals, from reproduction studies and from biochemical studies.

Effect of nutritional state on toxicity.—Because of the complexity of the relationships between nutritional state and toxicity, at present the evaluation of safety is best carried out by using healthy animals on adequate, balanced diets.

Duration of toxicity tests in experimental animals.—Flexibility of approach is essential in deciding the duration of tests necessary to establish that a compound is safe. In certain circumstances, tests carried out over a few months may suffice for the purpose of detecting any deviation from the established pattern in a group of closely related chemicals.

Enzyme studies.—The effects of food additives on basic enzyme systems, as a part of biochemical and metabolic studies, may be expected to contribute significantly to the understanding of the inter-relationships between the additive and other chemicals in the environment.

Mutagenicity.—At present no specific tests can be recommended for the assessment of mutagenic risk, but some safeguard is provided by multigeneration studies.

Teratogenicity.—At present no specific tests can be recommended for the detection of teratogens, but some safeguard is provided by multigeneration studies.

Decrease in rate of body-weight gain.—The observation of decreased rate of body-weight gain requires further study to differentiate between toxicologically relevant and irrelevant effects. A preference test may distinguish between palatability defect and toxic anorexia.

Inhibition of cholinesterases.—Blood cholinesterase levels may be useful as an indication of exposure to a substance with anticholinesterase activity, but not as an invariable guide to the degree of intoxication.

Liver enlargement.—Some additional studies are recommended in order to evaluate the significance of liver enlargement.

Local sarcomas.—The significance of the occurrence of local sarcomas following subcutaneous injection is discussed in section 3.3.4.

Margin of safety.—The factor of 100 is generally considered as a suitable margin of safety, but under certain conditions it may be increased or decreased.

Establishment of temporary acceptable daily intakes.—Provided that a number of conditions are fulfilled, temporary acceptable daily intakes may be established for food additives.

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