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THE TOXIC SUBSTANCES CONTROL ACT O 1971 AND AMENDMENT

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HEARINGS

BEFORE THE

SUBCOMMITTEE ON THE ENVIRONMENT

OF THE

COMMITTEE ON COMMERCE

UNITED STATES SENATE

NINETY-SECOND CONGRESS

FIRST SESSION

ON

S. 1478

TO AMEND THE FEDERAL HAZARDOUS SUBSTANCES ACT, AS AMENDED, AND FOR OTHER PURPOSES

AUGUST 3, 4, 5; OCTOBER 4, AND NOVEMBER 5, 1971

PART 1 OF 3 PARTS

TOXIC SUBSTANCES

Serial No. 92–50

Printed for the use of the Committee on Commerce



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THE TOXIC SUBSTANCES CONTROL ACT OF 1971 AND AMENDMENT

TUESDAY, AUGUST 3, 1971

U.S. SENATE,
COMMITTEE ON COMMERCE,
SUBCOMMITTEE ON THE ENVIRONMENT,
Washington, D.C.

The subcommittee met, pursuant to notice, at 10 a.m., in room 5110, New Senate Office Building, Hon. William B. Spong, Jr., presiding.

Present: Senators Spong and Hatfield.

OPENING STATEMENT BY SENATOR SPONG

Senator SPONG. The hearings will come to order.

This morning the Subcommittee on the Environment begins hearings on S. 1478, the administration's proposed Toxic Substances Control Act, and amendment 338 to that bill which I introduced on July 27.

Senator Hart is the chairman of the subcommittee, but for the purposes of these hearings he has relinquished the chair. I appreciate Senator Hart's gesture and I hope the quality of the hearings will not suffer unduly because of the able chairman's absence.

In requesting additional authority to regulate toxic substances the administration recognizes that gaps exist in our regulatory framework that permit public health and environmental hazards to occur without regulation. While I would disagree with the administration on the best method of dealing with this problem, we are in complete agreement that these gaps should be closed.

In the course of the next 3 days we will hear testimony from three prominent scientists on the hazards of three chemical substances which would be prime candidates for regulation under a toxic substances control statute. Later this morning we will hear that substantial quantities of mercury are reaching the environment by way of the disposal of consumer products. While we have achieved impressive reductions in mercury discharges from industrial sources, an even greater source of mercury has yet to be controlled. Tomorrow we will receive testimony on the dangers of PCBs including a description of the problems of rice oil contamination in Japan as it relates to the PCBs problem in this country. The need for further protection from PCBs has been accentuated by the recent discovery of contaminated chicken feed and the subsequent flare of activity caused by that discovery. On Thursday we will receive testimony concerning asbestos which is used extensively in

Staff members assigned to these hearings: Leonard Bickwit, Jr., and Michael Brownlee.

building construction, brake linings and for other purposes which may be contaminating the air we breathe.

In addition, the subcommittee will receive testimony from administration witnesses and a number of conservation and public interest groups.

Additional hearings will be scheduled in late September or early October to hear from industry witnesses, which should complete our hearing record.

(The bill and agency comments follow:)

92D CONGRESS
1ST SESSION

S. 1478

IN THE SENATE OF THE UNITED STATES

APRIL 1, 1971

Mr. HART (for Mr. MAGNUSON) (by request) introduced the following bill; which was read twice and referred to the Committee on Commerce

A BILL

To amend, the Federal Hazardous Substances Act, as amended, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the Toxic Substances Control Act of 1971.

SEC. 2. The Federal Hazardous Substances Act is amended by inserting before section 1 of such Act the following: "TITLE I—HAZARDOUS CONSUMER PRODUCTS".

SEC. 3. Such Act is further amended by adding after the aforesaid title I, that is, after section 18 of the Act, the following new title:

"TITLE II—TOXIC SUBSTANCES

"POLICY

"SEC. 201. Whereas the American people are being exposed to a large number of chemical substances each year; and

"Whereas among the many new substances constantly being developed are some which may be a danger to human health or the environment; and

"Whereas the effective regulation of interstate commerce in such chemicals necessitates the regulation of transactions in such chemicals in intrastate commerce as well;

"Therefore, it is the policy of the United States that new chemical substances should be adequately tested with respect to their safety to man and the environment; and

"That adequate authority should exist to restrict the distribution and use of chemicals found to be toxic; and

"That such authority over chemicals be exercised in such a manner as not to unduly impede technological innovation while fulfilling the primary purpose of this title to assure that such innovation and commerce does not endanger human health or the environment.

"DEFINITIONS

"SEC. 202. (a) 'Administrator' means the Administrator of the Environmental Protection Agency.

"(b) 'Chemical substance' means any organic or inor-

ganic substance of a particular molecular identity or any uncombined chemical radical or element.

"(c) 'Manufacturer' means any person engaged in the production or manufacture of chemical substances for purposes of sale or distribution in commercial quantities, or an importer thereof.

"(d) 'Processor' means any person engaged in the preparation of a chemical substance for distribution or use either in the form in which it is received or as part of another product, as defined by regulations of the Administrator.

"(e) 'Restrict use or distribution' means to prescribe the amount sold to given types of processors, or to limit the type of processor to whom a substance may be sold, or to prescribe the amount which may be utilized by a given type of processor.

"(f) 'Byproduct' means a chemical substance produced as a direct result of the production, manufacture, or processing of some other chemical substance which is subject to the provisions of this title.

"(g) 'Environment' includes water, air, land, all plants and animals living therein, and the interrelationships which exist among these.

"(h) 'Animal' means all vertebrate and invertebrate

species, including but not limited to man and other mammals, birds, fish, and shellfish.

"(i) 'Protect health and the environment' means protection against any injury to man and protection against any substantial adverse effects on environmental values, taking into account the public interest.

"(j) 'District court of the United States' includes the District Court of Guam, the District Court of the Virgin Islands, the District Court of the Canal Zone, and in the case of American Samoa and the Trust Territory of the Pacific Islands, the District Court of the United States for the District of Hawaii, which court shall have jurisdiction over actions arising under this title.

"RESTRICTIONS ON USE OR DISTRIBUTION

"Proposal To Adopt Restrictions

"SEC. 203. (a) For any chemical substance produced in commercial quantities, after evaluating all information developed by or otherwise provided to or made available to him, and after referring the matter to a committee in accordance with section 208, the Administrator may publish proposed regulations to:

"(1) restrict or prohibit the use or distribution of the chemical substance to the extent necessary to protect health and the environment; and

"(2) require that any or all persons engaged in

the distribution of the substance so regulated give notification to purchasers of the substance of such restriction in such form or manner as the Administrator deems advisable; and

"(3) require such other action as may be necessary to carry out such restrictions including prohibiting or restricting the sale, use, or removal of such substance or product.

"Objections, Notice, Hearing, Final Order

"(b) (1) On or before the thirtieth day after the day on which the proposed regulations under subsection (a) are made public, any person who will be adversely affected by such regulations if placed in effect may file objections thereto with the Administrator specifying with particularity the provisions of the regulations deemed objectionable, stating the grounds therefor, and requesting a public hearing upon such objections.

"(2) After such request for a public hearing, the Administrator, after due notice, shall upon request by a manufacturer or processor, and may, in his discretion, upon request by any other person adversely affected by such order, hold such a public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. At the hearing, any interested person may be heard in person or by representative.

"(3) As soon as practicable after the date for completion of the filing of objections and comments, and the hearing, if any such hearing has been held, the Administrator shall by order act upon such objections, if any, and make public an order promulgating, modifying, or withdrawing the proposed regulations issued under paragraph (a) (1). Such order shall be based only on the evidence of record and shall set forth, as part of the order, detailed findings of fact on which the order imposing restrictions is based and the relationship of such finding to the restrictions imposed. Such order must be based on the Administrator's finding that such regulations are necessary to protect health and the environment and that the proposed action is necessary to carry out the objectives of this title. In making such a finding the Administrator shall consider all relevant factors including: the effects on human health and the environment of the substance or its byproducts; the benefits to be derived from the use of the substance as compared with the risks; the normal circumstances of use; the degree to which release of the substance or byproducts to the general environment is controlled; and the magnitude of exposure of humans and the environment to the substance or its byproducts. The Administrator shall specify in the order the date on which it shall take effect, except that it shall not

be made to take effect prior to the ninetieth day after its publication.

"Modification or Rescission

"(c) Manufacturers or processors of a chemical substance affected by final regulations issued pursuant to this section may petition the Administrator for modification or rescission of the regulation. The Administrator may at any time modify or rescind such regulations. Proceedings respecting petitions from manufacturers or processors or respecting modifications or rescissions made by the Administrator shall be held in accordance with the standards and procedures established by this section, except that the Administrator may or may not, in his discretion, provide for a hearing regarding such modifications or rescissions.

"Judicial Review

"(d) (1) Any person who will be adversely affected by an order issued under subsection 203 (b) or (c) if placed in effect may at any time prior to the ninetieth day after such order is issued file a petition with the United States court of appeals for the circuit wherein such person resides or has his principal place of business, for a judicial review of such order. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Administrator or other officer designated by him for that purpose. The Administrator thereupon shall file in the court the record on

which he based his order, as provided in section 2112 of title 28 of the United States Code.

"(2) If the petitioner applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the record before the Administrator, the court may order such additional evidence (and evidence in rebuttal thereof) to be taken before the Administrator and to be adduced upon the hearing, in such manner and upon such terms and conditions as to the court may seem proper. The Administrator may modify his findings as to the facts, or make new findings by reason of the additional evidence so taken, and he shall file such modified or new findings, and his recommendation, if any, for the modification or setting aside of his original order, with the return of such additional evidence.

"(3) Upon the filing of the petition referred to in subsection (d) (1), the court shall have jurisdiction to affirm the order, or to set it aside in whole or in part, temporarily or permanently. If the order of the Administrator refuses to issue, amend, or repeal a regulation and such order is not in accordance with law the court shall by its judgment order the Administrator to take action, with respect to such regulation, in accordance with law. The findings of the Ad-

ministrator as to the facts shall be sustained if based upon substantial evidence on the record considered as a whole.

"(4) The judgment of the court affirming or setting aside, in whole or in part, any such order of the Administrator shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28 of the United States Code.

"IMMINENT HAZARD

"SEC. 204. (a) An imminent hazard shall be considered to exist when the evidence is sufficient to show that a use or distribution of a chemical substance creates a hazard to human health or the environment (1) that should be corrected immediately to prevent injury to health and (2) that should not be permitted to continue while an administrative hearing or other formal proceeding is being held.

"(b) If the Administrator has reason to believe that an imminent hazard exists he may request the Attorney General to petition an appropriate district court of the United States to restrain the uses or distribution of the chemical substance responsible for the hazard. Upon the filing of any such petition the district court shall have jurisdiction to grant such injunctive relief or temporary restraining order pending the outcome of proceedings pursuant to section 203 of this Act. Such proceedings shall be initiated contem-

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poraneously with the request of the Administrator to take action under this subsection. Such proceedings shall be deemed to be initiated when he has referred the matter to a committee under section 208 (c).

"(c) The initiation of any proceedings or actions under section 203 shall not prevent the Administrator from initiating action under this section if he has reason to believe that an imminent hazard exists.

"TESTING

"SEC. 205. As soon as practicable after enactment of the title and from time to time thereafter, the Administrator shall, after referral to the Toxic Substances Board, for various classes and uses of chemical substances, prescribe by regulation standards for test protocols, and for the results to be achieved therefrom, as are necessary to protect health and the environment. He shall afford opportunity for submission of written comments, and upon request of any affected person, a public hearing with respect to any such proposed regulation, and such regulation shall be based upon substantial evidence of record in such proceeding. He may supplement, modify, or withdraw any such regulation in the same manner. Regulations promulgated pursuant to this section shall be applicable only to chemical substances which are first produced in commercial quantities after the effective date of such regulations. The promulgation of regula-

tions as to a particular chemical substance under this section shall not preclude action with respect to such substance under section 203.

"REPORTS

"SEC. 206. (a) The Administrator may by regulation require any or all manufacturers of chemical substances to report to him annually or such more frequent times as the Administrator may reasonably require as to any or all of the following:

"(1) The names of any or all substances produced by the manufacturer;

"(2) The chemical identity and molecular structure of such substances;

"(3) The categories of use of each such substance, insofar as they are known to him;

"(4) Reasonable estimates of the amounts of each substance produced for each such category of use; and

"(5) A description of the byproducts, if any, resulting from the production of such substance, and, insofar as they are known to him, from the use thereof.

"(b) Whenever the Administrator determines that such action is necessary to accomplish the purposes of this title, he may direct manufacturers of a chemical substance to provide, within a specified period of time not to be less than thirty days, the results of any tests of the health or environ-

mental effects of the substance or its byproducts, which have been performed by or at the instance of the manufacturer or such results as are otherwise known to him, and any or all of the items of information listed in subsection (a).

"(c) Whenever the Administrator determines that such action would be productive and desirable to allow him to carry out his responsibilities and authorities under this title, he may by publishing a notice in the Federal Register invite and afford all interested persons an opportunity to provide in writing information respecting the health or environmental effects of the substance or its byproducts.

RELATIONSHIP TO OTHER LAWS

"SEC. 207. (a) This title shall not apply to—

"(1) economic poisons subject to the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, and chemical substances used solely in such poisons: *Provided,* That if a chemical substance which constitutes such a poison or such an ingredient is or may be used for any purpose which is not regulated by the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, this title shall apply to such other uses.

"(2) foods, food additives, drugs, and cosmetics subject to the Federal Food, Drug, and Cosmetic Act, as amended, the Federal Meat Inspection Act, and the

Poultry Products Inspection Act, and chemical substances used solely therein, and controlled substances regulated pursuant to the Comprehensive Drug Abuse Prevention and Control Act of 1970: *Provided*, That if such an item or substance is or may be used for any purpose which is not regulated by such acts this title shall apply to such other uses;

"(3) any source material, special nuclear material, or byproduct material as defined in the Atomic Energy Act of 1954, as amended, and regulations issued pursuant thereto by the Atomic Energy Commission;

"(4) the authority of the Secretary of the Department of Transportation to establish rules and regulations for the transportation of hazardous materials.

"(b) To the extent that such activities are subject to regulation by other Federal laws, including the Occupational Health and Safety Act of 1970 and title I of this Act, the Administrator shall not regulate the use or distribution of a new or existing chemical substance on the basis of any possible hazard to employees in their place of employment, or the hazard directly to consumers resulting from household use of marketed products which contain or might contain the substance. If it appears to the Administrator that any such substance may pose a hazard when transported, or when used on or in food or as a drug or cosmetic, or may

be a hazard to employees in their place of employment, or may pose a hazard directly to consumers resulting from household use of marketed products which contain or might contain the substance, he shall transmit any data received from manufacturers or processors relevant to such hazards to the Federal department or agency with authority to take legal action if a hazard is found to exist.

"(c) The Administrator shall coordinate actions taken under this Act with actions taken to enforce the Federal Water Pollution Control Act as amended and the Clean Air Act as amended, and shall, where appropriate, use the authorities contained in those Acts to regulate chemical substances.

"(d) The Administrator shall make every effort to maintain close coordination with the Department of Health, Education, and Welfare and other appropriate Federal agencies in administering the provisions of this title.

"(e) This title shall not be construed as superseding or impairing the provisions of any other law or treaty of the United States.

"TOXIC SUBSTANCES BOARD

"SEC. 208. (a) There shall be established in the Environmental Protection Agency a Toxic Substances Board consisting of a reasonable number of scientifically qualified persons. The Administrator shall appoint as the members of

the board the persons nominated to him by the National Academy of Sciences. One of the members may be designated at any time by the Director of the National Academy of Sciences to serve as Chairman of the Board.

"(b) The National Academy of Sciences, in consultation with the Board, shall establish, maintain, and publish a continuing list of qualified scientists, including experts in the areas likely to be covered by this title. Such scientists shall be consultants to the Toxic Substances Board.

"(c) Before proposing any regulations under authority of section 203 or 205 the Administrator shall refer his proposed action and the available evidence to a Committee drawn from members of the Board and the list of consultants to the Board. The Administrator shall appoint as the members of the Committee the consultants nominated to him by the Board. The Committee shall report its views, in writing, to the Administrator, within a reasonable time, not to be less than forty-five days, specified by the Administrator. If the Committee fails to report within the specified time, the Administrator may proceed to take action under this title. The report of the Committee shall be considered as part of the record in any proceeding taken with respect to the Administrator's action.

"(d) The Administrator may, at his discretion, also request the Board to convene a panel to consider other

actions proposed to be taken under this Act, including actions proposed to be taken under section 204(b).

"(e) The Administrator is authorized to reimburse the National Academy of Sciences for expenses incurred in carrying out this section.

"RESEARCH

"SEC. 209. The Administrator is authorized to conduct such research and monitoring as is necessary to carry out his functions and responsibilities under this title. Such research and monitoring shall not duplicate the efforts of other Federal agencies. To this end, the Administrator is authorized to establish research laboratories, including the acquisition of necessary land, buildings, or facilities, and to make contracts for such research and monitoring.

"ADMINISTRATIVE INSPECTIONS AND WARRANTS

"SEC. 210. (a) (1) For the purpose of inspecting, copying, and verifying the correctness of records, reports, or other documents required to be kept or made under this title and otherwise facilitating the carrying out of his functions under this title, the Administrator is authorized, in accordance with this section, to enter any factory, warehouse, or premises in which chemical substances are manufactured, processed, or held and to conduct administrative inspections thereof, and of the things specified in this section, relevant to those functions.

"(2) Such entries and inspections shall be carried out through officers of employees (hereinafter referred to as 'inspectors') designated by the Administrator. Any such inspector, upon stating his purpose and presenting to the owner, operator, or agent in charge of such premises (A) appropriate credentials and (B) his administrative inspection warrant or a written notice of his other inspection authority, shall have the right to enter such premises and conduct such inspection at reasonable times.

"(3) Except when the owner, operator, or agent in charge of such premises so consents in writing, no inspection authorized by this section shall extend to—

"(A) financial data;

"(B) sales data other than shipment data;

"(C) pricing data;

"(D) personnel data, or

"(E) research data (other than data relating to the tests described in subsection 206(b)).

"(b) A warrant under this section shall not be required for entries and administrative inspections (including seizures of property)—

"(1) with the consent of the owner, operator, or agent in charge of such premises;

"(2) in situations presenting imminent danger to health or safety;

"(3) in any other exceptional or emergency circumstances where time or opportunity to apply for a warrant is lacking; or

"(4) in any other situations where a warrant is not constitutionally required.

"(c) Issuance and execution of administrative inspection warrants shall be as follows:

"(1) Any judge of the United States or of a State court of record, or any United States magistrate, may, within his territorial jurisdiction, and upon proper oath or affirmation showing probable cause, issue warrants for the purpose of conducting administrative inspections authorized by this title or regulations thereunder, and seizures of property appropriate to such inspections. For the purposes of this section, the term 'probable cause' means a valid public interest in the effective enforcement of this title or regulations thereunder sufficient to justify administrative inspections of the area, premises, building, or contents thereof, in the circumstances specified in the application for the warrant.

"(2) A warrant shall issue only upon an affidavit of an officer or employee having knowledge of the facts alleged, sworn to before the judge or magistrate and establishing the grounds for issuing the warrant. If the judge or magistrate is satisfied that grounds for the application exist or that there is probable cause to believe they exist, he shall issue

a warrant identifying the area, premises, or building, to be inspected, the purpose of such inspection, and, where appropriate, the type of property to be inspected, if any. The warrant shall identify the items or types of property to be seized, if any. The warrant shall be directed to a person authorized under subsection (a) (2) to execute it. The warrant shall state the grounds for its issuance and the name of the person or persons whose affidavit has been taken in support thereof. It shall command the person to whom it is directed to inspect the area, premises, or building, identified for the purpose specified, and, where appropriate, shall direct the seizure of the property specified. The warrant shall direct that it be served during normal business hours. It shall designate the judge or magistrate to whom it shall be returned.

"(3) A warrant issued pursuant to this section must be executed and returned within ten days of its date unless, upon a showing by the United States of a need therefor, the judge or magistrate allows additional time in the warrant. If property is seized pursuant to a warrant, the person executing the warrant shall give to the person from whom or from whose premises the property was taken a copy of the warrant and a receipt for the property taken or shall leave the copy and receipt at the place from which the property was taken. The return of the warrant shall be made promptly and shall be accompanied by a written inventory of any property

taken. The inventory shall be made in the presence of the person executing the warrant and of the person from whose possession or premises the property was taken, if they are present, or in the presence of at least one credible person other than the person making such inventory, and shall be verified by the person executing the warrant. The judge or magistrate, upon request, shall deliver a copy of the inventory to the person from whom or from whose premises the property was taken and to the applicant for the warrant.

"(4) The judge or magistrate who has issued a warrant under this section shall attach to the warrant a copy of the return and all papers filed in connection therewith and shall file them with the clerk of the district court of the United States for the judicial district in which the inspection was made.

"EXPORTS AND IMPORTS

"SEC. 211. (a) Notwithstanding any other provision of this title, no substance shall be deemed in violation of this title when intended solely for export to any foreign country except if the Administrator finds that as exported and used the substance, or particular uses of the substance, will produce a significant direct or indirect hazard to human health or the environment in the United States.

"(b) The Secretary of the Treasury shall refuse entry into the United States of any chemical substance or article

containing such substance offered for entry if it violates any of the provisions of this title. If a substance or article is refused entry, the Secretary of the Treasury shall refuse delivery to the consignee and shall cause the disposal or storage of any substance or article refused delivery which has not been exported by the consignee within three months from the date of notice of such refusal under such regulations as the Secretary of Treasury may prescribe: *Provided*, That the Secretary of Treasury may deliver to the consignee such substance or article pending examination and decision in the matter on execution of bond for the amount of the full invoice value of such substance or article, together with the duty thereon, and on refusal to return such substance or article for any cause to the custody of the Secretary of the Treasury, when demanded, for the purpose of excluding them from the country, or for any other purpose, said consignee shall forfeit the full amount of said bond: *And provided further*, That all charges for storage, cartage, and labor on substances or articles which are refused admission or delivery shall be paid by the owner or consignee, and in default of such payment shall constitute a lien against any future importation made by such owner or consignee.

"(c) The Secretary of the Treasury, in consultation with the Administrator, shall issue regulations for the enforcement of subsection (b) above.

"CONFIDENTIALLY

"SEC. 212. (a) The information obtained from any manufacturer or processor shall be confidential to the extent that it comprises matters referred to in section 552 (b) (4) of title 5 of the United States Code.

"(b) The Administrator may at his own initiative or at the request of a manufacturer or processor issue a protective order respecting the confidentiality of information obtained from a manufacturer or processor pursuant to the provisions of this title, as he may deem appropriate to protect the manufacturer or processor from competitive injury.

"(c) Information deemed to be confidential in accordance with the provisions of subsections (a) or (b) may be disclosed to other Federal officers or employees when necessary to accomplish the purposes of this title except that the provisions of section 1905 of title 18 of the United States Code shall continue to apply, and such information may be disclosed in camera when relevant in any administrative or judicial proceeding under this title. In any such proceeding, the administrative body, the Administrator, or the court shall issue such orders as may be appropriate to protect the confidentiality of the materials designated as such by the aforegoing provisions.

"PROHIBITED ACTS

"SEC. 213. The following acts and the causing thereof are prohibited—

"(a) The failure to comply with any final regulation or order issued by the Administrator pursuant to this title;

"(b) The failure or refusal to provide information or results of tests as required by section 206 of this title;

"(c) The sale, distribution, or importation into the United States of a chemical substance subject to regulations promulgated under section 205 for which the standards applicable thereto required by such regulations have not been met;

"(d) The knowing or willful failure of any person who purchases or receives a substance and who is required to be given notice of restrictions on use or distribution of such substance pursuant to paragraph 203 (a) (2), to comply with such restrictions on use or distribution;

"(e) The failure to perform any other action required under this title.

"PENALTIES AND REMEDIES

"SEC. 214. (a) Any person willfully violating subsections 213 (a), (b), (c) or (d) shall on conviction be fined not more than $25,000 or imprisoned for not more than one year or both.

"(b) (1) Any person violating subsections 213 (a), (b), (c) or (d) shall be liable to a civil penalty to the United States of a sum which is not more than $25,000 for each day of violation, to be assessed by the Administra-

tor after notice and opportunity for hearing and after he has considered the nature, circumstances, and extent of such violation, the practicability of compliance with the provisions violated and any good faith efforts to comply with such provisions.

"(2) Upon failure of the offending party to pay the penalty, the Administrator may request the Attorney General to commence an action in the appropriate district court of the United States for such relief as may be appropriate.

"(c) The Attorney General or his delegate may bring an action in the appropriate district court of the United States for equitable relief to redress a violation by any person of any provision of section 213 of this title, and the district courts of the United States shall have jurisdiction to grant such relief as the equities of the case may require.

"ENVIRONMENTAL PREDICTION AND ASSESSMENT

"SEC. 215. The Environmental Protection Agency shall, in cooperation with other Federal agencies, develop the necessary personnel and information resources to predict the introduction of new chemical substances into the environment and assess the environmental consequences of such introduction.

"USE OF GOVERNMENT FACILITIES

"SEC. 216. The Administrator may use, by agreement, the personnel, services, and facilites of other Federal de-

partments, agencies, or instrumentalities, whether on a reimbursable or nonreimbursable basis.

"HEALTH AND ENVIRONMENTAL DATA

"SEC. 217. The Council on Environmental Quality in consultation with the Administrator, the Secretary of Health, Education, and Welfare, the Secretary of Commerce, and the heads of other appropriate departments or agencies, shall coordinate a study of the feasibility of establishing (1) a standard classification system for chemical compounds and related substances, and (2) a standard means for storing and for obtaining rapid access to information respecting such materials.

"STATE REGULATIONS

"SEC. 218. Nothing in this title shall affect the authority of any State or local government to restrict the distribution or use of a chemical substance or impose requirements of tests and test results for a chemical substance except that (1) if the Administrator has published proposed regulations under section 203 with respect to limiting particular uses of a particular substance a State or local government may not thereafter impose restrictions on such uses of such substance other than a total ban on such use or uses; (2) if the Administrator has published proposed regulations under section 205 with respect to tests for particular substances or uses, a State or local government may not impose test proto-

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cols or results to be achieved therefrom with respect to such substances and uses for the purposes similar to this title; and (3) if the Administrator has published proposed regulations under section 203 with respect to limiting particular uses of a particular substance or if the Administrator has published proposed regulations under section 205 with respect to tests for particular substances or uses, a State is not preempted from enforcing any restrictions or test protocols and results to be achieved therefrom existing at the time any such proposed regulation was published; provided that if the Administrator issues an order under section 203 (b) (3) restricting the use of such substance or withdrawing a proposed regulation restricting a use of such substance, or if the Administrator issues an order under section 205 prescribing tests or withdrawing a proposed regulation for such tests, the State may not enforce any such restrictions, test protocols, or results to be achieved therefrom after the effective date of such order, other than a total ban on such use or uses.

"REGULATIONS

"SEC. 219. The Administrator is authorized to issue such regulations as he may deem appropriate to carry out the purposes of this title and to amend them at any time.

"AUTHORIZATION FOR APPROPRIATIONS

"SEC. 220. There is hereby authorized to be appropriated to the Environmental Protection Agency such sums as may be necessary for the purposes and administration of this Act."

92D CONGRESS
1ST SESSION

S. 1478

IN THE SENATE OF THE UNITED STATES

JULY 27 (legislative day, JULY 26), 1971
Referred to the Committee on Commerce and ordered to be printed

AMENDMENT

Intended to be proposed by Mr. SPONG to S. 1478, a bill to amend the Federal Hazardous Substances Ace, as amended, and for other purposes, viz: Strike out all after the enacting clause and insert in lieu thereof the following:

SEC. 2. (a) The Federal Hazardous Substances Act is amended by inserting before section 1 of such Act the following:

"TITLE I—HAZARDOUS CONSUMER PRODUCTS".

(b) Such Act is further amended by adding after section 18 thereof the following new title:

Amdt. No. 338

"TITLE II—TOXIC SUBSTANCES

"POLICY

"SEC. 201. Whereas the American people are being exposed to a large number of chemical substances each year; and

"Whereas among the many chemical substances constantly being developed and produced are some which may be a danger to human health or the environment; and

"Whereas the effective regulation of interstate commerce in such chemicals necessitates the regulation of transactions in such chemicals in intrastate commerce as well;

"Therefore, it is the policy of the United States that—

"(1) new chemical substances and hazardous or potentially hazardous existing chemical substances should be adequately tested with respect to their safety to man and the environment; that such testing should be the responsibility of those who produce such chemicals; and

"(2) chemical substances should serve useful purposes; and,

"(3) adequate authority should exist to restrict the distribution and use of chemicals found to be harmful; and

"(4) authority over chemicals be exercised in such a manner as not to unduly impede technological innovation while fulfilling the primary purpose of this title

to assure that such innovation and commerce in such chemicals does not endanger human health or the environment.

"DEFINITIONS

"SEC. 202. As used in this Act the term—

"(1) 'Administrator' means the Administrator of the Environmental Protection Agency;

"(2) 'Chemical substance' means any organic or inorganic substance of a particular molecular identity, or any uncombined chemical radical or element, except such substances which are of no public health or environmental significance as determined by the Administrator by regulations;

"(3) 'Existing chemical substance' means any chemical substance which is first produced in commercial quantities before the effective date of initial regulations promulgated pursuant to section 203;

"(4) 'Manufacturer' means any person engaged in the production or manufacture of chemical substances for purposes of sale or distribution in commercial quantities, or an importer thereof;

"(5) 'Processor' means any person engaged in the preparation of a chemical substance for distribution or use either in the form in which it is received or as part

of another product, as defined by regulations of the Administrator;

"(6) 'Restrict use or distribution' means to prescribe the amount sold to given types of processors, or to limit the type of processor to whom a substance may be sold, or to prescribe the amount which may be utilized by a given type of processor, or to limit the manner in which a substance may be manufactured, used, handled, or disposed of by any person, and such restriction on use or distribution may include a total ban;

"(7) 'Byproduct' means a chemical substance produced as a direct result of the production, manufacture, processing, use, or disposal of some other chemical substance which is subject to the provisions of this title;

"(8) 'Environment' includes water, air, land, all plants and animals living therein, and the interrelationships which exist among these;

"(9) 'Animal' means all vertebrate and invertebrate species, including but not limited to man and other mammals, birds, fish, and shellfish;

"(10) 'Protect health and the environment' means protection against any unreasonable threat to human health or the environment resulting from any chemical reaction of a chemical substance taking into account the benefits of the chemical substance as compared to the risks to man or the environment;

"(11) 'District court of the United States' includes the District Court of Guam, the District Court of the Virgin Islands, the District Court of the Canal Zone, and in the case of American Samoa and the Trust Territory of the Pacific Islands, the District Court of the United States for the District of Hawaii, which court shall have jurisdiction over actions arising under this title;

"(12) 'New chemical substance' means any chemical substance which is first produced in commercial quantities after the effective date of initial regulations promulgated pursuant to section 203; and

"(14) 'Consumer' means any person who is not a manufacturer, processor, shipper, distributor, wholesaler, retailer, or commercial user of the chemical substance or its byproducts.

"TEST STANDARDS

"SEC. 203. Within one year after enactment of this title, and from time to time thereafter, the Administrator shall, after consultation with the Toxic Substances Board established under section 210, issue proposed regulations for such standards for test protocols for various classes and uses of chemical substances, and for the results to be achieved therefrom, as are necessary to protect health and the environment. In determining what is necessary to protect health and the

environment under the preceding sentence, the Administrator shall consider all relevant factors including—

"(1) the effects on human health of the substance;

"(2) the effects of the substance on the environment;

"(3) the benefits of the substance for various uses;

"(4) the normal circumstances of such use; and

"(5) the availability of less hazardous substitutes.

Such test protocols may include tests for carcinogenesis, teratogenesis, mutagenesis, persistence, the cumulative or synergistic effects of other chemical substances, and other types of hazards. The Administrator shall specify in the proposed regulations the date on which such standards shall take effect, except that such standards shall not take effect prior to the ninetieth day after the date of issue of final regulations nor later than eighteen months after such date.

"CERTIFICATION OF CHEMICAL SUBSTANCES

"SEC. 204. (a) After the effective date of initial regulations promulgated pursuant to section 203, any manufacturer of a new chemical substance shall be required to obtain a certification from the Administrator that such new chemical substance is in compliance with the testing requirements of section 203. Requests for certification shall begin by application from the manufacturer to the Administrator, who shall publish such application in the Federal Register to-

gether with his proposal to grant or deny such application and, if it is proposed to certify the applicant, any proposals to condition such certification pursuant to section 205. Thereafter, the procedures of section 222 (b) governing the promulgation of regulations shall apply. Application for certification under this section shall be in such form and contain or shall be accompanied by such information as the Administrator deems necessary to carry out his functions under this Act.

(b) Existing chemical substances are exempted from the requirement of certification by the Administrator for compliance with the test regulations promulgated pursuant section 203, except that the Administrator shall issue, within one year after enactment of this title and from time to time thereafter, proposed regulations specifying those existing chemical substances the manufacture, use, or distribution of which there is reason to believe may pose an unreasonable threat to man or the environment. The Administrator shall further specify in such proposed regulations such standards for test protocols for various classes and uses of such existing chemical substances, and the results to be achieved therefrom, as are necessary to protect health and environment. The Administrator shall specify in the proposed regulations the date on which such standards shall take effect, except that such standards shall not take effect prior to the ninetieth

day after the date of issue of final regulations nor later than eighteen months after such date. After the effective date of such regulations, any manufacturer of any such existing chemical substance shall be required to obtain a certification from the Administrator.

(c) Each manufacturer may submit a request for payment of the costs of complying with the testing requirements of section 203 or subsection b of this section with the application for certification required under this section. The Administrator shall approve for payment to the manufacturer requesting such payment, an amount equal to the costs of the required testing. Only costs legitimately incurred by a manufacturer for the required testing of each chemical substance relating to the hazards to health and the environment shall be approved for payment by the Administrator. Such payment authorization shall not duplicate any previous payment authorization for similar tests. Thereafter, the Administrator shall pay annually to such manufacturer an amount not to exceed the annual receipts collected for the sale of such chemical substance under subchapter F of chapter 36 of the Internal Revenue Code of 1954, until such time as full payment has been made of the amount approved by the Administrator.

"RESTRICTIONS ON USE OR DISTRIBUTION

"SEC. 205. (a) If warranted by data available to him, the Administrator shall propose by regulation to condition

a certification issued pursuant to section 204 of this Act (1) to restrict the use or distribution of the chemical substance to the extent necessary to protect health and the environment including such restrictions as are necessary for effective quality control; (2) to require that any or all persons engaged in the distribution of the substance so regulated give notification to purchasers of the substance of such restrictions in such form and manner as the Administrator determines is necessary to protect health and the environment including labeling requirements on consumer products containing chemical substances or their byproducts with appropriate warning provisions and directions for use and disposal; and (3) to require such other action as may be necessary to carry out such restrictions including prohibiting or restricting the sale, use, or removal of such substance or a product containing such a substance and recalling such product or substance from the market. Similar restrictions and requirements shall be imposed by regulation for chemical substances for which no certification exists if warranted by data available to the Administrator.

"(b) Proposed and final regulations issued under paragraph (1) of subsection (a) of this section shall set forth findings of fact on which the order imposing restrictions is based and the relationship of such findings to the restrictions imposed. The manufacturer shall be responsible for

supplying all necessary information for the Administrator to make findings under this subsection. All data relevant to the Administrator's findings shall be available to any interested party in accordance with section 213.

"IMMINENT HAZARD

"SEC. 206. (a) An imminent hazard shall be considered to exist when there is reason to believe that the manufacture, use, or distribution of a chemical substance will result in serious damage to human health or the environment prior to the completion of an administrative hearing or other formal proceeding held pursuant to this Act.

"(b) If an imminent hazard exists the Administrator shall issue an order requiring all reasonable measures to protect against the threat of such serious damage. The Administrator shall simultaneously, if he has not already done so, propose any regulation which may be warranted under section 205. Any order issued under this subsection shall become effective at such time as may be necessary to protect against the threat of such damage and shall remain effective pending the outcome of formal proceedings under section 205. Prior initiation of any such proceedings under section 205 shall not prevent the Administrator from issuing an order under this section.

"SEIZURE

"SEC. 207. (a) Any chemical substance which the Administrator finds (1) is manufactured, used, or distrib-

uted in violation of section 204, 205, or 206 and (2) of itself constitutes an imminent hazard may be seized summarily by the Administrator. Anyone adversely affected by such seizure may, within thirty days from the date of seizure, file objections thereto and request a public hearing, which shall consist of the oral and written presentation of data, views, or arguments pursuant to section 553 of title 5 of the United States Code. Any chemical substance so seized shall be segregated and, if no request for a hearing is made or if upon completion of any such hearing, such seizure is sustained by the Administrator, destroyed, or sold at auction under the supervision of the Administrator and his representative: Except (1) such chemical substance shall not be destroyed or sold and shall be released to the person from whom seized if, prior to destruction or sale, such chemical substance is made to comply with section 204, 205, or 206; (2) no such destruction or sale shall take place until at least thirty days after such seizure is sustained following a public hearing; (3) in the event of an action for judicial review or further appeal of the seizure, no such destruction or sale shall take place pending such action or appeal or within thirty days thereafter. Any proceeds from the sale of a chemical substance under this section shall be paid into the Treasury of the United States.

"(b) Any chemical substance which the Administrator

finds (1) is manufactured, used, or distributed in violation of section 204, 205, or 206 and (2) of itself constitutes an unreasonable threat to health or the environment but not an imminent hazard may be seized pursuant to the procedures of subsection (a) except that no seizure shall be made until after an opportunity for a public hearing.

"REPORTS

"SEC. 208. (a) The Administrator shall require all manufacturers of chemical substances to furnish reports to him annually and at such more frequent times as the Administrator may reasonably require containing any or all of the following—

"(1) the names of any or all chemical substances produced or imported by the manufacturer in commercial quantities;

"(2) the chemical identity and molecular structure of such substances insofar as is known;

"(3) the categories of use of each such substance, insofar as they are known to him;

"(4) reasonable estimates of the amounts of each substance produced for each such category of use; and

"(5) a description of the byproducts, if any, resulting from the production of each such substance, and, insofar as they are known to him, from the uses thereof.

"(b) If necessary to accomplish the purposes of this

title, the Administrator shall direct manufacturers of a chemical substance to provide, within a specified period of time not to be less than thirty days, the results of any tests not otherwise required by this Act of the health or environmental effects of the substance or its byproducts, which have been performed by or at the instance of the manufacturer or such results as are otherwise known to him, and any or all of the items of information listed in subsection (a).

"(c) Whenever the Administrator determines that such action would be productive and desirable to allow him to carry out his responsibilities and authorities under this title, he may by publishing a notice in the Federal Register invite and afford all interested persons an opportunity to provide in writing information respecting the health or environmental effects of the chemical substance or its byproducts.

"RELATIONSHIP TO OTHER LAWS

"SEC. 209. (a) This title shall not apply to—

"(1) economic poisons subject to the Federal Insecticide, Fungicide, and Rodenticide Act, and chemical substances used solely in such poisons, except that if a chemical substance which constitutes such a poison or such an ingredient is or may be used for any purpose which is not regulated by the Federal Insecticide, Fungicide, and Rodenticide Act, this title shall apply to such other uses;

"(2) foods, food additives, drugs, and cosmetics subject to the Federal Food, Drug, and Cosmetic Act, as amended, the Federal Meat Inspection Act, and the Poultry Products Inspection Act, and chemical substances used solely therein, and controlled substances regulated pursuant to the Comprehensive Drug Abuse Prevention and Control Act of 1970, except that if such an item or substance is or may be used for any purpose which is not regulated by such Acts this title shall apply to such other uses;

"(3) any source material, special nuclear material, or byproduct material as defined in the Atomic Energy Act of 1954, as amended, and regulations issued pursuant thereto by the Atomic Energy Commission;

"(4) the authority of the Secretary of the Department of Transportation to establish rules and regulations for the transportation of hazardous materials.

"(b) To the extent that such activities are subject to regulation by other Federal laws, including the Occupational Health and Safety Act of 1970 and title I of this Act, the Administrator shall not regulate the use or distribution of a new or existing chemical substance on the basis of any possible hazard to employees in their place of employment, or the hazard directly to consumers resulting from household use of marketed products which contain or

might contain the substance. If it appears to the Administrator that any such substance may pose a hazard when transported, or when used on or in food or as a drug or cosmetic, or may be a hazard to employees in their place of employment, or may pose a hazard directly to consumers resulting from household use of marketed products which contain or might contain the substance, he shall transmit any data received from manufacturers or processors relevant to such hazards to the Federal department or agency with authority to take legal action if a hazard is found to exist.

"(c) The Administrator shall coordinate actions taken under this Act with actions taken to enforce the Federal Water Pollution Control Act and the Clean Air Act, and shall, where appropriate, use the authorities contained in such Acts to regulate chemical substances.

"(d) The Administrator shall consult and coordinate with the Secretary of Health, Education, and Welfare and the heads of other appropriate Federal agencies in administering the provisions of this title.

"(e) This title shall not be construed as superseding or impairing the provisions of any other law or treaty of the United States.

"TOXIC SUBSTANCES BOARD

"SEC. 210. (a) There shall be established in the Environmental Protection Agency a Toxic Substances Board

consisting of not more than twelve members who shall be scientifically qualified individuals. The Administrator shall appoint members of the Board from a list of individuals recommended to him by the National Academy of Sciences. Such Board shall include equal numbers of qualified scientists representing industry, consumer or environmental groups, and the general public. One of the members shall be designated by the Administrator to serve as Chairman of the Board.

"(b) The National Academy of Sciences, in consultation with the Board, shall establish, maintain, and publish a continuing list of qualified scientists, to assist in carrying out the provisions of this section. Such scientists shall also be consultants to the Toxic Substances Board.

"(c) Before proposing any regulations under section 203 or 204(b) the Administrator shall refer his proposed action and the available evidence to a committee selected from members of the Board and the list of consultants to the Board. Such committee shall contain substantially equal numbers of scientists representing industry, consumer or environmental groups, and the general public. The committee shall report its views in writing to the Administrator, within a reasonable time, not to exceed ninety days, specified by the Administrator. Such time may be extended an additional ninety days if the Administrator determines the

extension necessary and such committee has made a good faith effort to report its views within the initial ninety-day period. If the committee fails to report within the specified time, the Administrator may proceed to take action under this title. The deliberations of all such committees shall be open to the public and all proceedings and deliberations of such committees shall be public record. The report of the committee and any dissenting views shall be considered as part of the record in any proceeding taken with respect to the Administrator's action.

"(d) The Administrator may, at his discretion, also request the Board to convene a panel to consider other actions proposed to be taken under this Act.

"(e) The Administrator is authorized to reimburse the National Academy of Sciences for expenses incurred in carrying out this section.

"RESEARCH

"SEC. 211. The Administrator is authorized to conduct such research and monitoring as is necessary to carry out his functions under this title. Such research and monitoring shall be limited to determining proper test protocols and results to be obtained therefrom under sections 203 and 204(b), determinations under paragraph (2) of section 202 and section 204(b), and such monitoring of chemical

substances in man and the environment as is necessary to carry out the purposes of this title. In addition, limited research may be undertaken to confirm the results of tests required by this title. To the extent possible, such research and monitoring shall not duplicate the efforts of other Federal agencies or the research required of manufacturers under this title. In order to carry out the provisions of this section, the Administrator is authorized to establish research laboratories, including the acquisition of necessary land, buildings, or facilities, and to make contracts for such research and monitoring.

"ADMINISTRATIVE INSPECTIONS AND WARRANTS

"SEC. 212. (a) (1) For the purpose of inspection, copying, and verifying the correctness of records, reports, or other documents required to be kept or made under this title and otherwise facilitating the carrying out of his function under this title, the Administrator is authorized, in accordance with this section, to enter any factory, warehouse, or premises in which chemical substances are manufactured, processed, or held and to conduct administrative inspections thereof.

"(2) Such entries and inspections shall be carried out through officers or employees (hereinafter referred to as 'inspectors') designated by the Administrator. Any such inspector, upon stating his purpose and presenting to the owner, operator, or agent in charge of such premises (A)

appropriate credentials and (B) his administrative inspection warrant or a written notice of his other inspection authority, shall have the right to enter such premises and conduct such inspection at reasonable times.

"(3) Except when the owner, operator, or agent in charge of such premises so consents in writing, no inspection authorized by this section shall extend to—

"(A) financial data;

"(B) sales data other than shipment data;

"(C) pricing data;

"(D) personnel data; or

"(E) research data (other than data relating to the tests described in subsection 207(b) or data otherwise required by this Act).

"(b) A warrant under this section shall not be required for entries and administrative inspections (including seizures of property)—

"(1) with the consent of the owner, operator, or agent in charge of such premises;

"(2) in situations presenting imminent danger to health or safety;

"(3) in any other exceptional or emergency circumstances where time or opportunity to apply for a warrant is lacking; or

"(4) in any other situations where a warrant is not constitutionally required.

"(c) Issuance and execution of administrative inspection warrants shall be as follows:

"(1) Any judge of the United States or of a State court of record, or any United States magistrate, may, within his territorial jurisdiction, and upon proper oath or affirmation showing probable cause, issue warrants for the purpose of conducting administrative inspections authorized by this title or regulations thereunder, and seizures of property appropriate to such inspections. For the purposes of this subsection the term 'probable cause' means a valid public interest in the effective enforcement of this title or regulations thereunder sufficient to justify administrative inspections of the area, premises, building, or contents thereof, in the circumstances specified in the application for the warrant.

"(2) A warrant shall issue only upon an affidavit of an officer or employee having knowledge of the facts alleged, sworn to before the judge or magistrate and establishing the grounds for issuing the warrant. If the judge or magistrate is satisfied that grounds for the application exist or that there is probable cause to believe they exist, he shall issue a warrant identifying the area, premises, or building, to be inspected, the purpose of such inspection, and, where appropriate, the type of property to be inspected, if any. The warrant

shall identify the items or types of property to be seized, if any. The warrant shall be directed to a person authorized under subsection (a) (2) to execute it. The warrant shall state the grounds for its issuance and the name of the person or persons whose affidavit has been taken in support thereof. It shall command the person to whom it is directed to inspect the area, premises, or building, identified for the purpose specified, and, where appropriate, shall direct the seizure of the property specified. The warrant shall direct that it be served during normal business hours. It shall designate the judge or magistrate to whom it shall be returned.

"(3) A warrant issued pursuant to this section must be executed and returned within ten days of its date unless, upon a showing by the United States of a need therefor, the judge or magistrate allows additional time in the warrant. If property is seized pursuant to a warrant, the person executing the warrant shall give to the person from whom or from whose premises the property was taken a copy of the warrant and a receipt for the property taken or shall leave the copy and receipt at the place from which the property was taken. The return of the warrant shall be made promptly and shall be accompanied by a written inventory of any property taken. The inventory shall be made in the presence of the person executing the warrant and of the person from whose possession or premises the property was taken, if they

are present, or in the presence of at least one credible person other than the person making such inventory, and shall be verified by the person executing the warrant. The judge or magistrate, upon request, shall deliver a copy of the inventory to the person from whom or from whose premises the property was taken and to the applicant for the warrant.

"(4) The judge or magistrate who has issued a warrant under this section shall attach to the warrant a copy of the return and all papers filed in connection therewith and shall file them with the clerk of the district court of the United States for the judicial district in which the inspection was made.

"EXPORTS AND IMPORTS

"SEC. 213. (a) Notwithstanding any other provision of this title, no chemical substance shall be deemed in violation of this title when intended solely for export to any foreign country except if the Administrator finds, by regulation, that as exported and used the chemical substance, or particular uses of the substance, will produce a significant direct or indirect hazard to human health or the environment in the United States.

"(b) The Secretary of the Treasury shall refuse entry into the United States of any chemical substance or article containing such substance offered for entry if it violates any

of the provisions of this title. If a chemical substance or article is refused entry, the Secretary of the Treasury shall refuse delivery to the consignee and shall cause the disposal or storage of any substance or article refused delivery which has not been exported by the consignee within three months from the date of notice of such refusal under such regulations as the Secretary of the Treasury may prescribe, except that the Secretary of the Treasury may deliver to the consignee such substance or article pending examination and decision in the matter on execution of bond for the amount of the full invoice value of such substance or article, together with the duty thereon, and on refusal to return such substance or article for any cause to the custody of the Secretary of the Treasury, when demanded, for the purpose of excluding them from the country, or for any other purpose, said consignee shall forfeit the full amount of said bond. All charges for storage, cartage, and labor on substances or articles which are refused admission or delivery under this section shall be paid by the owner or consignee, and in default of such payment shall constitute a lien against any future importation made by such owner or consignee.

"(c) The Secretary of the Treasury, in consultation with the Administrator, shall issue regulations for the enforcement of subsection (b) of this section.

"CONFIDENTIALITY

"SEC. 214. (a) The information obtained from any manufacturer shall be confidential to the extent that it includes matters referred to in section 552 (b) (4) of title 5 of the United States Code. For the purposes of this title any such information shall be confidential only if such information is unobtainable by competitors and its disclosure would lead to competitive injury to the manufacturer. Only such information as is relevant to the purposes of this title shall be disclosed to the public.

"(b) The Administrator may at his own initiative or at the request of a manufacturer or processor issue a protective order respecting the confidentiality of information referred to in subsection (a).

"(c) Information deemed to be confidential in accordance with the provisions of subsection (a) or (b) may be disclosed to other Federal officers or employees when necessary to accomplish the purposes of this title except that the provisions of section 1905 of title 18 of the United States Code shall continue to apply, and such information may be disclosed in camera when relevant in any administrative or judicial proceeding under this title. In any such proceeding, the administrative body, the Administrator, or the court shall issue such orders as may be appropriate to protect the confidentiality of the materials designated as such by the foregoing provisions.

"PROHIBITED ACTS

"SEC. 215. The following acts and the causing thereof are prohibited—

"(1) the failure to comply with any final regulation or order issued by the Administrator pursuant to this title;

"(2) the failure or refusal to provide information or results of tests as required by section 207 of this title;

"(3) the commercial production, sale, distribution, or importation into the United States of a chemical substance without a certification under section 204;

"(4) the failure of any person, other than a consumer, who purchases or receives a chemical substance and who is required to be given notice of restrictions on use or distribution of such substance pursuant to paragraph 205(a)(2), to comply with such restrictions on use or distribution;

"(5) the knowing or willful failure of any consumer to use or dispose of a chemical substance or its byproducts in accordance with label instructions;

"(6) the failure to perform any other action required under this title.

"PENALTIES AND REMEDIES

"SEC. 216. (a) Any person willfully violating paragraph (1), (2), (3), or (4) of section 215 shall on con-

viction be fined not more than $25,000 or imprisoned for not more than one year, or both.

"(b) (1) Any person violating paragraph (1), (2), (3), (4), or (5) of section 215 shall be liable to a civil penalty to the United States of a sum which is not more than $25,000 for each day of violation, to be assessed by the Administrator after notice and opportunity for hearing and after he has considered the nature, circumstances, and extent of such violation, the practicability of compliance with the provisions violated, and any good-faith efforts to comply with such provisions.

"(2) Upon failure of the offending party to pay the penalty, the Administrator may commence an action in the appropriate district court of the United States for such relief as may be appropriate or request the Attorney General to commence such an action.

"(c) The Attorney General or the Administrator may bring an action in the appropriate district court of the United States for equitable relief to redress a violation by any person of any provision of section 215 of this title, and the district courts of the United States shall have jurisdiction to grant such relief as the equities of the case may require.

"CITIZEN CIVIL ACTIONS

"SEC. 217. (a) Except as provided in subsection (b), any person may commence a civil action for injunctive relief

on his own behalf, whenever such action constitutes a case or controversy—

"(1) against any person (including (i) the United States, and (ii) any other governmental instrumentality or agency to the extent permitted by the eleventh amendment to the Constitution) who is alleged to be in violation of any regulation or order promulgated under this title, or

"(2) against the Administrator where there is alleged a failure of the Administrator to perform any act or duty under this title which is not discretionary with the Administrator.

The district courts shall have jurisdiction, without regard to the amount in controversy or the citizenship of the parties, to enforce such regulation or order or to order the Administrator to perform such act or duty, as the case may be. Nothing herein shall be construed to prevent or preempt State courts from exercising jurisdiction in such action in appropriate cases.

"(b) No civil action may be commenced—

"(1) under subsection (a) (1)—

"(A) prior to sixty days after the plaintiff has given notice of the violation (i) to the Administrator, (ii) to the State in which the violation oc-

curs, and (iii) to any alleged violator of the regulation or order, or

"(B) if the Administrator or State has commenced and is diligently prosecuting a civil action in a court of the United States or a State to require compliance with the regulation or order, but in any such action in a court of the United States any person may intervene as a matter of right.

"(2) under subsection (a) (2) prior to sixty days after the plaintiff has given notice of such action to the Administrator, except that such action may be brought ten days after such notification in the case of an action under this section for the failure of the Administrator to act under section 206. Notice under this subsection shall be given in such manner as the Administrator shall prescribe by regulation.

"(c) In any action under this section, the Administrator, if not a party, may intervene as a matter of right.

"(d) The court, in issuing any final order in any action brought pursuant to subsection (a) of this section, may award costs of litigation (including reasonable attorney and expert witness fees) to any party, whenever the court determines such an award is appropriate.

"(e) Nothing in this section shall restrict any right which any person (or class of persons) may have under

any statute or common law to seek enforcement of any regulation or order or to seek any other relief (including relief against the Administrator or a State agency).

"(f) For purposes of this section, the term 'person' means an individual, corporation, partnership, association, State, municipality, or political subdivision of a State.

"ENVIRONMENTAL PREDICTION AND ASSESSMENT

"SEC. 218. The Environmental Protection Agency shall, in cooperation with other Federal agencies, develop the necessary personnel and information resources to predict the introduction of new chemical substances into the environment and assess the environmental consequences of such introduction.

"USE OF GOVERNMENT FACILITIES

"SEC. 219. The Administrator may use, by agreement, the personnel, services, and facilities of other Federal departments, agencies, or instrumentalities, whether on a reimbursable or nonreimbursable basis.

"HEALTH AND ENVIRONMENTAL DATA

"SEC. 220. The Council on Environmental Quality in consultation with the Administrator, the Secretary of Health, Education, and Welfare, the Secretary of Commerce, and the heads of other appropriate departments or agencies, shall coordinate a study of the feasibility of establishing (1) a standard classification system for chemical compounds

and related substances, and (2) a standard means for storing and for obtaining rapid access to information respecting such materials.

"STATE REGULATIONS

"SEC. 221. Nothing in this title shall affect the authority of any State or local government to restrict the distribution or use of a chemical substance or impose requirements of tests and test results for a chemical substance except that (1) if the Administrator has published proposed regulations under section 205 with respect to limiting particular uses of a particular substance a State or local government may not thereafter impose restrictions on such uses of such substance other than a total ban on such use or uses; (2) if the Administrator has published proposed regulations under section 203 or section 204 (b) with respect to test standards for particular substances or uses, a State or local government may not impose test protocols or results to be achieved therefrom with respect to such substances and uses for the purposes similar to this title; (3) if the Administrator has published proposed regulations under section 205 with respect to limiting particular uses of a particular substance or if the Administrator has published proposed regulations under section 203 or section 204 (b) with respect to tests for particular substances or uses, a State is not preempted from enforcing any restrictions or test protocols and results

to be achieved therefrom existing at the time any such proposed regulation was published; (4) if the Administrator issues a final regulation under section 205 restricting the use of such substances the State may not enforce any restriction of its own after the effective date of such regulation, other than a total ban on such use or uses; and (5) if the Administrator issues a final regulation under section 203 or section 204(b), the State may not enforce any test requirements of its own after the effective date of such regulations.

"REGULATIONS AND PROCEDURE

"SEC. 222. (a) The Administrator is authorized to issue such regulations as he may deem appropriate to carry out the purposes of this title and to amend them at any time.

"(b) The Administrator shall publish any regulations proposed under this title in the Federal Register at least sixty days prior to the time when such regulations shall become final. If any person adversely affected by a proposed regulation files objections and requests a public hearing within forty-five days of the date of publication of the proposed regulation, the Administrator shall grant such request. If a public hearing is held, final regulations shall not be promulgated by the Administrator until after the conclusion of such hearing. All public hearings authorized by this subsection shall consist of the oral and written presentation of data,

views, or arguments pursuant to section 553 of title 5 of the United States Code.

"AUTHORIZATION FOR APPROPRIATIONS

"SEC. 223. There is hereby authorized to be appropriated to the Environmental Protection Agency such sums as may be necessary for the purposes and administration of this Act."

SEC. 3. (a) Chapter 36 of the Internal Revenue Code of 1954 (relating to certain other excise taxes) is amended by adding at the end thereof the following new subchapter:

"Subchapter F—Chemical Substances

"Sec. 4496. Imposition of tax.
"Sec. 4497. Special rule.

"SEC. 4496. IMPOSITION OF TAX.

"(a) CHEMICAL SUBSTANCES.—There is hereby imposed on the sale by the manufacturer of any chemical substance manufactured or produced under a certification issued under section 204 of the Federal Hazardous Substances Act a tax equal to —— percent of the price for which such substance is sold.

"(b) SUSPENSION OF TAX.—The tax imposed by this section on any manufacturer shall be suspended whenever the amount collected from that manufacturer equals the amount approved for payment to him under section 204 (c) of the Federal Hazardous Substances Act. Such suspension

shall remain in effect until additional testing with respect to that manufacturer is required pursuant to section 203 or section 204(b) of such Act, but shall become effective again whenever, after such testing, the manufacturer again satisfies the requirement of the preceding sentence.

"SEC. 4497. SPECIAL RULE.

"Under regulations prescribed by the Secretary or his delegate, the provisions of subchapters F and G of chapter 32 and the provisions of subtitle F relating to the taxes imposed by chapter 32 shall apply to the taxes imposed by section 4496."

(b) The table of subchapters for such chapter 36 is amended by adding at the end thereof the following new item:

"SUBCHAPTER F. Chemical substances."

GENERAL COUNSEL OF THE DEPARTMENT OF DEFENSE,
Washington, D.C., October 5, 1971.

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

DEAR MR. CHAIRMAN: Reference is made to your request for the views of the Department of Defense on Amendment No. 338 to S. 1478, 92d Congress, a bill "To amend the Federal Hazardous Substances Act, as amended, and for other purposes."

The purpose of the Amendment is to provide for the regulation of toxic substances that may affect the safety of man or the quality of the environment.

Under the Amendment, the Administrator of the Environmental Protection Agency would be required to issue regulations, within one year after enactment of the Amendment, that specify test protocols for various classes and uses of chemical substances. Manufacturers of new chemical substances would be required to obtain a certification from the Administrator that the new substances meet the appropriate testing requirements. The Administrator would also be required to issue regulations that specify existing chemical substances that would be subject to test procedures. A manufacturer of a chemical substance manufactured or produced under a certification issued under the proposal would be required to pay a tax on his product until the Administrator had, by paying to the manufacturer annual amounts equal to the tax receipts, paid the manufacturer for the cost of testing the chemical substance.

The proposal would also give the Administrator the authority to restrict or prohibit the distribution or use of chemical substances and to seize substances that are manufactured, used or distributed in violation of the Federal Hazardous Substances Act. A Toxic Substances Board would be established in the Environmental Protection Agency to advise the Administrator on policies and procedures.

The Department of Defense is extremely concerned about the quality of the environment and recognizes that the unregulated use of toxic substances presents a great potential danger to that environment. In view of the large quantity of chemical substances that the Department of Defense procures, we would expect to benefit substantially from reasonable and effective regulation of the manufacturing of these substances.

As to the merits of the Amendment, the Department of Defense defers to the Council on Environmental Quality and the Administrator of the Environmental Protection Agency.

The Office of Management and Budget advises that, from the standpoint of the Administration's program, there would be no objection to the presentation of this report for the consideration of the Committee.

Sincerely,

J. FRED BUZHARDT.

Senator SPONG. Let me welcome our first witness, the Honorable Russell E. Train, Chairman of the Council on Environmental Quality.

Mr. Train, it is a pleasure to have you here this morning.

STATEMENT OF HON. RUSSELL TRAIN, CHAIRMAN, COUNCIL ON ENVIRONMENTAL QUALITY; ACCOMPANIED BY ALVIN L. ALM, STAFF DIRECTOR, PROGRAM DEVELOPMENT

Mr. TRAIN. Thank you, Mr. Chairman.

I appreciate the opportunity to appear before you to testify in support of S. 1478, the Toxic Substances Control Act of 1971. Since the committee will have an opportunity tomorrow to hear testimony from Mr. Robert Fri of the Environmental Protection Agency, which will have administrative responsibility with respect to S. 1478, I will confine myself to the basic concepts of this bill and the need for such legislation.

In the spring of 1970, shortly after the Council on Environmental Quality came into being, we turned to the question of chemical substances which might endanger human health and the environment.

Mr. Chairman, it was approximately at that time that the mercury problem surfaced publicly as a major environmental concern, and, of course, we in the Council shared that concern. At the same time it was our general view that as important as any one specific problem, such as mercury poisoning is, in the long run, the most effective approach to the protection of the overall public health and safety would be through some sort of general mechanism which could deal appropriately with toxic substances on an overall basis, and that was the general conceptual beginning of our study which we undertook at that time in the spring of 1970 of toxic substances.

A study initiated at that time resulted in the proposed Toxic Substance Control Act as part of the President's comprehensive program of environmental legislation, and a report this spring, which I have made available to all the committees of Congress. Allow me to highlight several of the findings in this report.

We live surrounded by growing amounts of new and displaced chemical substances, several of which pose hazards to human health or the environment even in minute quantities. Some 2 million chemical compounds have been identified and many thousands of new chemicals are discovered each year. Most new compounds are laboratory curiosities, but thousands of chemical compounds are already in commercial use and several hundred new chemicals are introduced into such use each year.

Approximately 9,000 synthetic organic compounds were in commercial use by 1968. Production has been increasing from over 103 billion pounds in 1967 to nearly 120 billion pounds in 1968. In fact, chemical production over the past decade has averaged an annual increase in excess of 15 percent. With changes in industrial needs and technological knowledge, new and more complex compounds with new and different uses are constantly being developed and introduced into use.

Many of these chemicals ultimately are discharged into our water, air, and soil systems. After the substances enter the environment, they may be diluted or concentrated by physical forces, and they may undergo chemical changes, including combination with other chemicals, that affect their toxicity. The substances may be picked up by living organisms which may further change and either store or eliminate them. The results of the interactions between living organisms and chemical species are often unpredictable, but such interactions may produce materials or concentrations that are more dangerous than that of the initial pollutants.

Many, perhaps most, metals are prerequisites to life, usually in trace amounts. However, some metals and/or their compounds can and do adversely affect human health if ingested or absorbed in excessive quantities. Serious adverse environmental and/or health effects, actual and potential, have been observed or indicated for roughly one-fourth of the metals in common usage today. A necessity of life at certain levels, they can be lethal at increased levels.

Without going into our experience with mercury pollution, with which your committee is familiar, let me cite two other examples to illustrate the reason for our concern.

Take for example polychlorinated biphenyls. PCB's, a group of chemicals also known as aroclors, are among the most persistent organic chemicals. They degrade very slowly in the environment. This class of compounds has been widely used as an additive in the production of plastics. PCB's are generally not chemically bound in the plastics and therefore may be easily released to the environment. In addition to use as plasticizers, they have also been used in electrical transformers, inks, lacquer resins, and as lubricants, heat transfer fluids, and carriers for some insecticides.

Structurally, PCB's resemble DDT. Like DDT, they are not soluble in water, but can collect in high concentrations in the fatty tissues of living things. This chemical resemblance has made analytical differentiation difficult and, as a result, it was only in April 1969 that PCB's in the environment were first recognized as residues in oysters in Escambia Bay, Fla.

Since this discovery, PCB's have been found in salt and fresh water fish, sediments, and water, and in crabs, shrimp, marine and terrestrial birds, seals, and man. A study of human tissue samples showed concentrations of from less than 1 part per million to as high as 250 parts per million. Another study found that over half the urban residents examined had detectable levels of PCB's in their blood.

Tests with PCB's have shown that concentration of 0.1 parts per million were fatal to juvenile pink shrimp after 48 hours exposure and the same concentration stopped oyster shell grown in 96 hours.

A residue level of 5 parts per million has been established by the Food and Drug Administration in marketed flesh. Within the last 2 weeks, a number of newspapers have reported that PCB contaminated broiler chickens are being tracked down in 12 Southern States. Last year in New York's Sullivan, Orange, and Ulster Counties alone, 146,000 chickens were destroyed because they were contaminated with PCB's.

Because of the recent disclosure of chlorinated biphenyls in the environment, the full range and effects of these chemicals are yet to be determined.

Cadmium provides another example. Like all metals, cadmium does not degrade in the environment. Thus, as more cadmium is refined, used, and disposed of, increased amounts may reach man. Cadmium becomes a pollutant through a variety of processes and is being used in increasing amounts by the storage battery, plastics, plating, and petroleum industries.

The metal is concentrated in shellfish in nature by a factor of 900 to 1,600 times. In man cadmium levels have been found to reach 30 milligrams total body burden in 50 years from a starting point of about 1 microgram at birth.

The effects of such accumulation vary according to the amount and time period of exposure. Some preliminary studies indicate that exposure levels of cadmium from sources present in the everyday environment may lead to hypertension, heart disease, and emphysema and perhaps to cancer. In the most publicized case of cadmium poisoning, over 100 persons died after eating rice irrigated by water from a cadmium polluted river in Japan in the 1950's.

We should provide for methods to evaluate and if necessary regulate that production and use of toxic substances such as PCB's and cad-

mium, which we find pose a significant threat to human health or the environment. Existing law does not entirely ignore these types of potentially harmful substances. Current laws, however, are inadequate to control the actual and potential damages of toxic substance comprehensively or systematically.

Toxic substances are now dealt with partially in the Hazardous Substances Act, section 12 of the Federal Water Pollution Control Act, the recent amendments to the Clean Air Act, and certain authorities of the Department of Transportation.

The Hazardous Substances Act covers household products and toys—but not the raw materials from which they are manufactured. Thus, it does not deal directly with most of the toxic substances which find their way into our environment.

Section 12 of the Federal Water Pollution Control Act is generally aimed at accidental spills of hazardous substances into water and thus does not completely cover either continuous discharges into water or releases into other media. Administration proposals would provide for effluent standards on toxic substances, but would not prevent their introduction into the environment through other than direct discharges. Moreover, even with the aid of amendments to the Water Pollution Control Act, it will be virtually impossible to control the introductions of certain potentially toxic substances through sources such as municipal plants without some control over their use and distribution.

The Clean Air Amendments of 1970 authorize emission standards and other measures for all existing and new sources of air pollutant emissions, including substances found to be toxic.

The Department of Transportation regulates interstate transportation of hazardous substances under several authorities. Most of the problems of toxic substances, however, relate to aspects of their use rather than to transportation and spills.

The current controls over the manufacture and distribution of the substances we are concerned about pertain to only a small percentage of the chemical substances which find their way into the environment. What controls over production and controls over effluents there are suffer from the limited focus of their authority.

Setting rational standards for many pollutants under existing legislation is almost impossible. The key factors involved in setting standards are the total human exposure to a substance and its total effect on the environment. An obvious limitation of the controls over effluents is that they generally deal with a problem only after it is manifest. They do not provide for obtaining information on potential pollutants before widespread damage has occurred.

Our awareness of environmental threats, our ability to screen and test substances for adverse effects, and our capabilities for monitoring and predicting, although inadequate, are now sufficiently developed that we need no longer remain in a purely reactive posture with respect to chemical hazards. We need no longer be limited to repairing damage after it has been done; nor should we allow our population to be used as a laboratory for discovering adverse health effects. There is no longer any valid reason for continued failure to develop and exercise reasonable controls over toxic substances in the environment.

The proposed Toxic Substances Control Act (S. 1478) would provide a mechanism for the comprehensive and systematic control of hazardous substances in our environment.

Under the proposed bill, the Administrator of the Environmental Protection Agency would be empowered to restrict the use or distribution, including a total prohibition, of a chemical substance, if such restrictions were necessary to protect health and the environment. In proposing such restriction the Administrator would be required to consider not only the adverse effects of the substance but also the benefits derived from the use of the substance as compared with the risks; the normal circumstances of the use; the degree to which the release of the substance or its byproducts to the general environment is controlled; and the magnitude of the exposure of humans and the environment to the substance or its byproducts.

The bill also provides for the issuance of standards for tests on the various classes and uses of new chemical substance. A new compound would be forbidden to be marketed if it did not meet these standards. This concept must be implemented carefully so as not to thwart technological innovation, and we must also keep in mind the impossibility of conclusively providing that a product is safe.

In additoin to these major authorities, S. 1478 would enable the Environmental Protection Agency to develop the resources necessary to predict the introduction of new chemical substances into the environment and to assess the environmental consequences of such introduction, and would charge the Council on Environmental Quality with coordinating efforts to establish a uniform system for classifying and handling information on chemical substances.

We believe that the provisions contained in the administration bill are necessary and workable, and that they present a sound framework for a balanced and rational scheme of toxic substances regulation.

Mr. Chairman, that concludes my prepared comments on S. 1478. If I may, however, I would like to very briefly comment on some of the provisions in amendment No. 338 to S. 1478, introduced by yourself on July 27, 1971, a week ago.

I express my appreciation, Mr. Chairman, for your support of the administration bill and the very careful study and efforts which you have made to improve and strengthen the bill.

The Council is concerned, however, that requirements for preclearance certification, mandatory reporting of tests, taxation, and reimbursement for testing, for the many chemicals covered under Amendment 338, could involve stifling and cumbersome administrative procedures and dilute the ability of the Administrator to effectively and efficiently regulate the most significant hazardous materials. With respect to the sections of amendment 338 which refer to seizure and confidentiality, we feel that S. 1478 adequately and effectively covers these areas. With respect to citizen suits, our general position is that we will accept a citizen suit clause, and support it, to enforce mandatory duties of EPA and federally sanctioned pollution control standards. S. 1478 does not involve these features to the extent that a citizen suit clause would seem appropriate.

Because toxic substances present such important environmental problems, we have attempted to draft as an effective a bill as possible. We have sought to provide comprehensive and systematic mechanisms for the control of hazardous chemicals, while at the same time, avoiding excessive administrative burdens.

Thank you for the opportunity to appear and present these additional comments on the pending legislation. I will be glad to answer any questions you may have, Mr. Chairman.

I would just note in concluding, as I intended at the beginning, to note that I am accompanied by Mr. Alvin Alm, who is the Staff Director for Program Development with the Council.

Senator SPONG. Thank you very much.

Mr. Alm, we are very pleased to have you with us this morning.

Mr. Train, you mention in your statement, and I quote, " . . . several hundred new chemicals are introduced into such use each year."

Does that mean that you would be promulgating test protocols under your bill for several hundred new chemicals a year, and would these chemicals be confined to industrial chemicals only or would be requiring tests for consumer products as well?

Mr. TRAIN. It is my belief that what is called for here is the establishment of test protocols, probably by class rather than for individual substances, although they could go to the individual substance, of chemical substances used in and marked as part of industrial processes, and not specifically because used in certain consumer products.

Of course, the end use could include a consumer product would enter into the decision on the part of the Administrator as to any restriction on use.

Senator SPONG. Would the test ever be run on consumer products as such under the bill?

Mr. TRAIN. In general, no. As I indicated, the administration bill is not intended to supplant the provisions of existing law in other areas, such as the Hazardous Substances Act, which does deal specifically with product safety.

Senator SPONG. If there is going to be no test required for consumer products, how do you answer the argument that there may be consumer products which have different chemical properties and thus pose different hazards to the environment than their components?

I understand the Hazardous Substances Act, but that only controls the effect upon the household user; I don't believe it goes to its effect upon the environment.

Mr. TRAIN. It is my understanding that the legislation the administration has submitted here would—to the extent that the Hazardous Substances Act did not cover the particular problem which you have referred to, that is, effects on the environment—cover it and permit the test.

Could I ask Mr. Alm to expand on that, please?

Senator SPONG. Thank you.

Mr. ALM. Possibly I could give you an example, Mr. Chairman. Nitrolotriacetic acid, NTA, has been an additive to detergents. An additive like this could have environmental impacts; I am not saying it necessarily does, but could have. This type of thing would be regulated under this bill and it is a consumer product.

Senator SPONG. Then you would amend your earlier answer to say that there are to be some consumer products that you foresee being tested under the bill.

Mr. TRAIN. As they affect the environment, yes.

Senator SPONG. Thank you.

The major difference between the administration's approach and that of the amendment we are considering is the amendment's requirement for premarket clearance of new chemical substances. One of the reasons I have opted for premarket clearance is that I believe the burden of proof as to safety should be shifted to industry.

In your statement you say you have also shifted the burden.

How can you shift the burden meaningfully without the notion of premarket clearance? Certainly the phrase "burden of proof" has been used to connote many different things, but one thing it always connotes is the obligation to prove something to someone other than the user.

Isn't your notion of premarket testing akin to requiring a would-be lawyer to determine whether or not he has passed the bar examination.

Mr. TRAIN. Obviously, Mr. Chairman, we considered very carefully the whole field of premarket clearance, and there are degrees to which burden of proof can be imposed or shifted. One could certainly go so far as to require with respect to any chemical substance intended to be marked that proof of its nondangerous character be established fully in advance and be accepted by the Government before the product can be marketed.

I would suppose that would be the complete shifting of burden of proof. We have not, as you understand and have pointed out, gone so far in the administration bill. We are dealing here, as I indicated in my opening remarks, with several hundred probably new substances a year, perhaps substantially more.

At the present time in view of the lack of reporting data, our information is not too accurate. To require in all cases of that sort the establishment of environmental and public health and safety in each case in advance would, as I have indicated, seem to us to impose a very substantial administrative burden upon the Government, and impose a very substantial amount of impediment to technological innovation. Also, because in most instances the substance is undoubtedly not deleterious so that we are only dealing with the exception, to impose this very burdensome administrative requirement on the Environmental Protection Agency could, as I have pointed out, weaken its ability to deal with the real cases of concern.

This is the primary thrust of our approach—to permit the administrator to concentrate on those cases rather than spreading the effort of administration sort of evenly across the entire waterfront.

We are also concerned that to set up a system of premarket clearance in effect could tend to shift responsibility from where we believe it belongs, namely, with the manufacturer, the introducer of the product, to the Government and to the public. It seems very unlikely, as I pointed out, that you can ever establish finally and conclusively that any product is completely without potential harm, either to health or to the environment. That has certainly been our experience.

So, if we impose upon Government the responsibility of reviewing prior to marketing the testing of all new chemical substances, it seems to me that one of two things would happen.

One, out of an excess of caution on the part of an administrator it would be exceedingly difficult to gain clearance, thereby imposing what we think very definitely would result in an unfortunate impediment to technological innovation in this field.

The other alternative is that the Administrator would go ahead and give a clearance in the absence probably of the last ounce of proof, and either alternative it seems to us results in an unfortunate situation and one that is not necessary.

Finally, I think that our approach to this problem recognizes that we are moving into a very new area, not a new problem so much, although one which is being rapidly compounded in terms of its seriousness, but a new area insofar as Federal administration is concerned, and that it would be the better part of wisdom at the beginning of a program of this sort to emphasize and direct the administrative effort to the real problems rather than to create a possible administrative Pandora's box of problems, and we believe that the proposal which we have included in this bill does meet the primary needs.

Of course, as experience is gained with the administration of such a provision as we have proposed and as experience indicates gaps in the ability of the Government to deal with real problems, then, I think would be prudent as always to review the legislation with a view to possible modification. But as a beginning we believe this legislation is very ample.

Senator SPONG. You have responded in terms of several hundred tests that will be taking place. I wonder if your opposition to preclearance in this instance isn't inconsistent with your Refuse Act permit program where you are dealing with from 40,000 to 100,000 permits a year. All the considerations which argue for preclearance of effluents under that program seem present here.

First, the need to control the sloppy workmen and the cheat; second, the need for the administrator to set conditions more specific than general standards; third, the need for an adequate inventory of what is going into the environment; and, fourth, the desirability of shifting the burden of proof, which we have already discussed.

Also, opposition to preclearance seems inconsistent with your stand on pesticides and with the food additives and drug provisions of the Food, Drug, and Cosmetic Act. The hazards here may be less, but we are dealing in those instances with several more applications or situations than we would have under this bill.

Mr. TRAIN. Mr. Chairman, those are both very pertinent comments, but I do think there are some important distinctions here.

Under the permit program, we are dealing with specific fixed water control standards and implementation schedules against which performance on the part of a discharger can be very accurately measured, and that is not the case here, where we are dealing with rather generalized standards of danger to health and the environment.

Secondly, in the pesticide field where we do have a clearly identified and identifiable group of substances about which we know quite a bit, the administration has in fact called for legislation which would provide very strong controls over the use of those pesticides.

I cite that simply to say that where we are sure of the class and sure of the problems, we have not hesitated to ask for very strong controls—preclearance in effect in those particular cases. I think as you are aware we are asking in some cases for a sort of prescription system covering the use of certain dangerous pesticides. But here we don't feel that this situation exists. We are dealing not with an identified class but with a very broad group of chemical substances whose

use is very diverse, and we simply feel that the circumstances such as I have described under the Refuse Act and under the pesticide legislation don't exist here. Again it would be the wiser step in instituting a new set of controls of this sort to move with the kind of premarketing testing requirement which our bill provides.

Senator SPONG. Another difference between S. 1478 and the amendment is that the amendment deals more extensively with existing chemicals. Isn't industries' responsibility to test for existing chemicals just as great as for new ones?

Mr. TRAIN. I think that certainly conceptually there is a responsibility on the part of industry to be sure of the safety, both in terms of human health and the environment, of the products it is selling, no question about it, and this goes to products already on the market as well as those to be marketed subsequent to the effective date of any legislation.

I think that it is also fair to comment that responsible industry, and I would hope that this is the large majority of industry, does do a very great deal of testing prior to the introduction of substances into the environment.

Our bill does provide authority in the administrator—I think I have it here in front of me, section 206(b)—to direct manufacturers of a chemical substance, including those obviously already on the market, to provide within a specified period of time not to be less than 30 days the results of any test of the health or environmental effects of the substance or its byproducts which have been performed by or at the insistence of the manufacturer, or such results as are otherwise known to him, and any or all of the items listed in subsection (a).

I think without requiring a blanket or imposing a blanket requirement on industry with respect to all products already on the market, this provision and others in the proposed bill give the administrator ample authority to move with respect to any substance on the market with respect to which he has some concern. Here again it is a rifle approach rather than a shotgun approach.

Senator SPONG. Under that rifle approach, is it your impression that you have the right to require any industry to do any testing? Isn't all you can require them to give you is the data that they already have? Does the bill provide that you require them to test?

Mr. TRAIN. That, Mr. Chairman, with respect to products already on the market, you are correct. The provision which I have just read, section 206(b), simply gives the Administrator authority to receive the data which has been produced by a test if a test was held, and if a test was not held there is no authority under that section for him to order a test. However, it seems to me that practically speaking the same result would probably be achieved. The Administrator is under the bill—I can't seem to find the exact section—yes, in section 203, the Administrator, where he has basis for concern after evaluating all information developed by or otherwise provided to or made available to him and after referring it to the committee described in the section, may publish regulations restricting or prohibiting the use of a product. In a practical sense, if he asks the manufacturer for the results of a test on a product which the administration has some concern about, and this is an existing substance on the market, and the manufacturer came back and said, "I didn't test it, and I am not going to test it," and in effect,

"it is none of your business," the Administrator would be well within his authority to move ahead under section 203, and in the absence of the kind of data which he has asked for, impose restrictions.

In a practical sense again, as I say, it is hard for me to believe that manufacturers would not respond upon an inquiry of that sort.

Senator SPONG. Another difference between S. 1478 and the amendment is the different treatment accorded imminent hazards. Under your bill the Administrator is authorized to request the Attorney General to seek preliminary injunctive relief pending the outcome of formal administrative proceedings. Under the amendment EPA would be permitted to issue an order summarily.

If the public health is truly in danger, does it make sense to require the Administrator to seek out the Attorney General and attempt to convince him of this, and furthermore to require the Attorney General then to attempt to convince a court? I again am looking for some consistency insofar as the pesticides bill is concerned where there are provisions for summary order. Section 204 deals with imminent hazards.

Mr. TRAIN. Yes, sir; I am just reading it.

Mr. Chairman, there is a distinction which you have pointed out. I think here again the basis for the distinction tends to be that we are dealing here with a new area of public concern the boundaries of which are really quite unclear as yet, and it seemed to be wise to provide the additional protection of judicial process. We do not feel and obviously the purpose of the provision is not to create undue delay in the ability of the Administrator to move in the case of imminent hazard to health and the environment.

It is certainly our expectation and anticipation that the courts—that is, the Attorney General and the courts upon application by the Administrator would move very rapidly. Obviously this cannot be done as rapidly as if the Administrator could move on his own authority without application to the court.

Senator SPONG. Generally I have been on the side of judicial review, despite the pleas of the Chief Justice that we were overloading the Federal courts, but I do have some concern here about the possibility of delay. I am very pleased to have your answer on the point.

Mr. TRAIN. That is certainly not our purpose. I would assure you that if in the administration of this act it did turn out that there were delays that added significantly to the problem with respect to health or environment, we would be the first ones to come up here and ask for a change in the legislation. We anticipate no such delays; our bill's provision is very similar to that found in section 13 of the Occupational Safety and Health Act.

Senator SPONG. In your statement you state, and I quote:

> With respect to the sections of amendment 338 which refer to seizure, we feel that S. 1478 adequately and effectively covers these areas.

How does your bill cover them? I find no language dealing with seizure.

Mr. TRAIN. There are various places in the bill where we deal in a related fashion with the same problem. I believe section 203(a)(3) includes in the Administrator's regulatory authority the authority to require such other action as may be necessary to carry out such restrictions, including prohibiting or restricting the sale, use or re-

moval of such substance or product. Now, that is not strictly speaking a seizure of the product, but it seems to us it is very close and probably would accomplish the same end.

I believe also in section 204(b) there is an authority here in the case of an imminent hazard for the Administrator to request of the court authority to restrain the use or distribution of the chemical substance. Here again it seems to us very close to what you are striving for in your amendment.

Senator SPONG. Under S. 1478 and the amendment exports are excluded from coverage unless the substance exported presents a hazard to people of this country. Many have said that we ought not to inflict hazards on others that we would not accept ourselves. How do you answer that argument? I am referring to section 211(a) in your bill and 213(a) in my amendment.

Mr. TRAIN. I am glad you agree with the administration's bill.

Senator SPONG. I do. We have it in there for discussion today.

Mr. TRAIN. I think that this certainly is a subject of considerable debate. We have as a general rule tried to avoid any impression that the setting of standards in this country—environmental standards—constitutes a hidden trade barrier. So I think we tend to avoid where possible the imposition of restrictions on the free flow of trade as a result of environmental factors.

Of course, on the import side the very nature of the public policy would be negated if you permitted imports to come in which did not meet our standards while our own manufacturers had to meet those standards. That reason does not apply to exports. What we are trying to do here is meet a public policy desire on the part of the American people—other peoples may—this is a somewhat philosophical approach—other peoples may have different standards that they are interested in, and I think there is a considerable feeling that we should not impose our standards on others.

Obviously they are perfectly free to impose such standards as they wish, including limitations on imports of our goods that do not meet those standards. We do make clear that where the export of a product does have an adverse effect on human health or the environment in the United States that the export would come under the proposed legislation.

So if an export did in fact have such an effect on the global environment, if you will, that the effect would extend to the United States, then it would be covered.

Senator SPONG. I believe Senator Hatfield wants to follow up on that.

Senator HATFIELD. Thank you, Mr. Chairman.

Mr. Train, this same subject came up during the fish inspection hearing that we had a few weeks ago. Don't you believe that this is a rather weak defense or weak argument which you are giving us this morning on this so-called restriction of trade implication in this section 211? I say this in light of the fact that we are now in preparation for the Stockholm conference which is an attempt to bring together the nations of the world to understand the growing truth—the understanding of this truth that environmental problems are global in character?

I just recently returned from a conference in the Soviet Union in which the environmental issue was discussed in the context that we

are facing a possibility of an ice age on this globe because of the pollution of the air. Dr. Federov made an estimate this could happen within 50 to 100 years and the American environmental experts thought he was a little bit conservative on his estimates.

We have been charged in this country frequently in the international realm of politics of putting our economic interests ahead of human values. It just seems to me that with the kind of leadership required to deal with environmental problems from a global perspective that we are really not taking the lead or the initiative we should be taking in such sections as 211. Even if you did put the word "may" in on line 22, it would certainly have indicated a little more concern than when it says, "The administrator finds that as exported and used the substance will produce." "Will produce," it seems to me, opens ourselves to the charge that we are really only interested in protecting our economic interest. We are sacrificing the environmental values here that we are trying to protect within our own country, but little concern is shown as it relates to other countries.

I have heard this reference to inhibiting the foreign trade possibilities and so forth, but I really feel in light of this other evidence that this is a rather weak argument. Is the administration frozen into this position? If we could come up with some wording that would apply the same standards to exports that we demand of our own domestic markets would the administration be receptive to such language?

Mr. TRAIN. Let me make two comments. One, I suppose this is argumentative, I do feel that our Government is taking a lead internationally on environmental matters. I do not think there is any question about it. I think the position of the administration and the bipartisan record of this Congress on environmental matters has been widely acclaimed around the world. So I would differ with you just on that very general point. I think we are taking a strong international——

Senator HATFIELD. Let me interrupt, I do not want the record to indicate or imply that I felt we were not taking a role of leadership. I simply feel we should be strengthening that leadership in every way. To me, this type of thing gives us another vehicle through which to strengthen that leadership.

Mr. TRAIN. I think you and I fully agree on that general point. I think we should be continually strengthening our role of international leadership in this area. I think I can readily say we are not frozen into this provision. I think that has really been a fairly standard provision, and it probably is included in this legislation pretty much because it has been included in the past, and I do not think it has been the subject of any special reexamination in the light of this particular legislation.

There are, as you know, a wide variety of environmental controls involving products such as automobiles which we apply in this country and which are not applied to exports, and there are substantial questions involved in determining whether we should or should not apply these standards. Not only are you imposing a standard which may not be necessary in some foreign country but you are also at the same time probably raising the price of the product to the foreign consumer, perhaps unnecessarily.

So there are questions I think that would have to be examined, and I would say simply in response we are not frozen in, we would be very happy within the administration to take a hard look at this whole question.

Senator HATFIELD. I appreciate your response, because the United States today is responsible for about 40 percent of the industrial pollution and the ocean is becoming a great conveyor of pollution. It no longer can be restricted just to national boundaries or national concerns, because of the international character of the air and the atmosphere. I think we must give strong leadership to advancing the global character and perspective of correcting these environmental problems. We just cannot look at these purely from a domestic or a national point of view, and especially as we are looked to in so many fields to give world leadership.

I think one of the things we are going to find difficult at the Stockholm meeting will be just on this very point: whether or not we are concerned about the world and the global problems here or are we just really advancing our economic interest by producing products that are not meeting the same standards for the world market that we require for our domestic market.

I would like to see us go to Stockholm with a good record within our own country, and a very definite program for the global aspects of this environmental issue. It just seems to me that if you are open to that, I would like to develop, with the chairman's permission, some language here that would give the same standard in effect to what we export as we require for our domestic market. I believe inhibiting the trade relationships really is not that important.

This may be a judgmental factor. But it seems to me that if we can produce a superior product, especially as the world becomes more conscious of environmental problems, that we will have a preference to our products issued by the buyers in the world market as they know our efforts are toward this objective.

Mr. TRAIN. I think there is a very real opportunity for American business in terms of the development of new export markets to take advantage of our environmental technology and knowhow. I think that more important than the trade aspects, which I did mention, is the question of imposing our standards upon other peoples. It is not a black and white question.

You are familiar with the issue over DDT exports. We have substantially reduced the amount of DDT used in the United States to a very small fraction of what it used to be, and yet at the same time there are those areas of the world, typically those that have major malaria problems, endemic malaria problems, that insist that they must have DDT. Without arguing the merits or demerits of that particular question, I simply cite it as an example of the two sides of the coin here that must be dealt with. The issue is not an open-and-shut one by any stretch of the imagination.

Senator HATFIELD. I appreciate that. I appreciate your response. But I would only say we cannot follow that to its ultimate conclusion, because that is the same argument we would get in the arms field, that after all, if we do not peddle arms in a certain country, they will buy it from somewhere else. Therefore, we get into this question here as to just exactly what we should or should not export.

Mr. TRAIN. But we do not have malaria in this country to any significant degree, so we can afford to be rather pure on this.

Senator HATFIELD. We can afford to be concerned about environmental problems because we have reached a certain standard of living which the undeveloped and the underdeveloped countries have not, who say we cannot be concerned with environmental problems until we reach your standard. Here again we must take leadership, and I think the leadership role sometimes is a sacrificing one, but which must be done if objectivity and the morality of it is on its side.

Senator SPONG. Mr. Train, we have a rollcall vote now, and I suppose this is a good time to cease our examination of you. We appreciate your appearance here this morning. There may be some followup questions that I will submit later in the hearings. We thank you very much for being here.

Senator Hatfield, you had no further questions?

Senator HATFIELD. No.

Senator SPONG. The committee will recess for 15 minutes while we vote. We will be back and resume then.

(Recess.)

Senator SPONG. The hearings will come to order.

The next witness will be Dr. David Klein.

Dr. Klein, you were kind enough to testify before this subcommittee last year and we are very pleased to have you back with us this morning.

STATEMENT OF DR. DAVID KLEIN, PROFESSOR OF CHEMISTRY, HOPE COLLEGE, HOLLAND, MICH.

Dr. KLEIN. Thank you for the opportunity to present some views and some data which I think will lend support to the legislation under consideration.

Before I start my prepared statement, listening to the prior discussion on the question of exports puts me in mind of a couple of specific instances which occurred during the great mercury controversy, and which I think may have some bearing on that general topic of whether we should or should not export things which we find bad.

Sweden, as you know, experienced difficulty with their wildlife as a result of alkylmercurials used in agriculture, and they began to restrict the use of those alkylmecurials in their agriculture in about 1966. Now, what they did with the materials which they could not use was to sell them to us and we just went along, apparently completely unaware that these things have bad effects, bought them and used them here. So we have been ourselves on the short end of that particular stick.

A similar incident on the export of technology occurred in connection with one of the Japanese factories involved in the Japanese environmental mercury poisonings. One of those factories exported its whole process to Italy, the process which involved discharging mercury from the production of acetaldehyde. They exported that process to Italy and apparently made no mention to the Italians that they had experienced some problems with their waste discharge. I think in neither of those cases did the economic interests in Japan or Sweden come off looking very good in the eyes of the world.

On the other side of the coin, Canada refuses to export fish which they find unsuitable for their own consumption. They will not ship out things that they do not think are suitable for themselves.

So there are I suppose precedents on both sides, but I do believe that Canada looks a little better than Sweden and Japan.

With that much preface I will begin with my prepared statement. I think with your permission I will omit the first two paragraphs, because as I read them over they are not too interesting. The essence, though, of that message is that I believe what we need is a combined approach in which we first develop improved waste treatment, and second, we limit the quantities of material which enter the treatment process.

The degree of waste treatment required to get satisfactory removal of toxic materials is very difficult to attain and the problem can be improved immeasurably if it is possible to initially limit the quantity of wastes that will enter the treatment plant.

Senator SPONG. Regardless of interest, we will receive your statement in its entirety, and you can testify as you will from it.

Dr. KLEIN. Fine.

Existing laws have tended to concentrate largely on industrial discharges and on a few specific major pollutants. However, a wide variety of products containing potential environmental pollutants reach individual consumers and are disposed of by them, and such disposal is very largely unregulated. I will confine my specific remarks to mercury, for which I have data, but we recognize the problem is of course not confined to mercury.

At the time this subcommittee had hearings last spring and summer on the effects of mercury on man and the environment, the major source of waste mercury to the environment was the chlor-alkali industry, which was losing mercury to air and water at the rate of 500 tons per year, about four-tenths of a pound per ton of chlorine produced. The most recent figures I have seen indicate that this loss has been cut to about two hundredths of a pound per ton, a twentieth of the former rate of loss. Direct discharge of mercury to the waters is now measured in pounds per day rather than thousands of pounds per day.

The second large use of mercury is in electrical products and about 500 tons is used annually in making batteries. How is this 500 tons of mercury thrown away when the batteries are burned out? Most probably goes to dumps or landfills where the cases eventually corrode away and the mercury is released to contaminate the groundwater.

Some of the batteries are burned, and their mercury is added to the atmospheric burden. The annual disposal of 500 tons of mercury by the chlor-alkali industry has been controlled; the annual disposal of 500 tons of mercury by consumers of mercury batteries has not been controlled. Surely mercury batteries are very fine gadgets, and everyone should have some. Their use presents minimal health or environmental hazard, but their disposal does. We need leadership in developing reclamation procedures for these products, and we need regulations preventing careless disposal.

Most other uses of mercury are small, involving tens or at most a few hundred tons, and the industrial discharges associated with these uses are already subject to regulation. However, a significant fraction

of this mercury ends up in consumer products, to be thrown away by the consumer. I have in the past estimated that 200 to 300 tons of mercury are discharged into the environment each year through disposal of consumer goods, roughly half to the atmosphere and half to the waters. This estimate was based on tabulations of the uses of mercury, and indicate that a city of a million people would annually discharge into its sewers about 1,000 pounds of mercury. This mercury is in part removed by the sewage treatment plant, and the balance is discharged with the liquid effluent into some water body.

I have since made a few measurements to check that estimate, and I am happy to say that estimate came out very close. The Holland, Mich., treatment plant serves about 30,000 people and handles only domestic wastes. There are no industrial discharges at all into that plant. Over a 10-day period last month, mercury entered the plant at an average rate of 27 grams per day, or 22 pounds per year. If we extrapolate that to pounds per year to million population, that could come out 750 pounds per year per million.

The Grand Rapids, Mich., treatment plant serves about a quarter of a million people, and handles both domestic and industrial wastes. Over the same period, mercury entered this plant at a rate of 360 grams per day, or 290 pounds per year. This would correspond to 1,100 pounds per year per million population. Significantly, in the case of Grand Rapids, the rate of discharge was highest on the weekend, when industrial activity is at a minimum.

In both these plants treatment of the effluent removed on the average only about one-quarter of the mercury. The balance was discharged to rivers. The Lake Michigan water which enters these cities contains mercury at a concentration of about 0.02 part per billion, so the entering waters contain less than half a pound of mercury per year for Holland and less than 2 pounds for Grand Rapids.

The great bulk of the mercury discharge was in fact added to the water system in its passage through the city.

I have found also some data on the city of Stockholm where some 600,000 people discharged 750 pounds of mercury per year. This would correspond to about 1,250 pounds per year per million population. So as a rough but fairly solid estimate, I think that it is safe to say that on the average a city of a million will discharge to its sewers about a thousand pounds of mercury per year.

The results indicate that the earlier estimate was close, and that non-manufacturing uses of mercury do lead to significant discharges. Where does this mercury come from? Hospital and college laboratories are a source. If we extrapolate some data available from Sweden and from Canada we will conclude that some 40 tons of mercury annually enters the U.S. environment through breaking clinical thermometers in hospitals, so I suppose we need nurses with stickier fingers when they shake those down. Possibly half of that enters the waters. In dental offices a fairly large portion of the amalgam which the dentist makes out does not end up in the teeth but is disposed of in other ways.

Mercury-containing pharmaceuticals are a source. Paint brushes and paint rags are washed out, and this is a source. In a recent report to the Michigan House of Representatives Dr. Frank M. D'ltri of Michigan State University listed some of the many uses of mercury. He states:

Mercury and especially the phenylmercurials have been used as preservatives or fungistats in consumer and industrial products such as floor waxes, furniture polishes, fabric softeners, air conditioner filters, toothbrushes, mattress inner components, cellulose sponges, rope, canvas, drywall products, wall plaster, adhesives, scatter rugs, brooms, furniture polishing rags, dust mops, and a variety of dust control preparations. And mercury is commonly used as an antimicrobial agent in many consumer products manufactured with plastics, rubber, leather and textile components.

We have also analyzed a few of the products listed by D'ltri. All contain mercury in small amounts ranging from 0.3 parts per million for a cellulose sponge and a floor wax, 0.1 parts per million in some fabric softeners. The total mercury contained in all the cellulose sponges in the country must be very small, but when added to the mercury in floor wax and fabric softeners, in pharmaceuticals and paints, the total quantity becomes large, and this total is collected from all over the city, combined and discharged at a point into a water body.

Mercury in these consumer products is of course quite dilute when discharged, the concentrations typically being a few parts per billion. In an earlier study involving sewage outfalls discharging into the ocean I observed that the sediments around these outfalls do concentrate the mercury by as much as a factor of 20 to 50 over the sediments at some distance from the outfall, and further that the organisms living in such sediments do show higher body burdens of mercury. In other words, mercury acts like mercury, regardless of the source and concentration.

If my data can be extended to the country, then the daily discharge of water by our sewage system is about 600 pounds per day, a total of nearly 200,000 pounds per year. To look at a more specific case, because it is in an area which is in trouble, the Detroit area, with a population of roughly 3 million, would annually discharge about 3,000 pounds of mercury into the troubled waters of the Midwest; this is about 8 pounds per day. A chlor-alkali plant with this discharge would be shut down quickly under the 1899 Refuse Act, but the mercury coming from the sewage outfalls is exempted from action under this act.

Much of what I have said about mercury is true, at least in a general way, of other environmental hazards. They occur in small amounts in a wide variety of consumer goods, the quantity in each class of consumer goods is quite small, but the total quantity, when collected, combined, and discharged, may be very large.

We need to extend our efforts in environmental protection to include those goods not now regulated. We need to evaluate new chemical products and to reevaluate old ones, to find out whether or when they endanger the environment. Environmentally hazardous substances should not be used unless there is no substitute. If there is no substitute, then the disposal of these substances must be regulated and the total quantity in circulation must be limited.

Senator SPONG. Thank you.

Doctor, if I understood your statement correctly, there are probably something like 600 pounds of mercury per day presently being discharged directly into our waters from municipal sewage plants.

Dr. KLEIN. That is the way it looks, yes.

Senator SPONG. Not only is that fact disheartening in and of itself, but it is especially so when pitted against the Interior Department's

release of last summer entitled "Secretary Hickel Reports Mercury Discharges Reduced by 86 Percent."

Now that release told us that mercury discharges from industrial sources had been reduced from 287 pounds per day in July to 40 pounds per day in September. I remember being very comforted by that, but when you crank that 600 pounds per day into the equation, isn't it the case that the reduction referred to represented only about 25 percent of the total direct discharges from industrial and municipal sources?

Becoming excited about that kind of a reduction is sort of like becoming excited about getting rid of the flu when you still have tuberculosis or cancer. We have been speaking of direct discharges into our water. What would you say is the total daily discharge into the environment?

Dr. KLEIN. It is roughly double the figure I gave you before, perhaps a little more. I can give you that probably somewhat more accurately. I am stuck on total daily discharge. It can give you a rough tonnage figure which would correspond at present to about 1,000 tons per year. What we would need to do to get daily poundage figures is divide by 365 and multiply by 2,000 which I am not capable of doing at this time.

But it is roughly a thousand tons per year as the total discharge of mercury which has been somehow dug up, mined, put into products, and then dispersed, in the order of a thousand tons per year.

Senator SPONG. While I am questioning you I will see if I can get the mathematics worked out over here on my left.

I am told that works out to about 5,500 pounds per day. Does that sound right?

Dr. KLEIN. I can believe that.

Senator SPONG. You will accept that?

Dr. KLEIN. Sure.

There was a lot of fine print in that release about the decrease in the mercury discharges that not everybody read.

Senator SPONG. In your statement you mention some sources of mercury that might be responsible for the levels of discharge you have found. Are there substitutes for mercury in these products, or is it absolutely essential that these uses of mercury continue?

Dr. KLEIN. In most cases there are substitutes, at least for a lot of the use. For example, in paints, mercury is used largely to increase the shelf life, to some extent to prevent the material from mildewing once it is on the wall. There are substitute materials which I think are adequate in all but a few cases, the few cases being light-colored exterior water-based paints for use in very humid regions. So it might, for example, be possible to continue the use of mercurial preservatives in those paints and restrict it in other paints. That is true, I think, of most sources.

I do believe that loss from thermometers could be cut down significantly by making the thermometers a little sturdier or by causing the nurses not to stand near the edge of the table when shaking them down. There is now no safe method for disposing of that mercury, but that material need not enter the water.

The same is true from the materials lost in dentistry. That material need not enter the water.

If there could be defined some mechanism by which the stuff could be shipped away somewhere and be recycled, then it need not enter the water. The same is true with mercury batteries. Given a mechanism for disposal, it could be kept away from the environment effectively.

I believe, just looking at the list of uses, without severely hurting anything except the miners, we could cut our losses down to about a third of the present level without doing anything very different from what we are doing now.

Senator SPONG. In your statement you mention that the Refuse Act of 1899 does not apply to sewage outfalls. Even if the Refuse Act, or the Federal Water Pollution Control Act for that matter, could be used to control discharges of this type, I wonder if this would solve the problem. I am told that the technology does not now exist to remove substances like mercury from municipal waste on a practical basis. In the absence of adequate treatment facilities it likewise seems a practical impossibility for a city to tell its individual homeowners that they cannot discharge mercury-containing sewage into municipal plants.

It appears to me that the only practical way to deal with this problem at this time is to control mercury at the source by banning or limiting the production of mercury-containing products. Do you agree?

Dr. KLEIN. I agree completely, yes. We really need more technology in the final end of this system, in the final disposal at the sewage plant, and that technology seems not available.

Senator SPONG. Do you see this bill as a means for instituting such control?

Dr. KLEIN. For instituting control of mercury at the source?

Senator SPONG. Yes.

Dr. KLEIN. Well, I have read both the bill and the amendment. Mercury and mercurials, of course, are existing chemicals. I assume, however, they present a sufficient hazard that they would be covered under either the original bill or the amendment. Certainly I think either of these bills would go a long way in controlling the quantities of mercury and of other heavy metals which are now released uncontrolled into the environment.

Senator SPONG. The legislation would not be very effective if it did not take cognizance of the present perils presented by mercury.

Dr. KLEIN. Right.

Senator SPONG. It is the intent of the amendment to S. 1478 that most final consumer products would be exempted from the testing requirements if the components of that product have been tested individually. However, the Administrator of EPA would have the authority to require testing on the final product as well, presumably if there is reason to believe that the components may act differently together than they do individually.

Do you think this option is necessary?

Dr. KLEIN. Yes, I do. As a matter of fact, if I had been writing the law that is just what I would have said.

Senator SPONG. Can you give us some indication of the degree to which components of a product may be innocuous individually but may present hazards if found together as a product?

Dr. KLEIN. Some indication of the degree? I am sorry to say nothing comes to mind. Nothing comes to mind that I know of.

Senator SPONG. Doctor, we appreciate very much your appearance this morning. Thank you for your testimony.

We will be in recess until 10 o'clock tomorrow morning in this room.

(The statement follows:)

STATEMENT OF DAVID H. KLEIN, PROFESSOR OF CHEMISTRY, HOPE COLLEGE, HOLLAND, MICH.

Our society and its technology have brought us into a very peculiar relationship with our environment. We have developed a huge, and increasing, body of products and processes which are used by consumers and thrown away by consumers, but we have just begun to learn how to throw them away without threat to our health or our environment. We have tended to act in the belief that the world is flat and that a waste product, once throw away, will drift to the edge of the world and fall off into space, never to reappear.

We are, however, beginning to believe that the world is round, and that throwing something away does not make it disappear. The tons of unburned hydrocarbons, oxides of nitrogen, and lead thrown away from our automobiles will be controlled, partly by improved waste treatment at the point of discharge, and partly by eliminating from the fuel the non-essential additives. The discharge of tons of phosphates, which has increased the rate of eutrophication of many of our waters, will be controlled by limiting the phosphates entering the treatment plant, and by improved waste treatment. This general approach of better treatment of discharge streams coupled with limitation of the total quantity of pollutants entering the treatment system, offers great promise for the preservation, and perhaps eventual reclamation, of the environment.

Existing laws have tended to concentrate largely on industrial discharges and on a few specific major pollutants. A wide variety of products containing potential environmental pollutants reach individual consumers and are disposed of by them, and such disposal is largely unregulated. I will confine my specific remarks to mercury, for which I have data, but the problem is of course not confined to mercury.

At the time this subcommittee had hearings last spring and summer on The Effects of Mercury on Man and the Environment, the major source of waste mercury to the environment was the chloralkali industry, which was losing mercury to air and water at the rate of 500 tons per year, about four tenths of a pound per ton of chlorine produced. The most recent figures I have seen indicate that this loss has been cut to about two hundredths of a pound per ton, a twentieth of the former rate. Direct discharge of mercury to the waters has been cut even further, and is now measured in pounds per day rather than thousands of pounds per day.

The second largest use of mercury is in electrical products, and about 500 tons is used annually in making batteries. How is this 500 tons of mercury thrown away when the batteries are burned out? Most probably goes to dumps or landfills where the cases eventually corrode away and the mercury is released to contaminate the groundwater. Some of the batteries are burned, and their mercury is added to the atmospheric burden. The annual disposal of 500 tons of mercury by the chloralkali industry has been controlled; the annual disposal of 500 tons of mercury by consumers of mercury batteries has not been controlled. Surely mercury batteries are very fine gadgets, and everyone should have some. Their use presents minimal health or environmental hazard, but their disposal does. We need leadership in developing reclamation procedures for these products, and we need regulations preventing careless disposal.

Most other uses of mercury are small, involving tens or at most a few hundred tons, and the industrial discharges associated with these uses are already subject to regulation. However, a significant fraction of this mercury ends up in consumer products, to be thrown away by the consumer. I have in the past estimated that two to three hundred tons of mercury are discharged into the environment each year through disposal of consumer goods, about half to the atmosphere and half to the waters. This estimate was based on tabulations of the uses of mercury, and also indicated that a city of a million people would annually discharge into its sewers about 1000 pounds of mercury. This mercury is in part removed by the sewage treatment plant, and the balance is discharged into some water body.

I have since made a few measurements, to check the estimate. The Holland, Michigan treatment plant serves about 30,000 people and handles only domestic wastes. Over a ten-day period last month, mercury entered the plant at an average rate of 27 grams per day, or 22 pounds per year. This would correspond to 750 pounds per year per million population. The Grand Rapids, Michigan treatment plant serves about a quarter of a million people, and handles both domestic and industrial wastes. Over the same period, mercury entered this plant at a rate of 360 grams per day, or 290 pounds per year. This would correspond to 1100 pounds per year per million population. Significantly, the rate of discharge was highest on the weekend when industrial activity is at a minimum. Treatment of the influent removed, on the average, only about one quarter of the mercury. The balance was discharged to rivers. The Lake Michigan water which enters these cities contains mercury at a concentration of about 0.02 ppb, so the entering waters contain less than half a pound of mercury per year for Holland, and less than 2 pounds for Grand Rapids.

The results indicate that the earlier estimate was close, and that non-manufacturing uses of mercury do lead to significant discharges. Where does this mercury come from? Hospital and college laboratories are a source. Mercury-containing pharmaceuticals are a source. Paint brushes and paint rags are washed out, and this is a source. In a recent report to the Michigan House of Representatives, Dr. Frank M. D'ltri of Michigan State University listed some of the many uses of mercury. He states:

". . . mercury and especially the phenylmercurials have been used as preservatives or fungistats in consumer and industrial products such as floor waxes, furniture polishes, fabric softeners, air conditioner filters, toothbrushes, mattress inner components, cellulose sponges, rope, canvas, drywall products, wall plaster, adhesives, scatter rugs, brooms, furniture polishing rags, dust mops, and a variety of dust control preparations. And mercury is commonly used as an antimicrobial agent in many consumer products manufactured with plastics, rubber, leather, and textile components."

We have analyzed a few of the products listed by D'ltri. All contain mercury in small amounts ranging from 0.3 ppm for a cellulose sponge and a floor wax, to 0.1 ppm in some fabric softeners. The total mercury contained in all the cellulose sponges in the country must be very small, but when added to the mercury in floor wax and fabric softeners, in pharmaceuticals and paints, the total becomes large, and this total is collected from all over the city, combined, and discharged at a point into a water body.

Mercury in these consumer products is of course, quite dilute when discharged, the concentrations being a few parts per billion. In an earlier study involving sewage outfalls discharging into the ocean, I found that the sediments around these outfalls do concentrate the mercury, and the organisms living in such sediments do show higher body burdens of mercury. In other words, mercury acts like mercury, regardless of the source and concentration.

If my data for western Michigan can be extended, then the Detroit area with a population of about three million, annually discharges about 3000 pounds of mercury into the troubled waters of the Midwest; This is about 8 pounds per day. A chlor-alkali plant with this discharge would be shut down quickly under the 1899 Refuse Act, but the mercury coming from the sewage outfalls is specifically exempted from action under this act.

Much of what I have said about mercury is true, at least in a general way, of other environmental hazards. They occur in small amounts in a wide variety of consumer goods, the quantity in each class of consumer goods is quite small, but the total quantity, when collected, combined, and discharged, may be very large.

We need to extend our efforts in environmental protection to include those goods not now regulated. We need to evaluate new chemical products, and to re-evaluate old ones, to find out whether, or when, they endanger the environment. Environmentally hazardous substances should not be used unless there is no substitute. If there is no substitute, then the disposal of these substances must be regulated, and the total quantity in circulation must be limited.

(Whereupon, at 11:15 a.m., the hearing was recessed, to reconvene at 10 a.m., Wednesday, August 4, 1971.)

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

HOPE COLLEGE,
Holland, Mich., August 9, 1971.

HON. MARK HATFIELD,
U.S. Senate,
Senate Office Building,
Washington, D.C.

DEAR SENATOR HATFIELD: On Tuesday August 3, I testified before the Subcommittee on Energy, National Resources, and the Environment, concerning the Toxic Substances Act. You questioned the previous witness, Mr. Train, about that section of the bill which permits export of products which are found unsafe for domestic use. I began my testimony with some true, but not too well thought-out comments on this export question, which had also bothered me. I am writing you now to certify those comments, in the hope that you will pursue the question further.

As a result of a wildlife die-off attributed to methylmercury seed dressings, and after studies indicating that some of the methylmercury was translocated from the seed to the final edible grain, Sweden began restricting the use of these chemicals in agriculture, in 1964. They did not ban manufacture of these chemicals for export, and the manufacturers found a market in the U.S. We bought and used these chemicals, thus contributing to our own mercury problem. The New Mexico poisonings were due to methylmercury treated seeds.

There were two epidemics of environmental mercury poisoning in Japan, both due to the discharge of mercury-containing wastes from chemical factories. One of the Japanese companies involved in the poisonings sold its chemical process to an Italian company, without informing the Italian company that the chemical process they were buying, had caused much sickness and death in Japan.

Canada has been, and is, faced with a roughly analogous situation, involving her inland commercial fishery. Since some countries, including Sweden, tolerate a higher mercury level in fish than does Canada, many of the fish condemned by Canada could be sold abroad. Canada, however, has chosen not to export fish which it consideres unsuitable for consumption by Canadians.

I hope that you will continue your efforts to turn the policy of the United States to the moral position already taken by Canada.

Very truly yours,

DAVID H. KLEIN,
Professor of Chemistry.

TOXIC SUBSTANCES CONTROL ACT OF 1971 AND AMENDMENT

WEDNESDAY, AUGUST 4, 1971

U.S. SENATE,
COMMITTEE ON COMMERCE,
SUBCOMMITTEE ON THE ENVIRONMENT,
Washington, D.C.

The subcommittee met, pursuant to recess, at 10:25 a.m., in room 5110, New Senate Office Building, Hon. William B. Spong, Jr., presiding.

Present: Senator Spong.

Senator SPONG. The hearings will come to order.

The first witness this morning is Mr. Robert Fri, the Deputy Administrator of the Environmental Protection Agency.

Mr. Fri, we are pleased to have you with us.

STATEMENT OF ROBERT FRI, DEPUTY ADMINISTRATOR, ENVIRONMENTAL PROTECTION AGENCY; ACCOMPANIED BY DR. JOHN BUCKLEY, OFFICE OF THE ASSISTANT ADMINISTRATOR FOR RESEARCH AND MONITORING

Mr. FRI. Thank you, Mr. Chairman.

I have with me Dr. John Buckley of our research organization. Dr. Buckley is a biologist who has been involved in the testing of pesticides and toxic substances for a number of years.

Mr. Chairman, I am pleased to have the opportunity of appearing before you today in support of S. 1478, the administration's proposed Toxic Substances Control Act.

Yesterday, Russell Train, chairman of the Council on Environmental Quality in his testimony described the nature and extent of the problem of toxic substances, including projections on the growing number of new chemicals entering commercial channels. We endorse Chairman Train's statement and share his concern for this critical environmental problem.

Today, in our testimony, I want to discuss EPA's thoughts on the proposed toxic substances program which this legislation would establish. Additional comments on the administration's proposal and on Senate amendment No. 338, which is also pending before the committee, are contained in our legislative report. We request this report be made a part of the hearing record.

Senator SPONG. Without objection, it will be included.

(The report follows:)

ENVIRONMENTAL PROTECTION AGENCY,
Washington, D.C., August 3, 1971.

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

DEAR MR. CHAIRMAN: This is in response to your request for the views of the Environmental Protection Agency on S. 1478, the Toxic Substances Control Act of 1971, and Senate Amendment No. 338 thereto.

S. 1478 is the Administration's proposal to begin a systematic and effective program to control the growing number of toxic chemicals entering the environment. Entry into this area has long been needed, and has recently acquired further urgency by the public disclosures of the possible hazards of such toxic substances as mercury and polychlorinated biphenyls (PCB's). Only a handful of chemicals among those recognized as potentially dangerous have any sort of direct Federal regulation. Many of these substances are not strictly air or water pollutants, but often find or may find their way into soil and food.

S. 1478 lays the foundation for a comprehensive toxic substances control program by authorizing the Administrator of the Environmental Protection Agency, in consultation with other agencies when appropriate to:

1. Require manufacturers to report among other things, the name, chemical identity, categories of use to the extent they are known, and amount of chemicals manufactured.
2. Set standards for test protocols for new chemical substances and for the results to be achieved of such testing, as are necessary to protect health and the environment.
3. Seek judicial limitations on the use or distribution of a chemical substance which "creates a hazard to human health or the environment that should be corrected immediately to prevent injury to health and that should not be permitted to continue while an administrative hearing or other formal proceedings are being held."
4. Promulgate rules or regulations restricting or prohibiting the use or distribution of chemical substances to the extent necessary to protect health and the environment.
5. Insure that the regulations promulgated pursuant to the Act are being complied with through the medium, among others, of administrative inspections. Both civil and criminal penalties are also provided for violation of the Act or regulations promulgated pursuant thereto.
6. Establish and maintain a Toxic Substances Board which shall advise the Administrator or test protocols and use and distribution restrictions. Membership of the Board will be composed of individuals nominated by the National Academy of Sciences.
7. Preempt, in large measure, State regulatory action once the provisions of this act have been applied to a chemical substance.

The Administration's proposal is not intended to supplant existing Federal product or distribution controls, nor laws dealing with exposure in the working environment.

The Environmental Protection Agency recommends enactment of S. 1478. It provides three crucial elements necessary to protect the public health and the environment from the adverse effects of toxic chemicals. First, a mechanism is provided for the identificaton of chemical substances which enter the environment. Periodic reports from the manufacturers of chemical substances will allow EPA to determine the chemicals including their production and usage.

Second, the effect of possibly hazardous materials upon the environment will be explored through a series of tests. Finally, when it is necessary to protect the environment or public health, a means of controlling the distribution and uses of the toxic substances will be prescribed. Hence enactment of S. 1478 would provide a mechanism for controlling hazardous chemical substances either ignored or inadequately covered by existing Federal statutes.

Senate Amendment No. 338 would change the Administration's proposal in a number of important respects by:

1. Establishing a procedure for premarket clearance of chemical substances.
2. Reimbursing manufacturers for legitimate testing expenses from a fund generated through an excise tax on certified chemical substances for those chemicals covered by testing standards.

3. Empowering the Administrator under certain circumstances to seize those substances found harmful.

4. Allowing citizen suits against alleged violators of the act or to require the Administrator to enforce the mandatory provisions.

5. Authorizing either the Administrator or the Attorney General to represent the United States in litigation under this act.

6. Allowing civil penalties to be assessed against consumers who willfully fail to dispose of a toxic substance in accordance with the label.

7. Limiting the Administartor's authority to conduct research on the possible harmful effects of chemical substances.

While EPA believes one of these amendments has the effect of strengthening S. 1478, others would be difficult, at best, to administer and could jeopardize the achievement of the bills basic goals.

Premarket certification could provide EPA with advance information as to new chemicals planned for introduction into the environment. Under the provision EPA would be expected to bring into being a comprehensive series of standards for protocols and test results covering the entire range of new chemicals within one year of enactment. We believe however that to require such across the board testing would divert resources available to EPA from concentration on the problems identified as the most pressing. To the extent a comparable requirement is imposed with respect to existing chemical compounds, the ability of the Administrator is further impeded. The Administrator should have the flexibility to determine those classes of compounds that in his judgment map present the most pressing problems.

Moreover, a requirement for comprehensive coverage of both new and existing chemical substances would significantly increase the risk of a backlog of unprocessed applications for certification. Even the anticipation of such a backlog might have a substantial tendency to discourage development of new chemical substances, a result which the Administration's proposal would not create.

Finally, a certification procedure tends to suggest to the public the lack of adverse environmental effects of a certified chemical. Although our knowledge about testing technology is significant and when applied will allow us a considerable measure of protection, we would not be in a position to insure against any adverse effects. We therefore strongly urge that no certification provision be inserted in the bill.

We understand the basis for some of the concerns expressed in favor of the testing cost reimbursement and excise tax provisions of Senate Amendment No. 338, but oppose the provision. It is true that the first developer of a new product frequently bears disproportionate costs, as well as the risk that others will take advantage of his efforts without compensating him. At the same time, he reaps benefits from his lead in the development which are not available to successor producers. The Senate Amendment apparently attempts to deal with this situation by reimbursing the first developer to complete certification procedures for his legitimate testing expenditures from a fund generated by a tax on the sales of the certified chemical substances. Apart from serious questions as to how these provisions would operate, they would be so complicated and costly in administration as to make them almost unworkable; in our opinion they do not represent a solution suitable to the problem identified. The Committee may wish to request the benefit of the views of the Treasury Department on this matter, especially their relationship to revenue policies.

Ample authority for seizure is contained under section 210 of S. 1478, "Administrative inspections and warrants," and accordingly, we oppose the additional seizure authority as unnecessary.

The section providing for citizen suits is a desirable addition to the bill. It is in line with the Administration's position that envronmental citizen's suit provisions conform with the comparable provision contained in the Clean Air Act.

Provision to allow the Administrator to represent the United States in litigation instead of the Attorney General would in our opinion add little to expeditious enforcement. It is also at odds with the long standing Federal policy of placing litigating authority in the Attorney General. Rather than to promote the duplication of such expertise in each of the Federal departments and agencies, we would prefer the sound administrative practice of relying on the Justice Department's established legal experts and resources. This policy has the added benefit of coordinating Federal litigation efforts.

Prohibiting the knowing failure of a consumer to dispose of a chemical substance or its by-products in accordance with instructions is impractical. Enforcement of such a provision would require the allocation of enormous resources. Naturally, these resources would have to be drawn from other socially desirable (and often achievable) activities.

The Administrator would be prohibited as far as possible from conducting in-depth effects testing, so that duplication of industry efforts does not occur. Such a provision is totally inconsistent with sound regulatory practice. Agencies administering regulatory programs should have the widest possible latitude in monitoring the performance of those falling within their purview.

The Office of Management and Budget has advised that there is no objection to the presentation of this report and that enactment of S. 1478, as introduced, would be in accord with the program of the President.

Sincerely yours,

ROBERT FRI,
(for William D. Ruckelshaus, Administrator.)

Mr. FRI. Mr. Chairman, a comprehensive and systematic approach in controlling toxic chemicals does not currently exist under Federal law. Controls over manufacture and distribution apply to only a small percentage of the chemicals that find their way into the environment. Media authorities can be effective in controlling toxic chemicals only to a limited degree, since exposure to these substances comes not only from effluent discharges, but also from a wide variety of consumer products. Clearly a need exists for authority to deal with toxic chemicals from the standpoint of total human and environmental exposure. The administration's Toxic Substances Control Act provides this needed authority.

As a general comment on this authority, let me indicate that the administration's proposal is supplementary to some of the authorities that already exist in the law and is not intended to supersede existing Federal authorities such as product, distribution, and effluent controls. Substances falling within the purview of the Food, Drug, and Cosmetic Act and similar authorities would continue to be regulated under those statutes.

Whenever possible EPA intends to use effluent authorities to control toxic substances. Section 112 of the Clean Air Act provides for Federal hazardous emission standards from new and existing stationary sources. Under the administration's proposed amendments to the Federal Water Pollution Control Act, effluent limitations would be established for toxic substances. Nevertheless some toxic chemicals would either not be sufficiently controlled or would elude control by the traditional media approach. For example, some substances are emitted in such small quantities into the air or water that they can not be readily controlled; for others, monitoring technology is inadequate to detect their presence in a media; while still others only become a problem at the point of disposal.

Currently, we have a task force at work to determine, among other things, the most effective approach in controlling the introduction of mercury into the environment. Some controls have been established over those discharges. Other approaches are being examined including the desirability of using the provisions of the proposed Toxic Substances Control Act.

Against that background, let me describe briefly the three crucial elements contained in the administration's proposal that we feel are necessary to protect our citizens and our heritage from the adverse effects of toxic chemicals:

1. A mechanism for determining what substances are entering the environment.

2. A means of assessing the effects of these substances, including provisions for testing.

3. A way of controlling those substances found to be harmful, particularly in cases that present an imminent hazard to health or the environment.

On the first point, to determine which substances are entering the environment, the Administrator can require manufacturers to provide information on the names, chemical identity, molecular structure, amount produced, usage—to the extent it is known—and a description of byproducts resulting from the chemicals they produce. We feel reporting would be required for all new substances. For chemicals already in use, initially we would require manufacturers to provide information on certain heavy metal and synthetic organic compounds.

Once EPA determines what substances are entering the environment and for what purposes, we would be able to make a preliminary judgment as to which ones or which uses pose a problem. Some will be safe for all known uses while possibly some others will be harmful under any conditions. For still others, we would need additional information, specifically, information derived from effects testing.

The Administrator could require manufacturers of chemicals already in the marketplace to provide him with the results of tests already conducted on such substances. In addition, the Administrator can request comments from the public on any known effects from such chemicals. Authority is provided for the Administrator to conduct such research and monitoring as is necessary to carry out his functions and responsibilites under the act. We believe this provision for research is essential. Unquestionably, additional research needs to be performed on manufactured chemicals found in the environment, particularly research directed at determining long-term, low-level exposure effects.

For new chemicals, the Administrator will be authorized to issue standards for test protocols to be performed by the manufacturer, and the results to be achieved from these tests, for various classes and uses of such substances. We have already started work on the development of test protocols for a select group of heavy metal compounds under our general research and monitoring authorities.

I believe the committee will be interested in knowing that in an effort to increase our effects research capabilities, we recently entered into a joint agreement with the Department of Health, Education, and Welfare to establish the National Center for Toxicological Research. The primary missions of the Center are to conduct chronic effects research and to develop test protocols, both of which are vital elements of an effective toxic substances control program. At the same time, we have broadened the scope and membership of our pesticides advisory committee in order to provide us with advice on issues relating to the use of hazardous materials in the environment.

Now going beyond reporting and effects testing, a prompt and effective means of preventing public and environmental exposure to toxic chemicals needs to exist. Under the administration's proposal, authority is provided to restrict the distribution or use of those sub-

stances found to pose an imminent hazard to public health or the environment as well as substances less critically hazardous.

In cases that present an imminent hazard to public health, the Administrator will be authorized to ask the Attorney General to seek a temporary restraining order or further injunctive relief in the Federal district courts to prevent the use or distribution of the chemical. If relief is granted, it will remain in effect until such a time as the Administrator promulgates regulations for the substance. This will provide a means of achieving speedy public protection while regulations are being promulgated. It will also serve we hope as an incentive to industry to insure the safe uses of the substances it manufactures.

Most chemicals entering the environment, however, are not known to pose an imminent hazard to the public health or environment. A substance may have many socially desirable uses, but a few uses could be dangerous particularly if combined with other chemicals or if allowed to build up in the environment. For such chemicals, the Administrator could propose regulations restricting all or some uses of a substance. Before the regulations become finalized, parties adversely affected by the limitations could request a public hearing.

That is the major thrust of the proposed legislation, Mr. Chairman. In addition, I would like to briefly point out a few other provisions contained in the administration's proposal that will assist us in implementing a comprehensive toxic substances control program.

First, the Council on Environmental Quality is directed to study the development of a standard classification system for toxic chemicals. Such a system will be of value to us in implementing the proposals' reporting provisions.

I might add, Mr. Chairman, I think it is an essential device to help us work our way through this very complicated maze of substances and uses to which those substances are put.

Second, a Toxic Substances Board is created to advise us on the promulgation of test protocol and use restriction regulations. The Board would be composed of members nominated by the National Academy of Sciences.

Third, EPA, in conjunction with other Federal departments and agencies, is directed to assess and evaluate the potential effects of new substances entering the environment. Through the reporting requirements of the proposal and through consultation with other Federal officials we will be able to determine what substances are increasing in usage, and what types of use are increasing so we can get out ahead of this problem instead of merely reacting to it.

Finally, we recognize that before creating a new toxic substances control program, this committee will consider a number of approaches to deal with this emerging problem. EPA is prepared to work with this committee in any way posible in order to achieve an effective and workable program in light of what we know about this problem today.

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

Senator SPONG. Thank you very much, Mr. Fri.

Yesterday we heard from Dr. David Klein of Hope College, Holland, Mich., that as many as 600 pounds per day of mercury may be going into our waters through municipal sewage plants.

Do you find that suggestion credible?

Mr. FRI. It is entirely posible. As you know, Mr. Chairman, we have undertaken a very substantial program over the last year to reduce mercury discharges from industrial waste, and it seems to me that the industrial discharges themselves are of that order of magnitude, without saying whether it is 400 or 600.

In addition, we have in being, as I indicated, a task force which is attempting to determine what all of the sources of mercury are, how they are getting into the environment, and to consider that problem as a whole, and it may very well be that substantial discharges are moving through municipal sewage systems.

Senator SPONG. You have mentioned that some testing and monitoring is taking place.

Is EPA doing any monitoring of municipal sewage plants to determine in fact how great this danger is?

Mr. FRI. Of course, we do a great deal of monitoring of effluents from a variety of sources. Dr. Buckley, who is from our Research and Monitoring Office, might be able to be more specific about that.

Senator SPONG. Dr. Buckley, before you respond to that, would you care to comment on Dr. Klein's statement about the 600 pounds per day of mercury?

Dr. BUCKLEY. Mr. Chairman, I wasn't here yesterday, but I did have the privilege of reading the statement last evening, The arithmetic looks reasonable. I have no data that suggests that it is grossly off in the estimates here.

To my knowledge, we are not monitoring systematically the effluents from the municipal systems. As you recognize, there are a very large number of such systems, and according to Dr. Klein's numbers it would be very low amounts in terms of concentration effluent.

I am not certain whether the methodologies available would be adequate to routinely measure it. So, my answer is, as far as we know, we are not routinely measuring mercury discharges from municipal sources.

Senator SPONG. I will put this question to both of you gentlemen. I have asked you about the municipal treatment plants. Are any steps now being taken to restrict mercury-containing products over which you have jurisdiction?

Yesterday, Dr. Klein touched on a number of these in his testimony.

Mr. FRI. We have relatively little jurisdiction over consumer products as such in EPA. We are, as I say, attempting to determine what all of the sources of mercury in the environment are, so as to develop a strategy which would get at the problem in such a way as to solve it. I think the authorities contained under this proposal, the Toxic Substances Control Act, will go a long way to give us the tools necessary to get at some of those problems.

John, would you comment on where the task force is at this point?

Dr. BUCKLEY. There is a fairly extensive series of uses of mercury that we have thought about. Certainly we have taken action on mercury-containing pesticides. There are a number of uses of mercury which are not subject to our control under existing authorities, and among those that were mentioned yesterday are mercury batteries, for example.

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I would like to point out that if this Toxic Substances Act were in existence, it doesn't necessarily imply that one would prohibit the use of mercury in batteries, but one certainly might look for ways in which one could recycle this or prevent it from eventually reaching the environment.

The other point I should have made earlier with regard to municipal waste is that the normal sewage treatment process does not in fact take any substantial amount of mercury from the effluents. It is designed through a bacterial system to remove organic materials, to break these down, but mercury is not subject to being broken down, and, therefore, it is not removed in any substantial amount in the treatment process.

Senator SPONG. EPA does have jurisdiction over paint, pesticides, glue, floor waxes, lumber and textiles; is that correct?

Dr. BUCKLEY. It has jurisdiction over these when the mercury is used as a fungicide, or algicide, or some kind of -cide.

On the other hand, mercury is also used in paint, as I understand it, as a preservative which is to extend the shelf life of some of these paints. I believe our authority does not extend to that particular kind of usage.

Mr. FRI. It extends, of course, to the extent mercury is used in the production process and may be discharged either into water or into the air. We have authority to control those sorts of discharges.

Senator SPONG. In your statement you cite some categories of substances for which controls under this legislation are needed to fill gaps in the air and water pollution control laws.

Would you cite some specific examples of substances which would fall into these categories?

Mr. FRI. I can cite some kinds of things that one might want to look at under this act. Perhaps Dr. Buckley can cite some others. The kind of problems which we wish to come to grip with, for example, is the question of, let's say, asbestos in building construction. There are controls that relate to the application of asbestos through occupational health and safety standards, and if the asbestos installation is properly applied, it shouldn't be any problem during the life of the building. However, when you knock the building down, you get some asbestos into the air.

Our query then is to what extent is that a hazard, and assuming that it is a significant hazard, how does one control it? Does one control the methods of disposal in how you knock the building down, or does one say maybe this ought to go in in the first place?

We presently really have no authorities if we were to determine, and of course we have not, that asbestos should not be used in buildings because its ultimate disposal would create a significant hazard to health or to the environment. A similar kind of situation might be involved in fertilizer runoff. If there are no pesticidal claims made for a fertilizer, we don't have any direct control over it. But a fertilizer may run off into the water. There was an instance, as I recall, in the Potomac Basin in the winter of 1970–71 which resulted in some contamination of water supply in Montgomery County, which was pretty much innocuous from the public health standpoint, but it smelled pretty bad and it affected the taste.

There are certain options in controlling fertilizer runoffs of this character. One would be through the water legislation to control the

way it is applied to control the runoff itself. It may prove, however, in certain basins that that is a very difficult thing to do and certain ingredients of fertilizer, that have adverse impacts on the health or environment, could best be controlled only by preventing the use of that substance for that purpose at the outset.

Those are two kinds of examples I think which are representative of control problems that we can face up to. We now really neither have the mechanism to collect information nor to test for health effects nor the full range of options available to us that we need to control the introduction of these kinds of materials into the environment.

Senator SPONG. Do you see the legislation before us as another enforcement tool on top of the existing air and water legislation?

Mr. FRI. It is complementary to much of the legislation that we already have. If it is, for example, practical to control industrial discharges of mercury in the production process, to control the discharges of mercury from the production process into the water—and we have had a pretty good record in doing that, we have been able to achieve more than 90-percent reduction, as high as 98-percent reduction in some industries—then that is an authority that perhaps is easier to use than simply banning mercury from the production process.

So, it may be wise in that case to use the water authority or the air authority.

In the case of pesticides, there are a number of chemical substances which have uses both as a so-called economic poison which fall under the pesticide legislation, FIFRA, but also have uses as noneconomic poison to which the FIFRA does not apply, and this legislation would help to fill that gap.

It is complementary to the legislation that we have, and I think it is an important device in helping us to step back and look at the total environmental cycle of a particular substance to determine where is the best place to step into that cycle to prevent the discharge of that substance into the environment and to take appropriate action.

So, in that sense, I think it is complementary to our existing media and product authorities.

Senator SPONG. There are certain instances where it would be easier to monitor the process than to monitor the discharge?

Mr. FRI. Yes, I would think that is right. What you are saying is there are cases where it would be more effective to say, let's not use it at all, rather than to say, let's see if we can't take it out of the effluent. There may very well be cases of that type.

Senator SPONG. One difference between the administration's bill and the amendment that has been offered is that under the amendment, EPA would be empowered to initiate legal actions directly without going through the Justice Department.

Would you be opposed to conferring that authority on EPA?

Mr. FRI. Well, we have taken the stand fairly consistently along with the rest of the administration that good administrative practice is to have the Department of Justice undertake litigation on behalf of whatever agency of the government needs it. We are confident that we are not going to have a problem, in such cases of an imminent hazard, of waking up a U.S. attorney and getting him into court.

I don't think this will confer any disadvantage, and I think it confers the advantage administratively of an orderly procedure, with a

U.S. attorney acting in a court with which he is familiar, and we support the administration's position on that.

Senator SPONG. You dont' foresee any undue delays?

Mr. FRI. No, sir.

Senator SPONG. Yesterday Chairman Train testified that while the administration was amenable to a citizens suit provision, the right of action authorized by the amendment was not acceptable.

Can you comment on the nature of any objection that the EPA has?

Mr. FRI. I have not analyzed the details of the citizens suit provision in this particular amendment, though I must admit it looks relatively familiar in most respects, and we have in general supported the notion of citizens suits in environmental legislation and I think would continue in principle to support that. We would be happy to work with the committee to determine if the appropriate provision could be worked out in the light of this bill.

Senator SPONG. This section is very similar to the citizen suits provisions of the air pollution legislation that was passed last year. I see here that the report of EPA dated August 3, 1971 says:

> The section providing for citizens suit is a desirable addition to the bill. It is in line with the administration's position that environmental citizens suits provsions conform with the comparable provision contained in the Clean Air Act.

So, I take it that EPA is not on all fours with Mr. Train insofar as the citizens suits are concerned.

Mr. FRI. There is some appearance of that.

Senator SPONG. Thank you very much.

Mr. FRI. Although in fairness to Chairman Train, I think I should say that as I understand his testimony yesterday he pointed out that there are far fewer mandatory actions under the Toxic Substances Act than we have here. There is good reason for that. In the clean air situation, we know pretty well what we want to do, and there is a very tight timetable for getting things done under that act, and those timetables must be enforced and we are working hard to enforce them, and the assistance of citizens in enforcing them is welcome.

Under this proposal, we are talking about a program which is much newer in character. We do not have the several years of experience with this program that we had before the passage of the Clean Air Act Amendments of 1970, and I think there is a significant question of how one applies a citizens suit provision here, where there are far fewer deadline milestone-type actions, in such a way as to ventilate the process to citizens action, and at the same time, avoid capricious action which would simply clog up the courts and keep Bill Ruckelshaus in court most of the time instead of running the agency.

So, I think there is a substantial question of how this provision should be applied in such a bill, and I think it requires careful thought.

Senator SPONG. In your statement, you mention the fact that controls over manufacture and distribution apply to only a small percentage of the chemicals that find their way into the environment. What specific chemicals are you referring to, and could you give us a brief description of the controls that do exist over the manufacture of these chemicals?

Mr. FRI. John, can you respond to that? I don't have a readymade list.

Dr. BUCKLEY. I don't have a list either, Mr. Chairman, but clearly the Pesticide Act, FIFRA, does provide controls over the introduction of those materials in the environment. The same thing occurs with the Food, Drug, and Cosmetic Act as it applies not only within our jurisdiction but also elsewhere. But by and large, our controls on these are only through the effluents.

Mr. FRI. There is something like 900 chemicals that are, in effect, subject to control under FIFRA. Many of those 900 substances have other uses than in pesticides.

Senator SPONG. Are these controls similar in nature to what might be embodied in a restriction on use or distribution under either S. 1478 or the amendment?

Mr. FRI. The existing controls over manufacture and distribution?

Senator SPONG. Yes.

Mr. FRI. It is my understanding, and perhaps we should provide a more detailed answer for the record, but it is my understanding that the substance of these controls is substantially over the end product, so that in the case of pesticides we register or refuse to register a particular product. If we suspend that product, we can get into the question of how it is distributed or not distributed.

Under the administration's proposed pesticide bill, we would have even more finely tuned controls over how the product is not only manufactured and distributed but applied as well.

Dr. BUCKLEY. It is true we do not have authority under the existing FIFRA for control over manufacturing.

Senator SPONG. You do not?

Dr. BUCKLEY. We do not under the existing law.

Senator SPONG. We would appreciate your adding to your response to this last question for the record in any way that you might wish.

(The information follows:)

Authority in the proposed bill would be used to regulate toxic substances (not consumer hazards, except as they are exerted through the environment) that can be more efficiently or effectively controlled through regulation of use rather than through regulation of ambient environmental levels. Regulation of use has the added advantage of being preventive rather than curative.

Substances to be considered for control would include such characteristics as persistence, and toxicity—acute and chronic—to man and other important living organisms. The kinds of substances that might be regulated under the proposed bill include:

Substances that occur as ingredients or impurities in manufactured products that are likely to reach the environment during the course of use of the product or at the time of disposal of the product. Examples include "dioxin" contaminants in products other than pesticides and arsenic in detergents.

Substances that are so inherently environmentally damaging that extreme precautions are required to prevent their reaching the environment. Some examples in this category are asbestos inhalation at the time of building demolition and PCB's as heat transformer agents in transformers.

Substances that may be deliberately applied to the environment to achieve a particular purpose, but that may have unwanted side effects either where they are applied or in other parts of the environment to which they have been transported. An example in this category would be fertilizers.

Substances that are used for a variety of purposes, only some of which are covered by existing laws. Examples include mirex as a fire retardant and mercury as a paint stabilizer.

Finally, substances that are difficult to remove in effluent treatments, either because of their inherent stability or because they occur in very small quantities.

The following chart depicts to the extent toxic substances are currently controlled by Federal statutes.

FEDERAL LAWS AND REGULATIONS CONCERNING HANDLING, TRANSPORTATION AND DISPOSAL OF TOXIC AND HAZARDOUS MATERIALS

Law	Department administering	Coverage
Atomic Energy Act (42 U.S.C. 2011 et seq.). Regulations: 10CFR 1 et seq.	AEC	Authorizes the Atomic Energy Commission to set standards regulating the possession and use of nuclear materials including the granting of licenses; also authorizes AEC to cooperate with the States.
Clean Air Act (42 U.S.C. 2011 et seq.). Regulations: 42CFR pts. 75, 76, 77, and 81.	EPA	Authorizes the establishment of national air quality standards, performance standards for new and modified stationary sources, hazardous emission standards for new and existing stationary sources, emission standards for new motor vehicles and aircraft emission standards.
Federal Aviation Act of 1958 (49 U.S.C. 1421–1430, 1472H). Regulations: 14CFR pt. 103.	DOT	Regulates the transportation of hazardous materials by air.
Federal Hazardous Substances Act (15 U.S.C. 1261–1273). Regulations: 21 CFR, pt. 191, subch. D.	HEW	Requires precautionary labeling for products defined as hazardous in containers intended as suitable for household use; authorizes the banning of toys or artic'es where a child may secure access to the hazardous substances and provides for the banning of a hazardous substance where necessary for health and safety.
Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 135–135h). Regulations: 7CFR pt. 362.	EPA	Requires registration of economic poisons (pesticides) with the Administrator, EPA; requires submission of proof of safety and efficacy of product and label to be used; also authorizes Secretary to establish specific coloration requirements for certain products.
Federal Water Pollution Control Act (33 U.S.C. 466–466n) as amended by 84 Stat. 91. Regulations: 18CFR pts. 601, 602, 606, 607, and 620.	EPA	Provides for Federal-State standards covering the quality of interstate and coastal waters. Recently, the 1899 Refuse Act, which requires Federal permit to discharge effluents other than municipal sewage, has been used to maintain and improve water quality.
Federal Drug and Cosmetic Act (21 U.S.C. 301 et seq.).	HEW	Authorizes the regulation of food labeling, food additives, drugs, some medical devices, and cosmetics.
Hazardous Cargo Act (46 U.S.C. 170 (49 U.S.C. 1421–1430, 1472H). Regulations: 33CFR pt. 126, 46CFR pts. 38, 39.	DOT	Regulates the transportation of hazardous materials by air.
Nonmailable Material (18 U.S.C. 1716). Regulations: Post Office Services Transmittal Letter 113, June 29, 1962, pts. 124, 125.	Post Office	Makes nonmailable certain poisons and other materials and provides for the regulation of certain permitted articles by the Postmaster General.
Occupational Health and Safety Act of 1970.	HEW/Labor	Labor sets standards based upon criteria developed by HEW. This statute preempts occupational safety standards promulgated under such statutes as the Welsh-Heeley Act, Construction Safety Act, and the Longshoremen and Harbor Workers' Compensation Act.
Protection of Navigable Waters (33 U.S.C. 407). Regulations: 19 CFR pt. 23, S. 23, 32.	Army	Makes it unlawful to deposit from a ship or from the shore any refuse matter into any navigable water of the United States, other than that flowing from streets and sewers.
Transportation of Explosives Act (18 U.S.C. 831–935). Regulations: 49CFR pts. 171–179, pts. 290–297.	DOT	Regulates the transportation of hazardous materials by land and by water.
Armed Service Explosives Safety Board (10 U.S.C. 172).	DOD	Establishes board to advise the Secretary of Defense on Safety matters.

Senator SPONG. Thank you very much, gentlemen, for your testimony.

Dr. Robert Risebrough, we are very pleased to have you with us this morning. We will accept your statement for the record in its entirety, and you may testify from it as you wish.

STATEMENT OF ROBERT RISEBROUGH, ASSOCIATE RESEARCH ECOLOGIST, BODEGA MARINE LABORATORY, UNIVERSITY OF CALIFORNIA

Mr. RISEBROUGH. Thank you, Chairman Spong and members of the subcommittee.

For several years I and a number of my colleagues have been studying a group of chemicals called polychlorinated biphenyls, one of the chemicals that might be regulated by the proposed bill. I would like,

therefore, to outline briefly to you some of the properties of these chemicals and some of their possible effects upon the environment and I would also like to discuss some priorities in research.

Briefly, PCB's are very much like the DDT compounds in their chemical properties. They are very resistant to degradation more so than the DDT compounds. In fact, it is this property that makes them useful in many industrial processes.

In the past, they have been widely used as additives to sealants and plastics, even to some insecticides at times, but their major use has been as insulating fluids in electrical equipment. Whenever there are high voltages that might constitute a fire hazard, it is desirable to add a substance that will not burn.

Their other major use, and continues to be, is as heat exchange fluids in factory equipment. These latter two uses, that as an insulating fluid and, as a heat exchange fluid, are considered to be closed systems in that under careful use PCB would not be released into the environment.

Now, when the studies were published of results obtained first in Sweden and then in other parts of Europe and then in North America that PCB was very widespread and a locally abundant environmental pollutant, the Monsanto Co., which is the sole manufacturer here in North America, recognized the ecological hazard of the substances and instituted a number of voluntary controls that they hoped would cut down on all uses that were not in closed systems.

They recommended, for example, that all use as plasticizers be suspended. This was done last year when they also constructed a high-temperature incinerator unit to burn waste PCB.

Relatively little research has been done about their effects upon man or upon other organisms. Earlier workers in factories making PCB developed a severe skin disease, "chloracne," and this disease was also common among workers in factories making other chlorinated organic compounds. This phenomenon was studied extensively in Germany, and the conclusion that emerged was that there were contaminants in the preparation that turned out to be the chlorinated dioxins, which are also contaminants in the herbicide 2,4,5-T.

In the course of those studies, it was discovered that another group of compounds which are chlorinated dibenzofurans were also potent introducers of this skin disease and were very poisonous. In my written report, I have given the structures of PCB, chlorinated dibenzofuran and chlorinated dioxin.

Two years ago in Japan a number of people came down with a severe skin disease. It was traced to a PCB leaking out of a heat exchange fluid in a factory making rice oil which is used for cooking in Japan.

There are many studies published from this and one of these reported that the oil contained approximately 200 p.p.m. PCB, and that symptoms were detected in families as little as 1 month after consumption, and from a rough calculation one can conclude from their figures that each person might have consumed a half liter of cooking oil over a month and that this amount of PCB was sufficient to produce the minimum effect.

From this we can make some rough calculations and then figure out how much fish or poultry we would have to eat to get the same

amount of PCB which turns out to be on the order of a tenth of a gram. However, there is a very serious uncertainty here because we do not know whether the toxicity of the PCB comes from the PCB itself or from small amounts of these contaminants present in the preparation.

One of the desirable features of the proposed bill might give us some data on the amounts of contaminants in a preparation and hopefully with these we would be able to start studies that might indicate whether these highly poisonous compounds are formed in the environment as well.

Perhaps the most conspicuous environmental effect that has been documented is the thin egg shell phenomenon, something that started in the late 1940's. When the PCB's were first discovered it seemed that this might be one of the possible causes of this phenomenon. A number of studies have been carried out in several laboratories and the consensus is they do not contribute to this particular phenomenon.

Late last year studies were published from Holland on the toxicity of PCB, and these workers compared three PCB preparations that had virtually the same amount of chlorine. Therefore, they should nave been exactly the same with respect to toxicity biological effects. In fact, they were very different. The French one was much more toxic than the German which in turn was much more toxic than the American.

These data suggest to us that the real toxicity problem of PCB comes from these contaminants. For example, the Bureau of Sports Fisheries and Wildlife has carried on a number of studies on the reproductive effect of PCB on several species of birds. In general, the effects are not very great. However, a poultry farmer recently found that his flocks were hatching fewer chicks than usual and this was traced to the PCB that was a contaminant in the fish meal which in turn had received the PCB's from the heat exchange fluid in the factory.

At first these results would appear to be inconsistent because the chicken suffered the reproductive effects from the PCB in the heat exchange fluid and the birds at the wildlife center showed no effects with the test samples of PCB. Again this inconsistency could be explained if the real effects were coming from the contaminants.

Briefly, the chief research problem that we as pollution ecologists face and which we think is the most serious is what will happen in the future given the present amounts of PCB now on the land and the amounts added each year. We would like to be able to construct an equation that would tell us how fast PCB will accumulate.

Already in the Northeast, around Long Island Sound, the levels are quite high. If they were to go up by a factor of 10, then we could say that the fishing in that area would be wiped out.

We assume that most of the PCB that has been in this country is still on the land and it is constantly reaching into the atmosphere or into municipal sewage or the rivers and gradually entering the sea. We cannot estimate what proportion of this PCB will enter the sea. If we are to seriously protect the oceans as a food source, we badly need to know certain kinds of data, production figures of PCB and good data on the relative amounts used for one thing or another, and in this

way we would be able to come up with some kind of prediction for the future.

We know that much PCB is getting into the environment through municipal sewage, probably the sum total of leaks from heat exchange equipment and various manufacturing processes in which PCB has been used.

That concludes my oral presentation.

Senator SPONG. Thank you very much, Doctor.

That buzz means they are having a rollcall on the floor. I am going to recess for about 10 minutes while I vote, and then I would like to ask you some questions.

Thank you.

(Recess.)

Senator SPONG. Let the committee come to order.

Doctor, your statement is one which should give all of us pause for concern and one which argues strongly for legislation of the kind the committee is presently considering. Before responding to your testimony may I ask your reaction to some data received late yesterday regarding the presence of PCB's in some Alabama fish?

Mr. Sam Spencer, the assistant chief of fisheries of the Alabama Department of Conservation, has written the following letter to the subcommittee. I am going to have this letter admitted to the record along with a telegram from Mr. Spencer authorizing our doing this.

I hope the fish samples we sent you will give some of the information you need. Enclosed you will find copies of the laboratory reports of fish samples collected in 1970 from some areas in Alabama. I am sending you copies of some of the higher PCB and insecticide results. The PCB results are as high as 365 parts per million, 72 times the FDA tolerance limits. All these results are on an edible portion basis which is much less than a fat basis.

You ask if FDA is cooperating with the states. I think they are cooperating to the extent they have to. We assisted them in collecting fish samples from Choccolocco Creek. They later sent us copies of the mercury analysis which were not high enough to be greatly concerned about.

I later wrote FDA asking for the results of their PCB analysis of these samples because I heard a rumor that they were very high. FDA then sent me the results, a copy of which I have attached. These results indicate PCB levels up to 277 parts per million in a catfish. Yet FDA apparently did not intend to advise us of this contamination problem.

You will find enclosed copies of several letters between FDA and this office concerning pesticide and heavy metal contamination. As you can see, mercury is the only heavy metal they have established tolerance limits for.

I hope this information will be helpful to you. If possible, I would prefer to remain anonymous.

He has left that cloud of anonymity.

However, I feel the consumers of fish or any other food product are entitled to know what they are eating. If this letter or the enclosed material is necessary to ensure the American fish consumer of a safe, wholesome product, please feel free to use it.

He has further related to us, Doctor, that the average concentration for these fish was about 90 parts per million. Additionally, he has told us that although the tests revealed in these letters were conducted approximately a year ago, no one has informed the public of the results.

Can you comment both on the danger involved here and on the propriety of failing to disclose these levels to the public?

Mr. RISEBROUGH. The only documented case in which PCB has produced an effect in people who have ingested the PCB's is this instance in Japan with the disease by the name of yusho.

To go back to the amount of PCB that they ingested and in my written testimony I calculated that if a person were eating fish containing 5 parts per million of PCB, how much fish, or poultry, would he eat until he had ingested the same amount. I think I came out with 45 pounds of fish. Ninety parts per million is 18 times as high. So we divide 45 by 18 to get something like 2½ pounds of fish.

So if the toxicity of the PCB in the fish in Alabama were the same as the toxicity of the PCB in Japan, then we might start seeing the same symptoms if one ate only 2½ pounds. Again the real question is the toxicity coming from the PCB itself or from very small amounts of highly poisonous contaminants. This we just cannot say until the tests have been done.

Now, what has in fact happened here is that huge amounts of this chemical have been released into the environment before any tests were made at all, and only within the last year or perhaps the last 2 years have both public and private agencies begun toxicity studies. They are far from complete. So I would certainly not advise eating those fish.

As for the propriety, those of us who are working in the universities, of course, have to get out our results and we work on a principle of free exchange of information, and we have many complaints about Government agencies who for some reason hesitate to make data such as this public.

Senator SPONG. Well, I have grave questions about there not making the data public, and it has been more than a year since these results have been known to those responsible for the protection of public health. We are going to be writing both the FDA and the Alabama State Health Department to inquire further into the facts of this matter and to request immediate action to remedy what appears to be a very dangerous situation.

You mentioned the situation in Japan. How much consumption there caused "chloracne?"

Mr. RISEBROUGH. Unfortunately the papers were in Japanese, and I was only able to read the English summaries. The leakage occurred one day in February of 1968, and the first cases reported were in March, and then additional ones were reported throughout the summer. It was in rice oil, the oil used for cooking.

One paper estimated that a family of four consumed about 2 liters in a month. That would be half a quart per person approximately over a month which contained about 200 parts per million of the PCB's.

Senator SPONG. What would that be in grams per month?

Mr. RISEBROUGH. That would be about a tenth of a gram.

Senator SPONG. In your statement you mention PCB in sewage. It is my understanding that the Monsanto Co. has placed restrictions on the sale of PCB to prevent its use in other than closed systems. If this is the case, how can you account for the presence of PCB in sewer outfalls?

Mr. RISEBROUGH. Well, there are at least three well-documented cases now of leakage from so-called closed systems. The first is the one in Japan. The second is the one that was reported in the press recently

about leakage from a closed system in a fishmeal factory, contaminating the fishmeal wtih PCB. The third well-documented case occurred in Florida in the vicinity of the Environmental Protection Agency laboratory at Gulf Breeze. PCB contaminated the local estuary and it was traced again to a closed system heat exchange unit in a factory.

So I think even if the system is designed as closed, there will at least with present equipment be a certain amount of leakage. At the moment we just cannot estimate what proportion will leak.

Then, I am sure that some of the PCB is still being used for the processes which it has been used in the past. For example, PCB has been used to impregnate cardboard to make it more water resistant. There have been instances of PCB getting into food from the cardboard.

Now, Monsanto has been doing this voluntarily. If one of the companies that has been using PCB, for example, as a component of marine paint could not get it from Monsanto, they could get it from Japan or from France, anywhere else in the world at the moment, and there is nothing to prevent them from doing so. I understand that Monsanto is concerned about this.

Then, too, such a vast amount of PCB has been used in the past to manufacture all kinds of equipment. We have a throw-away society, and everything we consume eventually becomes waste of some kind. So over many years all that PCB will enter the environment in some way or another. So I am sure it will be recorded in sewage waters in many years to come even though use for it has stopped right now.

Senator SPONG. A major difference between the administration bill and the amendment before us is the treatment of existing chemicals. Under the administration bill the administrator could restrict the use of an existing substance such as PCB but only after he has sufficient information to justify that restriction in court. There is no provision for systematically gathering data.

Under the amendment the administrator could require testing by the manufacturer if he has reason to believe an unreasonable hazard exists. In spite of all the publicity surrounding PCB, I gather that there is a great deal that we still do not know. Would you think a mechanism to require testing of an existing chemical would be helpful in the case of PCB?

Mr. RISEBROUGH. In my opinion, the original version is much too weak, it really would not accomplish that much. I say yes, we know very little still about PCB's. There are very few toxicity data available. We have no idea of the concentrations of the dibenzofurans contaminants in the PCB in this country. There are two published studies about these contaminants in PCB preparations in Europe.

We have no idea whether some forms of PCB have more of these contaminants than others. We have no idea whether these highly poisonous compounds can be formed from PCB by some biological or chemical process in the environment. This is quite possible.

So in addition to testing just the original, I would say we also need to consider what might be formed from this once it is discarded as a waste material in the environment.

In the case of DDT, for example, there were many studies done with the original DDT compound that was used as an insecticide, and it turned out that an environmental derivative of this was really the

one that was causing the damage to a number of species of birds. Tests were not done on this for many, many years. So I think some kind of at least recognition of possible toxic breakdown in products and testing thereof is highly desirable.

Senator SPONG. In your statement you indicate that the public health problems of PCB might be caused by a contaminant similar to a contaminant of the herbicide 2,4,5-T. Would you briefly describe what we now know of this contaminant? Do we know how much of the contaminant is present in the PCB used in this country, and, if so, are there industry controls to limit the quantities of the contaminant in PCB?

Mr. RISEBROUGH. The contaminant in the herbicide 2,4,5-T is chlorinated dioxin, which consists of a group of compounds. They are among the most poisonous substances ever known. The reason why they are so poisonous is they apparently have a flat structure that fits into the structure of the gene and interferes with its reproduction.

Now, the same contaminants are present in preparations of chlorinated phenols from which the herbicides are derived. For a number of years people were aware of a disease in chickens called the chick edema disease, and a number of studies were done by the Food and Drug Administration to find out what factors were causing this disease. So parallel studies were made on the causes of the chick edema disease and the cause of "chloracne," the skin disease observed in workers in factories manufacturing the organic compounds. It was only recently that both groups converged and found they were studying the same things, chlorinated dioxins.

The literature in this field was very adequately reviewed in the course of hearings held by the subcommittee in April of last year, and many of the pertinent papers in the field were published in that volume which has proved a blessing for those of us working in the field.

The contaminants discovered in PCB are very closely related. They differ only by the lack of an oxygen atom. They are not quite as poisonous as the dioxins, but nevertheless they are still among the most poisonous compounds known.

Now, I mentioned before that there are estimates of the concentrations of these compounds in only one paper of two preparations made in Europe. The American preparation that was considered in that study had lower amounts that were not detectable under this system. To my knowledge, they have not been measured in PCB preparations made in this country. I am sure the Monsanto Co. has considerable data on this matter.

What alerted public health people in the thirties and especially in the Second World War when vast amounts of this began to be made was the skin disease observed in the workers. The question is whether or not this was caused by the PCB or by the highly toxic contaminants. I am sure studies have been made that are not public that would cast some light on this. The people at Monsanto are very professional. I am sure they are very well aware of developments in this field.

Senator SPONG. Thank you very much, Dr. Risebrough. We want to thank you for your testimony and appearance here this morning.

(The statement follows:)

STATEMENT OF ROBERT RISEBROUGH

My name is Robert Risebrough. Since 1965 I have been employed by the Institute of Marine Resources at the University of California, Berkeley. On July 1, 1971 I joined the staff of the Bodega Marine Laboratory of the University of California, where I am an Associate Research Ecologist. With colleagues from several universities and other scientific institutions I have carried out research in the field of environmental pollution, primarily with the chlorinated hydrocarbons. These substances include several of the insecticides and the polychlorinated biphenyls. With my colleagues I have prepared approximately forty technical and semitechnical papers in this field.

In 1970 I was a member of the panel on Monitoring Persistent Pesticides in the Marine Environment of the Committee on Oceanography of the National Academy of Sciences. I also served as chairman of the Committee on Halogenated Hydrocarbons of the Seminar on Methods of Detection, Measurement and Monitoring of Pollutants in the Marine Environment, organized by the Food and Agriculture Organization of the United Nations in Rome, Italy. Currently I am a member of the panel on Marine Aquatic Life and Wildlife of the Committee on Water Quality Criteria of the National Academy of Sciences.

I am appearing before this committee as a scientist and a private individual. I welcome the opportunity to discuss before this committee the polychlorinated biphenyls, a class of industrial chemicals that have become widespread pollutants in the global environment. The polychlorinated biphenyls, or PCB, are among the toxic substances that would be regulated under the provisions of Senate Bill 1478. I shall therefore try to review briefly our current knowledge of the distribution and environmental effects of PCB. Scientific statements are documented by reference to the original research. The interpretation of these studies and all opinions expressed are necessarily my own, and not those of any public or private organization.

CHEMISTRY OF THE POLYCHLORINATED BIPHENYLS

The structure of chlorinated biphenyls is shown in Figure 1. Chlorine atoms may occupy any combination of the positions of the biphenyl molecule. Many such combinations containing one to 10 chlorine atoms in the various positions are therefore possible. PCB consists therefore of a mixture of chemical compounds. Commercial preparations in the United States, where the Monsanto Company is the only manufacturer, are designed by the tradename "Aroclor" followed by a number that indicates the approximate chlorine composition of the preparation. Thus, "Aroclor 1254" contains approximately 54% chlorine by weight.

PCB is frequently compared to the DDT compounds. Like them it is very insoluble in water, but highly soluble in oils, fats and non-polar liquids. It is highly resistent to degradation by heat, by the biological processes that degrade most chemicals released into the environment, and to chemical attack. These properties have made them useful in many industrial applications.

INDUSTRIAL USE OF PCB

PCB has been used as an additive to sealants, rubber, paints, plastics, adhesives, printing inks, insecticides, and many other commodities. The major uses, however, have been as insulating fluids in electrical equipment and as heat transfer fluids. These are considered to be "closed" systems.

Following the discoveries first made in Sweden (1) and later in other parts of Europe (2, 3) and in North America (4) that PCB had become a widespread and locally abundant environmental pollutant, the Monsanto Company recognized the ecological hazard of PCB, and sought to restrict all usage to that of closed systems. The sale of PCB for plasticizer use was discontinued on August 30, 1970. The industrial and hydraulic fluids manufactured by Monsanto were reformulated to exclude PCB, and a high temperature incineration unit was built by Monsanto at Sauget, Illinois, to destroy waste PCB (5).

OCCUPATIONAL EXPOSURE TO PCB

Occupational exposure to PCB has in the past produced a high incidence of chloracne, a severe skin disease, among factory workers. Although known as "chloracne" the skin lesions are not produced by chlorine gas, nor by inorganic

compounds of chlorine. The disease has also been prevalent among workers in factories manufacturing chlorinated napthalenes, chlorinated phenols, and compounds derived from them (6). The literature in this field was very adequately reviewed during the hearings held by this committee in April of 1970 which dealt with the effects of 2,4,5–T on man and the environment. Several of the most important papers in the field were reprinted in the Record of those hearings. The production of chloracne by chlorinated compounds among industrial workers has been extensively studied in Germany. The most potent inducers of chloracne were found to be the chlorinated dibenzodioxins. The chlorinated dibenzofurans were also shown to be potent inducers of chloracne. The structures of both the chlorinated dibenzodioxins and the chlorinated dibenzofurans are shown in Figure 1. Both groups of compounds are highly poisonous (7,8). Very small amounts of the chlorinated dibenzodioxins will produce embryonic defects in chicks, as Dr. Verrett described to this committee last year (9).

The chlorinated dibenzofurans have recently been discovered to be contaminants in some PCB preparations. The toxicity of three PCB preparations containing approximately the same amounts of chlorine was found to vary widely and to be correlated with very small amounts of the benzofurans present as contaminants. The French preparation was found to be more poisonous than the one from Germany, while the American preparation possessed the lowest toxicity when all three were fed to chickens (10,11). The contaminant in the French preparation was estimated to be present in the order of 20 ppm of the PCB preparation (11). So poisonous are the dibenzofurans that the Dutch scientists studying the relative toxicity of various PCB preparations did not wish to work with the pure dibenzofurans.

From the literature it is not clear whether chloracne conditions produced in the past by PCB preparations have been caused by the PCB or by very minute amounts of the contaminants. The Monsanto Company no doubt possesses considerable data on this subject.

A CASE OF NON-OCCUPATIONAL EXPOSURE TO PCB

In 1968 an outbreak of a peculiar skin disease occurred in Japan. More than 300 people were affected. Exhaustive studies were made by a number of Japanese scientists and an extensive series of papers describing their findings has been published. Unfortunately they are in Japanese, but each has an English summary. Several of these are attached as part of my testimony. The results may be summarized briefly. The disease was traced to a shipment of commercial rice oil used for cooking that had been contaminated with PCB used as a heat transfer fluid in the manufacturing equipment. Nine of the women affected were pregnant. Two of the babies were dead at birth, and all showed symptoms of chlorobiphenyl poisoning. None, however, possessed birth defects. Feeding of the oil to mice and monkeys produced comparable symptoms. One of the studies reported that the concentration of PCB in the rice oil was about 200 ppm, and that the amount of oil consumed by a family of four for over a month was in the order of 1.8 liters. The first symptoms appeared in March 1968 and it had been determined that the contamination occured on or about February 5, 1968. It is of interest to make a very rough calculation to determine how much fish or poultry contaminated with PCB at a level of 5 ppm in the edible flesh a person would have to eat to ingest a comparable amount of PCB. On the assumption that half a liter of cooking oil was sufficient to produce the symptoms, .45 pounds containing 5 ppm of PCB of contaminated fish or poultry might produce the same effect.

It is not clear, however, whether the symptoms produced by consuming the contaminated cooking oil in Japan were in fact produced by the PCB or by very small amounts of the contaminants mentioned above. Studies to determine this should clearly receive a high priority.

It is also of interest to compare the levels found in the fat of the people affected with the few values so far obtained for PCB concentrations in human fat in the United States. Biopsy of samples of subcutaneous fat in the affected Japanese ranged from 13 to 76 ppm. In our laboratory we have measured PCB in nine samples of human milk from Berkeley, California, and 7 samples from nursing mothers in the Los Angeles area. Concentrations in the fat portion of the milk averaged 2.6 ppm in the Berkeley samples, and 2.1 in the Los Angeles samples. Minute amounts were also detected in cows' milk. Confirmation of the occur-

rence of PCB in human fat by mass spectrometry has recently been reported by research workers of the Food and Drug Administration (12).

BIOLOGICAL EFFECTS OF PCB

An earlier study sponsored by the Monsanto Company of the toxicity of the vapors of two PCB preparations, Aroclor 1242 and Aroclor 1254 (13) demonstrated no injury to several animals at concentrations in the air of Aroclor 1242 below 8.6 micrograms per liter. Reversible degenerative changes in some of the viscera were produced by comparable concentrations of Aroclor 1254. A study reported by the United States Public Health Service in 1944 (14) showed that liver and skin damage was produced in guinea pigs, rats and rabbits exposed to Aroclor 1242 by subcutaneous injections and applications to the skin. The skin lesions were comparable to those found in the chloracne condition in man.

Three studies have recently reported data on the toxicity of PCB to birds. A British study carried out at the Monks Wood Experimental Station (15) found that Aroclor 1254 had only one-thirteenth the toxicity of DDT to Bengalese finches. The Bureau of Sport Fisheries and Wildlife at the Patuxent Wildlife Research Center has reported toxicity data of 6 PCB preparations to mallard ducks, pheasants, bobwhite quail and Japanese quail. In general, the insecticide dieldrin was approximately 4 times as toxic as any of the PCB preparations, and DDT was approximately 4 times as toxic. Toxicity tended to increase with increasing chlorine content of the PCB (16). A Dutch study (10) found, however, that toxicity of PCB preparations containing the same amount of chlorine varied widely because of different concentrations of chlorinated dibenzofurans present as contaminants. Until the amounts of these contaminants have been measured in each PCB preparation, it is not possible to determine how much toxicity derives from PCB and how much from the contaminants. The recent studies of the Monsanto Company, which I have not yet had the opportunity to examine will no doubt clarify this point.

PCB, like most other chlorinated hydrocarbons, and like many chemicals foreign to the animal body have the capacity to increase the activity of certain liver enzymes (4, 17). This is an adaptive response since the enzymes permit the body to eliminate foreign compounds which are frequently harmful. The more highly chlorinated of the PCB preparations, however, appear to induce the sythesis of these enzymes and the associated supporting material known as the smooth endoplasmic reticulum without being degraded themselves. Some of the naturally occurring compounds in the body, including the sex hormones and other steroids, are then broke down at more rapid rates than is usual. The regulatory mechanisms, however, cause more of the steroidal compounds to be synthesized so that the levels frequently do not change. The significance of the phenomenon either to the environment or the human health is not clear. One of the Japanese studies of the Yusho disease reported hypertrophy of the smooth endoplasmic reticulum in liver biopsy specimens. Much of the cholesterol synthesized by the liver is produced in the smooth endoplasmic reticulum fraction. A study carried out in Israel (18) on the effect of organochlorine insecticides on serum cholesterol level in people occupationally exposed to those compounds reported that while serum cholesterol increased with age in both the exposed workers and the control groups, the increase was greater in exposed workers. These scientists concluded that the organochlorine compounds induced an increase of cholesterol synthesis, but that the regulatory processes of the body were able to increase the rate of breakdown in younger people. In older people past the age of 45, however, the regulation mechanism worked less well, and cholesterol levels increased.

Several studies (11, 19) have shown that PCB may produce symptoms in chicks identical to those produced by chick edema factors. These were discussed extensively in the hearings held by this committee to consider the environmental effects of the herbicide 2,4,5–T (9). It is likely that this effect is caused by the dibenzofuran contaminant (11).

PCB IN THE NORTH AMERICAN ENVIRONMENT

PCB is now universally distributed in the terrestrial, fresh-water and marine environments of North America. On the west coast concentration of PCB in a collection of northern anchovies from coastal waters of southern California was in the order of 1 ppm (20). Concentration in the body of a Peregrine Falcon in California was 65 ppm of the wet weight and 200 ppm of the body fat (4). All specimens examined of several species of petrels and shearwaters from the Pacific

Ocean all contained PCB (4). These are pelagic species which rarely approach land. Sixty-five eggs of the Brown Pelican from Anacapa Island, California, almost all of which were broken when found because of excessive shell thinning contained an average concentration of 210 ppm of PCB in the yolk lipid (21). PCB levels in the coastal waters of southern Florida are somewhat lower. 87 eggs of the same species from Florida, obtained in 1969 and 1970, contained an average concentration of 72 ppm (21). PCB concentrations in the yolk lipids of Ospreys, like the Brown Pelican a fish-eating bird, were highest in Massachusetts and Connecticut with values ranging between 500 and 2300 ppm and lower in New Jersey (22). PCB was found in all plankton analysed from the coastal waters of the northeastern United States. Concentrations were highest in the waters off Long Island and decreased southwards towards Maryland and eastwards towards the deeper water of the Atlantic (21). The PCB detected in the human milk samples most likely came from residues in food.

MOVEMENT OF PCB THROUGHOUT THE ENVIRONMENT

In November and December of 1970 we measured PCB concentrations in the effluent waters of the major sewage treatment plants of California (23). Several were discharging PCB into the local marine environments at rates equivalent to a ton per year. The high concentrations found in the waters near New York and New England most likely derive mainly from sewage outfalls. Once in an aqueous medium PCB readily passes into the fatty tissues of organisms because of its very low solubility in water and high solubility in fat and oils.

In order to look for the origins of the PCB reported in polar bears by the Canadian Wildlife Service we traveled in the summer of 1970 to remote lakes in the arctic terrain of northern Quebec. These are rarely if ever visited by man. All of the fish so far analysed contained measurable amounts of PCB. One lake trout had 12 ppm in its fat, equivalent to the amounts found in many ocean fish (21). We concluded that PCB, like the DDT compounds, is also dispersed through the atmosphere to fall out in areas remote from the sites of application.

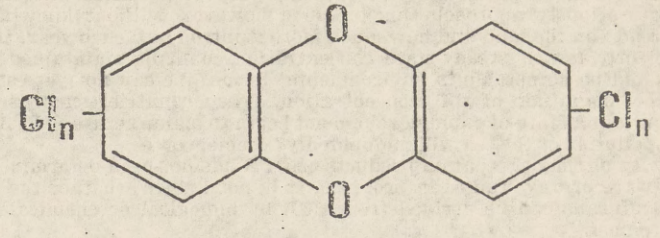
ENVIRONMENTAL EFFECTS OF PCB

In attemping to assess the environmental impact of PCB, the pollution ecologist finds himself in a position he was in up to 1968 in attempting to assess the environmental effects of the DDT compounds. Circumstantial evidence suggested effects upon wildlife populations, but the conclusive scientific evidence was not yet in. The most spectacular and the best documented of the environmental effects of pollutants has been the shell thinning of a number of species of fish-eating and raptorial birds. Several laboratories have investigated the possible effects of PCB upon shell-thinning, but no significant effect has been found. The laboratory of the Bureau of Sport Fisheries and Wildlife has fed PCB to mallard ducks and bobwhite quail but has found no shell thinning effects (16). Similarly the PCB given to doves produced no changes in shell thickness, whereas the DDT compound DDE did so (24).

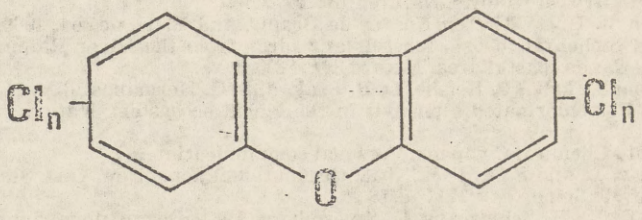
In attempting to determine the environmental pollutants responsible for phenomena such as shell thinning in birds, ecologists have attempted to correlate the magnitude of the effect with the measured concentrations of one or more pollutants. Frequently high amounts of PCB are found together with high amounts of other pollutants such as the DDT compounds. It is therefore difficult to sort out the effects of each pollutant. In examining both west coast and east coast samples of Brown Pelican eggs, containing many different proportions of PCB and the DDT compounds, we have concluded that PCB has no significant effect upon the shell thinning, which correlated well with the measured concentrations of the DDT compound DDE. (25).

An environmental effect that may be caused by PCB is the lowered fertility of some bird populations and the failure of eggs to hatch. This effect was noted by a commercial poultry breeder who became alarmed at the low rate of hatching of his eggs. The hens were subsequently shown to have accumulated PCB from contaminated fish meal. The source of this PCB was traced to a leak from the heat-exchange fluid in the factory equipment(26). This observation appears to be inconsistent with the findings reported by the U.S. Bureau of Sport Fisheries and Wildlife (16) that PCB had no significant effects upon the reproduction of mallards and of bobwhite quail. The inconsistency could be explained if the PCB in the heat-transfer fluid leaking from the machinery had higher amounts of the dibenzofuran contaminants.

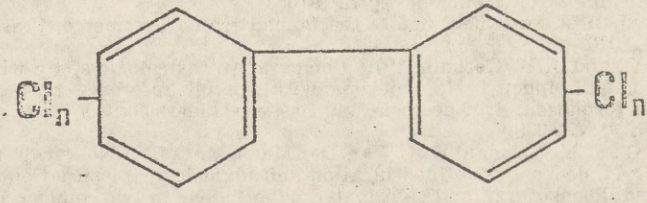
A crucial factor in assessing the environmental impact of PCB is the accumulation rate in "sinks" such as the sea which receive waste materials, including waste chemicals. We can assume that most of the PCB produced is so far still on the land, from which it is slowly leaching into the atmosphere, into sewage systems, and into rivers. It is difficult to estimate the fraction of the PCB now on the land that will eventually enter the sea, because of insufficient data on the amounts of PCB present and on the systems in which it is used. One of the principal research problems in pollution ecology at the present time is to predict



Chlorinated dibenzodioxin, n = 1, 2, 3, 4



Chlorinated dibenzofuran, n = 1, 2, 3, 4



Chlorinated biphenyl, n = 1, 2, 3, 4, 5

FIGURE 1.—Structures of chlorinated biphenyl, chlorinated dibenzofuran, and chlorinated dibenzo-p-dioxin. Chlorine atoms may occupy any of the available positions.

future rates of accumulation in the world-wide environment of synthetic chemicals. Most degrade readily to primary materials, but those with certain chemical properties that are produced in large amounts inevitably become pollutants. Necessary data are production figures, reliable estimates of the proportion of total production that will eventually enter the environment, present distribution of the pollutant in the water, air, soil, and biomass, and estimates of the rates of degradation and withdrawal into the sediments of the ocean bottom.

If the amounts of PCB already manufactured are sufficient to increase concentrations in fish in the coastal waters by a factor of 10 over the next 25 or 50 years, the coastal fisheries would be destroyed for the purpose of human consumption. We can not seriously approach this problem, however, without knowing how much is already on the land and how much more is introduced each year. If input were sufficiently low, a steady-state concentration could be maintained in the sea that would be acceptable in environmental terms. We can not yet estimate, however, the magnitude of this concentration. When countries such as Brazil which are now in a state of rapid development begin to manufacture PCB in large quantities, pollution of the sea will undoubtedly become worse.

The toxicity of the degradation products of PCB has not been determined, and I am not aware of any studies in progress. It is not known whether the highly toxic dibenzofurans can be derived from PCB by biological or chemical means in the environment.

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Senator SPONG. Mr. Wellford, Miss Billings, Mr. Love, Mr. Rathlesburger, and Mr. Pickelner. Miss Dunlap, I believe you are taking Mr. Rathlesburger's place. We are very pleased to have you.

Mr. Wellford, we will hear from you first.

STATEMENT OF HARRISON WELLFORD, ASSOCIATE FOR THE CENTER FOR THE STUDY OF RESPONSIVE LAW

Mr. WELLFORD. Thank you, Mr. Chairman. My name is Harrison Wellford. I am an associate of the Center for the Study of Responsive Law, and I have been working on legal questions involving pesticides as well as writing on these questions for the past 2 years here in Washington.

I appreciate the invitation to appear at these timely hearings on the Federal regulation of toxic substances. The hearings are timely because on July 23 it was reported that an accident in the use of only one toxic substance in only one plant imperiled a large portion of the poultry produced in the Southeastern United States, including the States of North Carolina, Virginia, Georgia, and probably the poultry sold in District of Columbia, although that is not certain.

The problem was that polychlorinated biphenyls, a toxic substance which would come under the jurisdiction of the pending legislation, in at least some of its uses, leaked from a heat transfer unit into fish meal which was then sold to 65 companies through the South as chicken feed. As a result of this incident, Holly Farms, which is the largest single producer of chickens in this area, has to date condemned 88,000 chickens in the last 2 weeks of last month.

We have done all we could in the preparation of this testimony to learn about the extent of the contamination here, and we have not received the cooperation of the Federal Government, but the investigation we conducted does lead me to suggest we need answers to the following questions if we are going to understand the full extent of what has happened.

First, there is a discrepancy between what the Department of Agriculture reports about the PCB levels in the chickens it has tested and the reaction of Holly Farms. We discussed this yesterday with the

company and with the USDA. Holly Farms reports that all of the chickens that they tested contained PCB's above 5 parts per million. Five parts per million is the administrative action level set by FDA as the upper limit of safe ingestion of PCB's.

The USDA reports that none of the chickens it has analyzed contained PCB's above 2 parts per million, which is below that FDA level.

This is interesting for several reasons. First, we have information that USDA and Holly Farms were testing some of the same chickens. So it is not clear why the results should be as different as they are.

Secondly, Holly Farms found residues up to 40 parts per million PCB's in their chickens. That is a very considerable addition of contamination compared to what the Department of Agriculture has reported.

But really I think the interesting question here is why Holly Farms has gone to the tremendous expense of condemning 88,000 chickens if the USDA is correct in saying that there is no danger to the American consumer from chickens which have been fed this feed.

The second question is whether or not the feed was fed to a large number of layers and, therefore, whether or not PCB's are turning up in the eggs from these layers. At this point neither FDA, which has jurisdiction over whole eggs, nor USDA, which has jurisdiction over broken eggs, has completed their test. We have no information as yet to reveal.

There is also a question about PCB's in turkeys and pigs which were also fed this contaminated feed.

The fish meal was contaminated, as I said, with PCB's which leaked from a heat transfer unit in the east coast terminal plant in Wilmington, N.C. The use of PCB's in a feed plant I think illustrates the urgency of the regulatory proposals before this committee.

Monsanto alleged that it has limited the use of PCB's in any form in food processing plants or any processing plant in which food can be contaminated, food or feed, and they were surprised that a heat transfer unit containing PCB's was being used in this plant in North Carolina. I think the fact of the matter is it is very difficult for Monsanto even with the very best of intentions to keep track of the PCB's once they have been sold. In this case if a company wants to use PCB's in a manner which Monsanto does not approve, there is really no sanction that Monsanto can bring against them, particularly since if Monsanto were to cut off their source of supply they could still buy it from foreign countries.

The proposed legislation with its provision for comprehensive monitoring of hazardous substances, its flexible arsenal of enforcement tools, and its approval of citizen suits I think will anticipate and prevent inappropriate use of these substances in the future. There are nevertheless some points at which this bill needs to be strengthened.

I think the exclusion sections, section 209 of the bill as amended—by the way, when I speak of the bill, I am speaking of the Spong amendments—excluding pesticides from the substances covered by this legislation preserves the maze of overlapping and contradictory regulatory responsibiilties which now embarrasses and confuses the Government's efforts to monitor hazardous chemicals in the environment.

I did a little study of exactly who has jurisdiction over PCBs at various points, and on page 3 of my testimony I go through that. I point out that the Department of Agriculture has responsibility for looking for PCB in meat and poultry, the FDA for looking for PCBs in whole eggs, USDA for PCBs in cracked eggs, FDA for PCBs in fish meal, EPA for PCBs in pesticides, and so forth.

Looking at this conflict of jurisdiction with regard to PCBs, I begin to wonder exactly how much is left for this particular proposed legislation to cover. That is one of the reasons why I am concerned about the exclusion from jurisdiction of this bill of pesticides.

A second reason is the fact that the legislation, as far as it goes, is a vast improvement over existing pesticide law and the proposed pesticide amendments to the Federal Insecticide Act which are now pending before the House Agriculture Committee as described in the House Committee's Print No. 3. I will not go into the detail on these points. I have listed them here in the testimony.

The only point that I want to mention specifically here is the interpretation or the definition of "imminent hazard" as it is stated in the bill before this committee and as apparently is going to be stated in the bill that emerges from the House committee. The House draft requires a finding of "substantial adverse effects" as a likely result of continued use of a pesticide before suspension action can be taken against it.

The bill S. 1478 as amended requires only that there be a "reason to believe" that continued use will result in "serious damage" to human health or the environment. That distinction may seem subtle, but it is very important. I think it should be made clear that in the definition of "imminent hazard" in S. 1478 as amended that this definition does encompass serious potential hazards such as an increase in the incidence of birth defects or cancer which may develop months or years after an individual is exposed to a chemical.

There has been a lot of litigation on that point. At this point the law is interpreted somewhat more broadly than the Department of Agriculture did in the past, but I think you can still use some clarification as defined in this act.

While the requirement for premarket clearance of hazardous substances is commendable and the test standards you set out in section 203 are really an excellent step on the whole, you must remember the effectiveness of test procedures depends on the competence and the impartiality of the testers. This bill still permits the manufacturers of hazardous substances to conduct their own testing. It preserves the conflict of interest which has led to abuses in the past and will lead to abuses in the future.

Under the proposed legislation the maker of the hazardous substance, through its own laboratories or by contracts with independent testing laboratories, arranges for the testing necessary to satisfy safety criteria established by EPA. The incentives and opportunities for abuse are obvious. The commercial laboratory, anxious to retain its industry contracts, has the incentives to choose a testing methodology which will reveal the least negative characteristics of the chemical. The chemical company has incentives to avoid a laboratory which is embarrassingly thorough in its tests.

More important than that, even if the laboratory does perform the EPA test conscientiously, there is much more discretion here than the average citizen would believe. The maker of the chemical, not the laboratory that tests it and not EPA, decides exactly which data to submit to the Government.

The problem of biased and incomplete safety data will not be solved until the direct connection between the chemical industry and the testing laboratories is broken. One way to avoid this conflict of interest is for the Administrator of EPA to be responsible for the conducting of all tests on hazardous substances submitted for premarket clearance. The Administrator could then assign the required testing to laboratories certified and inspected by EPA. The test data would go direct from the laboratory to EPA, leaving no opportunity for a company to screen out data which might imperil the marketing of its product.

I point out in the testimony that this proposal would not lead to vast and new Federal expenditures and laboratories. Basically it transfers from the maker of a substance to the EPA the assignment and regulating of testing contracts. There will have to be some additional laboratory facilities probably, but it would not be a massive expense as some of the critics of this proposal have suggested.

That is the end of my prepared statement.

Senator SPONG. Thank you very much, Mr. Wellford.

Since you do have to leave, I will ask you a question or two before we hear from the rest of the panel.

In your statement you mention some additional potential problems that may be present from the contamination of eggs with PCB. Could you give us an idea of how a use restriction under these bills might have prevented the widespread contamination of poultry products that has occurred in the recent past?

Mr. WELLFORD. Yes. Basically, and I think Monsanto recognizes this, at least I understand that they have, even in a closed system, which as we have seen from Dr. Risebrough's testimony, closed systems are not really very closed, even in a closed system PCB's should not be used in any kind of plant environment where either food or feed which is fed to animals which produce food could be contaminated.

In this case Monsanto apparently made some efforts to keep PCB's out of these environments, but in the use restrictions which are available to the Administrator of EPA under the pending legislation there would be a chance to make this perfectly clear as a regulation and to make it clear that anyone who disobeys that regulation would be subject to Federal penalties.

Presently, if East Coast Terminal—I have no idea of what their knowledge was in this case—knew that Monsanto did not want them to use PCB's in their kind of plant but decided to do it anyway. There are no present sanctions that can be brought against East Coast Terminal for that use.

Under your legislation, assuming that the administrator of EPA did issue such a restriction, there would be penalties. Then this kind of incident would likely be avoided.

Senator SPONG. As is apparent in S. 1478, the administration has opted for a system for pretesting of new chemical substances rather than a requirement of preclearance. In your testimony you urge that the committee include pesticides under this regulatory scheme. With

the recent release of your book on pesticides regulation you have a great deal of knowledge that we can benefit from this morning. In your estimation, is there any difference in the need for preclearance system for pesticides and for toxic substances as was suggested yesterday by Chairman Train?

Mr. WELLFORD. I see no difference at all. In the first place, I am a little bit disturbed by the semantics here. I think that pesticides are toxic substances in the same way that PCB's are. Whether PCB's are used in pesticides or heat transfer units. Their risks are somewhat largely the same.

All the premarketing testing procedures to anticipate human and environmental haards that have been worked out over the years for the pesticides, even though they are still somewhat inadequate, should definitely be applied to toxic substances. I think it is really amazing they have not been in the past.

I do not want to push my volume—"Sowing the Wind"—on you, but I do discuss the subject in the book.

Senator SPONG. Thank you very much for your appearance here this morning.

We would be pleased to hear from the remainder of the panel in any order that they wish.

STATEMENT OF LINDA BILLINGS, SIERRA CLUB

Miss BILLINGS. Mr. Chairman and members of the committee, I am Linda M. Billings, assistant to the Washington representative of the Sierra Club, a national conservation organization with nine offices and over 130,000 members in 35 chapters throughout the United States. I appreciate the opportunity you have extended to speak on legislation to control pollution by toxic substances, specifically the administration's proposal, S. 1478, and amendments to S. 1478 offered by you, Senator Spong.

The Sierra Club and many other conservation organizations have on many occasions expressed concern about and protested pollution of our environment by chemical substances such as pesticides, mercury, lead, sulfur, nuclear materials, and oil, to name just a few; and they have called upon the Government to take measures to halt these abuses. Too often it has been a call to action after the fact, and the problems have exposed gaps in Government's ability to control pollution from unanticipated sources, as was the case with mercury or lead.

Therefore, the proposed legislation, and amendments, which considerably improve the legislation and definitely must be included, are welcome as attempts to close these gaps. But problems with toxic substances have also occurred where mechanisms for Government regulation do exist, and in reality what we are faced with is a proposal for further fragmentation when too much fragmentation already exists. The titles "Federal Hazardous Substances Act," "Hazardous Consumer Products," and "Toxic Substances" are misleading, for this legislation contains important exceptions for toxic substances which are equally as serious problems and also need Government action.

I am referring specifically to section 209 of the amendments (section 207 of the original bill), entitled "Relationship to Other Laws." Excluded are economic poisons (pesticides), foods, food additives. drugs,

cosmetics, and nuclear materials. Serious problems exist now from toxic substances in these excluded categories, and reforms in the current laws and regulations are clearly needed. Further, they are currently regulated by producer-oriented committees and departments. The needed reforms have been slow to occur or nonexistent.

For example, reforms in the regulation of pesticides have been needed for years. The current law is not truly adequate and administrative procedures have been found to be wanting. Many of the chemicals used are toxic to man and other animal life. Important evidence is accumulating of other serious hazards linked with reproductive failures and birth defects. Further, the abusive use and overdependence on chemical means of pest control poses future serious problems such as: creation of resistent species; contamination of food sources; elimination of useful predator species; lowering of productivity through elimination of pollinating bees; and lowering productivity of sea foods. Clearly these are effects from toxic substances and they pose a real threat to health and well being.

New legislation on the regulation of pesticides has been proposed in both the House and the Senate. So far no action has been taken by the Senate Agriculture Committee, other than to hold hearings. Mark-up of legislation has begun in the House Agriculture Committee; but it has been proceeding slowly and there is little assurance that adequate controls will emerge. As it now stands, there are not really effective controls over the sale and use of pesticides (even the very dangerous ones); there are no really adequate proposals for testing of products; labeling requirements are incomplete; and proposals to modernize agricultural pest control and decrease depedence on chemicals are not being strongly advanced. Clearly this is an inadequate response.

Friends of the Earth wish to commend you, Senator Spong for your environment is admittedly a complex matter. Use of chemicals is very widespread, and it is difficult to ascertain total amounts used and discharged. It is also difficult to predict what later combinations of chemicals will occur. Many compounds have long persistence and/or mobility. Other compounds are complicated by different breakdown and residue stages. Geographic areas will differ with respect to their capability to absorb and disperse chemicals. There are often effects on nontarget organisms and animals. Add to these problems, the heretofore inadequate systems of testing, surveillance, monitoring, and control over use and we begin to get a picture of the extremely serious situation with which we are faced today.

The benefits which have accrued to our health and well being from chemicals are not to be denied nor underestimated; however, our future enjoyment of these benefits depends upon wise use and effective controls. The current systems of regulating chemical compounds are fragmented, uncoordinated, incomplete, and producer oriented. They have worked to the detriment and confusion of the general public. The regulation of toxic and hazardous substances should be integrated and standardized, not further fragmented.

The task which this legislation should address itself to is more nearly expressed in section 220 of the amended version. That is, legislation which aims to control hazardous and toxic substances should include all chemical substances and should work toward developing

a standard classification system of chemical compounds and elements.

Included should be improved testing protocols and regulations over use and distribution. However, it should be cautioned that, although it is in many respects superior to the currently proposed pesticide legislation—and I am referring to the draft of the House Agriculture Committee—as it stands now even in the amended version the proposed legislation is not adequate to regulate the suggested additions, and additional provisions would be required.

In the interest of time I will conclude my remarks; however, I am including here further remarks on the proposed legislation for your consideration.

Senator SPONG. Thank you. They will be received.

(The attachment follows:)

The amended version of S. 1478 contains important strengthening provisions, and since this is the preferred version of the legislation I will address my comments to it.

1. Sec. 202(10) The definition of "protect health and the environment" should be expanded to include potential hazards and risk of hazards.

2. Sec. 203 The proposed regulations for standards for test protocols should be published in the Federal Register.

3. Sec. 204 Certification of chemical substances on the basis of test results is a vital step. Rather than have producers perform the tests (or contract on their own with other labs to perform the tests), a new system should be devised in which labs certified by or administered by the government would perform the tests. Producers would be assessed costs for these tests. This system would be similar to licensing fees.

4. Sec. 206 The definition of imminent hazard should be broadened to include potential or risk of potential hazard.

5. Sec. 209 This has been commented on in text of statement.

6. Sec. 210 The National Academy of Sciences should not be the only source for recommendations of representatives to serve on the Toxic Substances Board, particularly with respect to representatives of industry, consumer, environmental groups, and the general public. The administrator could name these representatives.

7. Sec. 231 State regulations should be allowed to be more strict.

8. Sec. 220 A provision should be added to make the data available to the public.

STATEMENT OF LOUISE C. DUNLAP, ASSISTANT LEGISLATIVE DIRECTOR, FRIENDS OF THE EARTH

Miss DUNLAP. Thank you, Mr. Chairman.

I am Louise C. Dunlap, assistant legislative director of Friends of the Earth, an international environmental organization, with Washington offices at 620 C Street, S.E. I appreciate this opportunity to testify, and shall condense my remarks.

Friends of the Earth wish to commend you, Senator Spong, for your thorough analysis of the administration bill and for the substantial improvements to S. 1478 offered in your amendment. The Spong amendment clearly provides a legislative mandate for more comprehensive public protection against broad discretionary actions of a weak administrator, as allowed under S. 1478. Although more stringent, your amendment seems to provide industry with more equitable regulations and administrative procedures.

Among the more obvious weaknesses of the administration bill is the failure to provide the administrator with mandatory obligations to promulgate specific sections of the act. Rather S. 1478 is riddled with loosely constructed discretionary authority which would obscure

effective promulgation of the act. This is evidenced in title II, sections 204(b), 205, 205(a), 206(b), 206(c) and 214(b)(2). Certainly an administrator should be allowed discretionary authority. In specific areas central to promulgating the legislative intent, however, mandatory provisions protect the public from ambivalent administrative commitment, and protect a strong administrative commitment from excessive industry pressures.

RESPONSIBILITY FOR TESTING

We fully concur with a basic policy articulated in section 201(1) of your amendment, which is not developed in S. 1478, that the burden of responsibility for testing new chemical substances and hazardous or potentially hazardous existing chemical substances should be placed on those who produce such chemicals.

TEST STANDARDS

We support the establishment of deadlines in section 203 of your amendment as an essential tool in providing uniform requirements for test protocols and for enforcement of final regulations. That is to say, we endorse the fact that you have provided specific time frames.

S. 1478 fails to specify deadlines. Friends of the Earth endorse the criteria for establishing standards in section 203(1–5) of your amendment, although we would recommend substituting "shall" in lieu of "may" following test protocols in section 203 to include all tests listed.

COSTS OF CERTIFICATION

We strongly endorse the procedure for certification of new and existing chemical substances, with deadlines for compliance, as provided in section 204(a) and 204(b) of your amendment. Such requirements are essential enforcement tools. The administration bill omits this valuable mechanism. We would recommend, however, that the costs of required testing, which section 204(c) transfers from the applicant to the administrator, instead remain with the applicant—or manufacturer.

It seems that the costs of testing and certification should be internalized by the manufacturer of the chemical substance. The Council on Environmental Quality report on Toxic Substances in April 1971 estimates that about 2 million chemical compounds are known, with an annual discovery rate of several thousand. CEQ reports that several hundred of these new chemicals are brought into commercial use each year.

Friends of the Earth suggest that it is the responsibility of the manufacturer to assume certification cost. This internalized cost will be passed on to the consumers of products containing that substance. A special provision might be made for some Federal reimbursement to small manufacturers who could demonstrate to the administrator that the certification cost if internalized would eliminate their already marginal competitive positions.

Certification costs of an existing chemical substance might be distributed among each manufacturer so as not to place an unreasonable

burden on the first of several manufacturers of the same chemical substance who comes forward to be certified.

The cost of certification could constitute, therefore, a prerequisite fee to initial or continuing manufacturing of chemical substances, with the fee for certification going to Environmental Protection Agency laboratories or independent research laboratories as authorized under section 211 of your amendment. And we do concur with what Mr. Welford said about independent laboratories.

RESTRICTIONS ON USE AND DISTRIBUTION

Friends of the Earth endorse the basic concept embodied in section 205 of your amendment, although we recognize certain difficulties in giving notification to purchasers and in labeling consumer products, as specified in section 205(a)(2) of the amendment. The obvious problem is that the chemical substance enters the food chain but may be lost when it enters the consumer chain. Under your amendment, section 105(a)(2), the potent weedkiller, 2,4,5–T, if it were included in your act, which we would hope it would be, and we realize it is not under its present form, could be restricted to pastures and ranges and powerline rights of way. Yet it might be difficult to trace the chemical through the consumer chain to the market where a pregnant woman is buying meat and milk from livestock that grazed in a 2,4,5–T treated pasture. I am assuming here the suspected correlation of widespread use of 2,4,5–T, in Vietnam and the increase in birth defects in South Vietnam.

TOXIC SUBSTANCES BOARD

While we favor the provisions for a Toxic Substances Board as outlined in your amendment (sec. 210) over the provisions in S. 1478, several problems still exist. We recommend that the National Academy of Sciences not be the exclusive source of a continuing list of qualified scientists. We would recommend that the administrator maintain a continuing list based on recommendations from the public, industry, the academic community, and consumer, environmental, and public interest groups. This could be done while setting high requirements for qualified scientists.

The recent Advisory Committee on 2,4,5–T, which made its recommendations to the administrator in May 1971, was selected from three NAS lists. Conferring with the nine-member Advisory Committee were 22 individuals, three of whom were employed by Dow Chemical and another three of whom were employed by Hercules Powder. Coincidentally, the Advisory Committee recommended eight to one that the administrator regulate the use of 2,4,5,–T rather than impose a ban on it. Dow and Hercules appealed a May 1970 court order cancelling all uses of 2,4,5–T and have been enjoying, as a result, a monopoly on its use as a lawn and garden weed killer.

Friends of the Earth would support a specific change in section 210(a) of your amendment to insert "consumer and environmental groups" in lieu of "consumer or environmental groups," so as to insure equal representation for both types of groups on a toxic substances board.

EXPORTS AND IMPORTS

Neither S. 1478 nor your amendment consider an export restriction on toxic chemical substances, unless as exported and used it will produce a significant direct or indirect hazard to human health or the environment of the United States. This provision seems to be unnecessarily narrow in its interpretation. If this legislation provides a potentially significant loophole for exporting chemical substances otherwise unacceptable for use in the United States, the Congress will be acting inconsistently with other simultaneous efforts to develop international environmental cooperation—particularly in ocean dumping.

CITIZEN ACTION

Friends of the Earth strongly endorse section 217 of your amendment, which provides for citizen civil actions. The administration bill has no such provision. In addition to the citizen suit provision, public availability of information contained in at least several categories required in the annual report by manufacturers to the administrator should be included. These categories subject to public disclosure should include section 208(a)(1)(3)(4)(5) and 208(b). Section 208(c) is a major step toward public availability of information.

RELATIONSHIP TO OTHER LAWS

Both S. 1478 and the Spong amendment provide for extensive exemptions under sections 207 and 209 respectively, with regard to other laws, including the Federal Insecticide, Fungicide, and Rodenticide Act; the Federal Food, Drug, and Cosmetic Act; the Federal Meat Inspection Act; the Poultry Products Inspection Act; the Comprehensive Drug Abuse Prevention and Control Act of 1970; and other laws and administrative regulations which extend beyond the purview of this committee. We would concur with the Sierra Club and Mr. Welford in recommendations in that regard.

Where new legislative mandate is given to the administration of EPA, it would certainly facilitate the regulation of these chemical substances through the food and consumer chains if those other areas of the consumer chain could be brought under the purview of the administrator and the provisions of your amendment.

We hope that members of this committee will insure strong toxic substances provisions in the Water Pollution Control Act of 1971 now before the Senate.

Thank you.

Senator SPONG. Thank you very much, Miss Dunlap.

Mr. Love.

STATEMENT OF SAM LOVE, ENVIRONMENTAL ACTION

Mr. LOVE. Mr. Chairman, my name is Sam Love, and I am administrative coordinator of Environmental Action. I also edited a citizen action guide, Earth Tool Kit.

In the interest of time, I will condense my introduction and get to the heart of the matter.

As a result of the Council's toxic substances report, we are now considering the bill S. 1478. It does not adequately deal with the enormous problems we are facing in this area. However, with the addition of the amendment offered by Senator Spong—amendment No. 338—the bill is tremendously improved.

Our organization commends you for the efforts you have made to improve the bill.

In light of the current concern generated by the recently discovered environmental impact of such toxic substances as mercury, PCB, and detergent additives, the amendment to the legislation under consideration is very necessary. In many ways amendment No. 338 is the best critique of S. 1478 so I will not take the committee's time outlining my criticism of the bill. I will concentrate on the amendments.

The provisions of amendment No. 338 which require preclearance of new hazardous material and testing of some existing toxic materials are very much needed in the bill.

I believe that testing should be controlled by the environmental testing agency, not the corporation which has a vested interest in certification.

Section 204(c) which creates an elaborate taxing mechanism on first sales of the product should be rewritten. Instead of a tax, corporations which are attempting to certify the chemical substances should pay a licensing or registration fee. The main function of the tax would be to pass the cost to the consumer. If the corporation seeking certification has to pay a registration fee, its costs would be added to the price of the product. This would achieve the same effect as a tax and it does not require the formation of another bureaucracy for collection.

I also find section 213 of the amendment unacceptable. It would allow export of chemicals found unsuitable for use in this country. Environmental problems have no appreciation for the artificial boundaries created by man. We must begin to respect the earth as an integrated system. A reverence for life would not allow us even to contemplate the exporting of unacceptable chemical substances.

A major reason for the existence of an act controlling toxic materials must be the orderly control of these substances. This cannot be accomplished until a unified procedure is developed for dealing with chemicals. This act and the amendments we are considering offers an opportunity for us to utilize a holistic approach. The mechanism to assess the environmental impact of chemical substances already exists in the National Environmental Policy Act. The registration, licensing, and certification process of chemicals must be considered a major Federal action. If it is considered such an action, then section 102 of the National Environmental Policy Act can provide the guidelines for handling information relating to chemicals.

The rudiments of this approach are included in sections 218 and 220 of amendment No. 338. These sections discuss environmental assessment and the handling of data surrounding the chemicals being certified. This committee should redraft these sections to state that the National Environmental Policy Act appiles.

I would like to thank the committee for allowing me to testify.

Senator SPONG. Thank you very much, Mr. Love.

STATEMENT OF JOEL PICKELNER, NATIONAL WILDLIFE FEDERATION

Mr. PICKELNER. Mr. Chairman, I am Joel M. Pickelner, legislative information specialist for the National Wildlife Federation, which has its national headquarters at 1421 16th Street here in Washington.

Ours is a private organization which seeks to attain conservation goals through educational means. Affiliates of the National Wildlife Federation are located in all 50 States and Virgin Islands. These affiliates, in turn, are made up of local groups and individuals who, when combined with associate members and other supporters of the federation, a number an estimated 3 million persons.

We welcome the invitation and opportunity to comment upon S. 1478.

Throughout the world, there are over a million different products which end up as waste. The vast majoirty of these wastes are not harmful in the amounts discharged; in fact, many are integral parts of the life cycle. However, a number of wastes are inherently hazardous, or are discharged in amounts which are harmful. In the past, these wastes were accepted as necessary for technical and economic progress and our ecosystem handled them effectively. Now, however, we have reached a point where our ecosystem no longer is capable of handling the vast amounts of waste which our lifestyle manufactures. Not only have we reached that point but gone beyond it, to a point where we are endangering not only the environment, but more important, the public health and safety as well.

For far too long, we have been treating discharges of hazardous substances as an accepted fact, concentrating our efforts on clearing them up after the fact. To reverse this trend, it is necessary that positive action be taken and taken quickly. The time has come to stop pollution at its source rather than trying to remedy the problem along the routes generally taken by pollutants. In terms of cost alone, remedial changes probably will be large in relation to stopping the pollution at its source.

The amended version of S. 1478 is a positive step forward in the direction of source pollution control. By regulating the chemical substances which may be produced by a manufacturer, it will be possible to determine and regulate the wastes or byproducts which are released into the natural environment. This bill is not a panacea, but it will give the Administrator of the Environmental Protection Agency the opportunity to provide incentives for big business or big polluters to clean up their own operations, thereby making possible the remedial cleanup of our natural environment.

Mr. Chairman, I am limiting my comments to the amended version of S. 1478 since this seems far superior to the original bill. There are, however, a few adverse criticisms of this version which must be made.

We also criticize section 209 which excepts pesticides and foods and drugs from the purview of this bill.

Strong objection must also be expressed to section 213, dealing with exports. Pollution has become a global problem and the solutions to it generally will require national as well as international cooperation on dealing with hazardous substances. Advanced industrial societies probably will have to lead the way, since developing nations are far

more concerned with economic growth and material progress than the side effects of technology. Allowing industries to ship their economic poisons outside the country will not only contribute to the environmental degradation of the country in which they are used but will, in all likelihood, come back to haunt us someday.

Section 221 is too restrictive on the State and local governments to regulate the use of economic poisons within their borders. Each State should have the opportunity to place any restrictions on economic poisons which its deems necessary. By restricting the State and local governments from making tighter regulations other than a total ban, the legislation does not take into consideration the various needs of the different areas of the country.

Mr. Chairman, the proposed Toxic Substances Control Act of 1971 along with amendment No. 338 could be a positive step toward cleaning up the environment. However, the bill must go farther than it now does to accomplish this task. The act should have jurisdiction over all hazardous substances and should be extensively amended to give the administrator sufficient authority to implement an effective program.

Thank you for the opportunity of making these remarks.

Senator SPONG. Thank you very much.

I should like to thank all of you for your testimony and your contributions to the record. We are going to have to close these hearings this morning. I regret that we were a little late getting started.

We have some quesions for you, some of them dealing with the export section which all of you have mentioned. We may want to look into some of the other suggestions that you have made and question you with regard to these.

These questions will be forwarded to you, and we would appreciate your replies and regret that time prohibits our proceeding further this morning.

Thank you very much for being with us.

The hearings will be in recess until 10 o'clock tomorrow morning.

(Whereupon, at 12:30 p.m., the hearing was recessed, to reconvene at 10 a.m., Thursday, August 5, 1971.)

THE TOXIC SUBSTANCES CONTROL ACT OF 1971 AND AMENDMENT

THURSDAY, AUGUST 5, 1971

U.S. SENATE,
COMMITTEE ON COMMERCE,
SUBCOMMITTEE ON THE ENVIRONMENT,
Washington, D.C.

The subcommittee met, pursuant to recess, at 10 a.m. in room 5110, New Senate Office Building, Hon. William B. Spong, Jr., presiding.

Present: Senators Spong, and Hatfield.

Senator SPONG. The hearings will please come to order.

The first witness this morning is Dr. William Nicholson, Mount Sinai School of Medicine, New York.

Dr. Nicholson, we are pleased to have you with us this morning.

STATEMENT OF DR. WILLIAM NICHOLSON, MOUNT SINAI SCHOOL OF MEDICINE, NEW YORK

Dr. NICHOLSON. Thank you very much. I am very pleased to be here.

Let me briefly identify myself.

My name is William J. Nicholson. I am assistant professor of community medicine at the Mount Sinai School of Medicine of the City University of New York. As a physicist, I have served as a coordinator of several projects undertaken by the Environmental Sciences Laboratory of Mount Sinai to evaluate the effects of asbestos exposure. These include an industrial hygiene research program designed to identify and control asbestos hazards in the insulation industry.

This program is jointly supported by the International Association of Heat and Frost Insulators and Asbestos Workers, the union which applies the material, and the Johns Mansville Corp., one of the major suppliers to that industry.

My work has also included the development of analytical techniques for the quantitation of asbestos in ambient air, and a study of asbestos air pollution in New York City and throughout the United States.

Legislation such as is under consideration there, to regulate the use of hazardous or toxic substances has long been needed to protect the consumer. To dramatize that need, I would like to describe this morning several uses of asbestos, a group of chemical substances that would fall within the province of this bill. I hope this description will help provide a base line against which you can measure the efficacy of the proposed legislation, and determine whether that legislation is necessary or is sufficient.

To establish a background of the description of the uses of asbestos against which one can judge the appropriateness of current and past

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uses, of asbestos, may I take a few minutes to detail the spectrum of deleterious health effects associated with this substance? The spectrum includes effects to asbestos workers from direct occupational exposures, effects from working in vicinity of its use, to effects from relatively low level environmental exposures.

The first moderate indication of hazard from asbestos came in 1900 when Montague Murray described the massive fibrosis found in the lungs of a man who had been the last survivor of a group of 10 men who had worked since 1886 in the carding room of an asbestos textile mill. Subsequently, improvement in factory conditions took place but data obtained from Great Britain 30 years later demonstrated a continuing problem. Over 80 percent of asbestos textile workers employed for 20 years had clinical evidence of asbestosis, the term applied to asbestos-induced scarring of the lungs. Again, particularly in Britain, regulations were implemented to improve conditions, but subsequently in 1935 an additional dimension was raised with respect to possible asbestos disease. Isolated cases were found in the United States and Great Britain of lung cancer in association with asbestosis. At that time both of these diseases were very rare. Lung cancer had yet to develop to the magnitude it has now as most people had not smoked for the preceding 20 years. Asbestosis was limited to the small group of workers employed in asbestos factories.

But in 1947, more documentation came of this possible association The chief inspector of factories in Britain at that time found that 13 percent of the deaths in which asbestosis was listed had lung cancer. Workers in the 1940's were still dying in significant numbers as a result of their occupational exposure.

To bring us up to date, 70 years after the first knowledge of asbestos disease, and to complete the picture of occupational exposure, let me present some data obtained by Dr. Irving J. Selikoff, director of the Environmental Sciences Laboratory, Mount Sinai School of Medicine. He has followed since January 1, 1943, the 632 members of the New York and New Jersey locals of the asbestos workers union, the International Association of Heat and Frost Insulators and Asbestos Workers.

Knowing their ages in 1943 and using standard tables, it was possible to calculate the expected mortality experience of these 632 workers

From 1943 through 1962, 203 deaths were expected of this group of workers, of the group of workers that had been employed for 20 years applying insulation. In fact there were 255. Fifty additional people died that should not have died. If we look at the death statistics, we can find the sources of these excess deaths. Forty-five men died of cancer of the lung, trachea or pleura where only six or seven were expected. Twelve died of asbestosis where none should have died. Three times as many died of gastrointestinal cancer as expected.

If one continues the observation of this group of workers through June 30, 1971, one finds that 20 percent have died of lung cancer, 20 percent of 425 men now, 10 percent have died of gastrointestinal cancer, and 6½ percent have died of a cancer called mesothelioma.

We should look specifically to this cancer. In the general population, it is so rare that perhaps 1 in 10,000 people die of it. It has yet to be listed separately in the International Classification of Causes of Death. Yet in this group of workers 1 in 16 died of the cancer mesothelioma. It

is a diffuse cancer of the lining of the chest or of the abdomen. As yet it is incurable.

Two other aspects of the research by Dr. Selikoff are important. These are the evidence of the long lapsed period between onset of exposure and incidence of disease. In long cancers this can exceed 20 years. For the incidence of mesothelioma, it can exceed 35 years.

A second aspect is a strong synergism found between asbestos exposure and cigarette smoking in the incidence of lung cancer. By personal interview in 1962, the smoking habits of 370 of the 632 men were established. By following the mortality experience of these 370 men, a special risk of cigarette smoking was established. From January 1, 1963, through February 1, 1971, in 283 men with a history of cigarette smoking, 40 lung cancers were observed. This is nearly 10 times the number expected in an equivalent cigarette smoking population. In 87 nonsmokers, only one lung cancer was seen. Thus, it is not asbestos alone, or cigarette smoking alone, but the combination of the two that produced these grim data.

These data are all occupational data. They demonstrate the spectrum of disease as one disease with asbestos. Were this to be the only case, this would not be germane to the hearings here today. But unfortunately in recent years evidence has accumulated that the problem of asbestos disease has disseminated from the occupational area into the general environment.

The first information on this came from South Africa in 1960. In that year, Wagner, Sleggs, and Marchand described 47 cases of mesothelioma found during a 4-year period in the northern Cape Province, an area with extensive crocidolite asbestos mines. None were seen in the neighboring Transvaal Province or in 10,000 autopsy cases of workers who had died with known exposures to silica. Of the 47 cases, approximately half were found to have had either industrial or mining exposures to asbestos. Virtually all of the remaining cases were in individuals who simply lived or worked in the vicinity of the asbestos mines or mills.

Confirmation of the possibility of environmental asbestos-associated disease soon appeared. Newhouse and Thompson reviewed all mesothelioma cases at the London hospital. They corroborated the close association with asbestos, 31 of the 76 cases having had documented occupational exposure. Of the remainder, 11 had lived, decades before, within one-half mile of an asbestos factory. A similar distribution of cases was found by Lieben and Pistawka in Pennsylvania. One insidious form of indirect asbestos exposure is that of families of asbestos workers. In the previously mentioned studies, nine of the London mesotheliomas were in family members, as were three of the 46 Pennsylvania cases. They had no occupational exposure.

Additionally, evidence is accumulating that mesothelioma is rapidly increasing among men who worked in the vicinity of asbestos application. In Holland, 22 cases werefound during a 6-year period in workers of the deShelde shipward. These cases occurred, however, not in asbestos workers, but in members of other trades, welders, carpenters, or painters, all of whom only worked in an area where asbestos insulation was applied or removed. Similar data have appeared from Great Britain. Here, 80 cases of mesothelioma were found in a survey

of the material in the pathology departments of Scottish hospitals and medical schools from the years 1950 through 1967.

An additional disconcerting feature of the Scottish data was the rapid rate of increase. In the early 1950's perhaps one case a year was seen. From 1964 through 1967, 51 cases were seen. This time period corresponds approximately to 30 years after the increased shipbuilding activities that took place prior to World War II. So the elapsed period between onset of exposure and onset of disease is evident here.

Unfortunately, this long lapsed period gives rise to a problem. We have no knowledge of the exposure that took place that gave rise to this disease experience 30 or 40 years ago. We only have knowledge of the fact that such exposure did lead to disease. The dose response relationship is unknown at this time. Obviously, additional research and continued surveillance are extremely necessary in this area.

With this background of disease, let us turn to some present day uses of asbestos, uses that would fall directly within the province of the legislation here under consideration.

Over 3,000 uses of asbestos have been documented and the list grows yearly. The total U.S. consumption has risen from 146,000 tons in 1920 to 730,000 tons in 1965. Fortunately, the largest growth in this case is in the use of asbestos that is unlikely to contribute to air pollution or to serious consumer exposure. Here the asbestos is locked into such variables as vinyl floor tiles, siding, and roof shingles, wallboard, and asbestos cement products.

Uses of asbestos in firable form with greater potential for environmental pollution include the application to and removal of insulation from pipes and boilers, the mixing and application of asbestos-containing dry cements, erosion from brake linings, and, in recent years, the fireproofing of high-rise buildings by a fibrous spray mixture containing from 12 to 30 percent asbestos. It is this latter use, particularly, that has given rise to extensive dissemination of asbestos into the business and residential community surrounding a construction site. For the past 10 years, during which spray fireproofing came to be extensively used, it was not uncommon to see extensive snowfalls of asbestos-containing material over widespread areas of New York and other metropolitan centers. In some cases, the fireproofing was even done with no attempt to enclose the spray area by tarpaulins or other means.

To verify that such fireproofing operations were indeed a significant source of respirable asbestos fiber, air sampling was conducted in lower Manhattan about construction sites where extensive spraying of asbestos-containing fireproofing was taking place. This work was done by our laboratory in conjunction with the Department of Air Resources of New York City. The results demonstrated that spray fireproofing can indeed contribute significantly to asbestos air pollution.

Up to one-fourth mile away, levels exceeding 0.1 micrograms per cubic meter were observed, which exceeds by 100 times background levels found in urban areas distant from construction sites. While 0.1 micrograms may appear to be a small amount, it could represent more than 10 million minute fibers of asbestos. Moreover, the large clumps of asbestos-containing material covering the sidewalk serve as a continuing source to be dispersed by passersby.

While I mentioned there was no known dose-response relationship between these levels and possible disease, if one looks at photographs which I will submit to you of this process taken 1 year ago in Manhattan where spraying was done with no attempt to control it or even when control measures were taken, it is difficult to imagine that factories even 40 years ago had more extensive emissions.

The method of fire protection for high rise buildings presents an additional, continuing risk to the occupants of those buildings. Often, the space between the false room ceiling and the underside of the floor above, which has been sprayed with asbestos, serves as a return plenum for the air supply system. After filtration, inadequate to remove most asbestos fibers that may have eroded into the airstream, this return air is recirculated throughout the building. The magnitude of this problem has yet to be defined. To date, in New York City, we have not been allowed to analyze the air in buildings that has been in direct contact with asbestos-containing insulation. Obviously, adequate testing of the effects of this procedure should be required.

Finally, this spray procedure leaves a legacy of potential risk to future generations. The lifetime of modern office buildings is short and the procedures for the safe future demolition of buildings that could contain more than 100 tons of asbestos as fireproofing have yet to be developed. Perhaps these procedures will be found in time and perhaps they will be followed. The bill under consideration here offers an appropriate instrument to require their development and use.

Unfortunately, safe procedures developed for the spray application of asbestos-containing materials have not been followed voluntarily by contractors. Because of this failure and because alternative procedures or materials are available, action banning this use of asbestos has been taken by four cities: Boston, Chicago, New York, and Philadelphia. However, in the absence of national legislation, residents of other urban centers are still subject to a serious risk from this practice which last year utilized approximately 10,000 tons of asbestos.

I would like to list some additional uses of asbestos that exist that give rise of concern to consumers.

One is the suggestion that children mix asbestos with cement or paste to make jewelry, puppets, masks or other play items. This suggestion has appeared in several books, in Girl Scout Brownie Handbooks, and in State Art Education Association manuals. One asbestos producer, Johns-Manville, has gone to considerable effort to prevent the use of asbestos in this manner. Unfortunately, such efforts are not industrywide, and the difficulty of preventing it is extremely high.

Recently, we learned of the existence of a woman's coat made with fiber material containing 8 percent asbestos. With the help of Mr. Henoch Mendelsund, president of the Cloak Joint Board of the International Ladies Garment Workers Union, the origin of the material was traced. An importer had the fabric made in Italy and attempted to import it into the United States as an "asbestos fabric." If allowed as an "asbestos fabric" the duty would have been 6 percent rather than the nearly 100 percent applicable to standard woolen textiles. More than 100,000 coats—and that was from one manufacturer—were made

of this fabric and are now worn by women throughout the United States. All had the fabric content appropriated listed; 72 percent reprocessed wool, 20 percent nylon, and 8 percent asbestos.

To assess the risk to users, we measured air concentrations of asbestos near a coat lightly brushed for 2 minutes. Levels of asbestos 10,000 times background were found. Ironically, there is, as yet, no mechanism to prevent future imporatation of similar material for use in clothing. The only defense consumers have at this time is the refusal of the Ladies Garment Union members to work with such cloth.

Unfortunately, they do not control the entire industry, and some of this cloth now exists in nonunion shops.

The description of inappropriate or questionable uses of asbestos can continue. Let me just touch on a few. In the 1950's, perhaps even today, handfuls of asbestos were added to bulk containers of wine in case small leaks developed—recall that the incidence of gastro-intestinal cancer in asbestos workers is three times normal. Asbestos is now one of the "stop leaks" in your antifreeze. Gas masks and cigarette filters at one time contained asbestos—the synergism between cigarette smoking and asbestos made this latter practice particularly objectionable.

The spraying of asbestos from airplanes had been contemplated in fighting forest fires. The dusting of asebstos mine tailings over farmland depleted in magnesium was once considered. Fortunately, when the possible risks were raised with the asbestos producer who proposed them, these two practices were never implemented.

Here was a case of an enlightened management taking action on a procedure that could provide a risk to many people, but are all producers or manufacturers so enlightened or so ready to abandon a profitable sale?

I might conclude this abbreviated list by mentioning that asbestos filters are used in the purification of foods and of drugs. While this is outside the scope of this legislation, it is worth noting that extensive erosion of asbestos fibers in these circumstances can occur. We have found up to microgram amounts of asbestos in single-dose samples of many widely used injectable drugs. Not only are people breathing asbestos, they are mainlining it.

I hope this information on the effects and uses of asbestos has proven useful to you. It is a particularly apt substance to consider in assessing the need for consumer protection legislation. The full spectrum of problems that might be encountered in the use of hazardous materials is presented by asbestos. Knowledge of the full health effects is limited. The evidence of deleterious effects following exposure may be delayed many years with the consequent buildup of a reservoir of potential disease should a use be found later to be harmful. Exposures in combination with other hazardous materials may provide greatly increased risks. Finally, widespread use, in many diverse circumstances, makes surveillance difficult, if not impossible, under existing regulations.

Thus, the legislation here considered can be especially useful. The development of test procedures to evaluate health effects, the certification for use only after the establishment of safety, and the limitation on inappropriate uses of hazardous materials will go far in protecting the consumer and the environment.

Senator SPONG. Thank you very much, Dr. Nicholson. You have presented a very thorough documentation of the hazards associated with asbestos exposure.

Do we have enough data to suggest a level of exposure at which no hazard would exist? How much can we tolerate?

Dr. NICHOLSON. We have no knowledge at this time of a threshold limit, a threshold value that could assure that there would be no possible disease in any population or people. We have just the beginnings of information indicating that there are levels of asbestos measurable in virtually all cities of the United States. So, we are living with a background of asbestos, some of which would come from occupational uses, some of which would come from natural resources. One natural source is the Appalachian Mountains, in part made up of serpentine rock, which contains within it chrysotile, an asbestos mineral. We only know that we have so far identified no observable disease at these background levels, but we don't know at what level greater amounts of asbestos might produce disease. Our knowledge at low levels is very poor.

Senator SPONG. In your statement, you mention the danger that might occur in the future from destroying buildings which are not now being built using asbestos as a fire retardant. I am curious as to whether asbestos is now being released from buildings which were built 50 years ago and which also contain asbestos.

Dr. NICHOLSON. The buildings that were built 50 years ago would have their asbestos predominantly in the insulation material, in the pipes and the boilers. Recently I saw one bizarre circumstnce at the time some of these pipes were being removed. The pipe insulation material was taken out by men who wore no respiratory protection in very small enclosed tunnels. It was loaded in a cart and wheeled through hallways with much of the material falling off. It was then loaded into an open truck and driven through the streets of New York.

The material after having had high temperatures applied to it for many years is extremely friable. So a considerable amount of asbestos was dispersed within the building and then into the environment of many people in New York City.

Senator SPONG. You have stated we are leaving a legacy to future generations by our use of asbestos in buildings and that when these buildings are torn down 50 or 75 years from now the asbestos once again will cause problems. Under the legislation we have before us, EPA would be authorized to set use restrictions on substances such as asbestos. I am curious as to how a use restriction might be fashioned to solve a problem like asbestos contamination from the demolition of old buildings. Do you have any thoughts on how this might be done?

Dr. NICHOLSON. This is a very difficult question to answer at this time. There has been absolutely no research done on the methods by which current buildings to which sprayed fireproofing material containing asbestos has been applied can be safely demolished. It is something that construction people simply say, "Wait until the time comes and we will find out what to do." We don't really know.

One could give some of the top-of-the-head answers. We are clearly going to need enclosures that will prevent the dissemination of asbestos. The form of these enclosures has as yet to be developed. We need a lot of work in that area.

Senator SPONG. In your statement, you cite the risk associated with asbestos-coated air ducts. Would you give us an estimate of how many structures contain this type of duct system so we might get an indication of the magnitude of the problem?

Dr. NICHOLSON. In New York at this time, there are perhaps 40 buildings being constructed. I would guess, and it is only a guess since I did not survey those buildings, that at least half of them have an air-conditioning system constructed in this way. It is by far the most economical procedure to use. It is in a very large number of buildings.

Senator SPONG. It has come to my attention that asbestos is used in the brake lining of automobiles. If this is correct, the possibility exists that asbestos may be released as the brake linings wear out.

Could you tell us if brake linings are indeed a source of asbestos and if there is any indication that a hazard may exist?

Dr. NICHOLSON. They are a probable source of asbestos. We have had a brief look at this question, but a considerable amount of work has to be done. In one of the very brief measurements made, we found levels of asbestos near where extensive braking took place that were perhaps two or three times higher than measured a few blocks distant. This could be due to variability in the sampling technique. It could be due to a real emission from the brakes. The levels indicate that it is not nearly the problem of sprayed asbestos where rise to extremely high levels. It is a problem, though, that should have much greater study done.

It is clear that some asbestos does get off the brakes when one does laboratory studies of the brakes themselves. How much gets into the environment through extensive use is still pretty much an unknown question.

Senator SPONG. It has been suggested that the definition of a chemical substance under the legislation might not include a substance like asbestos because asbestos is not an uncombined chemical radical or element and does not have one particular molecular identity.

Would you agree in this assessment?

Dr. NICHOLSON. It is true that asbestos is not a particular chemical substance. It is a generic term applied to a group of chemical substances. There are five or six mineral species which are definite chemical compounds to which the term asbestos is applied and each one of these separately would directly fall within the definition of chemical substance.

Senator SPONG. Would you say that asbestos comes within the definition of a chemical substance that I referred to?

Dr. NICHOLSON. I would say that the minerals to which the term asbestos is applied fall within the terms of this legislation, in particular chrysotile, crocidolite, amosite, tremolite, anthophyllite, all asbestos minerals which directly fall within the terms of this legislation. Since all forms of asbestos separately conform to the definition of a chemical substance, asbestos clearly falls within the scope of the legislation.

You could, if necessary, use the language of a specific mineral rather than the term asbestos, but the objection raised is a trivial semantic one with no real substance.

Senator SPONG. Your testimony says that asbestos presents a hazard to human health with its current usage. Are there any alternatives to these uses that present less hazard?

Dr. NICHOLSON. I would say that the intent of my testimony was that some uses of asbestos present a hazard. There are many uses that do not or for which the hazard is very unlikely. Perhaps we should have some research in some of these other uses. But on a very small fraction of the uses of asbestos there is serious concern. Many of these, such as sprayed fireproofing, can be altered by either using other materials or other procedures. This should be done in the case where risk to the health of people occurs. Virtually all of the hazard that I mentioned this morning can either be removed by substitution of materials or the implementation of different processes. But asbestos itself has many uses that need not give rise to serious concern.

Senator SPONG. Thank you very much.

We have a rollcall vote now, and I am going to recess for 15 minutes.

Dr. Nicholson, we are very appreciative of your presentation here this morning. You have given us some very helpful information.

My overall impression is that a great deal more research is going to be necessary in this particular field.

Dr. NICHOLSON. That is true.

If you would like, I would be glad to submit for your record some of the papers that I alluded to or I mentioned directly in the text of my testimony as well as the photographs that I have showed here.

Senator SPONG. Yes; they will be received as part of the record.[1]

Senator SPONG. We will recess for 15 minutes.

(Short recess.)

Senator SPONG. The hearings will come to order.

We will next hear from a panel of lawyers: Karin Sheldon, Robert Hallman, William Rodgers, Edward Strohbehn, John Dienelt.

We are very pleased to have all of you here this morning.

STATEMENT OF WILLIAM RODGERS, JR., ASSOCIATE PROFESSOR OF LAW, UNIVERSITY OF WASHINGTON

Mr. RODGERS. Good morning, Mr. Chairman. My name is William Rodgers. I am an associate professor of law at the University of Washington. I teach and have published in the fields of environmental and consumer law, and I have been directly involved in, among other controversies, the use of DDT and the controversy surrounding the use of phosphorous in detergents.

What I will try to do is to touch on a few of the issues that I do not believe will be dealt with in depth by some of the other witnesses.

At the outset I think it useful to affirm once again, this time from a lawyer's point of view, that we do not know very much about chemicals in the environment. The President, when he recommended legislation on toxic substances, cited PCB's as an illustration of the problem. Though his concern is now fully vindicated, I am sure he considers it no measure of success to learn that the Department of Agriculture not too long ago prompted the extermination of 146,000 chickens contaminated with PCB's.

You heard yesterday from Robert Riseborough, unquestionably a leading authority in the field, and he indicates that with PCB's we

[1] See p. 165.

have another DDT controversy, only a type of DDT that in fact is harder hitting. That issue I think illustrates quite clearly the type of problem that this legislation seeks to meet.

Also, at the general level I think it useful to affirm that the Congress in recent years has been heavily besieged with pleas for new approaches to technology assessment, and these hearings have been liberally sprinkled with references to DDT, enzymes, and the like. Senator Magnuson has talked about an "early warning system." Senator Baker has urged the adoption of national environmental laboratories, and so on.

The various proposals on toxic substances in my opinion afford an opportunity to implement these broad principles on a specific legislative mission basis. We are now talking about action on this general proposition of technology assessment.

On this analysis, I am strongly in favor of your amendment requiring premarketing clearance of chemicals of environmental and public health significance. This is a classic case of technology assessment, the wisdom of which is already recognized with respect to drugs and pesticides. It minimizes the likelihood of wholesale disasters proven only after the fact with painstaking documentation. It avoids economic damage to those who otherwise would become dependent upon the product. It affords a decision before commercial commitment begins to skew our ability to evaluate scientific alarms about continued use.

Now, certainly if we have learned anything from the past controversies over cyclamates, DDT, 2,4,5-T, phosphates, it is that once the technology is turned on and incorporated into the Nation's commercial fabric, turning it off calls for economic disruption, political strife, and governmental vacillation. That I think is an important point met by this legislation.

Briefly, I would like to anticipate some objections that might be made. No doubt you will be told that clearing the hurdle of a hostile bureaucracy will bleed the chemical industry of initiative and stifle development.

There is, however, no first amendment doctrine of prior restraint allowing dissemination of toxic chemicals throughout the community before the authorities step in. Progress, despite warnings to the contrary, was not noticeably set back by the adoption of the workmen's compensation laws. Paying the price of safety, in the chemical industry as elsewhere, exacts no exhorbitant toll from research and development.

Moreover, any R. & D. dollars diverted away from developing products likely to be losers under a preclearance scheme will probably go into developing winners, which are precisely the products a new regime of regulation is designed to encourage. A preclearance procedure reminds the manufacturer that his decisions cannot be preempted by a commercial fait accompli undone only by major conversion with widespread disruption.

A couple of other general points. I would like to affirm the wisdom, I believe, of the use of a toxic substances board or another independent peer group to evaluate scientific data submitted in support of certification or proposed use restrictions. I think it useful to point out that the process we are talking about is an adversary process. Heavy investments have been made by the time the manufacturer seeks certification. Time to him is money.

This momentum contributes to politicization of the registration process and conflict of interest pressures. These can be relieved by contracting out testing or evaluative responsibilities.

One idea would be to extend the responsibilities of this toxic substances board to allow it to let contracts to previously approved testing laboratories to confirm or further evaluate the merits of the application. I would like to call this "sanitizing" the research money. I think it helps the manufacturer, because it affords credibility for his data, and it assures reliability of the data for the public and the government.

By way of illustration, we have done this in Washington State in a related context under our Thermal Power Plant Siting Act. There, before approval is given to the building of a plant, the applicant must make a significant monetary contribution, in this case $25,000. The money is then used to retain outside experts—here at the behest of the government—in order to evaluate the siting proposals. Once again you have the process of "sanitizing" that research money.

I would like to touch on a couple of points. One is the recurring problem of trade secrets. Now, the trade secret argument for too long has stood in the way of dissemination of legitimate scientific information. I have been told that one reason we know so little about industrial PCB's is that they are shielded by a perpetual screen of commercialism. I believe that all data submitted in support of a certification and testing data thereafter derived should be public information, making it possible for the outsider to comment on the risks being evaluated and to pursue research.

As an aside, this trade secret argument comes up perpetually in discussions pertaining to securing environmental and consumer data. I think the Congress should take a broader look at this question, although obviously these hearings are not the appropriate forum. I would be anxious, for example, to hear about a single case where the production of environmental or safety data resulted in a competitive injury.

I think it is fair to say that the chemical industry is competitive, strongly proprietary minded and no doubt generally opposed to opening the registration process in the interests of scientific discourse or otherwise. Given the high cost of development, one can sympathize with the industry's protective huddle. One way of meeting the objection that forced disclosure in the interests of safety inflicts competitive injury is to declare that commercial appropriation of what otherwise would be a trade secret is a tort deserving compensation. I think this could be included in the provision with very little language change.

The last general point I would like to raise pertains to the reporting requirements, and I would like to affirm that the reporting provisions here are a logical application of the same principles of divestiture of ignorance that have inspired recent initiatives to accumulate emission data on air pollution sources and effluent data on water pollution sources. The long-delayed initiative on the industrial water wastes inventory, which was held up at least 4 or 5 years, helped to explode the notion that the amount and type of chemical contributions to the environment and food chain ranked as classified iformation. The effluent from the Hanford Nuclear Works understandably is classified information.

It is difficult to understand how that same principle was applied across the board for many years to industrial manufacturing establishments. Once again the trade secret argument was invoked in this context to deter the informational inquiry. I think the need for information can be affirmed by the scientific realities that have been demonstrated at this hearing by other witnesses. We know that distinguishing between what goes into the air and water and what is manufactured is impossible. Qualities of persistence, solubility, mobility, and toxicity attest to the fact that controlled use is a fiction in large domains of the chemical world. One hundred forty-six thousand chickens and who knows what other damage is a persuasive indicator that Monsanto's closed system for curtailing PCB's is less than foolproof. Now, reporting by manufacturer I think is a first step toward setting regulatory priorities.

I would at this point, although several other points will be covered in my written statement, like simply to conclude at about the same point where I began. I feel this very strongly based upon the limited, I think, but quite real experiences I have had with respect to litigation in the environmental area. A rising concern about air and water pollution in recent years in large part has been a depressing search for elusive chemicals. We try to detect them, measure them, monitor them, put something on the end of the pipe to make sure they cannot escape, and occassionally punish somebody for allowing them to get away. We look for chemicals in the birds, the fish, and with greater trepidation, in the human population. We rush to the scene where there is a fish kill or a find of contaminated chickens and we even talk of scientific advances that would reduce residues in an affected population. That reference is to a recent publication with respect to a potential drug that would effectively reduce levels of DDT and its metabolites in human tissues.

That is why I strongly favor this legislation. I believe that legislation on toxic substances is most commendable when it reaches into the manufacturing process to enforce human health and environmental values as an early principle of decisionmaking.

I think the amendments you have suggested would influence R. & D. and marketing priorities at a stage where they have not yet succumbed to the demands of the marketplace. I believe the legislation would restore some influence over our destiny in a livable environment.

Thank you.

Senator SPONG. Thank you very much, Mr. Rodgers. That was a very fine, comprehensive statement.

We will hear from all members of the panel and then the questions will be submitted to all of you.

(The statement follows:)

STATEMENT OF WILLIAM H. RODGERS, JR.

Mr. Chairman and Members of the Subcommittee: My name is William H. Rodgers, Jr. I am an Associate Professor of Law at the University of Washington. I teach and have published in the fields of environmental and consumer law. I have been directly involved in, among others, the legal controversies surrounding the use of DDT [1] and phosphorous in detergents.[2]

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[1] Rodgers, The Persistent Problem of the Persistent Pesticides: A Lesson In Environmental Law, 70 Colum. L. Rev. 567 (1970).

[2] I have filed a statement on behalf of the Environmental Defense Fund in support of the FTC's proposed regulation with respect to labeling of phosphate content in detergents.

1. Need for the Legislation

You will hear from sources more qualified than I about the stealthy chemical encroachment upon the population and the environment that has given rise to bipartisan support for new legislation on toxic substances. Suffice it to say that there is universal scientific agreement that our knowledge of chemicals in the environment is abysmal.[3] As long ago as 1965 the Manufacturing Chemists' Association reported that *water-borne* wastes were produced by over 5,000 separate chemical processes,[4] a number obviously increasing in an expanding industry with each passing year. The "consensus," according to the Coast Guard's recent report on the Control of Hazardous Polluting Substances,[5] "was that spills and deliberate discharges of hazardous substances into our waters are a present problem of considerable magnitude and furthermore pose the threat of catastrophic consequences." The figures of the Manufacturing Chemists' Association on solid wastes generated by the chemical industry in California in 1966–67 (9.5 tons/employee/year) are a little more than half of what a Governor's Task Force found in 1969.[6] Disparities in data convey the uncertainty. None other than the President of the United States cited polychlorinated biphenyls (PCB's) as illustrative of the threat justifying new legislation to regulate toxic substances.[7] Though his concern is now fully vindicated, I am sure he considers it no measure of success to learn that the Department of Agriculture not too long ago prompted the extermination of 146,000 chickens contaminated with PCB's.[8] Dr. Robert Risebrough no doubt has told you that PCB's are another DDT—only harder hitting. The problem is a classic instance of what the legislation is aimed at.

I think it also useful to affirm that the Congress, in recent years, has been heavily beseiged with pleas for new approaches to technology assessment,[9] usually liberally sprinkled with references to DDT, phosphates, enzymes and the like. Senator Magnuson has called for an environmental "early warning" system. Senator Baker has urged the establishment of National Environmental Laboratories to assist in predicting the effects of new technologies.[10] The various proposals to regulate toxic substances, in my opinion, afford an opportunity to implement these principles on a specific legislative mission. The objective is to keep environmental thalidomides out of action.

2. Specifics of Proposals

(i) *Pre-clearance procedure:*

On this analysis, I'm in favor of Senator Spong's amendment to require premarketing clearance of chemicals of environmental or public health significance.[11] This is a classic case of technology assessment, the wisdom of which is already recognized with respect to drugs and pesticides. It minimizes the likelihood of wholesale disasters proven only with painstaking after-the-fact documentation. It avoids economic damage to those who otherwise would become dependent upon the product. It affords a decision before a commercial commitment begins to skew our ability to evaluate scientific alarms about continued use. Certainly we should have learned from cyclamates, DDT, 2,4,5-T, or phosphates that once a technology is turned on and incorporated into the nation's commercial fabric, turning it off calls for economic disruption, political turmoil and governmental vacillation. Scientific integrity is sacrificed under the assaults of the market place with the cry of "no available substitutes." I think we barely escaped a serious battle over NTA because the warning was sounded before the commercial juggernaut began to roll.

Let me anticipate objections to the pre-clearance procedure. Clearing the hurdle of a hostile bureaucracy, you will be told, will bleed the chemical industry of initiative and stifle development.

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[3] *See, e.g.*, Report of the Secretary of the Interior to the United States Congress, The National Estuarine Pollution Study, S. Doc. No. 91–58, 91st Cong., 2d Sess. (1970).

[4] *National Association of Manufacturers, Water in Industry* 58 (1965).

[5] Page I–3 (1971).

[6] California Governor's Task Force on Solid Waste Management, Report of the Hazardous Wastes Working Group, Jan. 1970, p. 13, in Hearings on S. 2005, Before the Senate Subcommittee on Air and Water Pollution, 91st Cong., 2d Sess., pt. 5 at 2606, 2609 (1970).

[7] The President's Message to the Congress Outlining His 1971 Environmental Program, 7 Weekly Comp. Pres. Doc. 187, 194 (1971).

[8] *See* New York Times, July 24, 1971, p. 30, col. 1.

[9] *See* Hearings on Technology Assessment, Before the House Subcommittee on Science, Research and Development, 91st Cong., 1st Sess. (1969) ; Hearings on Technology Assessment—1970, Before the House Subcommittee on Science, Research and Development, 91st Cong., 2d Sess. (1970).

[10] *See* Committee Print on National Environmental Laboratories, Prepared for the Use of the Committee on Public Works (Jan. 1971).

[11] Section 104, in Cong. Rec., July 27, 1971, S 12297.

There is, however, no first amendment doctrine of prior restraint allowing dissemination of a toxic chemical throughout the community before the authorities step in. Progress, despite warnings to the contrary, was not noticeably set back by the adoption of the workmen's compensation laws. Paying the price of safety, in the chemical industry as elsewhere, exacts no exhorbitant toll from research and development.

Moreover, any R & D dollars diverted away from developing products likely to be losers under a pre-clearance scheme will probably go into developing winners, which are precisely the products a new regime of regulation is designed to encourage. A pre-clearance procedure forces the manufacturer to internalize early in R. & D. decisions possible effects on human health and the environment. It reminds him that these decisions cannot be pre-empted by a commerical *fait accompli* undone only by a major conversion with widespread disruption.

(ii) *Evaluation by Toxic Substances Board:*

Evaluation of the data advanced to support certifications and use restrictions by an independent Toxic Substances Board or similar body is highly desirable. At the point of registration, the process is distinctly adversary. A 1969 survey of 13 companies in the pesticides business discloses that one compound out of 5,000 tested emerged as a marketable product; testing continues for approximately five years prior to marketing at a cost of about four million dollars.[12] Includes process development and pilot plant studies in the cost and it may approach ten million dollars.[13] What this means is that by the time an applicant seeks certification he is fully committed to marketing his product. Time is money. This momentum contributes to politicization of the registration process and conflict of interest pressures. These can be relieved by contracting out testing or evaluative responsibilities.

One idea would be to extend the responsibilities of this Toxic Substances Board to allow it to let contracts to previously approved testing laboratories to confirm or further evaluate the merits of the application.[14] The costs of establishing safety are part of the R & D burden of the applicant and, to the extent his own data is open to question or in need of confirmation, he should be assessed for additonal testing. Thus "sanitizing" the research contribution helps the manufacturer secure credibility for the data on his product and assures reliability for the government and the public.

(iii) *Trade secrets:*

The trade secret argument for too long has stood in the way of the dissemination of legitimate scientific information. One reason we know so little about industrial PCB's is that they are shielded by a perpetual screen of commercialism. All data submitted in support of a certification and testing data thereafter derived should be public information, making it possible for the outsider to comment on the risks being evaluated and to pursue research.

The chemical industry is competitive, strongly proprietary-minded and no doubt generally opposed to opening of the registration process in the interests of scientific discourse or otherwise. Given the high costs of development, one can sympathize with the industry's protective huddle. One way of meeting the objection that forced disclosure in the interests of safety inflicts competitive injury is to declare specifically that commercial appropriation of what otherwise would be a trade secret is a tort deserving compensation. This could be accomplished very simply in the bill. That safety or environmental testing might effectively shorten the life of a patent is another concern that deserves a sympathetic airing. One possible response would be to extend the life of a patent to make up the difference, subject to mandatory licensing provisions similar to those in the Clean Air Amendments of 1970.

(iv) *Specificity in testing requirements:*

I applaud references to carcinogenesis, teratogenesis and mutagenesis in recommended test protocols. The much mooted Delany Amendment of course outlaws food additives found to induce cancer when ingested by man or animal.[15] As I

[12] Reported in Johnson, Safety in the Development of Herbicides, Presented to the California Weed Conference, Jan. 19, 1971, p. 5. Mr. Johnson is a representative of Dow Chemical Co.

[13] *Ibid.*

[14] *See* Hearings on Effects of 2,4,5-T and Related Herbicides on Man and the Environment, Before the Senate Subcom. on Energy, Natural Resources and the Environment, 91st Cong., 2d Sess. 33 (1970), for a discussion of this concept.

[15] 21 U.S.C. § 348(c)(3)(A).

understand it, the theory is that there are no known safe dosage levels of a carcinogen. Causing birth defects or genetic damage would appear no less deserving of scrutiny where human exposure is anticipated and safe dosage levels unknown.

In addition to recommending tests for "persistence," the suggested protocols should include references to the stability, movement, spectrum and accumulation of a particular chemical. There is no disagreement that the legislation should encourage an expansion of safety evaluation requirements in accordance with the dictates of disinterested science.

(v) *Reporting requirements:*

The reporting requirements in section 8 are a logical application of the same principles of divestiture of ignorance that have inspired recent initiatives to accumulate emission data on air pollution sources and effluent data on water pollution sources. EPA's long delayed initiative on the industrial water wastes inventory [16] helped to explode the notion that the amount and type of chemical contributions to the environment and food chain ranked as classified information. The trade secret argument had served to frustrate this intelligence for a number of years. By now we know that distinguishing between what goes into the air and water and what is manufactured is impossible. Qualities of persistence, solubility, mobility and toxicity attest to the fact that controlled use is a fiction in large domains of the chemical world. One hundred forty-six thousand chickens and who knows what other damage is a persuasive indicator that Monsanto's "closed system" for curtailing PCB's was less than foolproof. Reporting by manufacturers is a first step to setting regulatory priorities.

(vi) *Burden of proof:*

The burden of proof controversy has raged regularly and unnecessarily over the years in connection with the registration of drugs and pesticides and can be expected to recur with respect to other toxic chemicals. It is indisputable that the burden of proving that the benefits derived from use exceed the risks should be on the manufacturer. The legislation should be explicit in slamming the door on future efforts to assure operational annihilation of this generally accepted premise. I would suggest inclusion of this language following the first sentence of amended § 204(a): "The burden shall be upon the manufacturer to prove compliance with standards to protect health and the environment promulgated by the Administrator pursuant to § 203."

(vii) *Existing chemicals:*

How to handle chemical substances now in commercial channels raises a problem comparable to the GRAS (Generally Recognized As Safe) list that has long been hotly debated in connection with the FDA's regulation of food additives. Amended § 204 allows exemption of existing chemical substances, except for those "there is reason to believe may pose an unreasonable threat to man or the environment." This turns the burden of proof around and could be strengthened by exempting only those chemicals "which are generally recognized as posing no unreasonable threat to man or the environment." (What is "reasonable" would require further definition, most likely by reference to satisfaction of specified test protocols). Failure to pass muster under the Administrator's "GRAS" criteria means only that the manufacturer must come forward to meet his burden of proof on safety and the environment. No blind "grandfather" clause is due those chemicals which happened to sneak into our lives before scientific wisdom and regulatory authority began to catch up.

3. *Conclusion:*

Rising concern about air and water pollution in recent years in large part has been a depressing search for elusive chemicals. We try to detect them, measure them, put something on the end of the pipe to make sure they can't escape, and occasionally punish somebody for allowing them to get away. We look for chemicals in the birds, the fish and, with greater trepidation, the human population. We rush to the scene where there is a fish kill or a find of contaminated chickens. We even talk of scientific advances that would reduce residues in an affected population.

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[16] *See* Hearings on the Establishment of a National Industrial Wastes Inventory, Before the House Conservation and Natural Resources Subcommittee, 91st Cong., 2d Sess. (1970).

Legislation on toxic substances is most commendable when it reaches back into the manufacturing process to enforce human health and environmental values as an early principle of decision-making. It would influence R. & D. and marketing priorities at a stage where they have not yet succumbed to the demands of the market place. The legislation would restore some influence over our destiny in a livable invironment.

Thank you.

STATEMENT OF KARIN SHELDON, PUBLIC INTEREST RESEARCH GROUP

Mrs. SHELDON. I appreciate the opportunity to speak this morning in support of this legislation. I hardly need to add anything to Professor Rodgers' statement, but I do have several comments that I would like to make.

My name is Karin Sheldon. I am an attorney with Ralph Nader's Public Interest Research Group and my area of concern in the past year has been the environment and the environmental law.

When I first saw a draft of this bill, I really did not know very much about toxic substances or ways of controlling them. So I did a little research on the problem and one of the things I discovered was that every 20 minutes a new and potentially toxic chemical is introduced into industry.

If this happens every 20 minutes in the industrial environment, one can only imagine how many chemical substances are being introduced into the marketplace and into the general environment of citizens everywhere.

This is why I have chosen to speak primarily about what I consider to be a major aspect of this bill—the protection of the environment which it affords. I would also like to talk about the shift it represents in marketplace responsibility.

In section 101(b) of the National Environmental Policy Act, Congress has declared that it is the continuing responsibility of the Federal Government to use all practicable means to insure that environmental considerations are an integral part of governmental planning and policy.

Congress has recognized here that there is a need to speak for creatures which cannot represent themselves and for values and interests that are not readily measurable in dollars and cents.

For it is not only people who are exposed to the massive amounts of chemical substances which enter our environment every year. The total environment which surrounds us, our air, water, land and wildlife, receive doses of this array. This bill, the Toxic Substances Control Act and the amendments which you have proposed, Mr. Spong, are a response to the realization that chemical substances with a potential for damage to human health and to the environment ought to be regulated and controlled.

These bills also reflect a growing awareness that we must know what it is we are putting into our environment and what it will do once it is there.

Unfortunately, much of the older legislation regulating hazardous substances does not take into account environmental impact and effects. This is not a willful mission. Rather, it is due to the fact that our awareness of our environmental degradation has come upon us only in the

last few years, and we have suddenly realized that we are losing the quality of air, water, and land, and we are losing our wildlife at a very rapid rate.

To illustrate the environmental damage that can result when environmental considerations are not a part of a bill regulating hazardous substances, we need only look at the inability of the administrator of the EPA to ban DDT and 2,4,5-T.

I feel, although I don't know what is in Mr. Ruckelshaus' mind, that it must be anguish for him to be unable to ban these persistent pesticides because, as yet, there is no evidence of imminent danger to human health and thus within the context of the law, no reason to prohibit their sale. Although there is no imminent danger to human health he knows that we may already have lost the peregrine falcon, and the brown pelican due to DDT poisoning. We are unable to protect this wildlife from these pesticides because purely environmental factors were not made an integral part of the law regulating them.

This is why this bill, the Toxic Substances Control Act, is so different and so important. As presently drafted, as you know, neither the administration bill nor the Spong amendments cover the introduction of new pesticides, and I would like to digress here and urge that the bill be expanded to cover pesticides as well as other chemical substances.

In terms of protecting the environment, I think the Spong amendment to the bill is superior to that of the administration in its straightforward language. I call your attention to section 202(11) of the Spong amendment, which defines protection of the environment as protection against an "unreasonable threat."

The administration bill section 202(i) on the other hand, provides for protection against "any substantial adverse effect," not upon the environment, but on "environmental values."

What these values are and who is to define them is not clear. It may very well be that a "substantial adverse effect" permits considerably more environmental damage than does an "unreasonable threat." I see no reason for this change in language, and I would urge that the environment be protected against an "unreasonable threat." We are talking about the environment as a whole and not "environmental values" as they may be defined by mankind.

The second aspect of this bill that I would like to comment on briefly is the shift in marketplace responsibility which it represents.

In the past the burden of showing that a substance or a product, was defective, unsafe, or unwholesome, was on the person who bought it, on the consuming public.

I think we have come some distance since the time of caveat emptor, at least in the field of consumer goods, and it is now doubtful that anyone would dispute the consumer's right to buy a safe, reliable product or his right to rely on representations or warranties made by the manufacturer.

This Toxic Substances Act extends this principle into the area of environment and environmental health. It indicates that there is no inherent right to place a product on the market which may damage mankind or eradicate a species of animal or contribute to the contamination of our air and water. This is absolutely vital.

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For too long it has been up to the public, up to the consumer, to prove that something is dangerous before it is removed, before it is adequately tested.

We cannot continue to have that. Manufacturers must bear the burden of testing, of showing that something is safe before it is permitted to go onto the market.

The public recognizes that it has a responsibility to do its part in achieving environmental quality. To exercise that responsibility, we must have access to the information upon which the Administrator will be making his decisions, and the opportunity to go to court, as we do in this bill, to protect the public interest, and to insure that manufacturers are doing proper testing before products appear on the market.

Mankind has a great responsibility. We must realize we are part of a whole, and that even if we are not affected immediately by a chemical substance, we are only a few steps up the food chain from something that is dying or being damaged.

If we are going to speak for these creatures, we must do it now, and we must do it in all our legislation, not just specifically in environmental bills.

I would urge the passage of the amendments which have been proposed by Senator Spong to the Toxic Substances Control Act. Through the provisions for testing we will increase our understanding of the effects of a variety of unnatural items that we introduce into our natural world and with the authority to restrict or even prohibit substances we will help bring about environmental quality for us all.

Senator SPONG. Thank you very much, Mrs. Sheldon.

(The statement follows:)

STATEMENT OF KARIN P. SHELDON

This statement is submitted in support of the amendment to S. 1478—The Toxic Substances Control Act—proposed by the Senate Commerce Committee, Subcommittee on the Environment. Specific section by section comments on the bill are included separately.

According to the Department of Health, Education, and Welfare, every 20 minutes a new chemical substance is introduced into industry. No figures are available for the large number of others that are placed on the market each day.

It is not only people who are exposed to these possibly dangerous substances. The environment which surrounds us, our air, water, land and wildlife also receive doses of the array of chemical substances produced each year. S. 1478—the Toxic Substances Act—and the amendment proposed by the Commerce Committee are a response to the realization that chemical substances with a potential for environmental and health damage ought to be regulated and controlled. The bills reflect a growing awareness that we must know what we are putting into the environment, and what it will do once it is there.

Much of the older legislation regulating hazardous substances did not take into account environmental factors. The effect of this is beginning to be seen in tragic environmental disasters. The two examples which comes immediately to my mind are the recent decimation of a large number of eagles from chemical poisoning, and the inability of Administrator Ruckelshaus of the Environmental Protection Agency to ban DDT and 2–4–5 T. Mr. Ruckelshaus stated at the time of the eagle deaths that he was powerless to prevent them without new and stronger legislation. He was also unable to ban the persistent pesticides because there is no evidence, as of yet, of imminent danger to human health, and thus within the context of the law, no reason to prohibit their sale. It must anguish for such a public official, charged with the responsibility of protecting and caring for the environment, to make such decisions knowing that we may have already lost the Peregrin Falcon and the Brown Pelican to DDT poisoning, and that we may have to choose a new national symbol when all the eagles are poisoned.

There is a need to speak for creatures which cannot represent themselves, and for values and interests that are not measurable in dollars and cents. Bills of the kind proposed are a step in the right direction.

Of course, as presently drafted, neither the Committee nor the Administration bill covers the introduction of new pesticides. To strengthen this legislation I would urge that it be extended to regulate pesticides as well as other new chemical substances.

The Commerce Committee bill is superior to that of the Administration, in my judgment, in its straightforward protection of the environment. Section 202(11) of the Committee bill defines protection of the environment as protection against an "unreasonable threat". The Administration bill, Section 202(i) weakens this to protection against "any substantial adverse effects" not upon the environment, but on "environmental values". What these values are and who is to define them is not clear, and it may well be that a "substantial adverse effect" permits considerable more environmental damage than does an "unreasonable threat". No reason for the change in language is apparent, but it is consistent with the general pattern of the Administration bill which contains more opportunities for persons adversely affected by its provisions, presumably manufacturers, to object to regulations than it does for members of the public to participate in the decision making process. (See Section 203, (b)(1), (e), (d)(1)).

The proposed bill is of major importance for a second reason. It represents the beginning of a shift in marketplace responsibility. The burden of testing and showing a chemical substance to be safe is placed on the manufacturer. In the past, this burden was borne by the public, with manufactured goods innocent until proven guilty. The result, of course, was *caveat emptor*, let the buyer beware.

We have come some distance since then. It is doubtful that anyone would dispute the right of a consumer to purchase safe, reliable merchandise, or his right to rely on representations and warranties made by the manufacturer. The proposed Toxic Substances Act extends this principal into the area of the environment and environmental health. It indicates that there is no unlimited right to place a product on the market which may damage man, or eradicate a species of animal, or contaminate air or water. Manufacturers of such substances have certain fundamental responsibilities to assure that the public and the environment are protected.

The public has a responsibility as well to do its part in achieving environmental quality. This requires access to information and a role in governmental decision making. Sec. 217 of the bill provides for citizen suits to protect the public interest and redress grievances. Such citizen access to the courts is vital, but it alone is not enough. The public ought to have channels of communication with the Administrator at every phase of introduction and certification of chemical substances.

It is not stated in Section 204 and 205 whether the data upon which the Administrator is making these decisions may be supplied by members of the public. Other than responding to the publication of the certification application in the Federal Register, the public has no opportunity clearly set forth for involvement in the process at this point. It should not be necessary to wait for a lawsuit to have the public interest represented.

Under Section 205 it is the manufacturer who has the responsibility of providing the information needed by the Administrator. This is as it should be, but there should also be a public interest check on the accuracy of the information.

One of the bill's major problems, and one which it is seemingly impossible to do anything about, is the fact that it fills in a blank left by legislation regulating economic poisons, foods, drugs and cosmetics, atomic materials and so on. It does not apply to materials already regulated or already in use. This is unfortunate because to achieve a rational, unified system for the introduction and regulation of potentially dangerous materials its provisions ought to apply across the board. Some method should be developed which extends the authority of the Administrator in Section 205 to condition or restrict the uses of existing substances so that all such substances on the market or in the environment could be tested. Although this represents a mammoth undertaking, it would greatly increase our understanding of the effects of the variety of "unnatural" items we introduce into our natural world.

In sum, the Toxic Substances Act will serve a valuable function in the effort to bring about environmental quality not only for people, but for all aspects of the environment which envelopes us.

SECTION BY SECTION COMMENTS

This section by section analysis of the amendment to S. 1478 is submitted along with my general statement, for the use and information of the Committee. I have seen several drafts of the bill. The one presented for hearings is the best of all the drafts. It has no major faults, and it is, on the whole, clear and complete. The amendment to S. 1478 is a good bill, serving a useful purpose. It is stronger in its protection of the environment than the Administration bill. My comments are intended to point out small areas where it could be better. They do not include sections discussed in the statement.

Section 201

It is not only the American people who are being exposed to a large number of chemical substances each year. The rest of the bill speaks clearly to the fact that the total environment is affected by chemical substances, and oftentimes it is not mankind which is damaged, but wildlife, air or water. It would be more appropriate, therefore, if the words "and their environment" were included after "American people."

The final paragraph of Section 201 urges moderation in the use of the authority over chemical substances of the Administrator so as not to "unduly impede" the research and development of new materials. The difficulty with this is its implicit rejection or limitation of the possibiltiy of alternatives to technology. Biological controls, for example, may be available as substitutes for new chemicals. Technology is not always the answer. Sometimes no substance may be better than a new one.

Section 202(7) defines the powers of the Administrator to restrict the use or distribution of chemical substances. This is a strong and thorough allocation of authority, and I heartily approve of it.

Section 203

The only question I raise about the setting of standards and tests for new chemical substances is the length of time the bill permits for the issuance of the regulations. A year is a long time, and much harm could happen.

There are trememdous time lags in the second portion of this section as well. The standards do not take effect until 90 days after the issuance of final regulations, and there is an additional 18 months period before they must be in effect. Nearly two years could pass without standards. This will prove as difficult for the manufacturers of chemical substances as it will for persons attempting to regulate them. Lengthy time periods lessen the effectiveness of a piece of legislation. They have almost a "chilling effect" on its use and enforcement. I would recommend that the time periods be shortened considerably to get this bill moving.

Section 204

Requires certification of new chemical substances and calls for publication of applications in the Federal Register, and thus offers anyone concerned with an opportunity for comment is good.

Section 204(c): I do not feel it is the responsibility of the taxpayer to pay the costs of testing these substances. The manufacturer of a potentially hazardous substances has no inherent right to have that substance on the market.

Section 212

The definition of probable cause for an administrative search remains a problem. Under the criminal law "probable cause" is defined as facts and circumstances which warrant a police officer's belief that criminal activity is afoot. In other words, the officer must be able to point to particular facts which led him to believe that a crime for which a search was necessary was being committed.

The Fourth Amendment protects persons from unreasonable administrative searches as well as from unreasonable criminal ones. Thus there must be sufficient facts on which to base the issuance of a search warrant. A "valid public interest" is not enough.

Section 213

It still seems hypocritical to me to ban or restrict certain substances in the United States while continuing to export them abroad. We cannot clean our own house while contributing to the degradation of another.

Section 214

Assures manufacturers that certain information, presumably "trade secrets," will be kept confidential by the Administrator. It is important that the manufacturer makes a strong showing to the Administrator that such confidentiality is warranted.

Senator SPONG. Mr. Hallman.

STATEMENT OF ROBERT MARSHALL HALLMAN, CENTER FOR LAW AND SOCIAL POLICY

Mr. HALLMAN. My name is Robert Marshall Hallman. I have recently joined the Center for Law and Social Policy, a public interest law firm in Washington, D.C., after serving for approximately 15 months as deputy general counsel of the New York City Environmental Protection Administration. I very much appreciate the invitation from Senator Hart to testify today concerning the Toxic Substances Control Act of 1971, S. 1478, proposed by the administration, and the amended version thereof, Amendment No. 338, proposed by Senator Spong. I have submitted a written statement for the record, which I will briefly summarize and then be glad to answer any questions.

The need for a new regulatory framework designed to prevent harm to human health and the environment from the growing number of chemical substances being introduced into commercial use is clear. My comments will focus primarily on the adequacy of the proposed legislation in controlling the manufacture, use and distribution of harmful chemical substances, with particular emphasis on enforcement mechanisms and opportunities for citizen involvement and education.

My basic conclusions after examining the proposed legislation are these:

First, the administration bill should not be supported, primarily because it provides very little protection for the public; it is very clearly weighted in favor of commercial, as opposed to citizen and environmental interests; it establishes unnecessarily cumbersome enforcement procedures which limit the enforcement. Authority's flexibility; and it fails entirely to provide for citizen suits and enforcement.

Second, I have concluded that, while the amendments proposed by Senator Spong substantially correct many of the shortcomings of the administration proposal, the amended bill requires several modifications in order to achieve meaningful and effective regulation. I will briefly discuss my recommended changes. Moreover, Mr. Strohbehn, of the National Resources Defense Council and I will jointly submit more detailed comments on the amended bill to the committee at a later date.

My third conclusion is that both bills really fail to adopt a comprehensive regulatory approach, rather, each perpetuates the existing division of authority over a variety of chemical substances: for example, food additives, drugs, and household products are exempted from coverage. The effectiveness and adequacy of existing regulation of these exempted areas warrants a thorough investigation either before the enactment of a toxic substances control law of the kind that is before the committee or at least within a reasonable time thereafter, with a view to broadening any law's coverage based on the results of such

an investigation. I, therefore, recommend that any legislation should provide for the establishment of an independent body of qualified experts to study thoroughly existing regulatory activities that are exempted from coverage, with a mandate to report its findings to the Congress within a year after its first working meeting. Certainly, it can't be claimed that the conclusory Toxic Substances Report prepared by the Council on Environmental Quality, or the environmental impact statement which accompanied the administration bill, adequately considered the need to reform, and perhaps consolidate in one agency, existing regulatory activities pertaining to chemical substances exempted by the proposed legislation.

Now, I will comment briefly on several changes in S. 1478 contained in Senator Spong's amendment.

The provision for remarketing clearance and testing is a substantial improvement and is essential for any meaningful regulation. As I understand it, the intention of the Spong amendment is to provide for premarket testing and satisfaction of established standards before chemical substances are put on the market. However, the definition of the term "chemical substance" appears to be inconsistent with this objective. The term "chemical substance" is defined to exclude "substances which are of no public health or environmental significance as determined by the Administrator by regulation." The bill therefore excludes "nonharmful" substances from test requirements. This seems contrary to the overall purpose of the legislation and may give rise to an unintended loophole. It would seem preferable to subject all chemical substances to test procedures and standards promulgated by the Administrators relying on them to identify "nonharmful" substances.

I would like to emphasize the importance of imposing a mandatory duty on the Administrator to regulate the use, distribution and sale of toxic substances. The administration bill does not impose such a mandatory duty, and the amended bill is somewhat ambiguous in this regard. The ambiguity could be eliminated by striking the phrase "if warranted by data available to the Administrator" in section 205(a). This qualifying phrase, to my mind, implies a certain degree of discretion which should not be present.

A third commendable aspect of the amended bill is the opportunity for any person "adversely affected" to request a public hearing regarding regulations. The administration bill provides for hearings only at the request of any manufacturer or processor, clearly deferring to commercial interests. However, there is one thing that I would like to see clarified in the legislative history, if not in actual redrafting, of the amended bill, to wit, the meaning of the term "adversely affected." This is a term of art which has some judicial gloss on it in court decisions. However, I think it should be made absolutely clear that the term "person adversely affected" includes consumers, conservation organizations, and other members of the public, as well as manufacturers and other commercial interests which clearly would be affected by any regulations imposing restrictions on the use or distribution of chemical substances.

Senator SPONG. I might interrupt and say that is certainly the intention of the amendment. If the committee adopts the amendment language, I am sure the report will try to reflect that.

Mr. HALLMAN. Fine.

Another aspect of the amended bill, which I think improves substantially on the administration bill is the mandatory duty placed on the Administrator to obtain all information relevant to carrying out the bill's objectives. The administration bill merely provides that the Administrator "may"—if he so desires—gather such information. Clearly that should be an obligation.

Also the Administrator should be required to make all information he receives available to the public. Here I would pick up on Mr. Rodgers' comment with respect to the trade secrets doctrine, which has traditionally served as a severe obstacle to obtaining information to lawyers, like myself and the other panelists, in the environmental area. That doctrine should be carefully reexamined to see whether it serves any useful purpose.

One aspect of both bills that bothers me is the authorization for the Administrator to issue protective orders regarding information received from a manufacturer "at his own initiative." I frankly can see no reason for providing the Administrator with such authority, particularly when it is recognized that this power could be utilized to keep important information from the public in an attempt to shield the Administrator, as well as perhaps some of the commercial interests that have been able to apply pressure on him, from public criticism.

While the requirement for manufacturers to report information is essential, I think the information required from them under the amended bill is not broad enough. Much more information that could be useful to the Administrator, as well as the public in monitoring this kind of legislation should be included. I would suggest three additional types of information. There may be many others. First, all tests and results thereof which relate in any way to the health and environmental effects of chemical substances should be made available to the Administrator. He should not have the right to disregard such clearly relevant information, as he does under the amended bill (see section 208(b)).

Secondly, there should be an absolute duty imposed upon manufacturers to make available any newly discovered or newly reported adverse effects resulting from chemical substances and any efforts made to reduce or eliminate those effects. Neither bill provides for such a duty now.

Thirdly, manufacturers should provide information detailing all major customers, including processors, to whom they supply chemical substances. This would provide a means for tracing chemical substances throughout the distribution chain.

I would like to comment on two other aspects of the amended bill. First, it substantially improves upon the enforcement aspects of the administration bill by authorizing the Administrator himself to go to court, thereby enabling him to avoid the unnecessary step of clearing his efforts with the Justice Department.

Also, although the amendment provides that the Administrator can assess civil penalties against violators, it should also grant the power to issue cease and desist orders or at least orders to comply with regulations. This is not in the bill. Comparable authority has been granted to the Administrator in the Clean Air Act of 1970 (see sec. 113).

This power would provide the Administrator with greater flexibility to enforce the act.

Just a couple of comments on the citizen enforcement aspects of the amendment. Again, I think the inclusion of a citizen enforcement power is a substantial improvement. However, at least the following two changes should be made in the citizen enforcement section.

First, in addition to the authority to seek injunctive relief, citizens should be authorized to initiate legal action to collect civil penalties where the Administrator has failed to sue to collect fines that he has assessed. If successful, citizens ought to be able to receive reasonable attorney's fees and perhaps a certain percentage of the penalties assessed as a bounty, similar to the type of bounty authorized under the Rivers and Harbors Act of 1899. The Administrator, I would point out, is not obligated to sue to collect civil penalties even though he may assess them. He merely has the power to sue, if he so desires.

Secondly, with respect to fees for attorneys and expert witnesses, the courts should be required to award reasonable fees to successful private plaintiffs. As the amended bill now reads, judges may in their discretion award litigation costs to any party. I think that the interests of justice would be well served by awarding reasonable litigation costs to successful claimants.

Thank you.

Senator SPONG. Thank you very much, Mr. Hallman.

At your leisure I wish you would have another look at the amendment. I think the cease-and-desist provisions are in there. It may be a matter of clarifying the language. We will be continuing these hearings for another couple of months. Look at it and then give me your comment, because I believe it is there.

Mr. HALLMAN. Just one comment on that.

I would agree, as I think I recall it is in there for imminent hazards.

Senator SPONG. The authority is there without a hearing for imminent hazards, and otherwise under section 205(a)(3).

STATEMENT OF JOHN DIENELT, ENVIRONMENTAL DEFENSE FUND

Mr. DIENELT. Mr. Chairman, I am John Dienelt, Washington counsel for the Environmental Defense Fund. EDF is a nonprofit public benefit corporation with a national membership of more than 20,000 scientists, lawyers, educators, and other citizens who are dedicated to the protection of the environment and wise use of our natural resources. In view of our interest and purposes, EDF was pleased to be invited by the subcommittee to testify today on the proposed Toxic Substances Control Act and the proposed amendment to that act.

There is evident great need to provide the Federal Government and specifically the Administrator of the Environmental Protection Agency with the authority to restrict the use and distribution of the range of toxic substances covered by this bill. Recent and continuing evidence such as the disaster with PCB's, which Professor Rodgers alluded to, emphasize the need for this kind of legislation.

I might note at this point that there is a great deal of common ground among, I believe, all the members of this panel. Indeed we made some effort not to have our statements overlap. Particularly I

would like to indicate that EDF fully supports the statements made by Professor Rodgers, who is a trustee of our organization, although he is here today on the basis of his own individual, and very considerable, reputation and experence in this field.

The basic position of EDF with respect to this bill is twofold. First, we believe that the proposed amendment 338 is decidedly superior to the bill that was initially proposed by the administration. We take this position essentially for many of the reasons set forth by Senator Spong in introducing the amendment.

Specifically, we believe, and we agree with the other panelists who have gone into greater detail on this, that the bill should provide coverage for existing as well as new chemicals; a mechanism for clearance and certification before marketing; and the fullest access to information regarding the materials and to the courts by concerned citizens.

Our second basic point with respect to this bill—this also has been mentioned by other attorneys here—is that it should have a broader scope than it presently does. As we understand the bill, it is designed essentially to cover toxic substances that are not covered by other legislation such as the Federal Insecticide, Fungicide and Rodenticide Act.

This function of the bill is, of course, vitally important, because we need to have coverage of these substances. But there is no reason in our view, practically or logically, why substances such as pesticides, which clearly meet the definition of a toxic substance but are now covered under separate legislation, should not be subject to the same procedural system as other toxic substances are. And we simply believe that the procedures under proposed amendment 338 are superior to those that exist, for example, under the Federal Insecticide, Fungicide and Rodenticide Act for pesticides.

Turning to the specifics of the bill, and I am focusing now on amendment No. 338, I would like to address my comments to two areas about which EDF is concerned. These are the provisions with respect to exportation of toxic substances in section 213(a) and confidentiality of the information supplied by manufacturers in section 208 and 214.

Seciton 213(a) presently provides in essence that the provisions of this bill not apply to a chemical intended for export unless use of that substance as exported will produce a significant threat to the health or the environment of the United States. There is no provision prohibiting export of toxic substances which the United States totally bans for use here, nor is there a provision requiring exporters to provide foreign users with information regarding restrictions that we place on substances, or the danger of those substances when we do export them, that is, the substances that we permit to be used for some purposes. Such restrictions for exports and full information regarding the substances we do export are, in our view, essential to the fulfillment by this country to its international responsibilities. They are also consistent with the letter and the spirit of the National Environmental Policy Act.

Senator SPONG. I will hope you will excuse me for interrupting you in the middle of your testimony. I am reluctant to do so, but they have called us to the floor for another rollcall vote. Senator Hatfield and I will be back in about 20 minutes. We will recess until then, and you can pick up when we return.

(Recess.)

Senator SPONG. The hearing will come to order.

Mr. DIENELT. Mr. Chairman, I was pointing out that the bill, in our view, needs to have provisions for restricting exports in at least some circumstances and for providing full information for the products that are exported.

When we export a product, we are giving the people of other countries both the hazards and the benefits of it, and foreign countries may not be as sophisticated with respect to these products as we are. The testimony this week has emphasized and Professor Rodgers has pointed out that we are not all that sophisticated ourselves. We are just beginning, despite our technical competence, to recognize and initiate measures that will protect us from the adverse impact of toxic substances and other material on the health and the environment.

In circumstances where we have decided that, for our people, there is no use of a toxic substance which outweighs its harm, EDF believes that we cannot as a country in good conscience permit the export of that substance to other countries.

Of course, we have got in this bill provisions for restricting use of substances; so, we have got potentially situations where we find that they are valid for some purposes but not for others. It would be very difficult and probably unwise to attempt to tell a foreign country what it can use a substance for and what it can't.

In that circumstance, it seems to EDF—in face of the alternative of excluding exports entirely, even though we feel that in this country they may have legitimate uses—that we should do the best we can in providing information, the fullest information possible to foreign countries and international agencies with respect to the dangers that the substances pose and with respect to the uses that we feel in this country they can have legitimately.

Yet there is no provision in this bill at this time for sharing the information with respect to substances that we export. The suggestion for full disclosure to foreign users is also consistent with the National Environmental Policy Act. Section 102(e) of that act specifically provides that this country "should recognize the worldwide and long-range character of environmental problems and where consistent with the foreign policy of the United States, lend appropriate support, initiative, resolutions and programs designed to maximize international cooperation in anticipating and preventing the decline and quality of mankind's world environment."

The legislative history of the act, parts of which I have referred to in the statement here and which I won't go into now, confirms the concern of Congress at that time with the international environmental and ecological implications of acts that this country takes. So, I think it is fully appropriate to add to this bill proper provisions regarding exports.

The second area to which I would like to address myself concerns public access to reports and other information provided by manufacturers of toxic substances to the Environmental Protection Agency. The provisions of amendment No. 338, as I suggested earlier, are a step in the right direction of providing the fullest information to the public with regard to the activities of manufacturers and the hazards of distribution and use of toxic substances.

EDF, therefore, generally approves of the sections providing for disclosure, such as section 205(b) which requires that the data which the manufacturer must provide to EPA for its determination of restrictions be made available to interested parties.

Similarly, we believe that it is helpful to limit the confidentiality of information which is supplied to the Administrator; to employ the pertinent provision in the Freedom of Information Act in limiting confidentiality; and to specify the standard of confidentiality, that is, that information is confidential only if it is "unobtainable by competitors and its disclosure would lead to competitive injury to the manufacturer."

We fully agree, however, with the statement that Professor Rodgers has made and the reference that Mr. Hallman has made to the problem of trade secrets, and we believe that some further work in this area of the bill is necessary.

Section 208 now requires reports to the Administrator on an annual or more frequent basis by the manufacturers of toxic substances. The information in the reports, we believe, will not be generally confidential or at least should not be confidential. We believe the informtaion will be relevant to carrying out the purposes of this act and that it is desirable to have public access to this information.

But as it stands now, there is no specific requirement in section 208 that the reports required by subsection (a) or the results of tests or other material required by subsection (b) be made public. We believe that section 208 should require the reports to the Administrator and to the public at the time that they are given to him.

If the manufacturer believes that anything in the reports is confidential or is a trade secret and should be kept from the public, we believe he should be the burden of applying to the Administrator for a protective order under section 214(b) and of proving that the information meets the standard of confidentiality under section 214(a).

Finally, we believe that the public should have an opportunity to participate at the administrative level on the decision as to whether or not to withhold disclosure of material claimed to be confidential.

I regret that we are unable to offer anything more specific in this area in our statement, and I don't feel terribly qualified at this point to amplify it. We have simply said that we believe there should be notice and an opportunity for concerned citiens to be heard with respect to such order, or if the orders are requested in written form, for concerned citizens to respond in written form to create something of an adversary setting which will help focus the inquiry for the Administrator.

Our feeling is it shouldn't be an ex parte proceeding whereby a manufacturer under section 214(b) comes to the Administrator and hands him the report with one hand and requests to suppress the report with the other and having concerned citizens find out about it and attempt to challenge the confidentiality of it later.

Just like, in a way, the provision for present marketing clearance which stresses having the public get access to information and having these materials tested and their hazards determined early, we feel the same kind of things should be applied to any kind of information that a manufacturer provides.

In summary, then, our position is that the proposed amendment No. 338 is a definite improvement over the proposed Toxic Substances Control Act and an excellent beginning. We believe, however, that it would be appropriate to expand the coverage of the bill; that the public interest will be served by strengthening the provisions requiring disclosure of information; and that our international responsibilities dictate disclosure of information to countries to whom toxic substances will be exported, and, at least in certain circumstances, prohibition of exports altogether.

Thank you.

(The statement follows:)

STATEMENT OF JOHN F. DIENELT

My name is John F. Dienelt. I am Washington Counsel of the Environmental Defense Fund (EDF). The Environmental Defense Fund is a non-profit public-benefit corporation organized under the laws of the State of New York, with a national membership of more than 20,000 scientists, lawyers, educators, and other citizens dedicated to the protection of our environment and the wise use of natural resources. As its bylaws provide, EDF's objectives are "to effect a joining of the best scientific findings with the most appropriate social action discovered by the social sciences and legal theory in order . . . best (to) promote a quality environment". EDF's "social action" includes education, research, and when necessary "to prevent . . . environmental degradation", legal action which is designed in part "to provide scientists fair and impartial forums in which their findings may be presented objectively to their fellow citizens."

In accordance with its objectives, EDF through its Scientific and Legal Advisory Committees evaluates and defines environmental issues, collects research data relating to those issues, and determines whether litigation is the appropriate course to follow. Its national membership and professional resources thus enable EDF to focus public attention upon environmental incursions that would otherwise go unrecognized. Its prosecution of many major environmental lawsuits has established it as one of the nation's most effective and responsible litigants in this important field.

In view of the purposes of EDF, we were pleased to be invited by the Subcommittee to testify today on the proposed Toxic Substances Control Act (S. 1478) and the proposed amendment to that act (No. 338). There is evident great need to provide the federal government, and specifically the Administrator of the Environmental Protection Agency, with the authority to restrict use and distribution of the range of toxic substances covered by this bill. Recent and continuing evidence of the danger to health and the environment which such substances pose plainly emphasizes this need.

The basic position of EDF with respect to this bill is two-fold. First, we believe that the proposed amendment is decidedly superior to the bill, as initially proposed. We take this position essentially for many of the reasons set forth by Senator Spong in introducing the amendment. Specifically, we believe that the bill should provide coverage of existing, as well as new, chemicals; a mechanism for clearance and certification before the product is marketed; and the fullest access to information regarding the materials and to the courts by concerned citizens.

Our second basic point with respect to this bill is that it should have a broader scope than it presently does. As we understand the bill, it is designed essentially to cover toxic substances which are not covered by other legislation, such as the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). This is, of course, vitally important. But there is no reason, in our view, practically or logically, why substances, such as pesticides, which clearly meet the definition of a toxic substance, but are now covered under separate legislation, should not be subject to the same procedural system as are toxic substances generally. And we believe that the procedures under proposed amendment No. 338 are superior to those, for example, under FIFRA or proposed amendments to FIFRA for pesticides, particularly in that they permit public participation to a greater degree.

Turning to the specific of the bill—and I am focusing primarily on Amendment No. 338—I would like to address my comments to two areas about which EDF is concerned. These are the provisions with respect to exportation of toxic sub-

stances (Section 213(a)) and confidentiality of the information supplied by manufacturers of them (Sections 208, 214).

Section 213(a) presently provides in essence that the provisions of the bill do not apply to a chemical substance intended for export unless use of the substance, as exported, will produce a significant threat to health or the environment in the United States. There is no provision prohibiting export of toxic substances which are totally banned from use in this country. Nor is there a provision requiring exporters to provide foreign users with information regarding the restrictions on use in this country of substances which may be used for some purposes and concerning the dangers to health and the environment which those substances pose. Such provisions for restriction of exports and full information regarding exported substances are, in our view, essential to the fulfillment by this country of its international responsibilities. They are, moreover, consistent with the letter and spirit of the National Environmental Policy Act.

By exporting toxic substances abroad, we are providing other people of other nations with the hazards, as well as the benefits of such substances. Foreign countries may not, however, be sophisticated with respect to them. Indeed, despite our developing technical competence with many toxic substances, we are only now beginning to recognize, and to initiate measures that will protect us adequately from their adverse impact on health and the environment. It is to be expected that many of these other countries will not have adequate laws or surveillance to protect against such hazards. We cannot in good conscience permit export of articles abroad which we consider too dangerous to be used domestically for any purpose, regardless of whether we advise countries to which we export them that we believe that they have no legitimate use whose value outweighs the environmental hazards, for it is quite possible that persons abroad will simply not appreciate the dangers.

It would, of course, be difficult, and perhaps unwise, for this government to interfere with the government of another country by attempting to impose particular use and distribution restrictions on a toxic substance in a foreign country. If we permit export of toxic substances which may be used for some purposes in this country, we should at least provide the fullest disclosure to foreign countries and international agencies of information with respect to these substances, so that they will be advised of the hazards. Yet there is no provision in the present bill for such sharing of information.

The suggestion for full disclosure to foreign users is consistent with the National Environmental Policy Act for Congress there clearly demonstrated its concern with actions by the United States which have international, as well as purely national, environmental implications. Both the language and history of the National Environmental Policy Act reflect this concern. Thus, Section 102(E), introduced as an amendment by Senator Jackson, responded to the need, as he put it, to "seek solutions to environmental problems on an international level, because they are international in origin and scope." That section provides that all agencies of the federal government shall "recognize the worldwide and long-range character of environmental problems and, where consistent with the foreign policy of the United States, lend appropriate support to initiative, resolutions, and programs designed to maximize international cooperation in anticipating and preventing a decline in the quality of mankind's world environment." The same view was expressed by the Department of State in a letter from Mr. William Macomber, Jr., Assistant Secretary for International Relations, to Mr. Jackson on the proposed National Environmental Policy Act. Mr. Macomber wrote that "the Department wishes to call attention to the fact, moreover, that the objectives of the bill or, for that matter, of any proposition dedicated to the protection of the national environment, cannot be effectively achieved unless it recognizes that existing ecosystems are interrelated by nature or by the activities of man, and that the environmental forces affecting our natural resources disregard political and geographical frontiers."

In view of this nation's international responsibilities, particularly as recognized in the National Environmental Policy Act, it seems appropriate, in short, to require the fullest disclosure of information by this country to countries to which it exports toxic substances regarding the limitations it imposes on use of them and the environmental dangers they pose.

The second area to which I would like to address myself concerns public access to reports and other information provided by manufacturers of toxic substances to the Environmental Protection Agency. The provisions of Amendment No. 338, are, as I suggested earlier, a step in the right direction of providing the fullest

information to the public with regard to the activities of manufacturers and the hazards of distribution and use of toxic substances. We therefore generally approve of the sections providing for disclosure, such as Section 205(b) which requires that the data which the manufacturer must provide to the Administrator of the Environmental Protection Agency in determining restrictions on use and distribution be made available to interested parties. Similarly, we believe that it is helpful to limit the confidentiality of information which is supplied to the Administrator; to employ the pertinent provision in the Freedom of Information Act in limiting confidentiality; and to specify the standard of confidentiality, that is, that information is confidential only if it is "unobtainable by competitors and its disclosure would lead to competitive injury to the manufacturer." We have, however, certain suggestions which we believe will further insure the full disclosure of information which we believe is required by the public interest.

Section 208 requires reports to the Administrator on an annual or more frequent basis. The information in the reports, we believe, will generally not be confidential. We also believe that the information will be relevant to carrying out the purposes of this act and that it will therefore be desirable to have public access to this information. However, there is no specific requirement in Section 208 that the reports required by subsection (a) or the results of tests and other material required by subsection (b) be made public. We believe that Section 208 should require that reports to the Administrator be made public at the time they are given to the Administrator. If the manufacturer believes that anything in such reports is confidential and should be kept from the public, we believe he should have the burden of applying to the Administrator for a protective order under Section 214(b) and of proving that the information meets the standard of confidentiality under Section 214(a). Finally, we believe that the public should have an opportunity to participate, at the administrative level, in the decision whether or not to withhold disclosure of the material claimed to be confidential. There should, in other words, be notice and an opportunity for concerned citizens to be heard or, at least, to submit written material in response to a written request by a manufacturer, in order to help focus the inquiry regarding confidentiality.

In summary then, our position is that proposed Amendment No. 338 is a definite improvement over the proposed Toxic Substances Control Act and an excellent beginning. We believe, however, that it would be appropriate to expand the coverage of the bill; that the public interest will be served by strengthening the provisions requiring disclosure of information; and that our international responsibilities dictate disclosure of information to countries to whom toxic substances will be exported, and, at least in certain circumstances, prohibition of exports.

Thank you for the opportunity to present the views of the Environmental Defense Fund on this bill.

Senator SPONG. Thank you very much for your statement.

I am afraid the buzzer has sounded again. How much time do you all have this morning? Can you stay here until at least 1 o'clock today?

Mr. DIENELT. Certainly, if the committee has questions, we will stay here.

Senator SPONG. I have some questions. We could submit them for answer in writing, but I know you have been talking about a subject that Senator Hatfield has some interest in, the matter of exports.

Senator Hatfield, are you going to be able to return?

Senator HATFIELD. Yes.

Senator SPONG. Will you excuse us again to vote, with the caveat that this may be going on for the rest of the day. Mr. Strohbehn, are you going to testify?

Mr. STROHBEHN. Yes, sir.

You might cure our curiosity and tell us what bill it is that is pulling you away so frequently.

Senator SPONG. The military construction bill, and the last amendment was an environmental amendment.

Fifteen minute recess.

(Short recess.)

Senator SPONG. The hearings will come to order.

STATEMENT OF EDWARD STROHBEHN, STAFF ATTORNEY, NATURAL RESOURCES DEFENSE COUNCIL

Mr. STROHBEHN. I am a staff attorney of the Natural Resources Defense Council—an organization of lawyers, scientists, and private citizens which seeks to protect our environment from misuse and destruction, primarily by utilizing the courts and the administrative process. It is a privilege to appear before this committee to discuss the toxic substances bill (S. 1478) and relationships between it and the National Environmental Policy Act (NEPA). Although this committee was not primarily involved in the drafting of NEPA, it has played a principal role in attempting to insure that the policies embodied in NEPA are comprehensively and forcefully implemented. The amendments that you have made in the toxic substances bill which you are now considering represent an example of your efforts.

Many of those who have already appeared before this committee have noted, however, that while the amended bill is a distinct improvement on the administration's proposed bill, several aspects of the current bill still need to be strengthened in order to insure that environmental factors are fully taken into account in the setting of standards and that effective and comprehensive enforcement provisions are provided to prevent destruction or degradation of the environment or our health.

I concur with those who have commended the improvements that you have made—in particular, the amended bill:

(1) Places the burden upon the manufacturer of a chemical substance to prove that it will not harm man or the environment;

(2) Requires that certain new chemical substances be adequately tested and certified as safe before they can be manufactured;

(3) Grants the Administrator authority to seize chemical substances that present an imminent hazard to man or the environment and to seek injunctive or pecuniary relief for violations of the act without having to request action of the Attorney General; and

(4) Grants citizens a right to seek injunctive relief or to bring a civil action in order to insure that the provisions of the act are vigorously enforced.

I also concur with those who recommend strengthening these provisions and others of the proposed bill in order to protect man and the environment more adequately from the effects of toxic substances—in particular, amendments should be made:

(1) To require preclearance of all new chemical substances;

(2) To direct that the Administrator shall condition the use or distribution of chemical substances to the extent necessary to protect the environment;

(3) To eliminate the provision that permits the export of chemical substances which could not be manufactured or used in the United States because of their adverse environmental effects, a provision which violates the spirit if not the letter of NEPA.

(4) To grant the Administrator specific authority to issue cease and desist orders; and

(5) To state unequivocally that processors, distributors, shippers, wholesalers, retailers, and commercial users are liable for violating provisions of the act.

Mr. Hallman and I will jointly submit at a later date detailed written comments on the proposed bill. I will focus the remainder of my testimony on the adequacy of consideration given to environmental matters by the executive agency that submitted this bill to Congress.[1]

In considering the amended bill, the proposed administration bill, and the environmental impact statement prepared by the Council on Environmental Quality, I am struck by the amount of effort that this committee and its staff has devoted to amending the administration's bill so that our environment may be more healthful, our lives less threatened. Of great concern to me is that much of this time might have been utilized more efficiently if the Council on Environmental Quality had prepared an adequate environmental impact statement under NEPA and the agencies had properly commented on the statement. A copy of the final impact statement is attached, together with the comments received by the Council on the statement from four Federal agencies.

The President stated in his Environmental Message of 1970:

> The Council on Environmental Quality will be the keeper of our environmental conscience, and a goad to our ingenuity; beyond this, it will have responsibility for insuring that all our programs and actions are undertaken with a careful respect for the needs of environmental quality.

The Council should therefore produce model environmental statements—statements that complement its guidelines and which provide all Federal agencies with an example they can emulate. The statement submitted by the Council on the toxic substances bill does not meet this standard:

(1) The statement analyzes alternatives in a simplistic fashion considering only the polar extremes;

(2) The statement presents only a cursory treatment of the environmental impact of the legislation;

(3) The statement fails to consider the adverse environmental effects which will result from its decision to regulate toxic substances by the means chosen in the administration bill;

(4) The statement presents no data to support its conclusions;

(5) The substantive comments of two of the four Federal agencies that submitted comment were not made available to the public.

The remainder of my statement will be addressed to these points.

First, the impact statement describes the method chosen by the administration for regulating toxic substances: The most important regulatory power provided for protecting our health and the environment is exercisable solely at the discretion of the Administrator—he "may publish regulations to restrict or prohibit the use or distribution of chemical substances to the extent necessary to protect health and the environment." In discussing the alternatives to this method

[1] See p. 228.

of regulation, the Council does not analyze why the Administrator should not be required to condition the use of chemical substances that pose a threat, an unreasonable threat, or even an imminent hazard to our health and the environment. The Council's brief discussion of the alternatives—submitting no legislation or requiring the registration of all chemical substances—is simplistic and offers no analysis of the many more reasonable alternatives located between the two extremes mentioned.

Second, in discussing the probable environmental impact of the bill, the Council on Environmental Quality states that the "legislation is carefully drawn to prevent unnecessary interference with technological development." The increasing degradation of our environment being wrought by generally unregulated technological development makes one wonder why the Council did not offer some analysis of what constitutes necessary technological development and what kinds of criteria we might use, for instance, in determining when it is more important to permit a factory to operate more efficiently while it dumps toxic substances, such as mercury, in our waters.

Third, the Council on Environmental Quality states that "no direct adverse environmental impacts are foreseen" as a result of its proposed bill. Certainly the unregulated manufacture, distribution, or use of toxic substances have a direct adverse impact on the environment. Although the administration's bill permits the regulation of toxic substances and requires the certification of certain new toxic substances, the choice of this less comprehensive form of regulation will have a direct adverse impact on the environment. The issue of how much regulation ought to be required should have been studied and the reasons provided for the determination not to regulate such substances more comprehensively—reasons that relate to why adverse impacts on our environment and our health must be permitted. The Council's rationalization that a "bureaucratic quagmire" might occur if more comprehensive regulation were attempted suggests an inability to find competent administrators, hardly a sufficient reason for deciding to regulate less comprehensively.

Fourth, the Council on Environmental Quality has provided a detailed environmental impact statement of three pages on a major piece of legislation. Most of the details are missing. The comments of the Department of Commerce underscore this point:

> * * * the paucity of substantive data in support of the estimated impacts prevented us from reviewing in depth the substantive aspects of the environmental impact statements in the short time allotted for the reviews.
>
> Please be assured of our desire to be more responsive to your invitations to comment on your environmental impact statements. Should time permit, we should be happy to receive the substantive data supporting each environmental impact statement for our full review and comment as appropriate.

Fifth, the substantive comments of the Federal agencies on the environmental impact statement were not made available to the public, contrary to the clear command of NEPA.[1]

The President, in implementing NEPA, directed the heads of Federal agencies to "develop procedures to ensure the fullest practicable

[1] NEPA exempts only information that need not be made public pursuant to the Freedom of Information Act (FIA), 5 U.S.C. § 552; the General Counsel of OMB indicated that § 552(b)(5) (interagency memorandums) would probably be relied on as the basis under the FIA in not providing the public the comments submitted to OMB on proposed legislation.

provision of timely public information * * *. These procedures shall * * * provide the public with relevant information, including information on alternative course of action." In its guidelines on the preparation and submission of impact statements, the Council on Environmental Quality itself states that "the final text of the environmental statement and comments thereon should be available to the Congress and to the public * * *. In accord with the policy of [NEPA] * * * and (the President's) Executive order * * * agencies have a responsibility to insure the fullest practicable provision of timely public information and understanding of Federal * * * programs * * *." In sum, public access to environmental impact information is encouraged by NEPA; its basic policy is to provide—not deprive—the public of information.

In commenting on the proposed bill the Department of Health, Education, and Welfare stated:

> Insofar as your proposed statements analyze and discuss the merits of the three legislative proposals we have no comment beyond that which we have already given directly to the Office of Management and Budget in our proposed legislative reports on these same proposals.

Similarly, the Department of the Interior stated:

> Earlier we reviewed the legislative proposal and informed the Office of Management and Budget of our comments. In informal discussions between agency representatives our suggestions for clarifying the legislative proposal, and for making it more effective, have also been expressed.
>
> * * * If the proposed bill is modified in line with suggestions of this and other departments, it should insure an even more effective toxic substance control program.

Where is the public information? I called officials in the Office of Management and Budget (OMB), HEW,[2] and Interior to obtain the comments mentioned above. I was informed that these comments constituted privileged information being part of the President's legislative reference system.

Why has the Council on Environmental Quality permitted the commenting agencies to use the OMB legislative review process as a means for circumventing NEPA's requirement that comments of Federal agencies be made public? Although NEPA recognizes that some information provided by agencies must necessarily remain confidential under the provisions of the Freedom of Information Act, it was certainly not the intention of Congress that agencies could make all their comments on envirnmental impact statements to OMB through the President's legislative reference system and thereby deprive the public of any knowledge of the concerns and problems raised by Federal agencies, of alternatives considered, and of amendments suggested.

It is surprising that the agency which is primarily responsible for establishing what constitutes an adequate environmental impact statement should have submitted such an inadequate statement on the proposed toxic substances bill. And it is difficult to understand how an agency which informed all other Federal agencies that they "have a responsibility to develop procedures to insure the fullest practicable provision of timely public information" would condone an agency's

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[2] I was referred to several officials in HEW. The person whom I finally contacted never called me back to inform me if he could release HEW's comments to me. I presume that HEW's position would be identical to OMB's and Interior's, however.

concealing all its comments from the public by submitting them to OMB in the legislative review process.

Senator SPONG. Facetiously, I might ask if you have testified before Senator Ervin's subcommittee.

Mr. STROHBEHN. I have not.

If an adequate impact statement had been prepared, if detailed studies had been conducted and their results presented in the statement and the agency comments, if the agencies with technical expertise in the field of toxic substances had submitted comments which the public and the Congress could see, this committee could have more efficiently utilized the time it devoted to amending this bill to producing an even better bill in the same time or to considering other important legislation. Moreover, the committee staff—as able as they are—are not as knowledgeable or experienced with the technical problems of protecting us and our environment from toxic substances as are the professionals within the executive branch and the consultants they might retain to advise them. One of the primary reasons for preparing impact statements on proposed legislation is to insure that such expertise is brought to bear on legislation and that Congress receives the data and reasons that were developed to support the policy and provisions embodied in the draft bill, the alternatives that were studied and rejected, and the reasons therefor, and any dissenting views. Adequate environmental impact statements on proposed legislation accompanied by the substantive comments of agencies with expertise would do much to improve the legislation enacted by Congress.

I hope that this committee will express its concern—and will request new submissions from the responsible agencies—when inadequate environmental impact statements are prepared on proposed legislation and when the public is precluded from seeing agency comments because the agency utilized the OMB legislative review process to make its comments.

Thank you.

Senator SPONG. I thank all of you.

Since Mr. Strohbehn was last, his testimony is clearest in my mind. Let me respond to him before questioning. We appreciate your reminding the subcommittee of the mandates of the Policy Act, mandates to which many of us here are often insufficiently sensitive. While I am told there are some tricky legal problems about the public availability of interagency communications under the Policy Act, I think you are undoubtedly correct that the statement could have been more helpful. We will attempt to be more insistent in the future on adequate statements and will seek the Council's support of this stance.

Mr. STROHBEHN. Thank you very much.

Senator SPONG. I will put these questions to all of you, and you can decide among you who wishes to respond. We have 26 minutes. I think we can get them all in.

Section 222 of the proposed amendment to S. 1478 provides for an informal rulemaking procedure for the establishment of all regulations under the bill. Some would suggest that this is a bad idea and that when you are promulgating regulations which will have the force and effect of law, they ought to be based on a comprehensive factual record where cross-examination is available so that the ulti-

mate rules that are developed can be thoroughly examined by those who will have to abide by them.

How would any or all of you react to that argument?

Mr. RODGERS. The argument I do not find very persuasive. The two classic distinctions in administrative law are those between rulemaking proceedings and contested cases. And the principal difference between the two is often cited as the availability of examination. It seems to me we are talking about rulemaking cases. Consequently, no cross-examination.

Senator SPONG. On the question of burden of proof, under the amendments we do shift the burden from Government to industry, and many witnesses have testified here that this is a good idea. A shift, however, also occurs under the amendment in the form in which the proof must be made. For the most part the Administrator will be deciding if a product should be on or off the market. The courts would serve primarily in the capacity of reviewers of the administrative decision. Some would argue that this makes the Administrator both policemen and judge. Does this offend your notions of due process?

Mr. STROHBEHN. It does not offend my notion of due process. I find there is sufficient protection in judicial review. I would suggest that the standards under which the Administrator might act should be spelled out clearly. He should not be given broad discretion to make these judgments. Usually the argument of having too much administrative authority in one agency fits like the AEC which is both the promoter and the policeman. This does not occur in this case.

Senator SPONG. A related question focuses more specifically on the matter of seizure. The amendment provides for summary seizure by the Administrator in the case of an imminent hazard. This seems defensible on the basis of the seriousness and immediacy of the hazard involved. However, even where there is no imminent hazard, the amendment would authorize seizure after an administrative hearing without judicial process.

Do you find this defensible?

Mr. RODGERS. Sure, I find it quite defensible. It seems to me—first, initially there is no question under the old rotten meat/contaminated chicken/pure butter cases that the Government can act before the disaster strikes.

On the second question, the more delicate one you raised, it seems to me a question of getting out of the channels of commerce a product that should no longer be there. We have had a number of unfortunate experiences with respect principally to pesticides, 2,4,5-T products remaining in channels of commerce months after prohibtions were entered, and the same is true with respect to other pesticides, drug products.

It seems to me that administrative action is quite proper under those circumstances and the defendant is protected because, of course, he has opportunities for judicial review.

Mr. STROHBEHN. I was thinking, Senator, it might be wise in response to these questions to say that after one of us responds, the assent of the others might be noted for the record.

Senator SPONG. I was about to ask all of you if there was a presumption that there was no dissent.

Mr. STROHBEHN. I can say concerning the questions asked so far there has been no dissent from myself.

Senator SPONG. Senator Hatfield observes that it is a rare occasion when we get five lawyers to agree on anything.

Mr. STROHBEHN. I am not agreeing with the specific language of the testimony of any one person.

Senator SPONG. I understand.

As you have noted, the amendment calls for citizens suits against the Administrator when he fails to perform mandatory duties under the Act. While most of the duties are in fact mandatory, what would you think of extending the provision to all discretionary activity where the exercise of discretion is unreasonable?

Mrs. SHELDON. I have a comment on that. I think that is very wise. It is the same general strategy, if you will, that is in the Hart-McGovern citizens suit bill, and I for one am very much in support of that. I think this would further open up access to the courts on the part of citizens and that it would give us an opportunity to examine and have judicial review of all sorts of decisions, not ones which are merely set forth in the statutes but actions taken, decisions made, policies that were set within the discretion of the Administrator, and I would suggest that that be added to this bill. I think it is very good.

Senator SPONG. I participated in the drafting of this citizen's suit provisions of the Air Quality Act, and I know that all of you are aware that these matters were gone over very thoroughly before we could end up with any citizen's suit provision.

Senator Hatfield.

Senator HATFIELD. Thank you very much, Mr. Chairman.

Mr. Chairman, first of all, I would like to commend the witnesses for very profound and eloquent testimony this morning. I noted Mr. Strohbehn commented on page 3 of his testimony that he and Mr. Hallman would submit further data at a later time. With the chairman's approval, I would like to suggest at this time if you could submit some of this in the form of suggested draft language it would be very helpful to the committee. It is excellent to get your comments. We certainly want that as well. If you as lawyers could assist us in getting the specific wording that you think would cover the points that you are making in your comments, I think that would be an additional help to the committee.

Mr. STROHBEHN. Thank you for suggesting that, and that was one of the reasons why we decided to submit such comments later, since to read such language would possibly have been boring.

Senator HATFIELD. I was struck by each of the statements made, but especially by Professor Rodgers, and I would like to quote again this particular statement. He said:

> Certainly we should have learned from cyclamates, DDT, 2,4,5-T or phosphates that once a technology is turned on and incorporated into the nation's commercial fabric, turning it off calls for economic disruption, political turmoil and governmental vacillation. Scientific integrity is sacrificed under the assaults of the marketplace.

I couldn't agree more, and I would only add one comment to that merely to focus upon another segment of that scenario that you have developed here. This is leading to a specific question that relates to your suggestion that the language of this bill be broadened. Mr. Hall-

man has testified supporting not only include existing or rather new chemicals and substances, but also to cover existing products that are found in the marketplace that might be found conveying toxic and other such activity.

I have been advised by some medical people that alcohol could conceivably be included under the interpretation on page 2 of the definition, that a chemical substance means any organic or inorganic substance of a particular molecular identity or any uncombined element or radical. This gets back to the role of public education, and public understanding.

Would you perhaps not agree that toxicity and other such measurements were found incorporated in alcohol, and I am talking about fine bourbons, scotch, vodkas, wines, beers and any other, that we would be faced here with a rather interesting task as far as imposing this kind of regulatory restriction upon the public? How would you respond to that?

Mr. RODGERS. Yes, Senator, I think you raise a host of fundamental questions.

It seems to me first of all this committee would have to face up to an issue analgous to that of the GRAS list—generally recognized as safe list—that the Food and Drug Administration had to establish at the time of the 1958 amendment; that is, you are dealing with a problem of how to handle the grandfather clause or the grandfather cases, the existing products.

You would initially have that kind of determination, and I think generally the issue is met in this particular draft. Beyond that—that is singling out what products on the market we want to take a further look at—you have raised the question of alcohol.

It seems to me there one of the criteria that the Administrator would want to invoke, and I notice that this is not included in the specific language, would be whether the exposure was voluntarily undertaken by the particular individual or whether it was not. But in any event, assuming that alcohol would be covered by the language, and I at this point would not feel confident in offering an opinion on that, there would be initially a question for the Administrator to exclude on a wholesale basis—and that would be in a rulemaking proceeding—those products upon which additional testing would not be called for.

As indicated, that would be similar to the GRAS list with respect to the food and drug amendments.

Senator HATFIELD. Are we yielding, as you say, here to the scientific integrity—the point of scientific integrity for public demand or public request?

Mr. RODGERS. That point goes to the problem with respect to our ability to evaluate a future technology. I think the point we call all agree on is that when we have products in the marketplace, we are past a stage where scientific analysis can be fairly evaluated.

We are into the stage, and this is especially true with respect to the chemicals that have been mentioned here, where there is a commercial interest in further use, there is an invariable issue as to whether there are acceptable alternatives, and that issue is always hotly contested.

Then there is the further question that you raise about the desirability or where the interest of the public to continue to use. I think

that that interest would invariably be considered—well, it certainly would be considered in the formulation that appears in Senator Spong's amendments, but because that speaks of unreasonable threats, and it seems to me in that context of reasonableness, which, of course, we have our general tort law for negligence, we have to always evaluate the benefits and potential risks when it comes to a particular product.

Senator HATFIELD. I point this up because I think here again, if I may be so blunt, you are vascillating a little bit on the issue for this simple reason. I think to point up the difficulty, the real complexity of this whole matter when we begin to try to apply purely and exclusively scientific testing, it is awful easy to say this is from this day forward. But remember, let's go back to the essence of this bill, to protect health and environment. This includes animal life as well as the general national environment.

We must be careful when we imply in a rather decisive way that there is going to be a scientific test made and that that is going to be the governing factor, and it is going to govern the distribution and the sale and the consumption. We not only have to look at the point from the grandfather prospect, but we have to look at that public involvement as well and public acceptance or public attitude, and especially when we include citizens' suits.

We could say the same thing about tobacco warnings about health. We have legislated putting a warning on a package of cigarettes and all that goes with it. The public hasn't accepted it.

You see it has not become a part of the public realization or belief yet that this is truly injurious to health.

When I was on the American Cancer Society board of directors for a number of years, I would listen to the doctors chain smoke as they read their papers on the relationship between cigarettes and lung cancer. You would think that of all people, doctors and scientists, this would be something they would believe that they were trying to convey. But this shows the mortal character of all of us.

I think also we have to look at this factor. I sat on the Small Business Committee on the drug hearings, and constantly we were confronted with the proposition that on selected and short-time use certain drugs would produce no toxicity or other side effects. But, was that sufficient to make them marketable, or put them into the marketplace, because we also knew that in some drugs the long-term use would have a totally different result than the short-term use.

We also know that we were told by the scientists that you could not automatically transfer the results of tests shown in animals, such as rats or guinea pigs or monkeys, to the human. Therefore, we could not just say scientifically these are the results we have found in the testing of animals; therefore it has to be applied as the expected result in the human being.

We face some of these scientific problems as well as to getting down to these definitions that are going to be enforceable.

I am in total sympathy with your basic advocacy here this morning, especially I want to commend you on raising the question of exports. This to me is a fundamental point that we have not faced up to in this bill yet. We are ready to protect our own people, but not people in the rest of the world. I just wanted to raise these points—not as an antagonist—but just to raise them to illustrate some of the

difficulties we face as drafters of legislation. It shows why we gentlemen rely on you to help us out in defining it with legal language, so it will make it enforceable. I mean not only an enforceable act from the Administrator's point of view, but from the public's point of view also; recognizing the role we have to help educate.

I just raise these points, Mr. Chairman, as I say, not as an adversary, but really just to illustrate some of these problems we have to try to resolve on this committee, and why we need this kind of help that I think has been very positive today.

Senator SPONG. Thank you, Senator Hatfield.

Do any of you want to respond?

Mr. HALLMAN. I would just like to respond briefly with this notion:

I would not want to lose sight of the terrific potential this type of legislation has for performing the educational counterforce to the advertising, to the other forces that have perhaps been enplanted, and generated, the kind of pleasures you are speaking about.

It seems to me aside from the restricted actually saying I am going to say what is good or bad for you—that approach, which is in the bill, at the very least, it can serve as a kind of scientific testing, a kind of weighing of information that will be available to the Administrator, and making that kind of information available to the public at least would be a worthwhile effort to put them in a position to intelligently assess and determine whether he wants to adopt a particular risk that he is not aware of.

Senator HATFIELD. I think your point about the voluntary relationship to consumption of some of these things is a valid one, too. And I am not so sure I would feel as you might imply by your comments—maybe this is misinterpreting your comments—that merely making available to the public information and knowledge is sufficient to really get the kind of response that we would hope. We have even cut off advertising of tobacco on television to try to cut out some of that so-called stimulus. I am not aware that the sales have gone down.

Mr. HALLMAN. Advertising in magazines has gone up. I didn't mean to imply that that would be an alternative. Perhaps you could strike a balance and say on existing products, you know, where you have got a terrific commercial investment, you may or may not want to stir up. But on existing products such as alcohol, I know there should be a terrific effort made to educate the public.

On the new products, I think that that is something that should be covered with the use concept.

Senator HATFIELD. As a former educator, I am not so sure we have really developed the effective technique in the formats of education we have used, for instance, on alcohol or on drugs, because it doesn't appear that we have gotten much result from our efforts.

Perhaps here again we need a little research on educational techniques or it may be broader than that. Of course, I feel there is a certain interrelationship to this whole matter of escapism that is often alcohol, drugs and so forth, and other public policy such as war and peace, Federal resources, certain military policies. I think there are interrelated points here that create some of the malice that we see the public using such escapist tactics.

But I agree that we are dealing with a very complex issue. I am not so sure that purely a legal approach having a hard-type bill which we all really want is going to get the job done, because if the public does not support the legislation, as we have learned in prohibition, it is not going to work. That is the point I want to make: It is awful easy to point to pesticides, because there is not the personal relationship that people have, say, to a glass of alcohol. It is simple to say it is their fault we must regulate them—but not me.

I feel that we have to convey somehow the personal responsibility and relationship we all have to any such laws that are really going to be for the protection of health nad environment and animal life. I think perhaps your organization is maybe making a greater contribution to this than you and we are aware at this point. From this foundation we may be able to move to a public awareness that is willing to accept some of this.

Mr. DIENELT. I would like to briefly make one comment that comes to mind from what Senator Hatfield said with regard to the use of science in deciding whether to use new products at least if not products that are already on the market.

It seems to me that the thrust of the bill is to place the burden on the manufacturers, and also I think to place the burden on science. When we have a situation where we can't transfer the findings of experiments on mice or monkeys to humans that at least when we have a new substance, perhaps the burden should be weighed until we can say more definitely with respect to the science than to go ahead attempting assumptions and creating situations where the substance is now in use and it is much harder to get rid of.

Senator HATFIELD. I would agree, technology is not always the answer.

I think we have to get back to the point of the human factor in all of these and the human being's response. They are not always going to be found in the laboratories.

Mrs. SHELDON. I have one comment on what you have been saying, Senator Hatfield.

In my experience in the country at large this year, I have done quite a bit of public speaking and participating in environmental workshops and community groups and things of this kind, and perhaps it is because the environment is such an attractive issue right now, it has gathered a lot of support that may or may not fall away; but I have found that most people, at least the people I have talked to, are very genuinely concerned about knowing what is going on and knowing what is the products they buy or use or are being used by industry.

The example that I think as relevant or as analagous to alcohol is detergents. We are told or have been told by detergent manufacturers that the American housewife will not have slightly less than dazzling white clothes, that we just couldn't send our husband to work in maybe a gray shirt instead of a whiter than white shirt.

I don't think this has been proven the case over the year. In talking with people and getting their reactions, I think that they are willing and happy to remove phosphates, to remove NTA, to remove enzymes so you can achieve a better water quality.

The first task is to know what is going into the product and with that knowledge we can make some kind of decision. I think you are

going to find that public taste is not going to be the universal criteria on that.

People have judgment. They have concern and that will make the necessary changes. I concur very heartedly with Mr. Hallman's comments that it is largely a matter of education. People have a right to know. We have a right to control what we buy, to have control over the decisions that affect our lives and environment and our larger environment.

For most of us, it is not possible. This is not possible now. You don't know what is in the food you buy; you don't know what is in the products you buy. This bill will throw many people in that direction. If people are allowed to make decisions with all of the items on the table, with all of the data available, then for the most part, and I guess this is my basic faith in human nature, they will make decisions that are rational and that are not only for their own personal good and personal taste but for the larger good, the larger environment.

Senator SPONG. I am inclined to agree with that. I think people are being very confused by the mass media commercials. I think the public is having a very difficult time determining what the facts really are. I have been extremely encouraged in speaking to younger groups. If you can give them a specific example, the Potomac River, for instance, what are the nutrients, the slowness of the flow, and what has contributed to a great deal of the pollution there, that they have no difficulty in translating that problem in terms of detergents and phosphates or anything else.

But I think we are going through a period where there are so many broad, sweeping rhetorical statements that the uninformed say, it's all black or it's all white.

I think the great responsibility of your organizations and those of us who are elected to represent the people, is to get accurate information to people so they can make these very judgments.

We have largely gone beyond the high rate of emotionalism with regard to problems like these, but I have been in meetings and the degree of unreasonableness I found was just unbelievable.

I just hope that as we explore this and other legislation, that all of us will continue to try to get the facts to people upon which they can make the judgments you spoke of.

Mr. RODGERS. One last point on the question of public information. I think the legislation speaks to that in some depth.

I understand that around 1950 our traditional analysis in the laboratories for testing chemicals was basically acute toxicity, and over the years the requirements for those tests have been increased accordingly. There is no question that this legislation that speaks of carcinogenic effects, cancer causing effects, the nature of the product in the environment, those are all new standards to be met, new scientific information to be gathered, and with scientific data at least for the new products we will have a chance to evaluate before we rush into the new technology.

Senator HATFIELD. I couldn't agree more, if I may just make one concluding comment, Mr. Chairman.

First of all, I think we have to move where there is cause and reason to move, and not wait for the public to be ready for that. I think we

have to take leadership. Therefore, if the public is going to respond in this area, then let's move in this area.

But I don't think we can neglect the simple fact that when it comes to the point of people's convenience at times they will reject the facts. They will reject the overwhelming evidence and they will reject all their past understanding. Perhaps it is because I have worked in the field of mental health and alcoholism and correctional problems within my own State for so many years that I have seen this.

I could take you into a prison and show you the human derelicts that are there because of alcohol. I could take you to any penitentiary or correction institution and relate the problem to alcohol. I could show you in the mental hospitals the relevance of alcoholism to the problems for which these people are institutionalized. That is pretty solid evidence, not just theory and statistics. Those are people.

In light of all of that, alcoholism continues to grow in this country. So, all I am saying is simply this: You may get this response on the detergent because there is an alternative perhaps or it is hopeful that technology will bring an alternative; this is good. Let's move on this.

But I still say we have some basic understanding of problems that go beyond the technical understanding, and statistical understanding that people will just reject. I think we have to face up to that and not be discouraged if we run into that kind of thing, but we must pursue it.

That is what this committee wants to do. I think it is going to take more than the idea that as long as people know the facts, they will judge them rationally. I just don't accept that amount of faith in humans, because I have never seen too much of it. I have seen too much evidence to the contrary. Maybe this is the way we are going to get this corrected, is get these citizens' suits here to see what the courts say about it.

Senator SPONG. They are all being confused by these jingles that proclaim it is all being taken care of by someone that is not.

Thank you all very much.

(Whereupon, at 1 p.m., Thursday, August 5, 1971, the hearing was recessed.)

(The following was referred to on p. 131:)

ASBESTOS INFORMATION ASSOCIATION,
New York, N.Y., August 4, 1971.

Hon. WARREN G. MAGNUSON,
Chairman, Senate Commerce Committee,

Hon. PHILIP A. HART,

Hon. WILLIAM B. SPONG, Jr.,
U.S. Senate
Washington, D.C.

DEAR SENATORS: In his opening statement Tuesday, August 3, at hearings on S. 1478 and amendments, Senator Spong stated that the Subcommittee on Environment would receive testimony concerning asbestos.

Existing evidence does not show that asbestos in its major and essential uses constitutes a threat to the general environment or to public health. Occupational, industrial and other related exposures to asbestos dust can be, and are being, controlled by both industry programs and by existing governmental regulations.

Because of this expressed interest by the Subcommittee in asbestos, we request your permission to submit for the committee's consideration and for inclusion in the record of the hearings the following two relevant documents:

I. *Airborne Asbestos*, a Report prepared by the Committee on Biologic Effects of Atmospheric Pollutants of the Division of Medical Sciences, National Research Council, and its panel of experts on asbestos. This Report, recently com-

pleted, concludes with a statement on the "Need for and Feasibility of Controls" as follows:

> Asbestos is too important in our technology and economy for its essential use to be stopped. But, because of the known serious effects of uncontrolled inhalation of asbestos minerals in industry and uncertainty as to the shape and character of the dose-response curve in man, it would be highly imprudent to permit unrestricted additional contamination of the public environment with asbestos. Continued use at minimal risk to the public requires that the major sources of man-made asbestos emission into the atmosphere be defined and controlled. In the absence of such controls, local fiber concentrations might at times approach those in occupational sites. Analytic methods and epidemiologic data are inadequate for the development of ambient air standards, but emission controls are needed and appear feasible.

The AIA/NA concurs in essence with this recommendation and the industry has taken initiative in programs to control at safe levels airborne asbestos in both occupational and public environments.

II. A summary of existing laws that encompass conditions of manufacture and use of asbestos products, with respect to protection of public and occupational environments. These establish mechanisms to attain the controls recommended by the NRC Report. As S. 1478 provides, these existing laws, which cover all major uses of asbestos, will continue to be implemented with respect to asbestos manufacturing and use.

We are in agreement with the general intent of the legislation being considered and with your committee's continuing efforts to provide for maximum protection of public health and of our environment. We hope our submissions will be useful in committee considerations.

Regarding asbestos specifically, we believe existing laws and regulations already provide for whatever controls are necessary and desirable to assure protection of the environment and public and occupational health.

Respectfully.

WILLIAM P. RAINES, *Secretary.*

Attachments.

SUMMARY OF NRC STUDY: AIRBORNE ASBESTOS

The attached report was prepared for the Environmental Protection Agency by a special panel on asbestos and the Committee on Biologic Effects of Atmospheric Pollutants of the Division of Medical Sciences, National Research Council. The Report was issued by the National Academy of Sciences.*

Although largely devoted to medical research aspects of industrial exposures, the Report discusses some of the many essential uses of asbestos in our modern society and concludes that "asbestos is too important in our technology and economy for its essential use to be stopped." The various occupational diseases associated with the heavy inhalation of asbestos fiber are described, and the question raised as to whether there is any hazard to the general public from the tiny amounts of fiber that have been demonstrated to exist in the ambient air.

With regard to fibrosis of the lung, the report states that "occupation-related asbestosis can be effectively controlled with airborne fiber concentrations much higher" than any the general public may be exposed to. Concerning lung cancer, the report points to the studies of Knox *et al*, Newhouse and McDonald *et al* as evidence that lung cancer associated with asbestos exposure will develop only among those workers with heavy and prolonged exposure, a situation not found among the general public.

Mesothelioma, a rare cancer of the lining of the lung and abdominal cavity, has occasionally been found among people living in close proximity to uncontrolled asbestos plants and mines; however, the report comments that "there is no evidence that persons in the general population—without occupational, household, or neighborhood exposures—have any increased risk of neoplasm."

The study further warns against extrapolating "from the mortality experience of those who are directly and indirectly exposed to asbestos in their employment

*PB 198–581, U.S. Department of Commerce, 1971.

to the general public who have had moderate or slight exposure from ambient air." The report notes the difficulty in making such projections due to the lack of reliable data, and suggests that there be more epidemiological studies, especially of populations in lower exposure ranges.

While the report concludes that "there is no evidence that the small number of fibers found in most members of the general population affect health or longevity," it nevertheless recommends that "major sources of man-made asbestos emission into the atmosphere be defined and controlled," and concludes that such controls are feasible.

AIRBORNE ASBESTOS—A Report Prepared by the Committee on Biologic Effects of Atmospheric Pollutants of the Division of Medical Sciences, National Research Council.

Dr. Arthur B. DuBois, Department of Physiology, School of Medicine, University of Pennsylvania, Philadelphia, Pa., *Chairman.*

Mr. Vinton W. Bacon, College of Applied Science and Engineering, University of Wisconsin, Milwaukee, Wis.

Dr. Anna M. Baetjer, Department of Environmental Medicine, School of Hygiene and Public Health, The Johns Hopkins University, Baltimore, Md.

Dr. W. Clark Cooper, School of Public Health, University of California, Berkeley, Calif.

Dr. Morton Corn, Graduate School of Public Health, University of Pittsburgh, Pittsburgh, Pa.

Dr. Bertram D. Dinman, School of Public Health, University of Michigan, Ann Arbor, Mich.

Dr. Leon Golberg, Institute of Experimental Pathology and Toxicology, Albany Medical College, Albany, N.Y.

Dr. Paul B. Hammond, Department of Physiology and Pharmacology, College of Veterinary Medicine, University of Minnesota, St. Paul, Minn.

Dr. Samuel P. Hicks, Department of Pathology, University of Michigan Medical Center, Ann Arbor, Mich.

Dr. Victor G. Laties, Department of Radiation Biology and Biophysics, University of Rochester Medical Center, Rochester, N.Y.

Dr. Abraham M. Lilienfeld, Department of Chronic Diseases, School of Hygiene and Public Health, The Johns Hopkins University, Baltimore, Md.

Dr. Paul Meier, Biomedical Computation Facilities, University of Chicago, Chicago, Ill.

Dr. James N. Pitts, Jr., Department of Chemistry, University of California, Riverside, Calif.

Dr. Gordon J. Stopps, Haskell Laboratory, E. I. duPont de Nemours & Co., Newark, Del.

Dr. O. Clifton Taylor, Department of Horticulture, University of California, Riverside, Calif.

Dr. Jaroslav J. Vostal, Department of Pharmacology and Toxicology, University of Rochester Medical Center, Rochester, N.Y.

Executive Director, T. D. Boaz, Jr., M.D.

PANEL ON ASBESTOS

Dr. W. Clark Cooper, School of Public Health, University of California, Berkeley, Calif., *Chairman.*

Dr. Lewis J. Cralley, Bureau of Occupational Health and Safety, Division of Epidemiology and Special Services, U.S. Public Health Service, Cincinnati, Ohio.

Dr. Benjamin G. Ferris, Jr., Department of Physiology, Harvard School of Public Health, Boston, Mass.

Dr. Paul Gross, Industrial Hygiene Foundation, Inc., Pittsburgh, Pa.

Mr. Duncan A. Holaday, Occupational Health Field Station, Salt Lake City, Utah.

Dr. Irving J. Selikoff, Environmental Sciences Laboratory, Mount Sinai Hospital, New York, N.Y.

Dr. George W. Wright, Medical Research Department, St. Luke's Hospital, Cleveland, Ohio.

Dr. Samuel P. Hicks, Department of Pathology, University of Michigan Medical Center, Ann Arbor, Mich., *Associate Editor.*

Dr. T. D. Boaz, Jr., Division of Medical Sciences, National Research Council, Washington, D.C., *Staff Officer.*

PREFACE

The naturally occurring fibrous silicates classified as "asbestos" have become almost indispensable in modern technology.[67,125,142] The world's annual production has grown from a few thousand tons in 1900 to over 3 million tons in 1968.[121] Annual consumption in the United States averaged nearly 800,000 tons during the period 1965-1969.[121] The potential of asbestos as a hazard to health has been the subject of a number of reviews in recent years.[22,49,60,134,137,146,148,168]

Although it has been known for a half-century that persons who inhaled large amounts of asbestos dust in the course of their work sometimes developed disabling or fatal fibrosis of the lungs, it has been only within the last three decades that other serious effects, such as cancer, have been associated with occupational exposures. Recently, the likelihood of exposure of the public at large to asbestos has been recognized and has led to a demand for more rigorous control of asbestos emissions into the atmosphere.

"Asbestos" is a generic term for a number of hydrated silicates that, when crushed or processed, separate into flexible fibers made up of fibrils.[46] Although there are many asbestos minerals, only six are of commercial importance: chrysotile, a tubular serpentine mineral, accounts for 95% of the world's production; the others, all amphiboles, are amosite, crocidolite, anthophyllite, tremolite, and actinolite. The asbestos minerals differ in their metallic elemental content, range of fiber diameters, flexibility or harshness, tensile strength, surface properties, and other

attributes that determine their industrial uses and may affect their respirability, deposition, retention, translocation, and biologic reactivity.

This report (1) summarizes the major evidence of the pathogenicity of asbestos in man and animals, (2) summarizes the evidence of human nonoccupational exposure to asbestos, (3) evaluates the evidence of a health risk associated with various degrees and types of exposure, (4) identifies sources of environmental contamination by asbestos, and (5) offers recommendations concerning the need for and feasibility of control measures.

W. Clark Cooper
Chairman

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CHAPTER 1

PATHOGENICITY OF ASBESTOS

The effects of fibers in biologic systems may result not only from the properties of the fibers themselves, but also from contamination with inorganic or organic substances that occur naturally or are added during mining, milling, processing, shipping, or use. Contaminants acquired from the atmosphere or in the respiratory tract may be carried on the surface of fibers. Fibers may act as cofactors; conversely, their action may be modified by other cofactors.

PATHOGENICITY IN MAN

The proven or suspected effects of asbestos minerals on human health include nonmalignant changes, such as pulmonary and pleural fibrosis, and several types of malignancy, notably of the lung, pleura, and peritoneum. Nearly all the positive evidence of an association between asbestos and human disease has come from occupational groups. With few exceptions, these have consisted of workers engaged in the mining and milling of asbestos, the manufacture of asbestos-containing products (such as textiles and construction materials), and the application and removal of asbestos-containing insulating materials.

Asbestosis

Asbestosis, or asbestotic pneumoconiosis, was the first clearly demonstrated adverse effect of asbestos in man. It is characterized by a pattern of roentgenographic changes in the lung consistent with diffuse interstitial fibrosis of variable degree and at times with fibrosis and calcification of the pleura; clinical changes that include fine rales,

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finger clubbing, and shortness of breath, each of which may be absent in an individual case; and physiologic changes consistent with a restrictive lung disorder.

The first published mention of a case, in a man who had worked for 10 years in the carding room of an asbestos factory, was by H. Montague Murray in 1907.[111] Cooke reported a second case in 1924[20] and in 1927 provided a more detailed description,[21] in which the term "asbestosis" was first used. In 1930, Merewether[105] reviewed the salient features of the disease and the environmental exposures of workers, including data derived from an epidemiologic study reported in more detail by Merewether and Price.[106] This led to the promulgation of regulations for environmental and medical control in the United Kingdom, which became effective in 1932.[7] Cases were first reported in the United States in 1930,[110,141] and guidelines for acceptable dust concentrations were proposed by Dreessen et al. in 1938.[32]

Industrial experience indicates that pulmonary fibrosis sufficient to interfere with respiratory or cardiovascular function can be prevented by reducing asbestos dust concentrations to levels that are still far above any likely to be encountered in community air.

Pleural Calcification

Calcified pleural plaques occur frequently in workers exposed to asbestos.[5,6,43,103,108,130] When multiple or bilateral, they are regarded by some as almost diagnostic of asbestos-related disease.[43,71] In asbestos workers, calcified plaques rarely appear until 20 years after first exposure and do not necessarily correlate with parenchymal fibrosis.[91]

Calcification appears to differ in frequency in different occupationally exposed groups, but studies are inadequate to verify or explain such differences.

Bronchogenic Carcinoma

No features of bronchogenic carcinoma associated with asbestos are pathognomonic. Primary sites are more often in the lower lobes, in contrast with the usually higher frequency of upper lobe tumors. Peripheral primary sites are common in asbestos-related lung cancer. All cell types are represented in most series.

The first suggestion that asbestos might be causally related to cancer of the lung was made in 1935 by Lynch and Smith,[91] who described squamous cell carcinoma in a South Carolina textile worker with asbestosis. Despite other isolated reports, an association was not firmly supported by epidemiologic evidence until 1947, when Merewether, Chief Inspector of Factories in the United Kingdom, reported 31 instances of cancer of the lung in 235 persons known by his department to have died with asbestosis between 1924 and 1946.[104] That constituted an incidence of 13.2%, compared with 1.32% (91/6884) in persons certified as having had silicosis during the same period. Gloyne in 1951[50] reported on the pathologic findings in 1205 lungs from workers whose cases were being evaluated for pneumoconiosis. In 132 asbestos workers, he found 121 with asbestosis, of whom 17, or 14.0% had cancer of the lung, compared with 55 (6.9%) of 796 persons who had silicosis. The study was done, however, in a hospital to which suspected tumor patients would have been referred; thus, there may have been an overestimate of risk. Doll in 1955,[31] after analyzing the causes

of death among 105 men who had worked for at least 20 years in areas of asbestos textile plants defined as dusty, concluded that the 18 cases of lung cancer that occurred indicated a risk about 10 times that in the general male population.

Other studies[11,13,15,18,23,24,33,34,38-40,59,70,74-76,80-82,87,93,94,98,101,112,131,149,154,155,161,169] have confirmed an association between occupational exposure to asbestos and a highter-than-expected incidence of bronchogenic cancer. Some studies[13] have demonstrated differences in the degree of risk among different occupationally exposed groups, probably related to dose, as well as to other factors.

Mesothelial Tumors

Primary malignant tumors of the pleura and peritoneum have been regarded as exceedingly rare by most pathologists; until recent years, some even questioned their existence. There are still differences of opinion as to diagnostic criteria.[18,70,98,149] Therefore, statistics on prevalence or incidence in one geographic area cannot be safely compared with those from another. Adherence to strict diagnostic criteria, including an autopsy complete enough to rule out other primary tumors that could metastasize to or involve serosal surfaces, is a difficult constraint on a retrospective series.

It was after 1960 that serious consideration was first given to asbestos as an etiologic factor in mesothelial malignancies. In that year, Wagner et al.[161] reported 33 cases of pleural mesothelioma in a part of South Africa important for crocidolite mining. For all but two of the patients, the authors discovered likely asbestos contacts two decades or

more earlier. However, only 17 of these had had occupational exposure. The remainder had lived near mines or had had household contacts. Although mesothelioma had previously been attributed by some to asbestos exposures,[86,164,165,169] no evidence of a strong association had been developed.

Additional information supporting a relationship between asbestos and malignant mesothelioma has accumulated since 1960.[9,12,36,37,41,42,59,75,80,88,93,95,99,100,102,113-116,132,134,136] An outstanding feature has been the long period, commonly over 30 years, between the first exposure to asbestos and the appearance of a tumor, as emphasized in reports by Wagner[158] and Selikoff et al.[134]

Other Neoplasia

Associations between asbestos exposures and malignancies of the gastrointestinal tract and of other sites have been reported, but the data are still inconclusive.[52,59,77,94,134]

Mutagenic Effects

There is no evidence that asbestos is associated with mutagenesis.

PATHOGENICITY IN LOWER ANIMALS

A comprehensive review of information derived from experimental work in animals entails consideration not only of the variables related to the type and dimensions of the asbestos fibers and of adsorbed or concurrently administered contaminants, but also of the species and strain of animal, the route of administration, and the time and dosage factors. There are at present no satisfactory experimental models to duplicate prolonged inhalation of asbestos by man, but many isolated segments of the problems have been elucidated. The studies are best divided into those dealing with asbestosis and those dealing with neoplasia.

Experimental Asbestosis

Asbestotic pulmonary fibrosis has been produced experimentally in various species of animals, including rats,[45,58,156,157] guinea pigs,[29,45,69,157] hamsters,[55] rabbits,[157] and monkeys.[157] In many of the studies, the disease resembled early asbestotic development in man--e.g., it was multifocal. Diffuse fibrosis has also been produced,[157] but to do so it was necessary to use very high concentrations of asbestos dust and long periods of exposure or observation after exposure. (In contrast, experimental silicosis can be produced with lower cumulative exposure.) In the course of the investigations, it has been asked whether the fibrogenicity of asbestos dust is mostly confined to fibers longer than 5 μm;[45,156] the question is still unanswered.

Experimental Neoplasia

Lung cancer from chrysotile dust has been produced experimentally in rats[58] and in mouse lung implants.[140] Other investigators who used different methods for introducing the dust[143] did not find lung cancer in the animals they studied. That some asbestos dust has an increased content of trace metals--particularly nickel, chromium, and cobalt--may explain these differing experiences. Rats whose lung clearance had been artificially impaired had twice the lung cancer rate of animals with normal clearance.[58]

Cancer of the pleural surface (mesothelioma) has been reported in rats and hamsters that received intrapleural injections of the three most common types of asbestos.[139,159,160] The amounts of asbestos dust introduced into the thoracic cavity were very large, and translation of results to human inhalation of asbestos is uncertain.

The studies of Roe et al.,[124] which involved pleural and peritoneal mesotheliomas of mice after subcutaneous injections of crocidolite, amosite, or chrysotile, are of particular interest because they yielded evidence of migrations of fibers.

Naturally Occurring Effects in Lower Animals

There is no evidence that effects on domestic or wild animals are important as criteria for controlling asbestos emissions. Schuster has described pulmonary asbestosis (without the development of asbestos bodies) in a dog that lived for nearly 10 years as a ratcatcher in a London asbestos factory.[128] Webster has demonstrated fibrosis in donkeys, baboons, and wild rodents in South Africa,[163] and Kiviluoto has described the finding of anthophyllite asbestos in the lungs of a cow in an anthophyllite-producing area of Finland.[79]

STUDIES IN VITRO

There have been limited studies of the effects of asbestos in biologic systems in vitro. For example, MacNab and Harington[92] demonstrated in 1967 that asbestos would hemolyze sheep erythrocytes. This has been confirmed by others.[127,129] Although chrysotile is markedly hemolytic, amosite, crocidolite, and anthophyllite have little or no activity under similar conditions.

Parazzi et al.[117] demonstrated in 1968 that both crocidolite and chrysotile were cytotoxic for guinea pig macrophages in culture. The activity of the former was greater; the cytotoxicity of neither was inhibited by

polyvinylpyridine N-oxide, a macromolecular chemical that is effective in preventing the cytotoxic damage caused by crystalline silica in experimental conditions.

Although the foregoing types of study have no known relationship to fibrogenic or carcinogenic effects in vivo, they provide systems that may prove useful in determining mechanisms of action and approaches to prophylactic or therapeutic measures.

INFLUENCE OF MAJOR VARIABLES ON PATHOGENICITY

When considering the importance of type of asbestos, fiber size, and cofactors on biologic effects, it is necessary to emphasize that a given attribute may influence in differing ways the respirability, deposition, retention, clearance, translocation, and biologic reactivity. Although some in vitro and laboratory studies yield different responses to different types of asbestos, the results do not justify drawing firm conclusions as to the relative pathogenicity of the different types. Nor do epidemiologic studies conclusively support such differences. All the commercially used forms of asbestos can produce asbestosis. In only relatively few studies has the incidence of malignancies been determined in groups with exposures to a single asbestos type. Where there are data that suggest a lower risk, as in the chrysotile-producing areas of Canada[13,100] and Italy,[154] there are possible explanations for the difference other than asbestos type. The high incidence of mesothelial tumors in the North Western Cape area of South Africa has led to the suggestion that crocidolite is unusually hazardous, but mesotheliomas have been rare in the Transvaal, where crocidolite is also produced.[49,138] Although Selikoff et al.[132] found

many mesotheliomas in insulation workers whose exposures had been largely to chrysotile and amosite, Sluis-Cremer[138] and Webster[162] have not found the incidence of mesothelioma high in areas where amosite was mined and milled, and McDonald[101] did not report an excess in the chrysotile mining and milling areas of Canada.

All epidemiologic studies that appear to indicate differences in pathogenicity among types of asbestos are flawed by their lack of quantitative data on cumulative exposures, fiber characteristics, and the presence of cofactors. The different types, therefore, cannot be graded as to relative risk with respect to either asbestosis or neoplasia.

Fiber size is critically important in determining respirability, deposition, retention, and clearance from the pulmonary tract and is probably an important determinant of the site and nature of biologic action. Little is known about the movement of fibers within the body, including their potential for entry through the gastrointestinal tract. The aerodynamic properties of fibers depend largely on their diameter; fibers below 3.5 μm in diameter are regarded as being in the respirable range.[152] Fiber length affects deposition, longer fibers apparently having greater fibrogenic effects.[44,156] Until recently, most work and speculation have involved only fibers detectable by the optical or light microscope (LM), approximately 0.5 μm in diameter and larger. The application of electron microscopic (EM) techniques[134] has enlarged our horizons as to the variables that must be considered. Tissues and air samples may contain many EM-sized fibrils for every LM-sized fiber that can be demonstrated.[84,134] There is, however, no body of knowledge that permits the assigning of relative risk factors to fibers in the EM

range, compared with fibers in the LM range. It is possible that the relative risks associated with fibers of different sizes are different for nonmalignant and malignant changes. The evidence that bundles of fibrils may be broken down within the body to individual fibrils is important.[147]

A number of investigators have postulated that a probable role of asbestos fibers in producing disease is to carry toxic or oncogenic substances to vulnerable sites. Studies bearing on this have included analysis of various types of asbestos to determine the contaminants present, with special emphasis on metals[26,27] and polycyclic hydrocarbons;[48,61-64] studies of the elution of contaminants in biologic materials;[26] and the concurrent exposure of animals to asbestos and to other materials.[109] The present consensus is that contaminants are present, but a special pathogenetic role is still speculative.

The work of Selikoff *et al.*[135] strongly suggests a synergism of cigarette smoking and asbestos exposure in the increased risk of lung cancer in insulation workers. It is not known whether this is because of reduced clearance of asbestos, transportation of cigarette-smoke carcinogens by asbestos fibers, or the promotion by one factor of cancer initiated by another.

CHAPTER 2

EVIDENCE OF HUMAN NONOCCUPATIONAL EXPOSURES

Direct and indirect evidence that persons other than those working directly with asbestos minerals are being exposed to asbestos is of several types. For example, asbestos fibers can be demonstrated in the lungs of persons not occupationally exposed. In a few geographic areas, pathologic changes regarded as representing a reaction to asbestos (e.g., pleural calcification) have been found in populations with no history of occupational exposure. Asbestos fibers have been demonstrated in ambient air.

FIBERS IN LUNG TISSUE

Structures that appear to be fibers coated with a pigmented material were described in lung tissue as early as 1907 by Marchand.[96] These structures were actually fibers coated with hemosiderin. In 1929, Cooke[19] described such "curious bodies" in association with pulmonary fibrosis. Stewart and Haddow[144] referred to them as "asbestosis bodies." Because those who work with asbestos exhibit them a few months after starting work, it was recognized that they were evidence of exposure, but not of asbestosis. The term "asbestos body" came to be the preferred designation.

As long as the coated fibers were found in persons known to have been occupationally exposed to asbestos, the identity of the central fiber was seldom questioned, although from time to time similar objects were found in persons with no known exposure to asbestos. Meurman[107] in 1966 summarized 19 reports published between 1932 and 1962 in which these objects were associated with exposure to graphite, coal, hornblende, rutile, diatomaceous earth, carborundum, and talc (in which case tremolite asbestos might have been involved). The demonstration by Gross[54,56] that other fibers may

produce such bodies in experimental animals indicates that they result from a nonspecific reaction to any sparingly soluble fibrous foreign body, as had first been suggested by Cooke in 1929.[19] There is thus ample justification for abandoning "asbestos body" as a generic term; Gough[51] in 1965 suggested the term "mineral fiber-body," and Gross[53] in 1966 recommended "ferruginous body."

Thomson et al.,[151] in 1963, were the first to show that these coated fibers were present in a high proportion of lungs obtained by routine autopsy. They found that 26.4% of lung smears in 500 consecutive autopsies in Cape Town showed what were called "asbestos bodies." Reports from many other areas have confirmed a high prevalence in lungs obtained in similar autopsy series.[3,8,17,30,47,107,118,123,150] Utidjian et al.[153] inferred that, if a sufficient volume of lung tissue were examined in each case, nearly all persons would be found to have such bodies; their study of 100 lungs in Pittsburgh confirmed their suggestion.

Identification of the core fibers has proved to be a formidable technical task.[57,84,119] Without fiber-by-fiber analysis, all that can be said is that coated fibers resembling those in asbestos workers are present in most persons in our urban centers. Stripping the coating and analyzing the cores by various techniques can sometimes demonstrate that the cores are asbestos, but the process is tedious and often inconclusive.

Attention is now being directed toward study, not of the ferruginous bodies alone, but of the total fiber content of the lungs, whether such fibers are coated or uncoated. In a study of 3,000 consecutive autopsies in New York City, Langer et al.[84] have found thin, uncoated, optically

visible fibers in two-thirds of the 1,449 lung specimens in which coated fibers were demonstrated and in one-fourth of those in which uncoated fibers were demonstrated. Twenty-eight consecutive samples of lung tissue from the same series examined by electron microscopy were found to contain EM-sized chrysotile fibers.[85] Pooley et al.[119] have reported similar findings.

Evidence is therefore strong that most human lungs harbor thousands or millions of fibers. Some of these are chrysotile asbestos, and other types of asbestos minerals are probably there also. In most persons not occupationally exposed to asbestos, the numbers of fibers are relatively small, compared with the numbers found in the occupationally exposed.[133] The systematic application of quantitative techniques, measuring both coated and uncoated fibers, is needed to define a gradient of accumulated fibers for correlation with incidence of disease, on the one hand, and history of environmental exposure, on the other.

Although there appears no doubt that asbestos fibers are present in many human lungs, there are sources of airborne fibers other than asbestos.[28,57] Some are probably derived from the burning of leaves and plant products, such as paper, wood, and coal. Man-made (mostly vitreous) fibers have also been identified in the sediment isolated from human lungs. Talc, often used generously as a dusting powder, may contain a significant amount of tremolite asbestos fibers.

Information is sparse concerning possible increase of fibers in lungs with increasing use of asbestos and concerning the existence of significant differences between urban and rural populations. Selikoff and Hammond[133] compared lung tissues obtained in 1934 and 1967 and found no significant

increase in the proportion containing ferruginous bodies. This suggested that, despite increasing use of asbestos in New York City between 1934 and 1967, fibers of a type producing ferruginous bodies had not been increasing at a corresponding rate. However, Chang-Hyun Um[73] reports an increase over each decade in asbestos bodies in samples of lungs from persons who died in London in 1936, 1946, 1956, 1966.

PLEURAL CALCIFICATION IN THE GENERAL POPULATION

Meurman[108] in 1968 reviewed critically the literature related to pleural calcification and asbestos exposure. A number of studies strongly suggested an association between pleural calcification and nonoccupational exposures to asbestos. For example, Kiviluoto[79] in 1960 reported calcifications in 9% of the adult population detected during mass roentgenographic surveys in a Finnish commune in which there was an asbestos mine and mill; the frequency was low for the remainder of the Finnish population. Raunio[120] enlarged on these observations in 1966, reporting that, of 633,201 chest films taken in Finland between 1960 and 1965, 1516 showed pleural calcifications; 1232 of the latter were among 43,483 films taken in 10 communes in which there were anthophyllite mines. Rock and soil in such areas also contain much asbestos, so that the demonstration that airborne anthophyllite could be demonstrated over 25 km from the mines is not necessarily relevant. Anspach[4] reported that, of 244 subjects with pleural calcification found in a chest roentgenographic survey in Dresden, 177 had either worked in or lived near an asbestos factory. Zolov et al.[170] described a 5.1% prevalence of pleural calcification in a rural population in Bulgaria and suggested that the most likely cause was asbestos in the soil. However, Hromek,[72] Marsová,[97] and Rous and

Studený,[126] reporting on a high prevalence of pleural plaques in a rural district of Czechoslovakia, have been unable to demonstrate a source of asbestos exposure. The consensus at present is that calcification alone may not invariably be considered an index of asbestos exposure in the general population, although it may prompt a search for an environmental source of asbestos.

MEASUREMENT OF AIRBORNE ASBESTOS

A more direct method of obtaining evidence on the likelihood of exposure of the general population would be the sampling of air to determine the presence and amount of respirable asbestos fibers. There are, however, many uncertainties as to the best methods of sampling, identifying, and quantitating airborne asbestos and interpreting data so obtained.[78,90,122,137] Limited information has been derived from measuring fibers on sampling sites, such as that by Laamanen et al.,[83] who showed asbestos fallout diminishing rapidly beyond 1 km from an anthophyllite quarry, but still detectable at 27 km. Counts of asbestos fibers collected on membrane filters by high-volume air sampling and estimated by light microscopic techniques similar to those used in industrial hygiene have shown small numbers of fibers in a few urban sites.[10,16] Such results, although showing numbers of fibers detectable by the light microscope that were low by occupational health experience, have been too few and variable to be used with confidence. Alternative methods that are currently under development, including estimations of the number and mass of fibers in the LM and the EM size ranges, have shown measurable concentrations of asbestos in many samples of ambient air.[1,66,137] Such environmental measurements are in their earliest stages and provide few clues to the extent or significance of the risk from this type of exposure to asbestos or to other mineral fibers.

CHAPTER 3

ESTIMATION OF RISK IN NONOCCUPATIONAL EXPOSURES

Industrial experience has shown that prolonged inhalation of asbestos can increase the risk of neoplastic disease. Examination of lung tissue has made it apparent that a much larger proportion of the general public has inhaled and retained asbestos fibers than had formerly been realized; in fact, most urban dwellers have some such fibers in their lungs. Can these facts be related? Does the general public--as well as persons working near occupational sources, living in the households of asbestos workers, living in the neighborhoods of asbestos plants, or having occasional random exposures--have a detectably increased risk of malignancy or other disease because of airborne asbestos? The limited information we have to answer these questions comes either from direct epidemiologic studies of groups with various levels of nonoccupational exposure or by extrapolation from the experience of industrial populations with direct or indirect asbestos exposures.

EPIDEMIOLOGIC STUDIES RELATED TO NONOCCUPATIONAL EXPOSURES

Two general indices of asbestos exposure are available for use in direct epidemiologic studies of groups not known to be occupationally exposed to asbestos. The first is based on knowledge of each member's place of work and place of residence; because of the long latent periods of asbestos-related disease, this knowledge must cover each person's whole lifetime. The second is a quantitative estimate of each member's lung content of asbestos fibers. There are few such direct epidemiologic studies, and they are inadequate to answer the questions at issue.

The only studies that appear to implicate asbestos in the development of malignancies in persons not occupationally exposed are those involving diffuse mesothelioma, a tumor that is uncommon and that has been the subject of special attention in recent years. Many of the mesotheliomas reported by Wagner et al.[161] in South Africa were attributed to household and neighborhood exposures in a crocidolite-producing area. Although non-occupational, these exposures have been described as substantial.[168] Newhouse[114] studied 76 patients with mesothelioma diagnosed in London Hospital from 1917 to 1964. Of these 31 (40.8%) had occupational exposures to asbestos, 9 (11.8%) had a relative who worked with asbestos, 11 (14.5%) had neither of those backgrounds but had lived within a half-mile of an asbestos factory, and 25 (32.9%) had no known contacts. Corresponding percentages for a group of matched control subjects (patients in the same hospital for other diseases) were 10.5%, 1.3%, 6.6%, and 81.6%. Stumphius and Meyer[145] reported no mesotheliomas in the community near the shipyard in Flushing (Holland), although 17 of 21 mesotheliomas reported in the province of Zeeland in 1964-1967 had been in workers in that yard. Raunio[120] found no excess of pulmonary, pleural, or peritoneal malignancies in the areas of Finland where pleural calcifications attributed to anthophyllite were present in 6%-9% of routine chest survey films. In a series of 17 mesotheliomas collected by Borow et al.,[12] all but two were in persons who had worked in an asbestos mill, although the autopsy series from which the cases were drawn came from an area that included inhabitants of the mill's environs. Lieben and Pistawka[87] found that of 42 persons with mesotheliomas reported in Pennsylvania, 10 had worked in asbestos plants, 8 lived or worked close to an asbestos industry, and 3 were members of families that

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included asbestos workers; in 11, no history of exposure could be obtained, and the remaining 10 had questionable random exposures. McDonald et al.[100] collected information on 165 fatal malignant mesotheliomas known to pathologists in Canada between 1959 and 1968. They confirmed an association with occupational exposure to asbestos but concluded that the excess was in the manufacture and industrial application of asbestos, rather than in mining or milling. It is apparent that no quantitative conclusions were possible from these studies, which present serious methodologic problems to the epidemiologist. They suggest a risk in household contacts and in residence in the immediate neighborhood of asbestos plants. There appear to be different levels of risk in different types of occupational exposures, and some of these may be reflected in corresponding household and neighborhood experience.

In no analysis of causes of death in a large population has there been quantitative estimation of the lung content of ferruginous bodies and bare asbestos fibers, to determine whether a detectable gradient of disease can be correlated with asbestos content. The series so far studied have been too small, and methods have been too variable, to permit any conclusions as to the importance of small numbers of fibers in the lung.

EXTRAPOLATION FROM OCCUPATIONAL EXPERIENCE

Another source of evidence of the relative risks associated with inhaling moderate or small numbers of asbestos fibers is the experience of persons who have had occupational exposures below those known to be definitely hazardous. The maximal airborne fiber concentrations recommended for prevention of asbestosis are much higher than any likely to be encountered in

nonoccupational situations. For example, one recommended standard would limit the average concentration of airborne chrysotile to 2000 fibers per liter as determined by light-field count.[14] Another that has been proposed would limit average concentrations of fibers to 5000 fibers per liter.[2] Occupation-related asbestosis can be effectively controlled with airborne fiber concentrations much higher than are likely to be encountered in non-occupational situations. It is important to determine whether workers whose exposures have been reduced to levels that prevent or greatly delay asbestosis, as well as others whose exposures are indirect, have a lower risk of lung cancer than those with higher and more direct exposures.

Workers who began employment in a British textile mill after 1933, when implementation of the Asbestos Industry Regulations of 1931 reduced (but did not abolish) dust exposures, were reported in 1968 to show no excess of neoplasms.[82] The long latent periods of asbestos-related lung cancer and mesothelioma, which would probably be even longer at lower dose levels, are such that it is too soon to draw final conclusions as to the eventual incidence of these malignancies. Nevertheless, reduced exposure seems to be having an effect. Another indication of reduced incidence or delayed onset of disease with lower exposure is in the observations of Newhouse,[112] who found that, although there were more deaths from lung cancer and chronic respiratory disease among those who had heavy exposures many years previously in a London asbestos-products plant, this was not true among those who had low or moderate exposures. McDonald *et al.*[101] recently reported the mortality experience of men who worked in chrysotile mines and mills of Quebec. There was a slight excess of lung cancer among the 2457 deaths in workers born 1890-1920, but all could be explained by the excess that

occurred in those who had been maximally exposed. This suggests that, insofar as chrysotile miners and millers are concerned, the risk drops off rapidly with decreasing accumulated dosage.

Most series of case reports of mesothelioma include some persons who have worked in the construction or shipbuilding industries, but in trades not involving direct contact with asbestos.[102] Such persons as plumbers, electricians, and metal workers often have more ferruginous bodies in their lungs than do white-collar workers.[134] Although Dunn and Weir,[33] in a study of occupational groups in California that revealed an excess of deaths from lung cancer in insulation workers, found no excess lung-cancer deaths in other construction trades, the groups they studied were diluted with many persons who were unlikely to have had exposures. Nevertheless, there may be a definable gradient of effect within the construction trades. More thorough studies of groups with indirect exposures are certainly needed.

We cannot extrapolate from the mortality experience of those who are directly and indirectly exposed to asbestos in their employment to the general public who have had moderate or slight exposures from ambient air. There is evidence to suggest a gradient of effect from direct occupational, to indirect occupational, to family and neighborhood situations, in all of which dust concentrations are probably high by comparison with most community air. This suggests that there are levels of asbestos exposure that will not be associated with any detectable risk. What those levels are is not known, but there is no evidence that persons in the general population--without occupational, household, or neighborhood exposures--have any increased risk of neoplasm, even though there may be ferruginous bodies of fibers in their lungs.

CHAPTER 4

SOURCES OF ASBESTOS FIBERS IN AMBIENT AIR

Precise information is not available on tonnages, numbers of fibers, fiber sizes and varieties, atmospheric dispersion, and ultimate fate of the asbestos emitted into ambient air. Although there are no reliable data to justify extrapolation from the more completely studied occupational exposure experience, information regarding actual and potential sources of emissions of asbestos fibers is of value both for directing future studies and for understanding the steps that might be taken now to safeguard the health of the public.

NATURAL SOURCES OF AIRBORNE ASBESTOS FIBERS

Several varieties of asbestos ore and counterpart rock (containing EM-sized asbestos fibers) occur as outcroppings or are just below the surface of the earth throughout the world. Asbestos fibers can become airborne from these formations during road-building, construction, and tilling of the soil, as well as by landslides, erosion, and weathering. Talc, mined and used extensively in the United States, exists in fibrous, as well as platy, form. Like asbestos ore and rock, talc exists on or close to the earth's surface and is subject to disseminating forces. Such naturally occurring talc, as well as the large quantities used as a diluent and carrier for pesticides, can add to the background fiber concentration in the ambient air.[166,167] It is thought that studies of fibers in glacial and polar ice now under way will permit comparisons of recent deposition with those in the past and thereby provide definite information on the relative contributions of natural and industrial sources.

MINING AND MILLING OF ASBESTOS

Mining and milling of asbestos provides another source of asbestos emissions. In the United States, such activity is presently confined to a few mines in California, Vermont, Arizona, and North Carolina. Fibers are emitted during removal of overburden and preparation of the ore body for open-pit mining. Further release occurs during drilling and ore-breaking. Waste dumps from mining and milling are exposed to wind and to disturbance by bulldozing. Fibers are emitted during drying, crushing, grinding, and screening of the ore. If dust collectors and air-cleaning devices are used, disposal of the collected dust provides a potential source of fiber emission.

TRANSPORTATION OF MATERIALS CONTAINING ASBESTOS

Transportation of asbestos ore, milled asbestos fiber, and asbestos-containing products and wastes is an emission source of varying importance. Movement of asbestos ore from mine to mill in open trucks contributes to the overall emission. The shipment of milled asbestos fiber, usually in bags, can result in emissions. If bags are reused, either in the asbestos industry or elsewhere, they will become a source of fibers. Occasionally, bags are broken and asbestos is spilled during handling. Similar emissions

occur during the shipment of products. Transporting asbestos-containing solid wastes in open vehicles through urban areas can be a more important emission source.

MANUFACTURE OF PRODUCTS CONTAINING ASBESTOS

Industries that must provide ventilation and other dust-control measures for the protection of workers may emit asbestos fibers into the surrounding environment unless effective air cleaning is applied to effluents. Fibers removed by ventilation and filtering devices and not reintroduced into the production process and asbestos-containing waste products of the manufacturing process ultimately are disposed of outside the plant.

USE OF PRODUCTS CONTAINING ASBESTOS

Many products, at times unknown to the user, contain asbestos of one kind or another. There are great variations among such products with respect to the chances of fiber release during the use of the product. The likelihood depends predominantly on the ease with which the fibers can be dislodged by the application of energy and on the degree to which the application of energy actually destroys the fibers during the use of the product. Almost all the asbestos fibers used in the United States for manufacturing products becomes tightly bound within the products and undergoes little actual abrasion or wear before being discarded. Asbestos cement products (accounting for most of the asbestos used in the United States), shingles, and floor tiles are in this category. Some asbestos-containing products, such as brakelinings, are subjected to high energy, and their rate of wear is considerable and at times almost complete. In the case of brakelinings, the application of energy is so intense and the heat created so great that

most chrysotile fibers are destroyed by being converted to another substance, which is nonfibrous.[65,68,89] Nevertheless, an appreciable percentage (1%-3%) remains as fibrous asbestos. In some products--for example, asbestos cloth, paper, and sprayed fireproofing materials--asbestos fibers are not tightly bound or mixed with other material that holds them in place. Fiber release from these products occurs primarily during application and removal. The spray fireproofing of buildings with asbestos-containing materials is a case in point. This operation can be a serious source of emission, in that it usually occurs in densely populated areas.' The total amount of asbestos fiber used in such procedures, however, is relatively small.

Talc is mined and milled and used in greater quantities than is asbestos in the United States. Because it contains asbestos fibers, its uses will add to the total number of fibers (including nonasbestos fibers) emitted. The use of talc in dispensing pesticides over wide areas of the country and its use in cosmetics are two examples of how this material may act as a source of asbestos and other fibers.

DEMOLITION

For years, asbestos has been incorporated in building materials. In some forms of insulation and wallboard, the amount present is less than 20% of the total; but other materials consist mostly or entirely of asbestos. When a building is demolished, areas of loosened asbestos are open to the ambient air and fibers are emitted. In general, single-family residential structures contain only small amounts of asbestos insulation. Demolition of industrial and commercial buildings that have been fireproofed

with asbestos-containing materials will prove to be an emission source in the future, requiring control measures.

SOLID-WASTE DISPOSAL

Solid wastes produced during manufacture of asbestos-containing products, use of such products, and demolition can be emission sources. These waste materials are usually disposed of without regard to their potential as emission sources. Alternate methods of disposal often result in commingling of asbestos-containing wastes with municipal wastes in open dumps and thus create a long-term emission source.

CHAPTER 5

PRINCIPLES OF CONTROL

The natural background level of asbestos fibers is difficult to quantify or modify. The major sources of local ambient-air contamination with asbestos are industrial processing and use of products containing asbestos. It is feasible to identify the sources of emission, select those to which presently available control procedures can be applied, and point out areas that need further study and development of new methods of control.

NATURAL SOURCES OF AIRBORNE ASBESTOS FIBERS

Natural sources of asbestos fibers have been identified in many areas of the United States. It is assumed that emissions of fibers from these reservoirs through erosion and wind make up a natural background of asbestos in ambient air. Few data are available on the magnitude of the contamination from natural sources, variation with geographic location, and seasonal variation. It is desirable to have information on the natural background, because it would assist in evaluating the effects of control measures and permit some estimates of the lower limits of contamination that might be achieved in different areas of the country.

MINING OF ASBESTOS

The standard techniques for dust control in underground or open-pit mines, if not already in use, can be applied in asbestos mines. Roadways in open pits should be treated with dust-suppressive agents; truckloads of ore should be covered with tarpaulins while being transported; handling of ore should be minimized; ore storage piles should be moistened to reduce wind erosion; and waste dumps should be treated with dust-suppressive agents.

MILLING OF ASBESTOS

An in-plant dust-control program for protecting workers in asbestos mills includes exhaust ventilation with efficient dust-collecting and air-cleaning equipment, isolation, enclosure, wet methods, and good housekeeping and maintenance.

MANUFACTURE OF PRODUCTS CONTAINING ASBESTOS

The elements of dust control recommended for the milling of asbestos ore also apply to the manufacture of asbestos-containing products. It is important that a dust-control system be specific to the operation for which it is used and that it be tested to ensure its effectiveness. Only persons especially trained and experienced in dust control should be used to develop and institute dust-control procedures.

USE OF PRODUCTS CONTAINING ASBESTOS

An important emission source is the use of insulating materials containing asbestos. This constitutes only a small fraction of the asbestos used. But the asbestos in some insulating materials is not bound as it is in cementitious products or tiles; construction activities usually are carried on in urban areas where many people are exposed to contaminated air; and control of dust during construction, although feasible, is difficult.

The most effective approach in reducing exposures of the general public to asbestos from this source involves controlling dust production and release at its origin during construction work. The generation of dust should be reduced by changing material-handling methods, work practices, and cleanup procedures. Local exhaust systems should be used for dust collection at points of generation; for example, dust collectors for band

saws are available, and hand-powered tools supplied with exhaust systems are being made. Much developmental work is needed to produce portable air-moving and air-cleaning systems for use in tunnels, crawl spaces, and other confined spaces. This subject has been neglected by industrial hygienists and ventilation engineers, and no satisfactory equipment is available.

DEMOLITION AND WASTE DISPOSAL

Demolition and waste disposal are likely to be emission sources if appreciable amounts of asbestos are used in construction, unless operational procedures are strictly controlled. Isolation, enclosure, and wetting down are useful. Caution must be observed not to demolish during high winds and to keep sludge from drying out and becoming airborne later through natural forces and from being introduced into sources of drinking water.

MEASUREMENT OF AIRBORNE ASBESTOS

An important consideration in the development of a strategy for control is whether there are methods for measuring airborne concentrations of asbestos that are sufficiently sensitive, specific, and reproducible. Present methods of sampling, identifying, and measuring airborne asbestos are not entirely satisfactory, especially if one is dealing with low concentrations and unidentified or mixed sources. Only within recent years have methods for determining concentrations of fibers for industrial hygiene purposes been standardized;[14,35] they use samples collected on membrane filters in which fibers are counted with phase-contrast illumination. Electron microscopic methods give a much more complete indication of the total fiber content

of the air; but when the need for fiber identification is included, they are tedious and expensive for routine use.[1,66,137] The relative biologic significance of different sizes of fibers is not known, nor is the relative importance of fiber numbers and fiber mass. There appear to be no published data on the efficiency of air-cleaning equipment as related to fibers of different sizes.

In spite of the difficulties, it is possible to sample air, determine the approximate concentration of airborne fibers, and identify the major types of asbestos. It is not desirable to limit environmental measurements to a single method until there is a clearer definition of the critical variables in terms of health. Because of methodologic and other uncertainties, it is not yet feasible to base control on numerical ambient air quality standards.

CHAPTER 6

RESEARCH NEEDS

Two recent reports[25,167] have discussed in some detail the many kinds of research needed to answer pressing questions concerning the effects of asbestos on health and the degree and nature of necessary controls. Investigations along the following lines should be given high priority.

Study of the mechanism of action of the asbestos minerals should continue, with particular attention to carcinogenic effects. It is important to learn more about the influence of asbestos type and fiber size on respirability, deposition, retention, translocation, and effects at the tissue, cellular, and molecular levels, with and without cofactors. It is especially important that the role of fibers below the LM range be clarified.

Methods of sampling, identifying, and quantitating airborne asbestos need continued development. Coordination with studies in animals and man is essential to ensure that environmental data will be biologically relevant. Similarly, methods for identifying and quantitating asbestos in biologic tissue need development and application.

Quantitative methods for measuring airborne asbestos should be applied widely to determine the natural background and the concentration and distribution of fibers in the air near various sources. Conventional LM methods and EM methods should be applied simultaneously in selected occupational and community situations.

More epidemiologic studies are needed. Populations in several different exposure ranges should be studied, including occupational, household, and neighborhood exposures. Special studies of mesothelioma are needed to determine whether the incidence has been increasing and to determine the current pattern of distribution. A large series of routine autopsies should be studied to determine whether causes of death can be related to amounts of asbestos in the lungs and other organs. All the above are urgent if a range of safe exposure is to be established with confidence.

CHAPTER 7

CONCLUSIONS AND RECOMMENDATIONS

PATHOGENICITY OF ASBESTOS MINERALS

Any of the commercially used asbestos minerals, when inhaled in sufficient numbers, as in uncontrolled occupational exposures, can cause disabling fibrosis of the lungs. An association between occupational exposures to asbestos and bronchogenic carcinoma has been established, but the dose relationship and the role of cofactors have not been defined. Evidence of a causal association between some but not all exposures to asbestos fibers and diffuse malignant mesotheliomas of the pleura and peritoneum is substantial, but evidence of such a relationship with other tumors is inconclusive. Although the different types of asbestos differ in some of their biologic effects, no type can be regarded as free of hazard. The hypothesis that asbestos fibers act as cofactors or carriers of carcinogens is attractive, but as yet unproved.

EVIDENCE OF HUMAN NONOCCUPATIONAL EXPOSURES TO ASBESTOS

The demonstration of ferruginous bodies, similar to those found in asbestos workers, in a large proportion of randomly selected lung specimens in many parts of the world is presumptive evidence that persons with no occupational contact may have inhaled and retained asbestos. Proof has come in some areas with positive identification of chrysotile asbestos fibers. Analyses of community air for asbestos have been too limited to define the sources, concentrations, and distribution of fibers in the environment. The fiber concentrations that have been demonstrated in ambient air are small, compared with those in industry, but data are inadequate for definitive comparisons.

ESTIMATION OF RISK IN HUMAN NONOCCUPATIONAL EXPOSURES TO ASBESTOS

The most important question in the case of persons with nonoccupational exposures to asbestos is whether there is an increased risk of malignancies. Industrial experience indicates that there is no likelihood of significant asbestosis in nonoccupational exposures. The major potential for risk appears to lie in those with indirect occupational contacts, household contacts, or residence in the immediate neighborhood of asbestos sources; and even there, the actual risk is poorly defined. But the fact that there appears to be a gradient of effect in such groups suggests that there are levels of inhaled asbestos without detectable risk. It is not known what range of respirable airborne asbestos fibers will ultimately be found to have no measurable effects on health. At present, there is no evidence that the small numbers of fibers found in most members of the general population affect health or longevity.

NEED FOR AND FEASIBILITY OF CONTROLS

Asbestos is too important in our technology and economy for its essential use to be stopped. But, because of the known serious effects of uncontrolled inhalation of asbestos minerals in industry and uncertainty as to the shape and character of the dose-response curve in man, it would be highly imprudent to permit unrestricted additional contamination of the public environment with asbestos. Continued use at minimal risk to the public requires that the major sources of man-made asbestos emission into the atmosphere be defined and controlled. In the absence of such controls, local fiber concentrations might at times approach those in occupational sites. Analytic methods and epidemiologic data are inadequate for the development of ambient air standards, but emission controls are needed and appear feasible.

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I. Asbestos and the Toxic Substances Act of 1971 (S 1478, HR 5390)

(a) Effects on the Asbestos Industry

The Toxic Substances Control Act, if enacted, would probably have little or no effect on the asbestos industry. The Act addresses itself to regulating "chemical substances," defined as "any organic or inorganic substance of a particular molecular identity or any uncombined chemical radical or element." Asbestos is not an uncombined chemical radical or element and does not have one particular molecular identity. This point aside, several other provisions limit this Act's applicability to the asbestos industry.

As most commonly interpreted, the Act is primarily directed toward regulating new chemical substances not yet introduced into production. This would not include asbestos itself, nor would it include any product containing asbestos that has already been marketed. Further, the Act does not address itself to new combinations of already produced substances, thereby leading to the presumption that new products containing only previously used substances would not be under its aegis.

The Act would affect the asbestos industry when it develops uses for asbestos that necessitate combining it with new substances. In this case, the testing and approval procedures prescribed by EPA for the new chemical substance would have to be concluded before the asbestos-containing product could be marketed.

(b) Interface with Other Legislation

Section 207 of the Act establishes its relationship to other federal laws. In general, it accedes to the jurisdiction of previous laws wherever a conflict exists. The Act specifically concedes jurisdiction to the Food, Drug and Cosmetic Act, the Occupational Safety and Health Act and any federal law that applies to a consumer hazard "resulting from household use of marketed products which contain or might contain the substance." By conceding jurisdiction in so many cases, the Act eliminates most of its jurisdiction over existing substances, including asbestos. The bill retains a general residual authority over existing substances, usable only in the event that some substance, use or situation falls between the cracks of existing laws.

II. Statutes and Agencies Regulating Asbestos

(a) The Clean Air Act and its 1970 Amendments (42 USC 1857 et seq.)

The Clean Air Act authorizes the federal government to regulate "the pollution of the air in any state or states which endangers the health or welfare of any persons."

The 1970 Amendments enable the Administrator of the Environmental Protection Agency to regulate asbestos emissions from stationary sources, motor vehicles and aircraft.

The EPA has already utilized its authority under Section 112 ("National Emission Standards for Hazardous Air Pollutants") to declare asbestos a hazardous air pollutant. This section enables the EPA to promulgate emission standards for designated pollutants from new, modified and existing stationary sources. The Administrator may establish emission standards at any levels he feels are needed to "provide an ample margin of safety to protect the public health from such hazardous air pollutant."

The EPA will propose many emission standards for asbestos in September 1971, each geared to different uses, sources or control techniques under this section. The limitations placed by Section 112 will limit the EPA to the use of emission standards pertaining solely to stationary sources.

Sections 202 and 231 of the same Act govern motor vehicle and aircraft emissions, respectively. It is noteworthy that the statute is not limited to engine emissions, therefore it retains jurisdiction over emissions from other areas of motor vehicles and aircraft, such as brake linings. The statute empowers the EPA to set emission standards solely for new motor vehicles or aircraft. The Administrator may set standards for a pollutant when he feels that its emissions cause, contribute to, or are likely to cause or contribute to "air pollution which endangers the public health or welfare."

(b) The Occupational Safety and Health Act of 1970 (P.L. 91-596)

The Act is administered by the Departments of Labor and Health, Education and Welfare. Labor is concerned with the adequacy of, and compliance with, job safety and health standards. Labor promulgates "national consensus standards," conducts inspections of employer's establishments and brings enforcement actions. HEW's role is oriented toward research into occupational hazards and recommending standards to Labor for promulgation.

This Act gives Labor and HEW jurisdiction over airborne asbestos hazards at the workplace, whether that is in-plant or at an outdoor site. At present, Labor and HEW are in the process of reducing the allowable concentration (Threshold Limit Value) of airborne asbestos in the workplace from 12 to 5 fibers per milliter, greater than 5 microns in length. In addition to air concentration standards, Labor can specify control techniques and protective equipment to be used by employers.

(c) Food and Drug Administration

The Food, Drug and Cosmetic Act (21 USC 301 et seq.) empowers the Food and Drug Administration to regulate any food that "bears or contains any poisonous or deleterious substance which may render it injurious to health," any drug that may have been contaminated with any poisonous or deleterious substance that may render it injurious to health, or any cosmetic "that bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions or use prescribed in the labeling thereof."

The FDA also administers the Labeling of Hazardous Substances Act (15 USC 1261 et seq.). This Act permits the agency to ban "highly toxic" substances from interstate commerce when proper labeling would not obviate the hazard. The health hazard may result from ingestion, inhalation or contact with any body surface.

In order to implement the Hazardous Substances Act, the FDA has created a Bureau of Product Safety that tests potentially hazardous products. This Bureau, whose laboratories are situated in Cincinnati, is currently testing a number of women's coats made of asbestos-containing fabrics.

(d) Federal Trade Commission (Title 15, USC)

The FTC has been empowered to regulate a large number of products through its own enabling act and several more specific statutes. These statutes encompass labeling of fur, wool and hazardous substances, textile fiber products identification and regulation of specific products, such as flammable fabrics.

Energetic leadership of the FTC has led recently to its more liberal interpretation of certain parts of its enabling statute. It will now use 15 USC 45, which states that "unfair methods of competition in commerce, and unfair or deceptive acts or practices in commerce, are declared unlawful," to combat distribution and marketing of products that could cause a health hazard if used as prescribed. This could, in theory, affect any asbestos product.

(e) Department of Transportation

DOT has the authority to control transportation of hazardous substances. Therefore, the department could issue regulations on the transportation or handling of asbestos or its products.

III. Statutes Governing Specific Products and Uses

The preceding section describes the scope of a number of laws which will continue in force, regardless of action on the Toxic Substances Control Act. Under these laws, regulatory authority exists to deal with virtually every aspect of the asbestos industry, from basic production to household usage.

The Clean Air Act gives the EPA general jurisdiction to regulate emissions of asbestos into the ambient air from any stationary source. It can also limit brake lining emissions from new motor vehicles and aircraft.

The 1970 Occupational Safety and Health Act regulates the exposure levels faced by workers, both in manufacturing and installation of asbestos. The law is administered by the Departments of Labor and Health, Education and Welfare.

Federal authority over possible health hazards accruing to the general public through the use of and exposure to asbestos-containing products rests with several federal regulatory agencies. Most prominent are the Federal Trade Commission and the Food and Drug Administration.

The FTC has recently used its power to regulate unfair practices in order to restrict products that constitute health hazards. Under this interpretation, FTC authority would apply to virtually all products, including those containing asbestos.

The FDA, through its enabling Act, can regulate asbestos in talc. Its authority stretches to any substance found in cosmetics, whether or not it occurs naturally. The FDA also has authority to ban or restrict the use of asbestos-containing products through the Labeling of Hazardous Substances Act if it can demonstrate sufficient toxicity in that product.

(The following information was referred to on p. 154:)

COMMENTS AND DRAFTING SUGGESTIONS ON AMENDMENT NO. 338 TO S. 1478, THE TOXIC SUBSTANCES CONTROL ACT OF 1971

(Prepared by Edward L. Strohbehn and Robert M. Hallman, Nov. 1, 1971)

The comments on and suggested changes in language in Amendment No. 338 to S. 1478, the Toxic Substances Control Act of 1971, (the Amendment) set forth herein and on the attached Committee Print have been prepared by Edward L. Srohbehn, staff attorney of the Natural Resources Defense Council, Washington, D.C., and Robert M. Hallman, staff attorney for the Center for Law and Social Policy, Washington, D.C., pursuant to requests of July 27 and August 3, 1971 by the Subcommittee on the Environment of the United States Senate Committee on Commerce. The views expressed are those of the auhors only and do not represent the position of NRDC or the Center.

To the extent practicable, all suggested changes have been inserted in the attached Commerce Committee Print of the Amendment (Marked "Draft Copy, November 1, 1971"), thereby indicating all deletions and additions that we suggest. Changes not so inserted are set out below. In addition, we have prepared a new, typewritten draft of the Amendment that incorporates all our suggested changes ("Exhibit A").

Significant changes in the substance of the Amendment are explained in the following comments.

SECTION 201—POLICY

Comments

The statement of policy should: (1) reflect the uncertainty of our knowledge regarding the toxicity of chemical substances and the need to test as well as to regulate the distribution and use of such substances in order to protect human health or the environment; (2) use the same language for defining the potential threat posed by chemical substances that is used for defining standards within the Act, *i.e.*, "unreasonable threat to human health or the environment"; (3) establish the need for the principal regulatory powers granted by the Act; (4) state the basic purpose of the Act that is set out in subparagraph (4) affirmatively; and, (5) acknowledge the desirability of citizen participation in effectuating the Act.

Draft Language

See Draft Copy.

SECTION 202—DEFINITIONS

Comments

The majority of the changes are directed at insuring consistency in the use of words and phrases within the Act.

The substantive changes provide the following.

(1) The definition of "chemical substance" is amended to permit the regulation of all new chemical substances.

(2) The term "commercial use" has been defined and used in place of "commercial quantities" which was undefined. This change permits regulation in terms of functional use rather than quantity of use. This distinction should reduce conflicts about whether the Act applies to a particular chemical substance and premises the regulatory decision on the basic purpose of the Act: the regulation of chemical substances that are used commercially.

(3) "Labelling" has been added as another means by which the Administrator may restrict the use or distribution of chemical substances to insure that the Administrator has such authority, particularly the authority to police the labelling of chemical substances found in commerce.

(4) The definition of "imminent hazard" contained in Section 206(a) has been moved to the Definitions Section.

Draft Language

See Draft Copy. Three additional terms are defined below.

"(14) 'Commercial use' means the manufacture, processing, sale, distribution, use, or disposal of chemical substances for purposes other than for research, theoretical analysis, experimentation, or personal use by a consumer.

"(15) 'Person' means an individual, corporation, partnership, association, State, municipality, political subdivision of a State, or federal agency or department, or any agent thereof.

"(16) 'Imminent Hazard' exists when there is reason to believe that the manufacture, processing, sale, distribution, use or disposal of a chemical substance or its byproducts is likely to result in a substantial adverse effect on human health or the environment."

SECTION 203—TEST STANDARDS

Comments

The Administrator's decision whether or not to require tests for specific hazards such as carcinogenesis and teratogenesis should be subject to challenge by citizens under Section 217. Therefore, he should have a mandatory duty to include tests for specific hazards when appropriate. The changes in line 9, p. 6 are intended to create such a mandatory duty.

Draft Language

See Draft Copy.

SECTION 204—CERTIFICATION OF CHEMICAL SUBSTANCES

Comments

As drafted, the Admendment imposes an unreasonable burden on the Administrator by requiring a decision regarding certification and restriction on use or distribution almost immediately upon receipt of a certification application. We recommend instead that upon receipt of an application the Administrator be required to publish a notice in the Federal Register describing the application and announcing the public availability of materials which accompany it. Following such publication, he should have thirty days to make and to publish his proposal to grant or deny the application, together with any proposals to condition the use or distribution of the chemical substance involved.

Minimum requirements for the contents of the application should be established. In particular, the applicant should be required to describe the formula of the chemical substance, all tests to which it has been subjected and the results thereof, and any claims to be made regarding it. Tests other than those prescribed by the test protocols may have been undertaken and may provide relevant information.

Further, we feel the Amendment would be significantly strengthened by requiring (a) each certification to be conditioned on compliance with restrictions on use or distribution imposed under Section 205, and (b) each recipient promptly to inform the Administrator of any adverse effects on human health or the environment (and complaints concerning such effects) which become known to him subsequent to certification.

Draft Language

See Draft Copy.

SECTION 205—RESTRICTIONS ON USE OR DISRIBUTION

Comments

The section should make absolutely clear that the Administrator *must* impose conditions on the manufacture, processing, sale, distribution, use, or disposal of a chemical substance to the extent necessary to protect human health or the environment (including such restrictions as are necessary for effective quality control) whether or not it has been certified under Section 204. Much of our redraft or subpart (a) is designed to serve this purpose.

All information submitted to, developed by or relied on by the Administrator in issuing regulations regarding the use or distribution of the chemical substance should be made available to the *public*, not just interested *parties*, consistent with the Act's confidentiality requirements.

Draft Language

See Draft Copy.

SECTION 206

We have moved the definitiona of "imminent hazard" to the Definitions Section (202) and broadened the concept to include any use which "is likely to result in a substantial adverse effect on human health or the environment." This definition is consistent with that contained in the proposed amendments to the

Federal Insecticide, Fungicide, and Rodenticide Act [H.R. Agriculture Committee Print No. 3, July 13, 1971, section 2(1)].

Draft Language

The following should replace Section 206:

"PROTECTION AGAINST IMMINENT HAZARDS

"SEC. 206. Whenever the Administrator determines that an imminent hazard exists, the Administrator shall issue an order requiring all necessary measures that must be taken in order to protect against the occurrence of any substantial adverse effect on human health or the environment. Such necessary measures include the power to seize the chemical substance or its byproducts pursuant to Section 207. If a Section 205 proceeding concerning the chemical substance or its byproducts is not being conducted, the Administrator shall simultaneously with the issuance of the order under this subsection propose a regulation under Section 205. Any order issued under this subsection shall become effective at such time as is necessary to protect against the occurrence of such substantial adverse effect and shall remain effective pending the outcome of formal proceedings under Section 205. Initiation of any such proceedings under Section 205 shall not prevent the Administrator from issuing an order under this Section."

SECTION 207—SEIZURE

Comments

The Administrator should be required to seize chemical substances that pose imminent hazards.

Since the seized chemical substance is in the possession of the Administrator, the person from whom it was taken should be required to demonstrate that he could make the chemical substance comply with the requirements of the Act if he were in possession of the substance.

Protective provisions regarding the custodial care that the Administrator must give to seized property should be provided and are included in our redraft of this section.

We have deleted subparagraph (b) of this section which would authorize the Administrator, after opportunity for a hearing, to seize substances manufactured, used or distributed in violation of sections 204, 205 or 206 and which constitute unreasonable threats to human health or the environment. In our view, the Administrator's authority to restrict the use or distribution of substances as necessary to protect human health or the environment—including the power to *prohibit* sale or use and to *recall* substances from commercial use—granted by section 205 is sufficient to carry out the purposes of the Amendment.

If the power to seize substances which fall short of posing imminent hazards is retained, we would recommend extending the power to any substances which constitute "an unreasonable threat to human health or the environment but not an imminent hazard" regardless of whether the substance is also being "manufactured, used, or distributed in violation of Sections 204, 205 or 206. . . ." The latter limitation on the Administrator's seizure power should be omitted.

Draft Language

See Draft Copy. The protective provisions which are to be inserted at page 11, line 9, as indicated, are set out below.

"and the person who seizes the chemical substance shall give to the person from whom or from whose premises the property was taken a receipt for the property taken or shall leave a receipt at the place from which the property was taken. A written inventory of any property taken shall be made in the presence of the person seizing the property and the person from whose possession or premises the property was taken, if he is present, or in the presence of at least one credible person other than the person making such inventory and shall be verified by the person seizing the property."

SECTION 208—REPORTS

Comments

Processors, as well as manufacturers, should be covered by the reporting requirements since they play an important role in the use and distribution of chemical substances.

The Administrator's capacity to enforce the Act intelligently would be considerably enhanced by requiring the submission of (1) descriptions of all tests (not otherwise required) of chemical substances and the results thereof which relate in any way to their health or environmental effects; and, (2) information identifying significant recipients of chemical substances from manufacturers or processors. Our redraft makes submission of such information mandatory.

No sound reason exists for qualifying the duty to provide information relating to the identity and use of chemical substances by the phrase "insofar as known." By stating an obvious limitation on the availability of information, it casts an unjustified passive and restrictive aura about the duty to report.

This section should make clear that information received by the Administrator is available to the public, consistent with confidentiality requirements.

Draft Language

See Draft Copy.

SECTION 209—RELATIONSHIP TO OTHER LAWS

Comments

To the extent that other laws preclude the Administrator from taking action pursuant to this title, the Administrator should be required a least to inform other departments or agencies of the existence of unreasonable threats to human health or the environment—the basic standard for action under this title—rather than of the existence of the more substantial threat—a hazard.

The provisions of the Federal Water Pollution Control Act and the Clean Air Act should supplement, not supplant, the mandatory duties required of the Administrator by this title.

This section includes references to several federal laws. For the convenience of those using and affected by the Act, citation to the relevant public law number or United States Code provisions should be included in the final Committee Print.

Draft Language

See Draft Copy.

SECTION 210—TOXIC SUBSTANCES BOARD

Comments

The Board and any committees thereof must contain equal numbers of qualified scientists representing industry, consumer *and* environmental interests, as well as the general public. We therefore deleted the word "or" in lines 6 and 20 on page 16.

All comments, studies, reports, tests, and other materials submitted to or prepared by or at the direction of the Board, all proceedings and hearings conducted by the Board, and all reports, together with dissenting views, prepared by the Board should be made available to the public and made part of the public record.

Interested persons should be encouraged to submit comments to the committee concerning the proposed action in order to reduce the likelihood that such persons will request a public hearing pursuant to section 222. The failure of a person to submit comments should not affect his right to a public hearing pursuant to section 222.

The mandatory nature of the Board's report should be emphasized, although the Administrator must still be permitted to act if the Board fails to submit its report. All materials, comments, reports, etc. submitted to or prepared by or at the direction of the Board and all records of any proceedings conducted by the Board should be part of the public record and available for purposes of judicial review of the Administrator's action whether or not the Board makes its final report.

Draft Language

See Draft Copy.

SECTION 211—RESEARCH

Comments

The Amendment does not authorize the Administrator to select the person who shall perform tests on chemical substances subject to the title. The Administrator therefore should have broad authority independently to substantiate test results. Such authority provides a very effective policing and enforcement device. Thus, we recommend deletion of the word "limited" in line 2, page 18, which unduly restricts the Administrator's authority.

Draft Language

See Draft Copy.

SECTION 212—ADMINISTRATIVE INSPECTIONS AND WARRANTS

Comments

None.

Draft Language

See Draft Copy.

SECTION 213—EXPORTS AND IMPORTS

Comments

Every possible attempt should be made to inform foreign countries, purchasers, and users of exported chemical substances, which would be subject to conditions imposed under section 205, of the threats which they pose to human health and the environment.

Draft Language

See Draft Copy.

SECTION 214—CONFIDENTIALITY

Comments

As little material as is possible should be deemed confidential in order to facilitate review of the Administrator's actions and to increase the public acceptance of and trust in the Administrator's actions.

We recommend deletion of the last sentence in subsection (a). It is unnecessary and by its presence suggests an unjustified restrictive view of the public availability of information under the Amendment.

As regards subsection (b), we are aware of no valid reason for permitting the Administrator to issue protective orders on his own initiative: such authority could be utilized to shield important information bearing on agency action from the public.

Agency protective orders should be subject to review de novo by the federal courts. Section 552(a)(3) of title 5 of the United States Code, referred to in our redraft, so provides.

Draft Language

See Draft Copy.

SECTION 215—PROHIBITED ACTS

Comments

"Secretary of the Treasury" should be added to subsection (1) since he is authorized by Section 213 to issue regulations governing entry of certain chemical substances into the United States.

Draft Language

See Draft Copy.

SECTION 216—PENALTIES AND REMEDIES

Comments

We recommend deletion of the requirements set forth in lines 9–11, page 26, that the Administrator, in assessing civil penalties, consider the "extent" of violations, the "practicability of compliance", and "good-faith efforts to comply". The deleted language unduly emphasizes the Administrator's responsibility for considering mitigating factors. The requirement that the Administrator consider the "nature and circumstances" of a violation is a sufficient standard for taking into account mitigating factors.

The Administrator should not be permitted to refrain from suing a violator who fails to pay civil penalties assessed against him. Thus, the word "shall" should be substituted for the word "may" in line 13, page 26.

Draft Language

See Draft Copy.

SECTION 217—CITIZEN CIVIL ACTIONS

Comments

This section should explicitly provide for class actions. We recommend addition of the phrase "or as a representative of a class" in line 1, page 27.

The Amendment should require the courts to award reasonable fees for attorneys and expert witnesses to persons who bring a successful action under the Act since they are performing a vital public service. The Amendment should also empower the courts, in their discretion, to award litigation costs to unsuccessful plaintiffs, as well as other parties, if the interests of justice require it. Our redraft of subsection (d), page 28, is designed to achieve these objectives.

The definition of "person" in subsection (f), page 29, has been moved to the Definitions Section (202).

Draft Language

See Draft Copy.

SECTION 218—ENVIRONMENTAL PROTECTION AND ASSESSMENT

Comments

None.

Draft Language

See Draft Copy.

SECTION 219—USE OF GOVERNMENT FACILITIES

Comments

None.

Draft Language

None.

SECTION 220—HEALTH AND ENVIRONMENTAL DATA

Comments

The Secretaries of HEW and Commerce should not be singled out. A general direction to consult with the heads of appropriate federal, state, and local departments is sufficient.

Draft Language

See Draft Copy.

SECTION 221—STATE REGULATIONS

Comments

This section is poorly drafted, *e.g.*, much of its phrasing is inconsistent with the rest of the Amendment and some of the material is redundant.

Draft Language

The following should replace Section 221:

"STATE REGULATIONS

"SEC. 221. Nothing in this title shall affect the authority of any State or local government to restrict the use or distribution of any chemical substance, or its byproducts, or to establish and enforce standards for test protocols for various classes and uses of chemical substances, and for the results to be achieved therefrom, to protect human health or the environment except that:

"(1)(a) if the Administrator has published proposed regulations under section 205 restricting the use or distribution of a chemical substance, a State or local government may not thereafter impose restrictions on the use or distribution of such substance other than a total ban;

"(b) if the Administrator has published proposed regulations under section 203 or section 204(b), a State or local government may not thereafter establish standards for test protocols and results to be achieved therefrom for such substance to protect human health or the environment;

"(c) publication by the Administrator of proposed regulations under sections 203, 204(b) or 205 shall not preempt a State or local government from enforcing any standards for test protocols and results to be achieved therefrom, or any restrictions on the use or distribution of any chemical substance, or its byproducts, in effect at the time any such proposed regulation is published.

"(2)(a) if the Administrator issues a final regulation under section 205 restricting the use or distribution of a chemical substance, a State may not enforce any such restriction of its own after the effective date of such regulation, other than a total ban on use or distribution; and,

"(b) if the Administrator issues a final regulation under section 203 or section 204(b), a State may not enforce any standards for test protocols and the results to be achieved therefrom of its own after the effective date of such regulation."

SECTION 222—REGULATIONS AND PROCEDURE

Comments

Any person affected by (rather than "adversely" affected by) a proposed regulation or action should be permitted to file objections and request a public hearing. This approach is not unprecedented (for example, it is utilized by the Atomic Energy Commission in proceedings regarding the licensing of nuclear production and utilization facilities) and would ensure that interested members of the public could participate effectively in agency decisions.

Draft language

See Draft Copy.

REDRAFT OF AMENDMENT NO. 338 TO S. 1478 (PREPARED BY EDWARD L. STROHBEHN AND ROBERT M. HALLMAN, JULY 27, 1971)

AMENDMENT

A bill to amend the Federal Hazardous Substances Act, as amended, and for other purposes.

SEC. 2. (a) The Federal Hazardous Substances Act is amended by inserting before section 1 of such Act the following:

"TITLE I—HAZARDOUS CONSUMER PRODUCTS"

(b) Such Act is further amended by adding after Section 18 thereof the following new title:

"TITLE II—TOXIC CHEMICAL SUBSTANCES

"POLICY

"SEC. 201. Whereas man and the environment are being exposed to a growing number of chemical substances each year; and

"Whereas many chemical substances are constantly being developed and produced, some of which may pose an unreasonable threat to human health or the environment; and

"Whereas the effective regulation of interstate commerce in chemical substances necessitates the regulation of transactions in such chemicals in intrastate commerce as well;

"Therefore, it is the policy of the United States that—

"(1) existing chemical substances that pose an unreasonable threat to human health or the environment and all new chemical substances should be adequately tested to determine their effects on human health and the environment; that for new chemical substances such testing should occur prior to introduction into commercial use; that such testing should be the responsibility of those who produce such chemicals for commercial use; and

"(2) chemical substances should serve beneficial purposes; and,

"(3) adequate authority should exist to certify that adequate tests have been conducted, to restrict or to condition the use or distribution of chemical substances that pose an unreasonable threat to human health or the environment, and to seize chemical substances which pose an imminent hazard to human health or the environment; and

"(4) authority over chemical substances should be exercised to fulfill the primary purpose of this title to assure that technological innovation and commerce in such chemicals does not pose an unreasonable threat to human health or the environment taking into account the public interest, including the benefits of chemical substances, as compared to the risks they pose to human health or the environment; and

"(5) citizens should be encouraged to participate in the carrying out of the purposes and provisions of this title.

"DEFINITIONS

"SEC. 202. As used in this Act the term—

"(1) 'Administrator' means the Administrator of the Environmental Protection Agency;

"(2) 'Chemical substance' means any organic or inorganic substance of a particular molecular identity, or any uncombined chemical radical or element;

"(3) 'Existing chemical substance' means any chemical substance which is first produced for commercial use before the effective date of initial regulations promulgated pursuant to section 203;

"(4) 'Manufacturer' means any person engaged in the production or importation of chemical substances for purposse of commercial use;

"(5) 'Processor' means any person engaged in the preparation of a chemical substance for distribution or use either in the form in which it is received or as part of another product, as defined by regulations of the Administrator;

"(6) 'Restrict the use of distribution' means to prescribe the amount sold to given types of processors, or to limit the type of processor to whom a substance may be sold, or to prescribe the amount which may be utilized by a given type of processor, either absolutely or as a proportion of a product prepared by the processor, or to limit the manner or amount in which a substance may be manufactured, used, handled, sold, distributed, disposed of, or labelled by any person, and such limitation may include a total ban;

"(7) 'Byproduct' means a chemical substance produced as a direct result of the production, manufacture, processing, sale, distribution, use, or disposal of some other chemical substance which is subject to the provisions of this title;

"(8) 'Environment' includes water, air, land, all plants and animals living therein, and the interrelationships which exist among these;

"(9) 'Animal' means all vertebrate and invertebrate species, including but not limited to man and other mammals, birds, fish, and shellfish;

"(10) 'Protect human health or the environment' means protection against any unreasonable threat to human health or the environment resulting from a chemical substance or its byproducts taking into account the public interest, including the benefits of the chemical substance as compared to the risks to human health or the environment;

"(11) 'District court of the United States' which court shall have jurisdiction over actions arising under this title, includes the District Court of Guam, the District Court of the Virgin Islands, the District Court of the Canal Zone, and in the case of American Samoa and the Trust Territory of the Pacific Islands, the District Court of the United States for the District of Hawaii;

"(12) 'New chemical substance' means any chemical substance which is first produced for commercial use after the effective date of initial regulations promulgated pursuant to section 203;

"(13) 'Consumer' means any person who is not a manufacturer, processor, shipper, distributor, wholesaler, retailer, or commercial user of the chemical substance or its byproducts;

"(14) 'Commercial use' means the manufacture, processing, sale, distribution, use, or disposal of chemical substances for purposes other than for research, theoretical analysis, experimentation, or personal use by a consumer;

"(15) 'Person' means an individual, corporation, partnership, association, State, municipality, political subdivision of a State, or federal agency or department, or any agent thereof; and

"(16) 'Imminent hazard' exists when there is reason to believe that the manufacture, processing, sale, distribution, use or disposal of a chemical substance or its byproducts is likely to result in a substantial adverse effect on human health or the environment.

"TEST STANDARDS

"SEC. 203. As soon as possible but no later than one year after the enactment of this title, and from time to time thereafter, the Administrator shall, after consulting with the Toxic Substances Board pursuant to the requirements of section 210, issue proposed regulations, and amendments or changes thereto, which shall establish such standards for test protocols for various classes and uses of chemical substances and for such result that must be achieved therefrom, as are necessary to protect human health or the environment. In determining what is necessary to protect human health or the environment under this section the Administrator shall consider all relevant factors including—

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"(1) the effects on human health of the chemical substance and its by-products;

"(2) the effects on the environment of the chemical substance and its byproducts;

"(3) the benefits of the substance for various uses and the risks of such uses to human health or the environment;

"(4) the normal circumstances in which the chemical substance may be used; and

"(5) the availability of substitutes which are less harmful to human health or the environment.

Such test protocols shall include tests, when appropriate for carcinogenesis, teratogenesis, mutagenesis, persistence, the cumulative or synergistic effects of other chemical substances, and other types of hazards and epidemiological studies of the effects of the chemical substances on mortality and morbidity. The Administrator shall specify in the proposed regulations, and amendments or changes thereto, the date on which such standards shall take effect, which shall be as soon as possible, except that such standards shall not take effect prior to the ninetieth day after the date of issue of the final regulations or amendments or changes thereto and shall take effect no later than twelve months after such date.

"CERTIFICATION OF CHEMICAL SUBSTANCES

"SEC. 204. (a) After the effective date of initial regulations promulgated pursuant to section 203, or any amendments or changes thereto, any manufacturer of a new chemical substance shall be required to obtain a certification from the Administrator that such new chemical substance or its byproducts is in compliance with the test protocols established under section 203. The manufacturer shall submit an application for certification to the Administrator which application shall be in such form and contain or shall be accompanied by such information as the Administrator deems appropriate. As a minimum, each application shall contain the name and address of the applicant, the name and formula of the chemical substance, a description of all tests to which the chemical substance has been subjected and results thereof, a copy of the proposed label for the chemical substance, and a statement of all claims to be made for the chemical substance and directions for its use. A notice of each application, which shall include the name and address of the applicant, the common name and formula of the chemical substance, a summary of the proposed uses, and any other information required by the Administrator, shall be published in the Federal Register upon its receipt by the Administrator. Within thirty days after receipt of an application, the Administrator shall publish in the Federal Register his proposal to grant or deny such application and, if it is proposed to certify the applicant, any proposals to restrict the use or distribution of the chemical substance or its byproducts pursuant to section 205. Thereafter, the procedures of section 222(b) governing the promulgation of regulations shall apply.

"(b) Existing chemical substances are exempted from the requirement of certification by the Administrator for compliance with the test protocols promulgated pursuant to section 203, except that as soon as possible but no later than one year after enactment of this title, and from time to time thereafter, the Administrator shall issue proposed regulations, and amendments or changes thereto, specifying those existing chemical substances the manufacture, processing, sale, distribution, use, or disposal of which there is reason to believe may pose an unreasonable threat to human health or the environment. The Administrator shall issue proposed regulations, and amendments or changes thereto, which shall establish such standards for test protocols for various classes and uses of such existing chemical substances and for such results that must be achieved therefrom, as are necessary to protect human health or the environment. The Administrator shall specify in the proposed regulations, and amendments or changes thereto, the date on which such standards shall take effect, which shall be as soon as possible, except that such standards shall not take effect prior to the ninetieth day after the date of issue of final regulations, or amendments or changes thereto, and shall take effect no later than one year after such date. After the effective date of such regulations, or amendments or changes thereto, any manufacturer of any such existing chemical substance shall be required to obtain a certification from the Administrator pursuant to the procedures of subsection (a).

"(c) Any certification issued under this section shall be conditioned to require compliance with any restrictions on use or distribution of the chemical substance or its byproducts imposed pursuant to section 205.

"(d) Each certification issued under this section shall require the recipient promptly to inform the Administrator in writing of any adverse effects on human health or the environment of the chemical substance, or its byproducts, and any complaints concerning such effects discovered by or that become known to the recipient subsequent to the issuance of the certification.

"(e) Each manufacturer may submit a request for payment of the costs of compling with the tests protocols of section 203 or subsection (b) of this section with the application for certification required by this section. The Administrator shall approve for payment to any manufacturer so requesting such payment an amount equal to the costs legitimately incurred by him for the required testing of each chemical substance relating to protection of human health or the environment. Such payment authorization shall not duplicate any previous payment authorization for similar tests. Thereafter, the Administrator shall pay annually to such manufacturer an amount not to exceed the annual receipts collected for the sale of such chemical substance under subchapter F of chapter 36 of the Internal Revenue Code of 1954, until such time as full payment has been made of the amount approved by the Administrator.

"RESTRICTIONS ON THE USE OR DISTRIBUTION

"SEC. 205. (a) Whether or not a chemical substance is certified pursuant to section 204, to the extent necessary to protect human health or the environment, including such restrictions as are necessary for effective quality control, the Administrator shall by regulation (1) restrict the manufacture, processing, sale, distribution, use, or disposal of the chemical substance or its byproducts; (2) require that any or all persons engaged in the distribution or disposal of the chemical substance or its byproducts so restricted give notification to purchasers or other recipients of the substance of such restrictions in such form and manner as the Administrator determines, including labeling requirements that provide appropriate warning provisions and directions fo ruse and disposal; and (3) require such other action as may be necessary, including prohibiting or restricting the sale, distribution, use, or disposal of such substance, its byproducts or a product containing such a substance and recalling such substances or products from commercial use. Such regulations shall become final pursuant to the procedures, provided in section 222(b).

"(b) In issuing proposed and final regulations under subsection (a) of this section, the Administrator shall set forth the findings of fact and the reasons which support such regulations. The manufacturer shall be responsible for supplying all necessary information for the Administrator to make findings under this subsection. All data submitted to, developed by, or relied on by the Administrator in issuing such regulations shall be available to the public except as precluded by section 214.

"PROTECTION AGAINST IMMINENT HAZARDS

"SEC. 206. Whenever the Administrator determines that an imminent hazard exists, the Administrator shall issue an order requiring all necessary measures that must be taken in order to protect against the occurrence of any substantial adverse effect on human health or the environment. Such necessary measures include the power to seize the chemical substance or its byproducts pursuant to Section 207. If a Section 205 proceeding concerning the chemical substance or its byproducts is not being conducted, the Administrator shall simultaneously with the issuance of the order under this subsection propose a regulation under Section 205. Any order issued under this subsection shall become effective at such time as is necessary to protect against the occurrence of such substantial adverse effect and shall remain effective pending the outcome of formal proceedings under Section 205. Initiation of any such proceedings under Section 205 shall not prevent the Administrator from issuing an order under this Section.

"SEIZURE

"SEC. 207. Any chemical substance or its byproducts which the Administrator determines to be an imminent hazard shall be seized summarily by the Adminis-

trator. Anyone adversely affected by such seizure may, within thirty days from the date of seizure, file objections thereto and request a public hearing, which shall consist of the oral and written presentation of data, views, and arguments pursuant to section 553 of title 5 of the United States Code. Any substance so seized shall be segregated. And the person who seizes the chemical substance shall give to the person from whom or from whose premises the property was taken a receipt for the property taken or shall leave a receipt at the place from which the property was taken. A written inventory of any property taken shall be made in the presence of the person seizing the property and the person from whose possession or premises the property was taken, if he is present, or in the presence of at least one credible person other than the person making such inventory and shall be verified by the person seizing the property. If no request for a hearing is made or if such seizure is sustained by the Administrator pursuant to such a hearing, the seized substance shall be destroyed or sold at auction, subject to appropriate conditions, under the supervision of the Administrator or his representative: Except (1) such substance shall not be destroyed or sold and shall be released to the person from whom seized if, prior to destruction or sale, such person can demonstrate to the Administrator that the seized substance can be made to comply with section 204, 205, or 206, as relevant; (2) no such destruction or sale shall take place until at least thirty days after such seizure or after the completion of a public hearing requested under this section and the decision of the Administrator sustaining the seizure has been promulgated, which must be no later than 14 days after the conclusion of the hearing; (3) in the event of an action for judicial review or further appeal of the seizure, no such destruction or sale shall take place pending such action or appeal or within thirty days thereafter. Any proceeds obtained from the sale of a substance under this section shall be paid into the Treasury of the United States.

"REPORTS

"SEC. 208. (a) The Administrator shall require all manufacturers, and processors where appropriate, of chemical substances to submit written reports to him annually, and at such more frequent times as he may reasonably require, containing such information as is necessary to carry out this title. As a minimum, such reports shall include:

"(1) the names of any or all chemical substances produced, imported, processed, or prepared by the manufacturer or processor for commercial use;

"(2) the chemical identity and molecular structure of such substances;

"(3) the categories of use of each such substance;

"(4) reasonable estimates of the amounts of each substance produced, imported, processed, or prepared for each such category of use;

"(5) a description of the byproducts, if any, resulting from the production of each such substance, and, insofar as they are known to him, from the processing, use, or disposal thereof;

"(6) the names and addresses of, and dates of sale or distribution to, persons receiving significant quantities of such substance as determined by regulation by the Administrator; and,

"(7) the description and results of any tests not otherwise required by this Act which results provide information on the human health or environmental effects of the chemical substance or its byproducts and which tests have been performed by or at the instance of the manufacturers or the results of which are otherwise known to them,

"(b) Whenever the Administrator determines that such action is appropriate to carry out the purposes of this title, he may, by publishing a notice in the Federal Register, invite and afford all interested persons an opportunity to provide information in writing respecting the effects of a chemical substance or its byproducts on human health or the environment.

"(c) Any and all information furnished to the Administrator under this section shall be made available to the public except as precluded by section 214.

"RELATIONSHIP TO OTHER LAWS

"SEC. 209. (a) This title shall not apply to—

"(1) economic poisons subject to the Federal Insecticide, Fungicide, and Rodenticide Act, and chemical substances used solely in such poisons, except

that if a chemical substance which constitutes such a poison or such an ingredient is or may be used for any purpose which is not regulated by the Federal Insecticide, Fungicide, and Rodenticide Act, this title shall apply to such other uses;

"(2) foods, food additives, drugs, and cosmetics subject to the Federal Food, Drug, and Cosmetic Act, as amended, the Federal Meat Inspection Act, and the Poultry Products Inspection Act, and chemical substances used solely therein, and controlled substances regulated pursuant to the Comprehensive Drug Abuse Prevention and Control Act of 1970, except that if such an item or substance is or may be used for any purpose which is not regulated by such Acts this title shall apply to such other uses;

"(3) any source material, special nuclear material, or byproduct material as defined in the Atomic Energy Act of 1954, as amended;

"(4) the transportation of hazardous materials insofar as it is regulated by the [organic acts should be put in here].

"(b) To the extent that such activities are subject to regulation by other Federal laws, including the Occupational Health and Safety Act of 1970 and title I of this Act, the Administrator shall not regulate the manufacture, processing, sale, distribution, use or disposal of a chemical substance on the basis of any possible hazard to employees in their place of employment, or directly to consumers resulting from household use of marketed products which contain or might contain the substance.

"(c) If the Administrator determines that a chemical substance may pose an unreasonable threat to human health or the environment of employees in their place of employment or of consumers resulting from household use of marketed products which contain or might contain the substance, or when transported or when used on or in food or as a drug or cosmetic, he shall transmit any data in his possession relevant to such threats or hazards to the Federal department or agency with authority to take legal action if such a threat or hazard is found to exist.

"(d) The Administrator shall coordinate actions taken under this Act with actions taken to implement the Federal Water Pollution Control Act and the Clean Air Act, and shall, where appropriate, use the authorities contained in such Acts to regulate chemical substances in addition to the authorities provided in this title.

"(e) The Administrator shall consult and coordinate with the heads of other appropriate Federal agencies in administering the provisions of this title.

"(f) This title shall not be construed as superseding or impairing the provisions of any other law or treaty of the United States.

"TOXIC SUBSTANCES BOARD

"SEC. 210. (a) There shall be established in the Environmental Protection Agency a Toxic Substances Board consisting of not more than twelve members who shall be scientifically qualified individuals. The Administrator shall appoint members of the Board from a list of individuals recommended to him by the National Academy of Sciences. Such Board shall include equal numbers of qualified scientists representing the following interests: industry, consumer, environmental, and the general public. One of the members shall be designated by the Administrator to serve as Chairman of the Board; a new Chairman shall be appointed annually; each interest group shall have one of its members appointed Chairman once every four years. The Board shall be divided into three committees, each of which shall have one member from each interest group.

"(b) The National Academy of Sciences, in consultation with the Board, shall establish, maintain, and publish a continuing list of qualified scientists, who shall also be consultants to the Toxic Substances Board, to assist in carrying out the provisions of this section.

"(c) Before proposing any regulations under sections 203 or 204(b) the Administrator shall refer his proposed action and the available evidence, which shall include a statement detailing the consideration of factors and tests which the Administrator is required to undertake pursuant to sections 203 and 204(b) and an environmental impact statement if required by the National Environmental Policy Act, 42 U.S.C. 4321 *et. seq.*, to the Board. The Administrator shall publish in the Federal Register a notice of his proposed action together with information about where the materials submitted to the Board may be obtained by the public. The Board shall refer the proposed action, with the accompanying

materials to a committee, augmented as necessary, by persons from the list of consultants to the Board. Such committee shall contain substantially equal numbers of qualified scientists representing the following interests: industry, consumer, environmental, and the general public. Any person may, and is encouraged to, submit comments to the committee. The committee shall report its views, including a report that it has no views on the proposed action, in writing to the Administrator within a reasonable time, not to exceed one hundred twenty days, specified by the Administrator. Such time may be extended to the full one hundred twenty days if the Administrator determines the extension necessary and such committee has made a good faith effort to report its views within the initial period established by the Administrator. In the event that the committee fails to submit its required report to the Administrator, the Administrator may proceed to take action under this title. The deliberations and proceedings of all such committees shall be open to the public, a public record thereof shall be made, and all materials, reports, studies or comments submitted to or prepared by the committee shall be made public and become part of the public record. The report of the committee, if it is submitted, and any dissenting views together with the public record developed pursuant to this section shall be considered as part of the record in any proceeding taken with respect to the Administrator's action or any hearing requested pursuant to section 222 concerning proposed regulations which are referred to the Board pursuant to this section.

"(d) The Administrator may, at his discretion, also request the Board to convene a panel to consider other actions proposed to be taken under this Act. All provisions of subsection (c) of this section shall apply to any proceedings undertaken pursuant to this subsection, except that the Board shall not be required to make a report.

"(e) The Administrator is authorized to reimburse the National Academy of Sciences for expenses incurred in carrying out this section.

"(f) The failure of a person to submit comments to a committee pursuant to subsection (c) shall not affect the right of such person to a hearing pursuant to section 222.

"RESEARCH

"SEC. 211. The Administrator is authorized to conduct such research and monitoring as is necessary to carry out his responsibilities under this title. Such research and monitoring shall be limited to determining proper test protocols and results to be obtained therefrom under sections 203 and 204(b), determinations under section 204(b), and such monitoring of chemical substances in man and the environment as is necessary to carry out the purposes of this title. In addition, research may be undertaken to confirm the results of tests required by this title. To the extent possible, such research and monitoring shall not duplicate the efforts of other Federal agencies or the research required of manufacturers under this title. In order to carry out the provisions of this section, the Administator is authorized to establish research laboratories, including the acquisition of necessary land, buildings, or facilities, and to make contracts for such research and monitoring.

"ADMINISTRATIVE INSPECTIONS AND WARRANTS

"SEC. 212. (a)(1) For the purpose of inspecting, copying, and verifying the correctness of records, reports, or other documents required to be kept or made under this title and otherwise facilitating the carrying out of his responsibilities under this title, the Administrator is authorized, in accordance with this section, to enter any factory, warehouse, or other premises in which chemical substances are manufactured, processed, stored, or maintained, including retail establishments, and to conduct administrative inspections thereof.

"(2) Such entries and inspections shall be carried out through officers or employees (hereinafter referred to as 'inspectors') designated by the Administrator. Any such inspector, upon stating his purpose and presenting to the owner, operator, or agent in charge of such premises (A) appropriate credentials and (B) his administrative inspection warrant or a written notice of his other inspection authority, shall have the right to enter such premises and conduct such inspection at reasonable times.

"(3) Except when the owner, operator, or agent in charge of such premises so consents in writing, no inspection authorized by this section shall extend to—

"(A) financial data;

"(B) sales data other than shipment data;

"(C) pricing data;

"(D) personnel data; or

"(E) research data (other than data relating to the tests described in subsection 208(b) or data otherwise required by this Act).

"(b) A warrant under this section shall not be required for entries and administrative inspections (including seizures of property)—

"(1) conducted with the consent of the owner, operator, or agent in charge of such premises;

"(2) in situations where an imminent hazard to human health or the environment, exists;

"(3) in any other exceptional or emergency circumstance where time or opportunity to apply for a warrant is lacking; or

"(4) in any other situations where a warrant is not constitutionally required.

"(c) Issuance and execution of administrative inspection warrants shall be as follows:

"(1) Any judge of the United States or of a State court of record, or any United States magistrate, may, within his territorial jurisdiction, and upon proper oath or affirmation showing probable cause, issue warrants for the purpose of conducting administrative inspections authorized by this title, and seizures of property appropriate to such inspections. For the purposes of this subsection the term 'probable cause' means a valid public interest in the effective enforcement of this title or regulations thereunder sufficient to justify administrative inspections of the area, premises, building, or contents thereof, in the circumstances specified in the application for the warrant.

"(2) A warrant shall issue only upon an affidavit of an officer or employee having knowledge of the facts alleged, sworn to before the judge or magistrate and establishing the grounds for issuing the warrant. If the judge or magistrate is satisfied that grounds for the application exist or that there is probable cause to believe they exist, he shall issue a warrant identifying the premises to be inspected, the purpose of such inspection, and, where appropriate, the type of property to be inspected, if any. The warrant shall identify the items or types of property to be seized, if any. The warrant shall be directed to a person authorized under subsection (a)(2) to execute it. The warrant shall state the grounds for its issuance and the name of the person or persons whose affidavit has been taken in support thereof. It shall command the person to whom it is directed to inspect the premises identified for the purpose specified, and, where appropriate, shall direct the seizure of the property specified. The warrant shall direct that it be served during normal business hours. It shall designate the judge or magistrate to whom it shall be returned.

"(3) A warrant issued pursuant to this section must be executed and returned within ten days of its date unless, upon a showing by the United States of a need therefor, the judge or magistrate allows additional time in the warrant. If property is seized pursuant to a warrant, the person executing the warrant shall give to the person from whom or from whose premises the property was taken a copy of the warrant and a receipt for the property taken or shall leave the copy and receipt at the place from which the property was taken.The return of the warrant shall be made promptly and shall be accompanied by a written inventory of any property taken. The inventory shall be made in the presence of the person executing the warrant and of the person from whose possession or premises the property was taken, if they are present, or in the presence of at least one credible person other than the person making such inventory, and shall be verified by the person executing the warrant. The judge or magistrate, upon request, shall deliver a copy of the inventory to the person from whom or from whose premises the property was taken and to the applicant for the warrant.

"(4) The judge or magistrate who has issued a warrant under this section shall attach to the warrant a copy of the return and all papers filed in connection therewith and shall file them with the clerk of the district court of the United States for the judicial district in which the inspection was made.

"EXPORTS AND IMPORTS

"SEC. 213. (a) No chemical substance may be exported to any foreign country if the chemical substance is subject to conditions imposed under section 205. unless the exporter explicitly notifies the purchaser of such conditions, places

labels on the product which contains such conditions, and meets any other requirements imposed by the Administrator, none of which may be more restrictive than those imposed on the chemical substance for domestic manufacture, processing, sale, use, distribution, or disposal pursuant to this title, except that no chemical substance may be exported if the chemical substance, as exported and used, or other particular uses of the chemical substance, will produce directly or indirectly pose an unreasonable threat to human health or the environment in the United States. A report of any exports of chemical substances so conditioned should be made to the government of the foreign country by the exporter pursuant to regulations established by the Administrator.

"(b) The Secretary of the Treasury shall refuse entry into the United States of any chemical substance or article containing such substance if it violates any of the provisions of this title. If a chemical substance or article is refused entry, the Secretary of the Treasury shall refuse delivery to the consignee and shall cause the disposal or storage of any substance or article refused delivery which has not been exported by the consignee within three months from the date of notice of such refusal under such regulations as the Secretary of the Treasury may prescribe, except that the Secretary of the Treasury may deliver to the consignee such substance or article pending examination and decision in the matter on execution of bond for the amount of the full invoice value of such substance or article, together with the duty thereon, and on refusal to return such substance or article for any cause to the custody of the Secretary of the Treasury, when demanded, for the purpose of excluding them from the country, or for any other purpose, said consignee shall forfeit the full amount of said bond. All charges for storage, cartage, and labor on substances or articles which are refused admission or delivery under this section shall be paid by the owner or consignee, and in default of such payment shall constitute a lien against any future importation made by such owner or consignee.

"(c) The Secretary of the Treasury, in consultation with the Administrator, shall issue regulations for the enforcement of subsection (b) of this section, which regulations shall be issued in accordance with section 222.

"CONFIDENTIALITY

"SEC. 214. (a) The information obtained from any manufacturer or processor shall be confidential to the extent that it includes matters referred to in section 552(b)(4) of title 5 of the United Sates Code. For the purposes of this title any such information shall be confidential only if such information is unobtainable by competitors and its disclosure would lead to competitive injury to the manufacturer.

"(b) If, at the request of a manufacturer or processor, the Administrator determines that information is within subsection (a), he shall issue a protective order respecting the confidentiality of information referred to in subsection (a). Such orders shall be made public and shall be subject to de novo judicial review in accordance with section 552(a)(3) of title 57 of the United States Code.

"(c) Information deemed to be confidential in accordance with the provisions of this section may be disclosed to other Federal officers or employees when necessary to accomplish the purposes of this title except that the provisions of section 1905 of title 18 of the United States Code shall continue to apply. Such information may be disclosed in camera when relevant in any administrative or judicial proceeding under this title. In any such proceeding, the administrative body, the Administrator, or the court shall issue such orders as may be appropriate to protect the confidentiality of the materials designated as such by the foregoing provisions.

"PROHIBITED ACTS

"SEC. 215. The following acts and the causing thereof are prohibited—

"(1) the failure to comply with any final regulation or order issued by the Administrator or Secretary of the Treasury pursuant to this title;

"(2) the failure or refusal to provide information or results of tests as required by section 208 of this title;

"(3) the manufacture of any chemical substance for commercial use, or the processing, sale, distribution, use, disposal or importation into the United States of a chemical substance or its byproducts which has not been certified in accordance with section 204;

"(4) the failure of any person, other than a consumer, who purchases or receives a chemical substance or its byproducts and who is required to be given notice of restrictions on use or distribution of such substance pursuant to paragraph 205(a)(2), to comply with such restrictions on use or distribution;

"(5) the knowing or willful failure of any consumer to use or dispose of a chemical substance or its byproducts in accordance with label instructions;

"(6) the failure to perform any other action required under this title.

"PENALTIES AND REMEDIES

"SEC. 216. (a) Any person willfully violating paragraph (1), (2), (3), or (4) of section 215 shall on conviction be fined not more than $25,000 or imprisoned for not more than one year, or both.

"(b)(1) Any person violating paragraph (1), (2), (3), (4), or (5) of section 215 shall be liable to the United States for a civil penalty of not more than $25,000 for each day of violation. Such penalty shall be assesssed by the Administrator after notice and opportunity for hearing and after he has considered the nature and circumstances of such violation.

"(2) Upon failure of the offending party promtply to pay the civil penalty, the Administrator shall commence an action in the appropriate district court of the United States for such relief as may be appropriate or request the Attorney General to commence such an action.

"(c) The Attorney General or the Administrator may bring an action in the appropriate district court of the United States for equitable relief to redress a violation by any person of any provision of section 215 of this title, and the district courts of the United States shall have jurisdiction to grant such relief as the equities of the case may require.

"CITIZEN CIVIL ACTIONS

"SEC. 217. (a) Except as provided in subsection (b), any person may commence a civil action for injunctive relief on his own behalf, or as a representative of a class whenever such action constitutes a case or controversy—

"(1) against any person, including (i) the United States, and (ii) any other governmental instrumentality or agency to the extent permitted by the eleventh amendment to the Constitution, who is alleged to be in violation of any provision of section 215, or

"(2) against the Administrator where there is alleged a failure of the Administrator to perform any act or duty under this title which is not discretionary with the Administrator. The district courts shall have jurisdiction, without regard to the amount in controversy or the citizenship of the parties, over suits brought under this section. Nothing herein shall be construed to prevent or preempt State courts from exercising jurisdiction over such actions.

"(b) No civil action may be commenced—

"(1) under subsection (a)(1)—

"(A) prior to sixty days after the plaintiff has given notice of the violation (i) to the Admiinstrator, (ii) to the State in which the violation occurs, and (iii) to any alleged violator of section 215, or

"(B) if the Administrator or State has commenced and is diligent'y prosecuting a civil action in a court of the United States or a State to require compliance with section 215, but in any such action in a court of the United States any person may intervene as a matter of right.

"(2) under subsection (a)(2) prior to sixty days after the plaintiff has given notice of such action to the Administrator, except that such action may be brought ten days after such notification in the case of an action under this section for the failure of the Administrator to act under section 206. Notice under this subsection shall be given in such manner as the Administrator shall prescribe by regulation pursuant to section 222.

"(c) In any action under this section, the Administrator, if not a party, may intervene as a matter of right.

"(d) The court, in issuing any final order in any action brought pursuant to subsection (a) of this section, shall award costs of litigation, including reasonable attorney and expert witness fees, to any person who brings a successful action under section 217(a) and may award such costs to any party whenever

the court determines such an award is appropriate. The United States shall be liable for such costs in the same manner as a private person.

"(e) Nothing in this section shall restrict any right which any person (or class of persons) may have under any statute or common law to seek enforcement of any regulation or order or to seek any other relief (including relief against the Administrator or a State agency).

"ENVIRONMENTAL PREDICTION AND ASSESSMENT

"SEC. 218. The Environmental Protection Agency shall, in cooperation with other Federal agencies, develop the personnel and information resources necessary to predict the introduction of new chemical substances into commercial use and assess the effects on human health and the environment of the introduction of such chemical substances into commercial use.

"USE OF GOVERNMENT FACILITIES

"SEC. 219. The Administrator may use, by agreement, the personnel, services, and facilities of other Federal departments, agencies, or instrumentalities, whether on a reimbursable or nonreimbursable basis.

"HEALTH AND ENVIRONMENTAL DATA

"SEC. 220. The Council on Environmental Quality in consultation with the Administrator, and the heads of other appropriate federal, state and local departments or agencies, shall coordinate a study of the feasibility of establishing (1) a standard classification system for chemical compounds and related substances, and (2) a standard means for storing and for obtaining rapid access to information respecting such materials.

"STATE REGULATIONS

"SEC. 221. Nothing in this title shall affect the authority of any State or local government to restrict the use or distribution of any chemical substance, or its byproducts, or to establish and enforce standards for test protocols for various classes and uses of chemical substances, and for the results to be achieved therefrom, to protect human health or the environment except that:

"(1) (a) if the Administrator has published proposed regulations under section 205 restricting the use or distribution of a chemical substance, a State or local government may not thereafter impose restrictions on the use or distribution of such substance other than a total ban;

"(b) if the Administrator has published proposed regulations under section 203 or section 204(b), a State or local government may not establish standards for test protocols and results to be achieved therefrom for such substance to protect human health or the environment;

"(c) publication by the Administrator of proposed regulations under sections 203, 204(b) or 205 shall not preempt a State or local government from enforcing any standards for test protocols and results to be achieved therefrom, or any restrictions on the use or distribution of any chemical substance, or its byproducts, in effect at the time any such proposed regulation is published.

"(2) (a) if the Administrator issues a final regulation under section 205 restricting the use or distribution of a chemical substance, a State may not enforce any such restriction of its own after the effective date of such regulation, other than a total ban on use or distribution; and,

"(b) if the Administrator issues a final regulation under section 203 or section 204(b), a State may not enforce any standards for test protocols and the results to be achieved therefrom of its own after the effective date of such regulation.

"REGULATIONS AND PROCEDURE

"SEC. 222. (a) The Administrator is authorized to issue regulations to carry out the purposes of this title.

"(b) The Administration shall publish any regulations or actions proposed under this title in the Federal Register at least sixty days prior to the time when such regulations or actions shall become final. If any person adversely affected by a proposed regulation or action files objections and requests a public hearing within forty-five days of the date of publication of the proposed regulation or

action the Administrator shall grant such requests. The public hearing shall be commenced within fourteen days of such request. If a public hearing is held, final regulations or actions shall not be promulgated by the Administrator until after the conclusion of such hearing, but shall be promulgated within fourteen days after the conclusion of such hearing. All comments, reports, materials, records of proceedings or tests, and other information developed pursuant to actions under this title shall be available to the public unless precluded by section 214 of this title. All public hearings authorized by this subsection shall consist of the oral and written presentation of data, views, or arguments pursuant to section 553 of title 5 of the United Staees Code.

"AUTHORIZATION FOR APPROPRIATIONS

"SEC. 223. There is hereby authorized to be appropriated to the Environmental Protection Agency such sums as may be necessary for the purposes and administration of this Act."

SEC. 3. (a) Chapter 36 of the Internal Revenue Code of 1954 (relating to certain other excise taxes) is amended by adding at the end thereof the following new subchapter:

"SUBCHAPTER F—CHEMICAL SUBSTANCES

"Sec. 4496. Imposition of tax.
"Sec. 4497. Special rule.

"Sec. 4496. Imposition of Tax.

"(a) CHEMICAL SUBSTANCES.—There is hereby imposed on the sale by the manufacturer of any chemical substance manufactured or produced under a certification issued under section 204 of the Federal Hazardous Substances Act a tax equal to — percent of the price for which such substance is sold.

"(b) SUSPENSION OF TAX.—The tax imposed by this section on any manufacturer shall be suspended whenever the amount collected from that manufacturer equals the amount approved for payment to him under section 204(c) of the Federal Hazardous Substances Act. Such suspension shall remain in effect until additional testing with respect to that manufacturer is required pursuant to section 203 or section 204(b) of such Act, but shall become effective again whenever, after such testing the manufacturer again satisfies the requirement of the preceding sentence.

Sec. 4497. Special Rule.

"Under regulations prescribed by the Secretary or his delegate. the provisions of subchapters F and G of chapter 32 and the provisions of subtitle F relating to the taxes imposed by chapter 32 shall apply to the taxes imposed by section 4496."

(b) The table of subchapters for such chapter 36 is amended by adding at the end thereof the following new item:

"Subchapter F. CHEMICAL SUBSTANCES"

THE TOXIC SUBSTANCES CONTROL ACT OF 1971 AND AMENDMENT

MONDAY, OCTOBER 4, 1971

U.S. SENATE,
COMMITTEE ON COMMERCE,
SUBCOMMITTEE ON THE ENVIRONMENT,
Washington, D.C.

The subcommittee met at 10:15 a.m. in room 1114. New Senate Office Building, Hon. William B. Spong, Jr., presiding.

Present: Senators Spong and Hatfield.

Senator SPONG. The hearings will come to order.

Before we hear from any witnesses, allow me to first clear up some confusion that may exist concerning future hearings of this subcommittee on S. 1478, amendment No. 338 thereto, and S. 2553. We had planned to hear today from those detergent manufacturers who wanted to respond to last Friday's testimony. In order to give us all more time to prepare, we will now devote October 15 to testimony from those industry witnesses. Additional hearings will be scheduled to hear witnesses on S. 1478 and the amendment that had been originally scheduled for the 15th.

Our first witness this morning is Mr. Anthony Mazzocchi of the Oil, Chemical & Atomic Workers Union.

We are very pleased to have you with us this morning. I am sorry I am a little late in getting the hearings started.

STATEMENT OF ANTHONY MAZZOCCHI, CITIZENSHIP-LEGISLATIVE DIRECTOR, OIL, CHEMICAL & ATOMIC WORKERS INTERNATIONAL UNION, WASHINGTON, D.C.; ACCOMPANIED BY FRED LINDE, PRESIDENTIAL ASSISTANT FOR HEALTH AND SAFETY, OIL, CHEMICAL & ATOMIC WORKERS INTERNATIONAL UNION; AND STEVEN WODKA, RESEARCH ASSISTANT

Mr. MAZZOCCHI. I would like to introduce two of my associates who will be assisting me here this morning. On my right is Mr. Fred Linde, who is a chemical engineer employed by our union and is an assistant to the president of our union. On my left is my own assistant, Steven Wodka.

The proposed Toxic Substances Act (S. 1478) as amended (No. 338) by Senator Spong must be seen as an historic advancement for both environmental protection and for the betterment of the public health. For many years our international union, the Oil, Chemical & Atomic Workers, has contended that all new technology, particularly chemical substances, must be presumed guilty of potential environ-

mental degradation and adverse health effects until proven safe. The section in the Spong amendment dealing with premarket clearances of new chemicals goes a long way toward implementing this goal.

Another significant concept found in the Spong amendment is the shifting of the burden of proven safety and the costs incurred to the introducer of the new product. This is a more efficient research mechanism than trying to develop a large, but inevitably cumbersome, governmental testing facility.

However, we should never assume that science is objective and the results will be the same no matter who is in charge of the laboratory. The current controversies over the supersonic transport, the Amchitka atomic bomb test, and the Alaska pipeline show how deeply the scientific community can divide over the same issue. In each case, scientists connected with the project's vested interests minimized and disputed the views and fears of environmental scientists connected with the opposition groups.

This experience must be carried over to the realm of toxic substances. The proposed legislation could allow the wolves to guard the chickens. Thus we proposed that the Environmental Protection Agency be provided with more extensive surveillance authority to insure that industry does not issue false and misleading data on the safety of new substances. This committee must not overlook this very prevalent mode of American business operation. In our collective bargaining agreements with industry, for example, particularly in the occupational health and safety arena, we are constantly meeting up with corporate delusion and falsification.

For example, we had deep suspicions that our members at an Allied Chemical Co. plant in Moundsville, W. Va., were suffering from overexposure to mercury fumes and vapors. Allied continually denied our claims. But earlier this year the company performed a urinalysis for mercury on each employee, a test which is usually a good indicator as to the extent of exposure.

The company's results came back showing levels of mercury quite close to the threshold limit value for mercury content in the urine of industrial workers. Fortunately, however, the Department of Health, Education, and Welfare had already entered the situation and had split each of these workers urine samples with the company and had proceeded to run their own urinalysis in Cincinnati. Remarkably, HEW's mercury levels came out a nearly constant average of 275 percent over those found by Allied in the same urine sample. HEW's results were later verified by further urinalysis and air sampling, Later, the plant won the dubious honor of receiving the first citation for violation of the new Occupational Safety and Health Act.

This incident in West Virginia with this major industrial concern is not isolated and we could spend the rest of the day citing case after case of similar corporate delusion. Thus we urge this committee to consider provisions for effective Federal surveillance of private industry's testing and research.

Also necessary but lacking in this bill are provisions guaranteeing nondiscrimination for an employee of a company who decides to "blow the whistle" against his own management and spill the beans on some corporate falsification and reveal the true facts in a case. Such clauses

can be found in recent antipollution legislation and the Occupational Safety and Health Act.

Our other major criticism of both the administration's bill and the Spong amendment is the refusal to deal effectively with the current national disaster in the field of worker health and safety. Many of you will recall the battle last fall over the Federal Occupational Safety and Health Act, a bill supposedly designed "to assure safe and healthful working conditions for working men and women." The act has only been in effect for 5 months, but already we are able to point out some serious design flaws and some highly partisan acts of administration. The Department of Labor has made every effort to bend interpretations of the new law and to issue regulations that are to the likes of management. In fact, Ralph Nader, in reviewing the administration of the new act so far has charged the Labor Department with acting more like its neighbor across the street, the Commerce Department, in its advocacy of the management viewpoint.

These concerns will probably be brought out in oversight hearings in January. In the meantime we must recognize a fundamental flaw in the Health and Safety Act that can be corrected with an improvement in the legislation that we are considering today. We refer to the exclusion of workers from the provisions of the Toxic Substances Act as indicated in section 209(b) because of other existing statutes.

There is a myth in this country that holds working people as more durable and healthy than the rest of the U.S. population. Thus workers can be exposed to very high pollution levels in the workplace. For example, the carbon monoxide standard for workers is 50 ppm, for the rest of the U.S. population, 9 ppm. For sulfur dioxide, the factory standard is 5 ppm, while the community standard is way under 1 ppm. Unfortunately, the standard makers failed to see past the Popeye image of the American worker to realize that the laboring population contains the young and the old men and women, the sick and the healthy, and many with poor hearts and battered lungs.

In spite of these facts, our people have been and still are the guinea pigs for American technology. In the Southwest 1,100 of 6,000 uranium miners will probably die of lung cancer because we failed to realize the danger of radon daughter gas released during such mining operations. In pesticide plants, the nervous systems of our members are permanently damaged by exposure to chlorinated hydrocarbon poisons. In petroleum refineries we have reason to be concerned about possible cancer from the exposure to aromatic fumes and vapors. The EPA wonders if the same will occur in large cities if auto exhausts continue to increase. And over a year ago this committee pondered the possibility that we were slowly poisoning ourselves through consumption of mercury-tainted fish. I can tell you right now that occupational mercury poisoning is occurring in those chemical plants responsible for that mercury pollution.

The detergent industry, specifically companies like Proctor & Gamble, Colgate-Palmolive, and Lever Bros., is a fine example of this cruel double standard. When enzyme detergents became "the new thing" on the market and were widely produced, we watched a dramatic rise in lung troubles among workers in factories, a group which had never before complained of serious occupational health problems. Several doctors did the necessary research and concluded that the breath-

lessness, the asthmatic-like attacks, and the permanent lung damage among detergent workers was due to occupational exposure to the new enzymes. We took our concerns and data to the companies and the Government. We pleaded for inplant environmental controls and enforcement. In some plants cleanup measures were begun, but for the most part the number of workers with lung trouble due to enzymes grew and grew.

But last winter, as the press carried more stories on the hazards of enzymes and housewives became more concerned with their exposure to enzyme detergents, sales of this product began to fall. Detergent makers began to cut back on the amount of enzymes used and in some cases eliminated them completely from some product lines. Now you can walk down the laundry soap aisle in your market and the boxes on the shelves proudly proclaim "no enzymes" or "enzyme-free."

The housewife may now relax. But for the detergent workers whose lungs have been permanently damaged by enzymes, life is constant misery.

Our point is that there is no provision in the Occupational Safety and Health Act of 1970 that can prevent this type of tragic episode from occurring again. There are no provisions in the Health and Safety Act for anticipating this kind of situation. The act only comes into play once damage, death, injury, or sickness has occurred. For our people, like in the enzyme case, action came too late. Thus we must have legislation that prevents the introduction of toxic substances into the workplace without the proper safeguards and restrictions. We ask that the Spong amendment, specifically section 209(b), be changed to bring coverage to employees in their place of employment.

We recognize the current provisions in section 209(b) which directs the Administrator of the EPA to transmit hazard information on substances to the Department of Labor. But again, and most importantly, the Occupational Safety and Health Administration in the Labor Department lacks the very direct effective authority like outright ban, seizure, or restrictive use that is found in the Spong amendment. If we are willing to provide such protection for birds and bees, why not for human beings?

Let me make one further proposal besides the inclusion of workers under the Toxic Substances Act. The HEW National Institute for Occupational Safety and Health (NIOSH) should be given central responsibility and adequate funding to direct research into the effects of new substances on human health. Such a provision is only logical as NIOSH has the responsibility for researching the effects of occupational health hazards on workers. Such a provision as I propose would reduce the possibility of duplication of effort among Federal agencies and would speed the recognition of new health hazards.

In summary then, it is high time that the health of working people be valued equal to every other segment of the population. Double standards and discrimination against workers' health must end. If Congress allows preventive detention of alleged criminals, then certainly we must have preventive detention of toxic substances that have the proven potential of endangering the health of millions of human beings. It would be much easier for us as a union to testify here on how this bill may cost our people some jobs. Instead, the OCAW is

asking you to pass this bill with the indicated changes in order to save the lives of our people.

Senator SPONG. Thank you very much.

In your statement you question the credibility of industry-sponsored research into the public health and environmental effects of chemical substances. As you point out, we are not yet ready to develop a large, cumbersome governmental testing facility. I am inclined to agree with this. So the burden is on us to develop a type of framework that will insure to the maximum extent possible that the data we get from industry is good data. Some have suggested that one means of accomplishing this would be to require the Environmental Protection Agency to certify all testing facilities that would be used in complying with the test regulations under this legislation. What is your comment on this suggestion?

Mr. MAZZOCCHI. Since he is a professional, I would like Mr. Linde to direct an answer to that question.

Mr. LINDE. Senator, I think the problem is probably being approached by industry and the other agencies that are responsible in this area better now than it has been in the past. But, if I may, I would like to cite some personal experiences from my own work experiences which cover three rather major producers of industrial chemicals.

I participated in some of the first production of DDT in 1946, I believe it was, and our worker protection was almost none. We supplied dust masks and that was all. It has been impossible for me to follow the subsequent medical histories of these people, and I do not know what has happened. I might add the company doing this work is an extremely responsible one. We just did not know and we did not know what to look for.

I think that is a significant thing. We had no idea at the time that this could be hazardous or would be so far as its effect on the environment. Experience, of course, is the better teacher.

I also have made 2,4-D, the herbicide, in a number of places, and again it was started in production with absolutely no worker protection. We had only the dimmest understanding of its influence on the environment biosphere. It was not until there was two facilities in our own plant that medical assistance was called in to establish programs.

There is, of course, the necessity for rushing into the marketplace, an economic necessity, and I think this at times has probably overcome some of the prudence that might be directed otherwise.

The worker in the plant is particularly vulnerable. He, by and large, is not technically trained nor does he have any scientific understanding, and he is not paid at any rate that would indicate professionalism. So he really does not know what he is working with.

Over the years the art, you might say, has developed to the point where people recognize that certain acids are harmful or that certain organic chemicals might be harmful, and recognize that some of the heavy metals such as beryllium and mercury create health hazards, but they do not know why, of course. That is the professional's job. It is the chemist's, the engineer's, and the medical scientist's job to understand the ramifications, the background, and the potentialities, and so on. And the only way to insure that the worker in the plant will be protected, operating it so that a man will have all the personal precautions as well

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as medical and so on, is to insist that these be demonstrated absolutely safe before they are put into production.

Mr. MAZZOCCHI. I think the answer to your question is we support the view that you have just expressed.

Senator SPONG. That EPA certify the testing facility?

Mr. MAZZOCCHI. That there be certification. The checks and balances would be one we would subscribe to.

Senator SPONG. In your statement you make a convincing argument for inclusion of occupational safety considerations within the scope of this legislation. As you know, the Environmental Protection Agency would administer the toxic substances program under both the administration's bill and under the amendment. Do you see any problem with an agency whose focus is primarily geared toward environmental concerns administering a statute for the protection of occupational hazards Many would argue that this ought to be within the province of a health-oriented or labor-oriented agency of Government.

Mr. MAZZOCCHI. Senator, this goes to the heart of the problem. We think the missing link in the whole environmental concern movement, both in the halls of the legislature and in the community generally, is the failure to recognize that this is an inseparable question. You cannot direct your concern to the outdoor environment without understanding what happens inside the plant gate, because this is the basis of all environmental degradation, it occurs inside the plant. With a human monitoring system that would exist if a worker were protected properly, and if he understood his plant environment, you would have the greatest shortcut to protecting the outdoor environment. It is one pie, and this slice that is out of it is the real bar to accomplishing anything of any substance on the environmental question generally.

If the worker knew precisely what he worked with, if the technology had to prove itself innocent, the concept being it is all guilty until it has proved it is innocent, and it would have to start from the time it is introduced, the type of problem that the legislation directs itself to would be halfway solved, because if you have to prove that something was safe for people inside the plant, you certainly would be a long way to accomplishing your total goal.

I see no reason why the administrative arrangements could not be worked out. I really think that is a question of mechanics. But on the question of substance, yes, certainly HEW and EPA could certainly work it out so they have total control of the situation.

Mr. LINDE. If I may add something here, I think the point that Mr. Mazzocchi has made is the in-plant environment, the concentration of these toxic substances in the in-plant environment is so much greater than it is in the total environment, in the case of carbon monoxide, sulfur dioxide, and chlorine, and so on, that this is the real testing ground. This is where it must be proven safe. If it is proven safe in the plant, to the workers there, it will be safe for the total population.

Senator SPONG. I appreciate what you are saying, but we have structural problems insofar as the administrative branches of the government are concerned, and we have a more immediate problem in the jurisdictions of these various Senate committees and the legislation that they hear.

I will certainly give consideration to your suggestion, but I would point out that there would be one or two other Senate committees immediately involved were we to move in that direction.

Mr. MAZZOCCHI. We understand your concern, and certainly it is our purpose here not to work out all the administrative details. We are really not capable of that. We think our responsibility is to raise this particular concern and leave it up to the Senate and the House to work out the details. We are sounding the alarm so to speak.

Senator SPONG. If we were to include the regulation of the workplace environment under this bill, would you then recommend repeal of the Occupational Safety and Health Act, or would the two statutes be compatible, or is it possible to amend the Occupational Safety and Health Act to anticipate hazardous situations rather than, as you say, dealing with occupational hazards only after damage, depth, injury or sickness hs occurred?

Mr. MAZZOCCHI. We think the acts can be compatible and complement each other, and certainly we would not ever urge the repeal of one or the other. We think you need to approach this question from many directions, of course.

Senator SPONG. In your testimony, you recommended a clause be added guaranteeing nondiscrimination for an employee who blows the whistle on his company. Has this clause in the Occupational Safety and Health Act been tested? Is it an effective device against recrimination?

Mr. MAZZOCCHI. The act is new, of course, and, the Occupational Health and Safety Act, and we know of only one case in our own union where a company sought to take punitive action, and just by indicating the provision of the law would prevent that. It seems to have stopped that situation.

We also recognize, however, that 75 percent of the work force is not protected by any trade union group, and this particular segment of the work force who should also act as environmental monitors should have some further protection. Many of these substances that get out on to the market are problems that have been detected in the workplace.

We mentioned enzymes. Workers who are first affected by it indicate to us that there was a problem, and then that acts as the catalyst for movement later on down the line. I mean the industry was aware of the problem simply because they conducted independent research in England but never bothered to feed the results of that research into the United States.

Senator SPONG. Well, we thank all of you gentlemen for your testimony here this morning.

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

ALLIED CHEMICAL CORPORATION,
New York, N.Y., October 19, 1971.

Hon. WILLIAM B. SPONG, Jr.,
New Senate Office Building,
Washington, D.C.

DEAR SENATOR SPONG: On October 4, 1971 ,Mr. Anthony Mazzocchi (Oil, Chemical and Atomic Workers International Union) testified before the Subcommittee on the Environment of the Senate Commerce Committee. His testimony cited the great discrepancy between the urinalysis results obtained by H.E.W. and those obtained by Allied Chemical when testing cell room employees this year at our

Moundsville chorine plant for mercury exposure. Mr. Mazzocchi cites this discrepancy as a possible example of corporate falsification of safety studies.

This letter is being sent to you to complete and correct the record.

First, the results obtained by H.E.W. on February 18, 1971 were in error. We have discussed at length the discrepancy in the February results with H.E.W. Cincinnati laboratory personnel who performed the H.E.W. analysis. After review of their laboratory notebook, they are now convinced that they obtained higher figures than Allied Chemical because the sample received by them in February were improperly split, perhaps after sediments had formed after aging.

Second, we are confident that the results obtained by our Moundsville laboratory were accurate. Our laboratory supervisors and our key analysts have many years of continuous experience with mercury. They have learned that the determination of trace quantities of mercury in biological specimens is difficult and the possibility of analytical failure or accidental contamination of samples is great. They are aware of the pitfalls and special precautions needed, and of the patterns of expected values so that they can run verification checks on their own work when the observed results appear abnormal.

Third, the accuracy of our testing procedures has been confirmed by other laboratories. Thus, after we became aware that our February urinalysis results were appreciably different from those obtained by H.E.W., we arranged for a second group of samples (taken April 16, 1971 under strict medical supervision) to be separately analyzed by H.E.W., our Moundsville Plant, another Allied Chemical laboratory at Syracuse, by one of PPG Industries' laboratories, and by an independent consulting laboratory (Environmental Health Laboratories, Inc.). The results set forth below show good inter-laboratory agreement within the accuracy tolerances of the test method:

Laboratory	*Deviation from Moundsville results*
H.E.W.-Cincinnati	14 percent higher.
Allied-Syracuse	13 percent lower.
PPG Industries-Natrium	identical.
Environmental Health Laboratories	13 percent higher.

Crucially, these April results are consistent with and thus confirm the February results of our Moundsville laboratory. Moreover, Mr. Mazzocchi's testimony that the earlier H.E.W. results were later verified by further urinalysis is factually wrong.

Mr. Mazzocchi was factually correct in stating that the Moundsville plant was cited for violation of the Occupational Safety and Health Act. Whether such citation should or should not have been issued is not the point. However, it should be noted that three days after the citation was served on June 1, the Labor Department in cooperation with H.E.W. reinspected the plant and found it in compliance with air quality standards required to protect employees' health, Attached is a copy of my letter of August 26, 1971, to Assistant Secretary of Labor, George Guenther. This letter reports various medical conclusions concerning physical examinations made of our cell room employees to the effect that there was not "a single positive finding that could be attributed to the effects of mercury."

In short, the facts do not support the implication that this company of H.E.W. deliberately issued false data.

Respectfully yours,

EDWARD W. CALLAHAN,
General Manager, Environmental Services.

ALLIED CHEMICAL CORP.,
New York, N.Y., August 26, 1971.

Re Moundsville, West Virginia.

Hon. GEORGE GUNTHER,
Assistant Secretary of Labor,
U.S. Department of Labor,
Washington, D.C.

DEAR MR. GUENTHER: Now that the immediate issue of compliance with the inspection and citation of May 28, 1971 has been resolved. I believe a brief summary of certain medical reports which may not have reached your personal attention might provide you with a useful perspective on such proceedings.

You will recall that the letter addressed to you by Mr. Mazzocchi of OCAW on May 14, 1971 and the contemporaneous press releases charged that employees at the Moundsville plant had been poisoned as a reuslt of exposure of mercury vapor. It was in the context of this widely published and often repeated accusation that the inspection took place, giving rise to a citation which allowed for a 24-hour compliance period. The actual medical conditions of the employees as reported by the various doctors concerned are therefore of interest.

The annexed report of Dr. F. H. Hochberg of the Public Health Service to the West Virginia Department of Health dated June 24, 1971, observed, "At the present time, we are unable to show a statistically significant greater incidence of signs or symptoms in the mercury exposed or high blood mercury groups than in the controls. This is not to say that individuals in either group may not have more signs and symptoms than the control group."

At the time of Dr. Hochberg's visit, the company availed itself of the services of Dr. Ralph C. Smith a distinguished toxicologist at the University of Michigan. Dr. Smith is the principal author of references cited by both Dr. Hochberg and Dr. P. G. Rentos in their reports. Dr. Smith inspected our plant, reviewed our practices, conferred with Dr. Hochberg, and reported in the attached letter that our procedures "should make it highly improbable that clinical mercurialism would occur in any worker."

To further assure ourselves, the union and the employees, we also engaged Dr. Leonard J. Goldwater, Professor of Community Health at Duke University and Professor Emeritus of Occupational Medicine, Columbia University, the leading medical authority on mercurialism, to examine the employees apparently referred to in the union's charges. Eight of the ten concerned agreed to the examination; one refused, and one was not available. Dr. Goldwater in his annexed report of July 9, 1971 concluded, "Among these eight individuals I did not detect a single positive finding that could be attributed to the effect of mercury." Dr. Goldwater further advised that the two employees not examined by him were examined by Dr. L. V. Tepper, Professor of Environmental Health of the University of Cincinnati, at the request of OCAW.

We have been unable to reach Dr. Tepper for his direct comments. However, both of the employees not examined by Dr. Goldwater were also examined by Dr. Kenneth J. Allen. After consultation with Dr. Tepper, Dr. Allen concluded that there was no evidence of mercurialism in either employee. Dr. Allen has authorized us to quote him to that effect.

Of particular interest is the attached letter dated July 12, 1971 from Dr. Allen regarding Paul Conner, one of the two employees examined by him and Dr. Tepper. Mr. Conner had entered the hospital, the union charging that this was a result of mercurialism. Dr. Allen reported, "Our conclusion is that Mr. Conner is not, nor has he ever showed signs and symptoms of mercury intoxication."

It might also be noted that the plant's long-standing program of urinary surveillance had been supplemented early in 1970 by semi-annual special medical examinations for workers exposed to mercury. This examination was specifically designed to detect early symtoms of mercurialism and to reveal non-occupational conditions which might otherwise be attributed to mercurialism. This program conducted by the plant physician, Dr. David E. Yoho, similarly found no evidence of clinical or sub-clinical mercurialism. Dr. Yoho's case files are not enclosed but they remain available for inspection by your medical officers.

I believe the above will confirm what I indicated at our original meeting, that while we appreciate the Department's and the union's concern, these compelling reports do not support the representations made to the press or your Department by the charging parties.

To complete the record, we are aware that Dr. Hochberg has issued a second report which shows differences in the frequency of specific signs and symptoms between groups of exposed and unexposed employees. We have reviewed this report in some detail with Dr. Hochberg. We accept his recommendations that we maintain our vigilance in medical surveillance of exposed personnel and continue our efforts to keep exposures at a minimum.

We wish to reassure you that our company continues to view the possibility of excessive exposure to mercury as a serious matter. We appreciate the efforts and recommendations of your staff for further improving our safeguards, and we have initiated significant engineering and work rule improvements to this effect.

Very truly yours,

EDWARD W. CALLAHAN,
General Manager, Environmental Services.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
Rockville, Md., November 26, 1971.

Hon. WILLIAM B. SPONG., Jr.,
U.S. Senate,
Washington, D.C.

DEAR SENATOR SPONG: The National Institute for Occupational Safety and Health appreciates the opportunity to comment on Mr. Edward W. Callahan's letter to you.

Dr. P. G. Rentos of my staff earlier had received from Mr. Callahan a copy of the same letter which you have referred to me. When this letter was received, I felt that the misunderstandings were so great that steps had to be taken to clarify the record; accordingly, I wrote to Mr. Warren S. Ferguson, Director of Occupational Health for the Allied Chemical Corporation. A copy of this letter is enclosed. It clearly states our objections to Mr. Callahan's implication that our laboratory conducted improper and inaccurate analysis of the urine samples.

Thank you for the opportunity to clarify the record in this matter.

Sincerely yours,

Enclosure.

MARCUS M. KEY, M.D.,
Director, Assistant Surgeon General.

NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH,
November 11, 1971.

Mr. WARREN S. FERGUSON,
Director, Occupational Health, Allied Chemical Corp.,
New York, N.Y.

DEAR MR. FERGUSON: We have received your letter of October 20, 1971, to Dr. P. G. Rentos of our staff, plus copies of Mr. Edward W. Callahan's letters to Senator William B. Spong, Jr. and to Assistant Secretary of Labor George C. Guenther, dated October 19, 1971, and August 26, 1971, respectively. These letters discuss the results of biological analyses for urinary mercury conducted at your Moundsville, West Virginia alkali-chlorine plant, by your two laboratories; the National Institute for Occupational Safety and Health laboratory in Cincinnati and two independent laboratories.

Since Mr. Callahan has made several comments concerning the accuracy and validity of the NIOSH analytical results, I feel obliged to respond directly to his criticisms. Let me state, first, that our intention here is not to criticize the analytical results or the integrity of your professional staff but to make two primary points:

(1) At the times of the February and April studies the analytical results of all five laboratories indicated that a significant number of workers in your plant showed excessively high levels of mercury excretion. This indicated that excessive exposures to and absorption of mercury occurred among your workers during their normal work operations. For example, according to the Allied Chemical Corporation analytical results, at the time of the February 18, 1971, study, 14 of 26 workers showed excretion levels above the hygienic limt of 250 micrograms (μg) per liter of urine. At the same time, NIOSH results indicated that 23 of 26 workers showed excretion levels above the recognized limit.

(2) We are assured by our laboratory staff in Cincinnati that the analytical results from our laboratory, on both the February and April samples, are valid and accurate *on the samples sent to us* by Allied Chemical Corporation, since our analytical procedures have been validated by numerous standardization procedures.

With respect to Mr. Callahan's letter to Senator Spong, we offer the following comments:

1. Page (1) paragraph 2 and 3. ". . . the results obtained by HEW on February 18 were in error. . . . After review of their laboratory notebook, they (HEW) are convinced that they obtained higher figures than Allied Chemical because the samples received by them in February were improperly split. . . .

"Second, we (Allied Chemical) are confident that the results obtained by our Moundsville laboratory were accurate."

Comment: Mr. Kupel of our NIOSH laboratory informs me that it is only our hypothesis that the samples were "improperly split." The splitting of the samples was done by Allied Chemical laboratory personnel before sending portions

of the samples to us. We, in fact, had no knowledge that the samples had been split until some time after results were sent to the company. Mr. Kupel further assures me that the analytical results obtained in our laboratory, on the February samples, were not "in error." The results were, in fact, accurate determinations of the samples presented to us by the company. In order to verify the accuracy of these tests, two analyses were run on each sample, with al sets showing highly consistent results. Furthermore, at the time these samples were run, in order to verify, further, the accuracy of these tests, known quantities of mercury in solution were analyzed, concurrently with the urine samples, to standardize the analytical procedure.

Mr. Callahan, while stating that his chemists "can run verification checks on their own work, when the observed results appear abnormal," does not state whether or not verification checks were run *at the time his February samples were run.*

Moreover, if we assume that the urine specimens were improperly split (by Allied Chemical staff) so that the HEW aliquots were excessively heavy in mercury content, how can one portion be accurate and the other portion be inaccurate? Is it not logical that, if the portions analyzed by HEW were excessively high in mercury content, then the other portions, analyzed by Allied Chemical, were excessively low? We suggest that the most probable conclusion to be drawn, as a result of the February analyses, is that more than 14 and less than 23 of the workers tested had excessive urinary mercury excretion. If, however, the results of the two laboratories are averaged, 24 of the 26 workers showed excessive urinary excretion.

2. Page (2) paragraph 2 "Crucially, these April results are consistent with and thus confirm the February results of our Moundsville laboratory. Moreover, Mr. Mazzocchi's testimony, that the earlier HEW results (of February 18) were later verified by further urinalyses, is factually wrong."

Comment: When a second set of urine samples were taken on April 6, and split into five aliquots for independent analyses, the following results were obtained.

Laboratory	Number in excess of hygienic standard 250 of μg/l	Percent in excess of hygienic limit
Allied Moundville	11 of 26	42
NIOSH HEW	13 of 26	50
Allied Syracuse	6 of 13	46
PPG	8 of 13	61
Environmental Health Lab	13 of 26	50

These results neither confirm or refute the analytical results of the February study of either HEW or Allied Chemical. They must be interpreted to indicate that exposures and excretion rates can vary from month to month (i.e., February to April) and therefore, should only be used to indicate the general order of magnitude of exposure and excretion rates. In our opinion, the significant point is that, at the time of the February and April studies, about 50% of the people in your plant still exhibited excessive absorption of mercury. Therefore, all efforts must continue to be directed toward expenditing the reduction of these excessive exposures.

Mr. Ferguson, we are glad to hear that you and Mr. Callahan both continue "to view the possibility of excessive exposure to mercury as a serious matter, and that you have initiated significant engineering and work rule improvements to this effect."

We share with you your concern that mercurialism is a serious occupational disease often with irreversible consequences. Fortunately, it can be eliminated as a work induced disease entity if proper engineering control methods are installed; if proper hygienic work habits are used by your work force; and if continuous environmental and biological monitoring procedures are carried out.

Sincerely yours,

MARCUS M. KEY, M.D.,
Director, Assistant Surgeon General.

Senator SPONG. Will Mr. Sheldon Samuels please come forward. Mr. Samuels, we are very pleased to save you before us this morning.

STATEMENT OF SHELDON W. SAMUELS, INDUSTRIAL UNION DEPARTMENT, AFL–CIO, WASHINGTON, D.C.

Mr. SAMUELS. I am very pleased to appear before you, Senator.

As director of occupational health, safety, and environmental affairs for the Industrial Union Department of the AFL–CIO, I feel especially privileged to appear before your committee to assist you and to represent the industrial union department, 60 unions and more than 6 million concerned members. I say "concerned" in the strictest sense. The men and women who work in our industries are not only consumers who share exposure to hazardous substances with other consumers. They are the producers of these substances. Their double exposure justifies double concern.

Our view of the two versions of S. 1478 under consideration today will be best understood by first stating a summary of our experience with the criteria used in this formulation.

We hear it said that the environmental crisis is in reality a social crisis. That statement is true, though not made more meaningful by repetition ad nauseum without identifying a concrete social problem which the proposed legislation can attack with some chance of success.

A key social problem relevant to dealing with hazardous substances is how to deal with the element of time in applying existing data. In March of this year we read in the journal of the American Industrial Hygiene Association that new and potentially toxic substances are introduced into industry every 20 minutes. In an issue of the journal of the American Public Health Association published the same month we read that our most highly trained medical personnel are unaware of relevant research and have difficulty understanding how research findings can be translated into program methods and procedures. This is reflected in Government programs.

The American Conference of Governmental Industrial Hygienists has published only about 400 threshold limit values when literally thousands need to be established. The Environmental Protection Agency has published ambient air quality standards for six contaminants. This is based on the work of 4 years by competent, hard-working scientists drawn from both the public and private sectors.

Obviously, something more needs to be done.

The industrial worker and the citizen, ideally, is protected against substances which may have an immediate and clinically obvious effect. But the concept of imminent danger now in use, at least in the working place, and usually under the public health provisions of the laws of most States, provides no protection against an increment of exposure during which the worker may as a result of this and previous exposures in the work place and the community, suffer permanent damage that may not appear until the end of his life.

Hopefully, you will change that concept.

The fact that exposure can occur in the work place or the community leads us to another key social problem: the consistency with which scientific information is applied. For example the accepted threshold limit value for carbon monoxide for 8 hours in the work place is 50 parts per million, with a maximum concentration permitted for a short time of 75 parts per million.

The Federal community air quality standard for this pollutant is a maximum 8-hour concentration of 9 parts per million, not to be exceeded more than once per year, at which time the limit is 35 parts per million.

The "TLV," as they say, for carbon monoxide enforced by the Secretary of Labor in the work place is precisely the level at which the Administrator of the Environmental Protection Agency may declare an emergency in a community and take action under the imminent danger provisions of the Clean Air Act.

Now a legitimate question is, Why are these social problems? The answer is that the problems are created by a lack of effective human organization, not essentially a lack of scientific information. The instruments of information dissemination and governmental application generally in use today were inadequate a generation ago. We have the technological capability for the immediate collection, transmission, and application of information. Potentially, we have the administrative capability of coordinating the development and use of this kind of system.

It is very important, however, that there be no confusion between what we are discussing and a glorified library system operated by another superagency.

For example, what is raw data for a scientific investigator, to be further analyzed before incorporation in a finished study, is grounds for action by a Government administrator. A community survey of levels of lead in people in Omaha, Nebr., funded by the Public Health Service included a sample of smeltermen. Based on data from that sample, an investigation was initiated by the United Steelworkers of America resulting in a citation issued by the Occupational Safety and Health Administration against the American Smelting & Refining Co.

Even though that information was not included in the consideration of the citation itself, the information served as a screening device for the uncovering of the hazard.

Nor are we suggesting simply more data studies as are already required by the Clean Air Act and the Occupational Safety and Health Act. Rather, we need the identification and application of critical data already known to us, adequate for emergency, interim use.

It is with these criteria that we have viewed the proposed legislation and wish to make some concrete remarks. But before doing so we would like to comment on the definition of "protect health and the environment." The original bill requires that EPA take into account "the public interest." But what is the "public interest?" We agree with Walter Lippmann, that the public interest is what men would choose if they saw clearly, thought rationally, acted disinterestedly and benevolently. This is an ideal to be achieved, not an achievable test. We prefer the guidelines in the amendment: a balancing of benefits and risks.

In regard to the heart of the legislative proposal, we recommend strongly reconsideration and new emphasis for the section on health and environmental data. In addition to the powers granted the Council on Environmental Quality, the Council should design a system of data retrieval reaching into ongoing research conducted or sponsored by any Government agency. The system should include a method of transmitting information on hazardous substances even before the studies

for which the data was collected are completed or published. Grants and contracts should be made with the condition that current information be made available to the Government on a continuing basis. The Government, in turn, should make this information available to all of its research and regulatory agencies, and easily available to researchers in the private sector.

On the basis of information gathered in this way the Administrator of EPA should be empowered to issue emergency orders in accordance with the procedures outlined in the amendment.

A second line of communication must also be provided. A scientist should be enabled to present a brief containing grounds for emergency action by the Administrator.

On receipt of such a brief, or on the recommendation of a staff scientist, the Administrator must be empowered to act as quickly as is necessary. He must be able to act under a definition of imminent danger consistent with protection against effects which may be expected to follow either immediately or after the lapse of a long period of time.

In the event of a serious, but not an imminent danger, the Administrator should be required to publish his proposed course of action and the substantiating brief or staff recommendation in the Federal Register. At least 30 days must be allowed for comment by the public. If as a result of a comment made in this way, the Administrator has reason to question the brief or recommendation, he should be required to publish the comment along with a discusion of the issue and a notice of a public hearing in which both sides of the scientific question can be fully explored. The Administrator's final decision should be based on that proceeding and published in the Federal Register with an explanation of his course of action.

Two issues in the proposed legislation which also must be reconsidered are the makeup and functions of the Toxic Substances Board and the relation of this act to other legislation.

On the issue of the Board we note that the Environmental Protection Agency already has numerous uncoordinated boards and committees that were established prior to its organization. The promise of a single environmental program envisioned in the creation of EPA suggests that a single board be created. More important, any board which does more than advise the Administrator and monitor his program is, in my opinion, an outdated and discredited means of distributing responsibility. Now matter how expert, boards with administrative powers have demonstrated an inability to respond rapidly in the face of the kind of critical situation we face.

We agree with the intent of the proposed amendment that even a board of scientists needs to be balanced. We would also like to recommend that all transactions, records, and meetings of this board be open to the public. On one hand we cannot expect citizens to be scientists. On the other hand, in a democracy the citizens must have access to information on the basis of which he will judge the experts and make his political decisions.

To be meaningful, the board should be required to meet often, to have an independent secretariat, and to have access to the work of the Government scientist.

On the issue of the relation of this act to related legislation, we agree that the Administrator ought not to duplicate nor supplant the functions of the Occupational Safety and Health Administration and other agencies. However, we feel very strongly that it is not enough to simply pass on information gathered under this act to other agencies. Nor is simple consultation and coordination sufficient. The fact is that the Administrator, because of his unusual position in the environmental field, should have the responsibility to gather information on the nature and impact of toxic substances when they are created, produced, distributed, and disposed. He must transmit this data to other agencies whose functions he does not duplicate along with guidelines recommended by his staff to insure that the standards and regulations of all agencies dealing with toxic substances are consistent with the scientific facts. These recommendations should, of course, be published in the Federal Register.

Finally, new emphasis and a reconsideration must be given to the research provisions of the proposal. The Administrator should be required to continually monitor toxic substances in conjunction with other Federal agencies. But in addition, EPA should have the responsibility for the operation of a central repository for the information gathered, something which does not exist and is rather critical if we are to do our job.

Thank you.

Senator SPONG. Thank you very much, Mr. Samuels.

In your statement, you point out that the administrative regulation of environmental health hazards often is not timely. You also make a case for increased data availability on scientific matters. Is the reason that administrators sometimes act slowly merely a matter of lack of communication on available data, or are other forces at work as well?

Mr. SAMUELS. I am sure the other forces are at work as well, but I think that it is criminal not to act simply because information is not available.

Senator SPONG. You discuss the difference in carbon monoxide standards for workers and for the general public. Has any effort been made to persuade HEW to impose more stringent standards for workers?

Mr. SAMUELS. We are asking the Secretary of Health, Education, and Welfare to speed up the process under the Occupation and Safety Act under which he would publish criteria and recommendations for standards to the Secretary of Labor. I am afraid that even this process is rather prolonged, and we are in the midst of developing another procedure which we will recommend to the Secretary of Labor and the Secretary of Health, Education, and Welfare.

Senator SPONG. In your statement you suggest the establishment in EPA of a single advisory board to advise the Administrator on environmental programs rather than a series of boards for each statute EPA administers. Do you think that one single board would be competent to advise EPA on all matters before it? EPA has rather diverse responsibility which runs from radiological matters to pesticides' application.

Mr. SAMUELS. I realize that there is some benefit in specialization. I think this has to be balanced by the fact that too often these pro-

grams and problems are kept in pigeon holes with little communication. The advisory committees, precisely the Water Advisory Board and the Air Pollution Control Board, do not meet very often, are not solely made up of experts. In fact, most of the members of these boards are not expert in any area of the environment in a very broad sense.

Really what they do is advise and monitor in a very, very general sense, and they do not really get into the meat of the scientific issues. It is my understanding, for example, that the Air Quality Board has only met a couple of times in the last 12 months. We are recommending that there be a large board with diverse membership from various fields with representation from many of the same interests that already exist in EPA; that they be combined with a secretariat that can manage the business of a real working committee that meets often, has information available to it, and is able to provide the advice and monitoring functions.

Senator SPONG. In your testimony you state that raw or interim scientific data might be used as the basis for regulatory decisions to protect health or the environment. If we were to do this, wouldn't we receive a great deal of criticism from the scientific community that we were acting prematurely?

This seems inconsistent with the scientific notion that conclusions are made only after all the evidence is in rather than only a part of it.

Mr. SAMUELS. There is this danger, and this recommendation, if implemented, needs to be handled very carefully. Let's think about the kind of raw data that we have in mind:

If a scientist, as part of his study, causes to have done several hundred blood samples for the purpose of a much larger study, we are not asking him to draw any conclusions about the cumulative data that he gets from these blood samples, but if, in the process of doing this blood analysis he finds that there are levels of toxic substances which are endangering the health of the people whose blood he has drawn, then, we feel that he has a moral obligation to do something at that time, and as quickly as possible, to transmit the information first, of course, to the person, and as an aggregate to some appropriate agency for action.

Now, that agency will be acting, if, for example, it is lead, only on the basis of a situation that would be similar if that agency were to go into a plant, let's say, and do some biological monitoring, that is, to do some blood sampling as part of its survey, and it doesn't really involve the heart of the experiment or the study that the scientist is involved in.

Senator SPONG. Thank you.

Senator Hatfield?

Senator HATFIELD. Mr. Samuels, I would only comment on what you have stated relating to the problem of retrieving data and the proper dissemination of that data. I think we can go back and cite many examples of that starting with areas that possibly were injurious a number of years ago, on through to the mercury content of certain fishery resources today.

Would you like to elaborate as to what you believe should be the type of approach to be taken to correct this problem, or at least minimize the problem of retrieval and dissemination beyond what you have

stated in that particular paragraph? I think this is an issue that transcends this bill and includes many other areas in governmental action and governmental policy.

Mr. SAMUELS. For one thing as I noted in response to Senator Spong's question, there is often the use of that which does not mean that a scientific conclusion is being drawn prematurely that can be made available. Some of this information is in fact already available in progress reports which government agents require of investigators who receive contracts and grants from them. There needs to be some means of culling these progress reports.

Another problem that exists is after a scientist completes his study and submits it to a journal for publication, there is often the lapse of a year or more. As a matter of fact, if you take into account the time it takes him to tailor his work to the particular editorial needs of a journal, finding a place to publish the material, which is becoming more and more of a problem, it may be that data which was actually gathered in 1960 was published in 1965. Five years lapse of time is not at all unusual.

For example, a study of the effects of sulfur oxides and particulate matter in Buffalo, N.Y., completed in 1963, is still in the process of being published piece-by-piece. This is not to criticize the competent scientist who conducted the study. As a matter of fact, the Environmental Protection Agency's standard on particulate matter depends on the parameters that were created by that study completed in 1963, and finally applied in the field of public health and environmental protection only last year.

But I think that we ought to devise a system whereby summaries of critical information are made available as soon as the scientist completes his study and in some sort of an abstract form sent to a central place where the information can then be disseminated through all of the new and really very efficient technological methods that we have.

Senator HATFIELD. Mr. Samuels, at this point this would involve only that which is to inform, alert, educate the public, rather than which might be utilized to restrict or prevent distribution of certain products; would this be true?

Mr. SAMUELS. I think that this information can be used at times for enforcement and regulation as well as for education.

Seantor HATFIELD. Banning and restricting?

Mr. SAMUELS. Yes.

Senator HATFIELD. You wouldn't delineate between that which would be to inform the public, alert the public, and that which might be utilized to restrict and ban the actual distribution?

Mr. SAMUELS. I think a scientist who submits a brief and asks for some emergency action to be taken on the basis of some data he has collected in the process of a larger experiment has a tremendous burden to show that his data is adequate for some kind of emergency action, and that burden would certainly be much less for purely educational and research purposes. But if in the process of a study he finds something which needs to be acted on immediately, he ought not be asked either by his profession or by the intent of the legislation before you to hold that information until he completes his study and publishes it.

Senator HATFIELD. You aren't implying that any one scientist findings would be sufficient bases to ban or totally restrict distribution?

Mr. SAMUELS. Certainly not.

Senator HATFIELD. Because we cannot assume that all scientists will come to the same conclusion or will automatically agree.

Mr. SAMUELS. I agree with that wholeheartedly, and that is why I suggested a scientist who prepares such a brief, one should know that it will be published and subject to the scrutiny of other scientists, and that if another scientist disagrees with that brief, that the brief will be the subject of a public hearing in which he has to defend his thesis.

Senator HATFIELD. When you talk about defining a social issue in the public interest, I find this very challenging, because I think you put your finger on a very sensitive point. That is just how far must Government go to assume the father role, the all-wise regulator, all-powerful source of restriction?

I find this a very interesting issue, because I don't think many people have addressed themselves to it. I find that many people will come before this or other committees with all sorts of great indignation about a certain product that might be called injurious to public health if they ate 10 gallons a day or such quantity or something; and yet, they will totally endanger their body by smoking, where we have much more conclusive data as to the relationship of heart disease and lung cancer and so forth. Yet, in one, there is creating an issue—a social issue or a public interest action—and the other, where public action already has been taken to identify and alert the public, has been totally ignored by many of those same people.

Here we get into this great problem of identifying what is the problem.

Mr. SAMUELS. I would agree with you, Senator. I would like to add the comment that there is a distinction, however; it is a moral distinction between suicide and homicide, as to whether someone develops emphysema because he smokes or because he develops emphysema where he works in a smokey factory.

Senator HATFIELD. Where he has a choice?

Mr. SAMUELS. Yes.

Senator HATFIELD. It was like where I spoke the other night. Some of the audience were living on brown rice and roasted soybeans, but they thought smoking grass was just great. They saw no connection at all. They were convinced there was a great national conspiracy by the food industry to poison all the people of this country by removing all the nutrients of the food.

Senator SPONG. Thank you, Mr. Samuels.

As a representative of the State of Virginia and a nonsmoker, I am not going to comment on Senator Hatfield's observations. We are very pleased to have you with us this morning.

Senator HATFIELD. Mr. Chairman, there was nothing personal.

Senator SPONG. I understand.

The next session of this committee will be on October 15 in room 1114 at 10 a.m.

The hearings are recessed.

(Whereupon at 11:10 a.m., October 4, 1971, the hearing was recessed, to reconvene at 10 a.m., October 15, 1971.)

THE TOXIC SUBSTANCES CONTROL ACT OF 1971 AND AMENDMENT

FRIDAY, NOVEMBER 5, 1971

U.S. SENATE,
COMMITTEE ON COMMERCE,
SUBCOMMITTEE ON THE ENVIRONMENT,
Washington, D.C.

The subcommittee met, pursuant to recess, at 10 a.m. in room 1114, New Senate Office Building, Hon. William B. Spong, Jr., presiding.

Present: Senator Spong.

Senator SPONG. The hearing will come to order.

This morning the Subcommittee on the Environment resumes hearings on S. 1478, the administration's Toxic Substances Control Act and the amendment 338 to that bill which I introduced [independently discussed] last July, including the subcommittee's examination of the detergent problem, this will be the eighth and final day of hearings into the desirability of this legislation.

In addition to witnesses testifying on detergents, we have heard from the administration, the scientific community, and environmental and consumer groups on the subject of toxic substances generally.

With the testimony this morning of the chemical industry, the subcommittee should have an ample record for consideration.

Before proceeding, let me thank this morning's witnesses for the timely submission of their written testimony. There is a legal requirement that written statements be submitted 24 hours in advance of a hearing. This requirement was met by our witnesses for today.

Our first witness is Dr. C. Boyd Shaffer, representing the Manufacturing Chemists Association.

STATEMENT OF DR. C. BOYD SHAFFER, MANUFACTURING CHEMISTS ASSOCIATION; ACCOMPANIED BY DR. WILLIAM SUTTON; TAYLOR HANAVAN; DR. MYRON V. ANTHONY; AND HARRY BUCHANAN

Senator SPONG. I see you have company, Dr. Shaffer. If you would be kind enough to identify each of these gentlemen for the record, I would very much appreciate it.

Dr. SHAFFER. Yes, sir.

Mr. Chairman, my name is C. Boyd Shaffer. I appear as a witness on behalf of the Manufacturing Chemists Association (MCA), a nonprofit trade association with 166 corporate members in the United States, representing more than 90 percent of the production capacity of basic industrial chemicals within this country.

I hold a doctoral degree in mammalian physiology, and I have devoted the 30 years of my professional career to date to the experimen-

tal investigation of the toxicity of synthetic organic chemicals while in the employ, successively, of two major chemical manufacturers.

During this time I have worked closely under Federal product registration laws commencing with the Insecticide, Fungicide, and Rodenticide Act of 1947, and continuing with the Pesticide Chemicals Amendment of 1954, the Food Additives Amendment of 1958, and the Color Additives Amendment of 1960.

To my extreme right is Dr. William L. Sutton, a physician with a long and productive career in industrial medicine. Next to Dr. Sutton is Mr. Taylor Hanavan, an attorney from another of our member companies, who has broad knowledge of the statutes referred to above. On my immediate left is Dr. Myron V. Anthony, a corporate vice president with responsibilities in the field of health and environmental protection. And on my extreme left is Mr. Harry Buchanan, the president of a long-established medium-sized chemical manufacturing concern. My colleagues are with me to assist in answering any questions you may have.

The President has recommended legislation (S. 1478) to establish new regulatory authorities for the control of chemicals. The stated purpose of this legislation is protection of health and the environment by authorizing the Administrator of the Environmental Protection Agency (EPA) to restrict or prohibit use or distribution of any chemical substance to the extent necessary to achieve this objective.

In the case of chemical substances developed after enactment of the law, the Administrator is empowered to establish, for various classes and uses, standards for test protocols and for the results to be achieved therefrom.

Since the members of MCA are the companies that would be most directly affected by such a law, we have given intensive and thoughtful study to the various legislative proposals as they have appeared and have attempted to focus our individual corporate viewpoints, through our technical committee system, on a constructive position.

Mr. Chairman, in order to keep the need for new legislation in perspective, we believe that it is important to recognize from the outset that the chemical industry is presently subject to broad and sometimes overlapping Federal legislation in the field of hazardous chemicals.

These laws regulate emissions, effluents, and solid wastes; occupational exposures; and large product areas such as pesticides, household products, food additives, drugs, and cosmetics. We know that this committee is familiar with these statutes, but we feel that a representative list should be enumerated for the sake of emphasis.

Premarket testing is now required for drugs, food additives, color additives, and pesticide chemicals under the Food, Drug, and Cosmetic Act, and the use of these substances must be authorized by regulation. Registration of pesticides, with attendant testing for safety and efficacy, is required by the Insecticide, Fungicide, and Rodenticide Act.

Further, authority to control chemicals is granted to Federal agencies under the Clean Air Act, the Water Pollution Control Act, the Hazardous Substances Act, the Occupational Safety and Health Act, the Meat Inspection Act, the Poultry Products Inspection Act, the Comprehensive Drug Abuse Prevention and Control Act, and the various statutes administered by the Department of Transportation.

We respectfully suggest to this committee that recognition of the comprehensive scope of existing regulation should underlie all of its deliberations on the content of a new law.

In view of the reguluatory statutes already in force, we believe that there is no need for sweeping new legislation. The key word in that conclusion is "sweeping."

We do recognize that existing authorities, despite the breadth of their coverage, may not give the Federal Government adequate control over use of chemical substances in all instances.

Therefore, we further conclude that it would be desirable for the Administrator of EPA to have specific authority to deal with existing chemical substances that reasonably could be expected to develop into a hazard to health or the environment, and to require, on a selective basis, premarket testing of new chemical substances from the point of view of restricting or prohibiting the use of those found to be harmful.

We applaud the policy enunciated in section 201 of both S. 1478 and amendment No. 338 that place primary emphasis on protection of health and the environment.

However, we urge that no one lose sight of the caveat that "* * * authority over chemicals be exercised in such a manner as not to unduly impede technological innovation * * *"

There should be no mistaking one point, Mr. Chairman: Any law of this nature is bound to impede innovation to some degree. In the new product area, compliance with a law of even selective scope will be expensive, time-consuming and detrimental to the introduction of new chemical products.

The problem that faces all of us in molding this legislation is that of giving our citizens the necessary protection without depriving them of the benefits of an advancing technology or having them bear the economic cost of elaborate investigations of nonexistent hazards.

The costs of compliance, in terms of both time and money, may be illustrated by a brief review of the test protocols now employed for chronic toxicity, including evaluation of carcinogenicity.

The standard test involves feeding of the substances over the lifespan of at least one species of experimental animal. Obviously, the small laboratory rodents are the only practicable species. The mean lifespan of a rat is considered to be 2 years and that of a mouse 18 months.

A 2-year feeding study is always preceded by approximately a year of acute and short-term tests in preparation for the longer study.

Upon completion of the feeding period, extensive pathologic evaluations must be conducted. It is at least 6 months, and sometimes as much as a year after completion of the actual feeding before the final report is available.

Moreover, since it is considered desirable to know something about species variability, the lifespan test is usually required on two rodent species. In addition, there are multigeneration reproduction studies as well as test for teratogenesis, and mutagenesis.

A manufacturer who is required to perform the range of animal tests that we have enumerated faces a delay of at least 3 or 4 years, and a cost, conservatively estimated, of about $200,000.

Protocols to determine effects of a substance on wildlife and the environment are not well defined at present, and this uncertainty makes any attempt to predict time and costs for these tests highly conjectural.

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We wish to emphasize in all sincerity that no one objects to doing any of these things if there is a valid reason for doing them, and if the results would appear to be susceptible to meaningful interpretation.

The danger is, however, that all conceivable tests become frozen into a stereotyped list that is applied to all candidate chemicals regardless of their inherent properties, the nature and extent of their use, and the probable level of human exposure.

The burden created by the indiscriminate imposition of excessive testing requirements would effectively eliminate the innovative role of the smaller chemical companies, who in the past have made so many fruitful contributions to the development of new chemical products.

As emphasized in President Nixon's August 1971 message to the Congress, we should:

> * * * approach the challenge of the environment with a strong sense of realism * * *. We must develop a realistic sense of what it will cost to achieve our national environmental goals and choose a specific level of goal with an understanding of its costs and benefits.

S. 1478 provides that the Administrator shall prescribe standards for test protocols for various classes and uses of chemical substances. Only those new chemical substances falling within such classes and uses would be subject to mandatory testing.

This approach represents a reasonable effort to make progress in the toxicological and environmental evaluation of new chemicals on a selective basis. It enables the Administrator to assure that adequate testing will be performed on those substances which experience to date indicates may present a hazard.

This is not to say that substances not covered by the Administrator's standards will not be tested at all. Voluntary testing by manufacturers has been substantial for many years, and may be expected to continue its present rapid rate of growth.

You will note that the administration bill—S. 1478—does not require mandatory premarket testing of all new chemical substances, or registration or certification procedures. With this we fully concur and we oppose such requirements as proposed in amendment No. 338.

The essential defects in the concept of mandatory testing of all new chemical substances are that it (1) assumes that scientific and technical resources for testing are unlimited, and (2) eliminates the exercise of scientific judgment in the evaluation of hazard.

A committee of the National Academy of Sciences—National Research Council has dealt with this question in the following statement:

> It is neither practicable nor necessary to undertake experimental toxicological studies of every chemical to which man is exposed; to do so would be to assign equal importance to problems of unequal risk. This would deny the value of experience in assessing probable risk. All environmental exposures must be subjected to scientific evaluation but not all exposures require experimental toxicological study.

Mr. Ruckelshaus, Administrator of EPA, has noted in his environmental impact statement on S. 1478 that:

> . . . A number of new compounds are minor variants of existing compounds known to be safe, and a cursory review of such new compounds often would be sufficient to indicate their safety.

The problems associated with a "registration" or "certification" system for all new chemical substances were dealt with by the Administrator in his environmental impact statement and by Chairman Train of the President's Council on Environmental Quality in his testimony before this committee.

Mr. Ruckelshaus acknowledged that a registration system was considered extensively and rejected as being both unnecessary and unworkable. He said:

> It was considered unworkable at least at the present time, because based on the experience with pesticide and drug registration systems, it is likely that a new registration system dealing with a large number of very heterogeneous substances would deteriorate into a bureaucratic quagmire.

This is a viewpoint with which those of us who clear new products under existing registration laws have a very deep sympathy.

Mr. Train reported the concern of the council that:

> Requirements for preclearance certification, mandatory reporting of tests, taxation, and reimbursement for testing for the many chemicals covered under Amendment 338, could involve stifling and cumbersome administrative procedures and dilute the ability of the Administrator to effectively and efficiently regulate the most significant hazardous materials.

In the colloquy with Senator Spong that followed his direct testimony, Mr. Train explored further the impracticality of a registration system.

Mr. Chairman, we believe that the imposition of a compulsory registration system for new chemicals would be a major disaster for the chemical industry and the future of chemical technology.

The actual testing that we can envision under the prescribed protocols is likely to run in the order of 1 to 5 years. To add several more years to this process for a clearance procedure is asking more than we think the technology can bear.

The EPA does not want registration. The Agency realizes that it does not possess the administrative manpower or scientific resources to cope with a registration process.

The problem is not simply one of an inability to find competent administrators, as was suggested in testimony before this committee, but it includes the very complex issues of developing the basic scientific information that we must have to formulate meaningful protocols from which to predict the possible effects of substances on health and the environment.

Moreover, and we must always return to this yardstick by which we gauge our actions, registration is unnecessary for adequate protection of the public.

In fact, as Mr. Train and Mr. Ruckelshaus have indicated, registration would actually compromise the ability of EPA to do an effective job of regulating hazardous chemical substances.

Of the various legislative proposals now pending, the Toxic Substances Control Act of 1971 (S. 1478) in our opinion, offers the most suitable regulatory framework.

We believe, however, that this bill needs some modification in language to make it more workable from the standpoint of both Government and industry, while maintaining the objective of protection of health and the environment.

These are detailed in an appendix to this statement, in which the affected sections of the bill are shown with their indicated changes. The reasons for most of these are self-evident, so that I shall not occupy the committee's time by describing them.

However, we deem a few of them to be of such importance that I ask the committee's indulgence to allow me to comment specifically upon them in this statement. The section references that follow apply to S. 1478:

1. Section 203 provides for no intermediate status for a new chemical substance between meeting the test requirements of section 205 and total banning under section 213(c). It would seem reasonable to incorporate in section 203 a provision under which a chemical that fails to pass the section 205 tests may still be approved for some limited use. The proposed language is intended to accomplish this. If this change is adopted, section 213 will have to be amended accordingly.

2. Of concern to us is the adequacy of hearing rights under section 203 relating to promulgation of regulations proposing use restrictions or prohibition on chemical substances, and under section 205 for standards for test protocols. It is most important that any party adversely affected have the right to request a hearing and, in such hearing, the right to put into evidence testimony of his own experts and have the opportunity to cross-examine the witnesses of the Government or other parties to the hearing.

It is not clear in S. 1478 that this type of hearing will be available. Therefore, we propose to add to the hearing provisions of section 203 (b)(2) an express statement to the effect that such hearings shall be conducted in accordance with the hearing requirements of 5 U.S.C., sections 554–557, Administrative Procedures.

In addition, section 205 relating to regulatory standards for test protocols should be modified to provide for hearing and judicial review rights comparable to those afforded regulatory proposals under our proposed amendment to section 203(b). Section 203(c) should be to deny a hearing in connection with the modification or rescission of regulations.

3. Under section 204(a) we believe that the definition of an imminent hazard should be changed to read as follows:

> An imminent hazard shall be considered to exist when the evidence is sufficient to show that a use or distribution of a chemical substance creates a significant hazard to human health or the environment which, if the use or distribution continued during the time required for an administrative hearing or other formal proceeding, would likely result in substantial adverse effects on health or the environment.

Section 204 authorizes the Administrator to seek injunctive relief for temporary restraining order in event of an "imminent hazard." A temporary restraining order is a drastic remedy and should be invoked only in cases of urgent public necessity.

Therefore, our proposed change is designed to limit the Administrator's right to immediate injunctive relief to those cases where the hazard is significant, and where it can be shown that substantial adverse effects would be likely.

(4) A matter of primary concern relates to the costs and delays in product development inherent in section 205, which authorizes the

Administrator to establish standards for tests protocols and the results to be achieved.

The danger here is the imposition of unreasonable testing requirements or a steady escalation of such requirements that is prompted more by the agency's desire to shield itself from all possible criticism than by a need to protect the public against putative hazards. Accordingly, we believe that the Administrator should have some statutory guidelines in standards setting. We propose that the law should explicitly direct him to consider all relevant factors including: The normal circumstances of use of classes of chemical substances, the degree to which the release of such substances to the environment is controlled, the magnitude of the exposure of humans and the environment to the substance, the extent to which the prescribed tests are reasonably predictive of the potential adverse effects of a substance on human health or the environment, and the manner in which available data on the safety of classes of chemical substances may be used in reducing the testing requirements.

(5) The reporting requirements in section 206(a) should be limited to those substances produced and distributed in commercial quantities by the manufacturer. A research laboratory may synthesize a large number of new chemical compounds that never develop beyond the laboratory stage. These would be of no worthwhile concern to the Administrator in accomplishing the objectives of this law.

(6) Section 207(a) should be amended to provide for the exclusion of chemical substances that are intended for use only as (a) Intermediates for chemical conversion in the manufacture of other chemical substances, (b) laboratory reagents, or (c) samples for research or testing. There would appear to be no justification for imposing upon the intermediate chemicals in a multistep synthesis any requirements for product safety testing. These remain under the control of the manufacturer, and are subject to the full range of industrial waste control regulations. Laboratory and research chemicals are very small-volume products; and if extensive testing were required, the manufacturer could not continue to provide the broad variety of such chemicals that is so urgently needed for research in the chemical, biological, and medical sciences.

(7) Section 208(a) provides for the establishment within EPA of a Toxic Substances Board to perform certain advisory functions for the Administrator. We consider it desirable that a limitation on the term of service of members of the Board should be specified. This would prevent the institutionalization of bias of any sort. We suggest that members of the Board should serve one term of 4 years, except that one-half of the members appointed after enactment of the law should be designated to serve one term of 2 years. Thereafter, one-half of the members of the Board would be appointed every 2 years. Members of the Board should not be reappointed for consecutive terms. We support the recommendation of the Society of Toxicology that the Board should "consist of a reasonable number of scientifically qualified persons, the majority of whom shall be recognized toxicologists, experienced in evaluating health hazards."

(8) Section 210(b) refers to seizures of property in connection with warrants required for entries and administrative inspections. We believe that it should be made explicitly clear that the "property" in

question consists only of chemical substances or products containing same manufactured in violation of regulations issued under this law.

(9) Section 218 deals with the relationship between the proposed legislation and State regulations. In our opinion, the preemption of Federal regulations promulgated pursuant to sections 203 and 205 should be complete. Each State and local authority has a right to be heard in the proceedings establishing such regulations and to challenge in the courts any regulation it feels would adversely affect it. If it is unable to make a convincing case before either the Administrator or the courts, there would appear to be little reason to subject interstate trade to the interference that would result from State or local action to impose a "total ban on such use or uses."

As we indicated earlier, we are offering an additional list of proposed language changed in S. 1478 of a more technical nature, not involving significant policy changes, and have appended to this statement an itemization of these changes together with the reasons therefor.

In the aggregate, they are important to the drafting of a sound, effective piece of legislation, and we ask that they be included in the record of these hearings. Should your staff wish to discuss them or any other of the points we have made today, we will hold ourselves ready to accommodate them.

Mr. Chairman, we thank you for the opportunity of presenting these views, and assure you that they have been offered in the sincere hope that they will be helpful as you seek to formulate a national policy that will maximize the net benefits to our society from a vigorous and creative chemical technology.

Senator SPONG. Thank you very much, Dr. Shaffer, for your statement.

You criticize Amendment 338 because it requires testing of all new chemical substances. Isn't the definition of chemical substances, which exempts those chemicals of no environmental significance, responsive to your concern about our covering the waterfront? What else would you exempt?

Dr. SHAFFER. We believe, Mr. Chairman, that that language would offer us no relief whatsoever in the practical administration of this law. It places upon the administrator the responsibility of affirmatively making that decision, and he is going to be exceedingly reluctant to do that.

In our opinion it is somewhat parallel to the situation we have, for example, under the packaging materials section of the food additive amendment. There, if we endeavor to get an opinion from the Commissioner of Food and Drugs that a substance is not a food additive, we may have evidence to support this viewpoint, but it is very difficult, if not impossible, to get such an opinion from the agency.

The attitude generally is that if there is a sufficient reason to raise the question, there is a sufficient reason to believe it may be a food additive.

Senator SPONG. I can appreciate your concern about the delay. You mention that in your statement.

Let me ask you if you have any suggestions for a better definition.

Dr. SHAFFER. Of a new chemical substance?

Senator SPONG. Yes.

Dr. SHAFFER. No, sir. We have no suggestions for a better definition.

Senator SPONG. You also object to the requirement the amendment for premarket clearance as opposed to the Administration's premarket testing. By calling for this requirement I have attempted to be responsive to the concerns which led to premarket clearance requirements in pesticide, drug, and food additive laws. Do you see a distinction between those chemicals and the chemicals covered by this bill which should be reflected in a different regulatory system?

Dr. SHAFFER. Yes, I do. Previous witnesses before this committee, for example Mr. Train and Mr. Fri, have pointed out that we are dealing with a distinctly different set of circumstances.

This booklet on toxic substances that was issued by the Council on Environmental Quality emphasized the fact that we are embarking here on an exceedingly comprehensive and systematic structure of regulation that we have not attempted before. We are attempting to control the use and distribution of chemical substances commencing from their extraction from natural sources, from their production in the case of the synthetic chemicals, extending through consumer use, distribution, and disposal.

The exact dimensions of this problem have not been explored. In the areas you refer to, sir, we are dealing with a rather well-defined set of compounds for specific uses, where the potentials for exposure of humans and the environment is well defined.

Senator SPONG. We have already discussed delay, as a possible risk of this procedure. Acknowledging that some delay may result, I have balanced this against the need for certainty as to a product's safety before it is produced and have come down on the side of a clearance requirement. To minimize the delay, what would you think of a provisional certification subject to recall?

Dr. SHAFFER. We have not studied or discussed that aspect, Mr. Chairman, so I cannot say I am prepared with an opinion on it. But it is our position that under any arrangements where we have to wait for the agency to go through the mechanims of the paperwork in issuing the certification and studying and reviewing our data and, incidentally, asking for additional data if they deem what has been presented is insufficient, that this does lead to considerable delay.

Senator SPONG. Would you and your associates like to give us further comment after you have had time to weigh this matter of provisional certification? We will hold the record open for that and would be pleased to hear from you.

Dr. SHAFFER. We shall do that, Mr. Chairman, submit this at a later date.

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

MANUFACTURING CHEMISTS ASSOCIATION,
Washington, D.C., January 5, 1972.

Hon. WILLIAM B. SPONG, Jr.,
Acting Chairman, Subcommittee on the Environment, Committee on Commerce, New Senate Office Building, Washington, D.C.

DEAR SENATOR SPONG: In your colloquy with our witnesses last November 5, you asked for more detailed views on two points relating to the registration requirements of Amendment No. 338. These were: (1) the adequacy and usefulness of the definition of "chemical substance," as stated in section 202 of that Amendment, as an alternative to the specific exclusions we proposed, and (2) the potential value of a "provisional certification subject to recall" as a means

of shortening the administrative delays incident to full certification. Our views and our justification for them are as follows.

Section 202(2) of Amendment 338 defines a chemical substance as "any organic or inorganic substance of a particular molecular identity, or any uncombined chemical radical or element, except such substances which are of no public health or environment significance as determined by the Administrator by regulations." The standard these proposed for exceptions, i.e., no public health or environmental significance, is so stringent that we can conceive of no substance meeting it. Even pure water is of major environmental significance, and the proposed definition places no bounds on the circumstances under which a showing of "no significance" would be adequate. Secondly, even with a more restricted and carefully defined specification of the proper bases for exception, it would require initiative and affirmative action on the part of the Administrator to bring this provision into force. No manufacturer could base any new product development and marketing strategy upon so uncertain an event. We would not visualize any effective use of this exception, particularly for new chemical substances, and regard the proposed definition as an unsatisfactory and ineffective substitute for the specific exemption of the classes and categories proposed in our testimony to be excluded from the provisions of the Act.

With respect to "provisional certification subject to recall" as a means of shortening the time required for a new chemical substance to reach the marketplace, we must reiterate our opposition to the certification process itself. This is not opposition to premarket testing; it relates only to the matter of who is to make the initial judgment as to the results of the tests. Under S. 1478, it would (and we believe it should) be the responsibility of the manufacturer, whereas Amendment No. 338 would place this in the hands of the Administrator. In either case, the primary evaluation would be subject to challenge in administrative or judicial hearings.

There is no reason why premarketing test regulations that would be promulgated under such a law could not be sufficiently clear and explicit that a manufacturer could make this decision on his own responsibility, and thereby avoid the delay of administrative review that realistically must be measured in years. Therefore, it is difficult for us to see how the public interest is placed in jeopardy by leaving this decision with the manufacturer. He has at least as much expertise available to him as does the Administrator, and in any case, there is nothing to preclude seeking an informal opinion from the Administrator.

The seriously detrimental consequences of a registration system were dealt with by the Administrator in his Environmental Impact Statement and by Mr. Train, representing the CEQ, and Mr. Fri, representing the EPA, in their testimony. We supported the views of these witnesses in our hearing statement. The deficiencies they pointed up are real, and one need only look at the administration of present registration laws to appreciate the serious consequences that would result from imposing certification on a regulatory system of the scale contemplated in the proposed legislation.

Would these difficulties be ameliorated by a "provisional certification subject to recall"? No guidelines have been offered as to how such a provisional certification might operate. Since it is our position, however, that certification offers no real added protection of the public interest, a less stringent form of certification would be equally without merit. A provisional certification procedure may be expected to generate a microcosm of all the problems of full certification. The vulnerability of the resulting provisional certification to preemptory recall would deprive it of any significant value to the manufacturer.

Sincerely,

W. J. DRIVER.

Senator SPONG. For an imminent hazard justifying immediate action by the Administrator, you argue that substantial adverse effects must be likely. What if substantial harm could be shown to be possible but not likely? Should the public be forced to run the risk of such harm while lengthy administrative procedures go on? What if the hazard is likely but not substantial? Are you again saying that the public must sit there and take it?

Dr. SHAFFER. I think, Mr. Chairman, that language deals with rather fine distinctions between degrees of hazard. I do not know that any one of us can precisely draw the line where prompt action is justified and where it is not. The only point that we wish to emphasize is that there should be a prospect of substantial injury or a substantial likelihood.

We have not attempted to suggest specific language for incorporation into the bill but, rather, to develop the concept. We would not wish to see such action taken lightly since a temporary restraining order is a very severe measure.

May I ask if Mr. Hanavan would like to comment on that?

Senator SPONG. Yes. And, Doctor, I would be very pleased to hear from any one of those with you in response to any question that I have asked. We are delighted to hear from any of them.

Dr. SHAFFER. Thank you.

Mr. HANAVAN. As Dr. Shaffer has stated, it is very hard to draw a line in language of this type. Our objective was similar to that in the Federal Environmental Pesticide Control Act of 1971 presently before the House, trying to distinguish between what is a claim of minor irritation and substantial evidence that there is some serious harm being caused by the presence of a chemical in the environment. A line like this has to be developed as a result of experience in implementing the legislation by the administrative agency.

Senator SPONG. We have experienced much trouble with the delay caused by lengthy formal rulemaking procedures and this committee has rather consistently been opting for informal rulemaking in the case of safety standards.

Can you elaborate on why informal rulemaking, with a right to judicial review, will not give you the protection you seek?

Dr. SHAFFER. The reason we ask for what we do is that these regulations in our opinion have a much more severe and far-reaching impact than the usual run-of-the-mill advisory and interpretive regulations.

We are issuing regulations here that not merely prescribe how a test should be done or how many copies of a petition should be submitted or the size and color of the paper, but we are issuing regulations that may mean a difference of life and death of a manufacturer's product line, and we believe he should not learn of these abruptly by reading of them in the Federal Register one morning but he ought to have a right for an input into the decisionmaking process. We believe our suggestions would implement such a right.

Senator SPONG. You are aware that under the informal rulemaking procedure you can comment?

Dr. SHAFFER. Yes——

Senator SPONG. And would have the right of judicial review?

Dr. SHAFFER. We realize we have that opportunity, Mr. Chairman, but we also want the right of cross-examination and we want to have the right to know the evidence upon which the agency bases its determination.

Mr. Hanavan, would you like to comment further on that?

Mr. HANAVAN. As Dr. Shaffer pointed out, either a proposal to prohibit or restrict uses or a proposal to establish test protocols and the results to be achieved with respect to particular classes of products

or uses of products, have a very serious and direct impact on the marketers of these products. Therefore we feel that because of the seriousness of impact that we should be entitled to at least the quasi-adjudicative hearing procedures which we are permitted in the Administrative Procedure Act, where you are dealing with a question of scientific fact and developing scientific standards to be applied to particular products and regulatory actions which may end up in banning or restricting the use of a product or class of products. Therefore, we feel it important to be able to cross-examine the witnesses who are testifying in a proceeding to determine—as best we can through the cross-examination procedure—the accuracy of the information which they are providing, their sources of information, and the validity of the information as it applies to the products that are the subject of the particular hearing.

Senator SPONG. The statement of the witness who will follow you contains an observation that this bill should be restricted in its application to consumer products. You do not make the same recommendation. The basis of SOCMA's argument is that there is sufficient regulatory authority already for all but consumer products. Do you disagree?

Dr. SHAFFER. We do not basically disagree with that position, Mr. Chairman.

Senator SPONG. In your statement you cite the high cost of performing tests that might be required under this bill. In order to gain some insight into the manner in which you currently recover these costs, are the products you produce patentable, and does this allow you to recover testing costs from others who would produce those same products? If not, would the cost-sharing provisions of amendment 338 help to spread the cost of testing among the other manufacturers who would benefit from that testing?

Dr. SHAFFER. We are not opposed in principle to the concept of reimbursement for the cost of testing, but we have not seen any proposal for accomplishing this that we approve of.

In the case of substances on which we currently expend this magnitude of investment, there is generally some type of patent protection. A good deal of this work is done in the pesticide and food additive field where there is a good patent protection. The product is a proprietary one and we feel we can recover the costs.

Senator SPONG. You cite the time that might be necessary to perform the tests required by this legislation. Is all of this time in addition to your regular development of a chemical, or could the safety testing and development of a product proceed simultaneously?

Dr. SHAFFER. Not very well, Mr. Chairman, because it is rather difficult to see in the very early stages of chemical development precisely what the substance will be used for. It has to progress to a certain stage of development before we recognize that we can manufacture it economically, and that it will have sufficient uses and properties to justify the investment that would have to be made in it.

I do not think the problem can be ameliorated by saying we will commence the biological testing when the first 1-gram amount has been synthesized in the test tube.

Senator SPONG. Now, EPA would be required to spell out the test protocols and, assuming they do this, wouldn't that help you?

Dr. SHAFFER. Well, it certainly would help in that we would know what was expected of us if we had a candidate chemical.

It seems to me the question for determination is at what stage and on what chemicals we undertake the tests. The usual situation in development is that we synthesize some new molecules and have not the slightest idea of what they may be good for, and we distribute small samples of these to potential customers and ask them if they can work them into their testing systems and give us some idea of what they would be useful commercially for one purpose or another. It is very difficult to predict.

Senator SPONG. Implicit in that last question I asked you is that the procedures under existing statutes for other things do not spell out the protocols to the degree that this will call for. This would be helpful to you if it were done, would it not, as compared to what you presently have?

Dr. SHAFFER. It would be, but the agencies issue guidelines of their requirements, and those of us who work in this field know full well what we have to do to get a pesticide tolerance or what we have to do to register an economic poison for a particular use.

The practical matter is that these facts are well understood.

Senator SPONG. Well, thank you very much, Dr. Shaffer, and I thank the members who appeared with you.

Dr. SHAFFER. Thank you, Mr. Chairman.

Senator SPONG. Our staff will go over very carefully the suggested language changes that you have made in your statement and undoubtedly will be corresponding with you further. And I will look forward to hearing from you on that matter that I wanted you to take some time to look at, the conditional certificate.

Dr. SHAFFER. Yes, sir.

(The statement follows:)

APPENDIX

STATEMENT OF DR. C. BOYD SHAFFER, MANUFACTURING CHEMISTS ASSOCIATION

The following pages itemize the language changes in S. 1478, The Toxic Substances Control Act of 1971, that are being suggested by the Manufacturing Chemists Association. Changes involving significant substantive or policy considerations have been discussed in their Statement before the Subcommittee on the Environment of the Senate Commerce Committee, to which Statement this document is an appendix.

Besides the changes that have been proposed in MCA's Statement, a number of more minor changes are also suggested. Where the intent of the change is self-evident from the context, such change is unaccompanied by comments. In other instances, brief explanations of the purpose for the suggested change follow such recommendation.

The pagination and line enumeration contained in this appendix are keyed to the Senate Bill print dated April 1.

SECTION 201 - POLICY

Proposed language change (in lines 15 and 16, p. 2)

"That adequate authority should exist to restrict the distribution and use of chemicals found to be ~~toxic~~ a danger to health and the environment, and;

Reason for change:

To maintain consistency of terminology with other language in the act; to focus attention on the potential "effects on health and the environment", rather than on an unquantified concept of "toxic" chemicals.

SECTION 202(i) - DEFINITIONS

Proposed language change:

"(i) 'Protect health and the environment' means protection against ~~any injury to man and protection against any substantial adverse effects on environmental values, taking into account the public interest.~~ injury to man and protection against any substantial adverse effects on the environment from a chemical substance due to its chemical properties and not to its physical presence,

taking into account the benefits of the chemical substance as compared to the risks to health or the environment.

Reason for change:

The definition of the phrase "protect health and the environment" in Subsection 202(i) does not provide specifically for the consideration of any of the benefits which can be obtained from the use of a chemical substance, as do other portions of the Act. In addition, any evaluation of a chemical substance must include consideration of the circumstances surrounding use of the substance and the extent of exposure of the substance to man and to the environment. It is conceivable that in a given use a chemical substance could be considered harmful to man or capable of causing substantial adverse effects to the environment, while in another use the same chemical substance could be of such a beneficial nature and have such minimal exposure to man and the environment that such other use would be in the best interests of the public.

SECTION 203(a) - PROPOSAL TO ADOPT RESTRICTIONS

Proposed language change:

"(a) For any chemical substance produced and distributed (a)
in commercial quantities, or at the request of the manufac- (b)
turer, any new chemical substance intended for such distri-
bution and use, after evaluating all information developed
by or otherwise provided to or made available to him, and after
referring the matter to and giving due consideration to the (c)
recommendations from a committee in accordance with section
208, the Administrator may publish proposed regulations to:

Reason for change:

a) to exempt from the regulatory authority granted by this section intermediates that remain at all times under the direct control of the manufacturer, and do not enter commerce as such;

b) to provide the Administrator with authority under which a chemical that fails to pass the section 205 tests may still be approved for limited distribution and use.

The corresponding amendment to section 213(c), exempting from the prohibition of that subsection chemical substances for which regulations have been promulgated under section 203, is an integral part of the proposed change.

c) to provide assurance that the Administrator will give due weight to the recommendations of his advisory committees.

SECTION 203(a)(3)

Proposed language change:

"(3) require such other action as may be necessary to carry out such restrictions including prohibiting or restricting the sale, or use ~~or removal~~ of such substance or product.

SECTION 203(b) - OBJECTIONS, NOTICE, HEARING, FINAL ORDER

Proposed language change:

"(b)(1) On or before the thirtieth day after the day on which the proposed regulations under subsection (a) are made public, any person who will be adversely affected by such regulations if placed in effect may file objections thereto with the Administrator specifying with particularity the provisions of the regulations deemed objectionable, stating the grounds therefor and if desired, requesting a public hearing upon such objections.

SECTION 203(b)(2)

Proposed language change:

"(2) After such request for a public hearing, the Administrator, after due notice, shall upon request by a manufacturer or processor, and may, in his discretion, upon request by any other person adversely affected by such order, hold such a public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. At the hearing, any interested person may be heard in person or by representative. Such hearings shall be conducted in accordance with the provisions of sections 554 ~~and~~ to 557 of Title 5 of the United States Code.

Reasons for change:

To assure interested parties full opportunity to present their testimony and to challenge the testimony of opposing witnesses. As the record of the hearing will provide the basis for any judicial review, it is essential that this record be established under advisory procedures.

SECTION 203(b)(3)

Proposed language change:

"(3) As soon as practicable after the date for completion of the filing of objections and comments, and the hearing, if

any such hearing has been held, the Administrator shall by order act upon such objections, if any, and make public an order promulgating, modifying, or withdrawing the proposed regulations issued under paragraph (a)(1). Such order shall be based only on substantial evidence ~~of~~ on the record considered as a whole, and shall set forth, as part of the order, detailed findings of fact on which the order imposing restrictions is based and the relationship of such finding to the restrictions imposed.

Reason for change:

To provide consistency of language with that of section 203(d)(3).

SECTION 203(c) - MODIFICATION OR RECISSION

Proposed language change:

"(c) Manufacturers or processors of a chemical substance affected by final regulations issued pursuant to this section may petition the Administration for modification or recission of the regulation. The Administrator may at any time modify or rescind such regulations. Proceedings respecting petitions from manufacturers or processors or respecting modifications or rescissions made by the Administrator shall be held in accordance with the standards and procedures established by

this section, ~~except that the Administration may or may not, in his discretion, provide for a hearing regarding such modifications or rescissions.~~

SECTION 204(a) - IMMINENT HAZARD

Proposed language change:

"Sec. 204. (a) An imminent hazard shall be considered to exist when the evidence is sufficient to show that a use or distribution of a chemical substance creates a significant hazard to human health or the environment (~~1~~) ~~that should be corrected immediately to prevent injury to health and~~ (~~2~~) ~~that should not be permitted to continue while~~, which, if the use or distribution continued during the time required for an administrative hearing or other formal proceeding ~~is being held,~~ would likely result in substantial adverse effects to health or the environment.

Reason for change:

See pages 13 and 14 of the MCA statement.

SECTION 205 - TESTING

Proposed language change:

"Sec. 205. As soon as practicable after enactment of the title and from time to time thereafter, the Administrator shall, after referral to the Toxic Substances Board, for various classes and uses of chemical substances, prescribe by regulation standards for test protocols, and for the results to be achieved therefrom, as are necessary to protect health and the environment. In prescribing standards for test protocols, and the results to be achieved therefrom, the Administrator shall consider all relevant factors including: the normal circumstances of use of classes of substances; the degree to which release of substances to the general environment is controlled; the extent of exposure of humans and the environment to a substance; the extent to which the prescribed tests are reasonably predictive of the potential adverse effects of a substance on human health or the environment; and the manner in which available data on the safety of classes of chemical substances may be used in reducing the testing requirements. He shall afford the opportunity for submission of written comments, and upon request of any affected person, a public hearing with respect to any such proposed regulation, and such regulation shall be based upon substantial evidence of record in such proceeding.....

Reason for change:

See pages 14 and 15 of the MCA statement.

SECTION 206(a) - REPORTS

"Sec. 206.(a) The Administrator may by regulation require any or all manufacturers of chemical substances to report to him annually or such more frequent times as the Administrator may reasonably require as to any or all of the following:

"(1) The names of any or all substances produced and distributed in commercial quantities by the manufacturer;

"(2) The chemical identity and molecular structure of such substances; insofar as they are known to him;

"(3) The categories of use of each such substance, insofar as they are known to him;

"(4) Reasonable estimates of the amounts of each substance produced and distributed in commercial quantities for each such category of use; and

SECTION 207 - EXCLUSIONS AND RELATIONSHIP TO OTHER LAWS

Proposed language change:

Insert new clause (4), and renumber present clause (4) as clause (5).

"(4) chemical substances intended for use:

(a) as intermediates for chemical conversion in the manufacture of other chemical substances.

(b) as laboratory reagents

(c) in research and testing; and

Reason for change:

See pages 15 and 16 of the MCA statement.

Proposed language change:

"(b) To the extent that such activities are subject to regulation by other Federal laws, including the Occupational ~~Health and Safety~~ Safety and Health Act of 1970 and title I of this Act, the Administrator shall not regulate the use or distribution of a new or existing chemical substance on the basis of any possible hazard to employees in their place of employment, or the hazard directly to consumers resulting from household use of marketed products which contain or might contain the substance.

SECTION 208 - TOXIC SUBSTANCES BOARD

Proposed language change:

"Sec. 208. (a) There shall be established in the Environmental Protection Agency a Toxic Substances Board consisting of a reasonable number of scientifically qualified persons. The Administrator shall appoint as the members of the board

the persons nominated to him by the National Academy of Scienes. One of the members may be designated at any time by the Director of the National Academy of Sciences to serve as Chairman of the Board. Members of the Board shall serve one term of four years, except that one-half of the members initially appointed after enactment of this title shall be designated to serve one term of two years. Members of the Board shall not be subject to reappointment for consecutive terms.

Reason for change:

See pages 16 and 17 of the MCA statement.

Proposed language change:

"(c) Before proposing any regulations under authority of section 203 or 205 the Administrator shall refer his proposed action and the available evidence to a Committee drawn from members of the Board and the list of consultants to the Board. The Administrator shall appoint as the members of the Committee the consultants nominated to him by the Board. The Committee shall report its views, in writing, to the Administrator, within ~~a-reasonable-time,-not-to-be-less-than-forty-five-days,-specified by-the-Administrator.--If-the-Committee-fails-to-report-within the-specified-time,-the-Administrator-may-proceed-to-take-action under-this-title.--The-report-of-the-Committee-~~

sixty days plus, if requested by the Committee, an additional sixty days after the proposed action has been referred to it. The report of the Committee, including dissenting views, shall be considered as part of the record in any proceeding taken with respect to the Administrator's action.

Reason for change:

To provide assurance that the Committee designated to advise the Administrator on any proposed legislation will have adequate time to make a meaningful study of the proposals and to further provide that, in the event of a division of the Committee, the views of both sides will be available to the courts in any judicial review of the actions of the Administrator.

SECTION 210 - ADMINISTRATIVE INSPECTIONS AND WARRANTS

Proposed language change:

"Sec. 210. (a)(1) For the purpose of inspecting, copying,and verifying the correctness of records, reports, or other documents ~~required-to-be-kept-or-made-under-this-title-and-otherwise-facilitating-the-carrying-out-of-his-functions-under-this-title,~~ relating to chemical substances regulated under this title and required to be kept or made thereunder, the Administrator is authorized, in accordance with this section, to enter any factory, warehouse or premises in which chemical substances are manufactured, processed, or held and to conduct administrative inspections thereof, and of the things specified in this section, relevant to those functions.

Reason for change:

To specify with greater precision those records subject to inspection under this section.

Proposed language change:

"(b) A warrant under this section shall not be required for entries and administrative inspections (including seizures of ~~property~~ chemical substances or products containing same manufactured in violation of regulations issued under this title.)

Reason for change:

See page 17 of the MCA statement.

Proposed language change (Sec. 210(b), continued):

"~~(2) in-situations-presenting-imminent-danger-to-health or-safety;~~

"~~(3) in-any-other-exceptional-or-emergency-circumstances where-time-or-opportunity-to-apply-for-a-warrant-is-lacking;-or-~~

Reason for change:

Section 210 on Administrative Inspections and Warrants appears to be modeled after the comparable section in the Comprehensive Control Substances Act of 1970. Whereas some of its provisions may be appropriate for the control of small amounts of materials surreptitiously handled, characteristic of the illicit narcotic traffic, they hardly seem necessary for the regulation of trade in commercial chemicals. Neither are they consistent with the orderly procedures of Section 204, Imminent Hazards. We particularly urge the deletion of the two indicated clauses.

SECTION 212 - CONFIDENTIALITY

Proposed language change:

"Sec. 212.(a) The information obtained from any manufacturer or processor or disclosed during any inspection shall be confidential to the extent that it comprises matters referred to in section 552(b)(4) of title 5 of the United States Code, and any disclosure of such information shall be a violation of this Act.

Reason for change:

To specify that the protection of this section is to extend to confidential information acquired with or without the cognizance of the plant operator during administrative inspections, and to make violations of the terms of this section subject to the criminal penalties of this title.

SECTION 214 - PENALTIES AND REMEDIES

Proposed language change:

"Sec. 214.(a) Any person wilfully violating subsections 212(a) or 213(a), (b), (c) or (d) shall on conviction be fined not more than $25,000 or imprisoned for not more than one year or both.

"(b)(1) Any person violating subsections 213(a), (b), (c) or (d) shall be liable to a civil ~~penalty~~ assessment to the United States of a sum which is not more than $25,000 for each day of violation, to be assessed by the Administrator after

notice and opportunity for hearing and after he has considered the nature, circumstances, and extent of such violation, the practicability of compliance with the provisions violated and any good faith efforts to comply with such provisions.

"(2) Upon failure of the offending party to pay the ~~penalty~~ assessment, the Administrator may request the Attorney General to commence an action in the appropriate district court of the United States for such relief as may be appropriate.

"(c) The Attorney General or his delegate may bring an action in the appropriate district court of the United States for equitable relief to redress a violation by any person of any provision of section 213 of this title, and the district courts of the United States shall have jurisdiction to grant such relief as the equities of the case may require."

SECTION 215 - ENVIRONMENTAL PREDICTION AND ASSESSMENT

Proposed language change:

"Sec. 215. The Environmental Protection Agency shall, in cooperation with other Federal agencies, develop the necessary personnel and information resources to predict ~~the introduction of new chemical substances into the environment and assess~~ the environmental consequences of the introduction of new chemical substances into the environment. ~~such introduction.~~

Reason for change:

To clarify meaning and to relieve the Administrator of the

impossible task of "predicting the introduction of new chemicals into the environment."

SECTION 217 - HEALTH AND ENVIRONMENTAL DATA

Proposed language change:

"Sec. 217. The Council on Environmental Quality in consultation with the Administrator, the Secretary of Health, Education, and Welfare, the Secretary of Commerce, and the heads of other appropriate departments or agencies and the chemical industry, shall coordinate a study of the feasibility of establishing (1) a standard classification system for chemical compounds and related substances, and (2) a standard means for storing and for obtaining rapid access to information respecting such materials.

SECTION 218 - STATE REGULATIONS

Proposed language change:

"Sec. 218. Nothing in this title shall affect the authority of any State or local government to restrict the distribution or use of a chemical substance or impose requirements of tests and test results for a chemical substance except that (1) if the Administrator has published proposed regulations under section 203 with respect to limiting particular uses of a particular substance a State or local government may not thereafter impose

restrictions on such uses of such substance ~~other than a total ban on such use or uses~~; (2) if the Administrator has published proposed regulations under section 205 with respect to tests for particular substances or uses, a State or local government may not impose test protocols or results to be achieved therefrom with respect to such substances and uses for the purposes similar to this title; and (3) if the Administrator has published proposed regulations under section 203 with respect to limiting particular uses of a particular substance or if the Administrator has published proposed regulations under section 205 with respect to tests for particular substances or uses, a State is not preempted from enforcing any restrictions or test protocols and results to be achieved therefrom existing at the time any such proposed regulation was published; provided that if the Administrator issues an order under section 203(b)(3) restricting the use of such substance or withdrawing a proposed regulation restricting a use of such substance, or if the Administrator issues an order under section 205 prescribing tests or withdrawing a proposed regulation for such tests, the State may not enforce any such restrictions, test protocols, or results to be achieved therefrom after the effective date of such order.

~~other than a total ban on such use or uses.~~

SECTION 219 - REGULATIONS

Proposed language change:

Strike all of this section, and redesignate Section 220 as Section 219.

Reason for change:

There has been no showing of need for regulatory authority beyond that granted for specific purposes, and with appropriate policy and procedural guidelines, in other sections of the Act. Section 219 provides neither procedural safeguards nor appropriate limitations of the discretionary authority that this section would provide.

Senator SPONG. Mr. Frederick L. Bissinger.

STATEMENT OF FREDERICK L. BISSINGER, PRESIDENT, SYNTHETIC ORGANIC CHEMICAL MANUFACTURERS ASSOCIATION; ACCOMPANIED BY ROLAND DERBY, PRESIDENT, NYANZA, INC.; AND DOUGLAS KLIEVER, COUNSEL

Senator SPONG. Good morning.

Mr. BISSINGER. Good morning, sir.

My name is Frederick L. Bissinger. I am president of Allied Chemical Corp. I appear here today as president of the Synthetic Organic Chemical Manufacturers Association, usually abbreviated as SOCMA.

With me today is Mr. Roland Derby, president of Nyanza, Inc., who will make a brief statement following my remarks. I am also accompanied by counsel, Mr. Douglas Kliever.

SOCMA is a nonprofit trade association of manufacturers of synthetic organic chemicals. We have 74 members, many of which are small concerns. With the committee's permission, I would like to present a list of our members for the record.

SOCMA members have some 600 plants in 45 States and employ about 650,000 persons. These companies manufacture thousands of products including dyes, pigments, pesticides, plastics, photographic chemicals, medicinals, pharmaceuticals, and flavor and perfume materials.

The industry is research minded. Indeed, because of the new products this industry has produced, it is frequently referred to as the seedbed of the chemical industry.

A large proportion of the chemicals produced by SOCMA's members are sold to chemical or other industrial manufacturers or are used within the producer's own plants for manufacturing other chemicals. These chemicals, usually referred to as intermediates, are used by industrial firms skilled in the handling of chemicals.

I. SOCMA's POSITION

SOCMA accepts the principle of testing of new chemicals as necessary to protect health and environment, and of appropriate action to minimize hazards to health or environment of existing chemicals.

Chemicals and chemical products, however, are subject now to a wide array of Federal regulatory legislation. Industrial wastes are regulated under air and water pollution control legislation. Employee working conditions are governed by comprehensive occupational safety and health legislation. Large product areas such as pesticides, foods, drugs, and hazardous consumer products, are subject to specific regulatory requirements.

Existing legislation should be examined in order to determine whether there are specific areas of concern for which additional legislation is needed.

Some witnesses have urged that a new law be enacted even though it overlaps existing authority. Duplicating existing legislation will not solve any problems which may exist. Indeed, duplication will lead to conflicting regulation, confusion, and waste.

A. AN ASSESSMENT OF EXISTING LEGISLATION REGULATING CHEMICAL SUBSTANCES MUST BE MADE

I do not wish to undertake in my testimony a detailed analysis of the broad and sometimes overlapping Federal legislation regulating chemical substances. We have prepared a memorandum outlining this legislation, which I should like to submit for the record.

I do believe it is important, however, to review this legislation briefly in light of the problems cited in support of new legislation.

We believe that this review demonstrates that there is only one area in which additional legislation is warranted. That is the use and disposition of consumer products—what might be termed "consumer pollution."

INTERMEDIATE CHEMICALS

I pointed out earlier in my testimony that a large proportion of the chemicals produced by SOCMA's members are intermediates. By intermediates, we mean chemicals which are used in the manufacture of other chemicals. In that process, they undergo a chemical change so that a different chemical is formed. Chemicals, when used as intermediates in industry, are not consumer products.

A consideration of existing legislation demonstrates that the health and environmental hazards arising from the manufacture and industrial use of chemicals as intermediates are now regulated. That legislation should not be duplicated. As a consequence, there is no need to include intermediates in the proposed legislation.

First, hazards to workers in plants. Stringent and comprehensive legislation in the form of the Occupational Safety and Health Act became effective earlier this year and is in the process of implementation.

The act deals with toxic substances and worker safety. It requires promulgation of standards limiting exposure to toxic substances. These standards must insure that an employee will not suffer impairment of health even if he has regular exposure to the substances during his entire working life.

The second area of hazards which might be associated with chemical manufacturing operations is industrail effluent and air emissions.

Industrial effluents are regulated under the Federal Water Pollution Control Act and the discharge permit program under the 1899 Refuse Act. New legislation in this area is pending.

These programs provide for effluent control over toxic and hazardous substances. In fact, we are now awaiting publication by EPA of the lists of hazardous and toxic substances subject to control under the permit program. Discharges of these substances will not be allowed unless the permit can be conditioned to avoid any significant risk to health or safety.

Perhaps it may be pointed out that the regulation under present law of discharges into municipal sewage systems is not as complete as that with respect to other industrial effluent. If this is a weakness, the solution is to deal with that problem directly through changes in the water pollution control legislation.

Air emissions are also regulated. The Clean Air Act, particularly as amended in 1970, grants EPA the power to deal with emissions of toxic and hazardous pollutants.

A third area may be the matter of solid waste disposal. This is covered by the Solid Waste Disposal Act as amended in 1970. If there are shortcomings, the best way is to meet the problem directly by further amendment to the Solid Waste Disposal Act.

Fourth is transportation of hazardous substances. The Department of Transportation has adequate authority now to regulate movement of such products. The Department has detailed regulations in effect.

In our view the present law provides a reasonable basis for dealing with the hazards related to the manufacture and use of chemical intermediates. At most, some amendments remedying shortcomings in present law may be required.

OCCUPATIONAL HAZARDS

I mentioned earlier the Occupational Safety and Health Act. That legislation is not limited to the chemical industry and is one of many Federal statutes protecting the worker from hazards of chemical substances. The legislation protects workers in all industries.

REGULATION OF PRODUCT AREAS

Existing law authorizes extensive regulation of food, drug, cosmetic, and pesticide products. For example, the Food, Drug, and Cosmetic Act provides ample authority for the FDA to regulate drugs contaminated from use of asbestos filters—what Dr. Nicholson in prior testimony called mainling of asbestos.

There has been considerable reference during the committee's hearings to pesticides. These are economic poisons, and that is what they are designed to be.

The Federal Insecticide, Fungicide, and Rodenticide Act and Food, Drug, and Cosmetic Act provide for advance testing, residues analyses, and Federal registration. Additional legislation is pending.

A subject of considerable testimony before the committee was the discovery of PCB contamination in poultry. There was no doubt that the Department of Agriculture had legal authority to deal with this problem when it arose. The manufacturer in August 1970 moved to withdraw PCB from a number of uses, including use in connection with food processing. The contamination arose in connection with a use that is not recommended by the manufacturer.

I believe it is appropriate to add another comment. PCB is important to the electrical industry because of its excellent fire-resistant qualities. It is used in transformers and other electrical equipment where there is a severe fire hazard. In this area the product serves an important need.

Another subject of testimony was mercury in fish, a topic which is still a matter of research and appraisal. About 3 weeks ago the press reported on a paper presented to the American Public Health Association by a team of Detroit scientists. Their research indicated results which were the "reverse of recent 'scare' announcements" regarding mercury in the environment.

Further research and appraisal are, of course, important. But the significant fact is that the FDA has authority to control any food containing a poisonous or deleterious substance. That authority can be and was used to deal with mercury in fish.

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CONTROL OF CONSUMER POLLUTION

This brings me to a discussion of the area which has been the subject of most of the testimony before this committee—control over consumer pollution.

The use and disposition of consumer products is an area where I believe existing legislation may not be adequate. I believe it is helpful in defining the problem to use examples of the specific subjects referred to by witnesses.

Professor Klein mentioned mercury batteries and pharmaceuticals, paint products and other items that contain mercury in small amounts. These products are useful and safe when used as intended.

The problem arises because the consumer throws the products away when their usefulness is ended. This is not a problem of hazards in manufacture. It is simply a matter of disposition of wastes by consumers, usually in municipal facilities. The consumer is not aware of disposal hazards and our systems are not equal to the problem.

Substantial efforts are being made to improve methods of disposition of consumer products to avoid hazards from municipal effluent, incinerators, and dumps. The Federal Hazardous Substances Act permits FDA to ban or require labels for dangerous household products.

However, despite this authority governing the use and disposition of consumer products, there is evidence before the subcommittee that a problem of sufficient magnitude exists to warrant new legislation. It is imperative that the legislation be tailored to the use and disposition of consumer products.

Certain witnesses have suggested to the committee that the fact that agencies other than EPA have authority to regulate certain classes or uses of chemicals justifies duplication of their jurisdiction. Such simplistic proposals are not justifiable or desirable. The enactment of duplicating legislation is far more likely to lead to conflicting and inadequate regulation than to coordinated regulation.

B. UNNECESSARY RESTRICTIONS OR TESTING WOULD HAVE SUBSTANTIAL ADVERSE EFFECTS ON THE CONSUMER AND THE INDUSTRY

Multiple regulation of chemical substances, unnecessary restrictions on use or distribution, requirements of testing of chemicals when there is no need to test, and the promulgation of unreasonable test standards would unnecessarily raise the cost to the consumer of everyday and perfectly safe products.

The impact would be felt by every company, large and small, but the effect is most obvious on the smaller companies, many of which have been in the forefront of research and development of new products. These small, dynamic companies would find it difficult and some would not be able to bear the burdens of unnecessary restrictions and testing requirements.

What are the costs of testing? A feeding study for carcinogenicity for one chemical ranges from $60,000 to $120,000. Depending upon the scope of testing and the substance involved, the total cost of testing for carcinogenic, teratogenic, mutagenic, and toxic effects could be from $200,000 to $250,000 or more for a single product.

That estimate does not include tests on fish and wildlife or for other environmental effects. These protocols are not established. Hence, we cannot anticipate such costs.

The cost of testing will be multipled in most instances A single chemical may require two, three, or 10 series of tests.

A separate series of tests may have to be conducted on byproducts. The effect of the chemical substance in combination with other chemicals may have to be separately tested. Different formulations using the chemical substance may have to be tested independently.

These direct testing costs are only a small portion of the costs from unnecessary restrictions or testing requirements. Delays in marketing because of an unwarranted testing requirement could be many times the cost of actual testing. The productive investment in plants and markets for new and existing chemicals could be delayed or even eliminated by the threat of unnecessary restrictions.

The industry is willing to conduct the tests and incur the costs if necessary to protect health and the environment. But the Congress must provide meaningful direction to the Administrator to insure the unwarranted testing is not required.

II. Opposition to Mandatory Certification

I would now like to turn to what I consider a most unnecessary and burdensome proposal—mandatory certification.

SOCMA opposes mandatory certification of new or existing chemicals. As succinctly stated by the Environmental Protection Agency in its Environmental Impact Statement on S. 1478, mandatory registration or certification of chemicals is unnecessary and likely to "deteriorate into a bureaucratic quagmire."

Very few of the chemicals to which the proposed legislation would apply are even suspected of having any adverse environmental effects. It is unnecessary to place on EPA the heavy burden of mandatory certification or regisrtation of all new chemicals to solve the problem of the occasional hazardous chemical.

Certification would also impose needless expenditures and delays in the development of important new chemicals. The costs and delays of certification under the proposed legislation could exceed those under the Federal Insecticide, Fungicide and Rodenticide Act.

A label registration under that act involves a specific end use of a particular formulation. The cost burden under that act has led several companies to reduce research on new pesticides.

Certification under the proposed bill might require assessment of a dozen formulations and a number of uses of each formulation. As a result, certification of a new chemical substance would be equivalent to many pesticide label registrations. The cost and delays would have to be multiplied accordingly.

III. SOCMA's Proposals

This brings me to a discussion of the specific proposals we have regarding the pending legislation. We endorse, and include in our proposals, the points which the Manufacturing Chemists Association has made.

These proposals are crucial. I wish merely to underline them without detailing the reasons.

First, the scope of the legislation should be redefined and clarified by precluding duplication of existing legislation, particularly air and water pollution control legislation. The legislation should exclude intermediate chemicals. It should explicitly exclude sales for research and testing and sales in less than commercial quantities.

Second, the legislation should include meaningful standards and criteria to be followed by EPA in imposing restrictions on the distribution of chemicals, in promulgating test standards, in determining the presence of imminent hazards, and in ordering recalls.

Third, the procedures for the promulgation of restrictions and test standards should conform with the provisions of the Administrative Procedure Act.

Fourth, the legislation should insure that the Toxic Substances Board is an objective, scientific body and require the Board to submit a report on all proposed regulations and testing requirements.

Fifth, the legislation should authorize use and distribution restrictions on specific generic products and establish labeling as a primary mode of regulation to avoid overly broad restrictions on basic chemicals.

Sixth, the legislation should provide reasonable procedures and standards for administrative inspections and reports and insure protection of trade secrets, particularly process information.

Seventh, enforcement of legislation further regulating the chemical industry should be in the hands of the Government agencies. Citizens' suits would throw into the courts complex scientific questions which the courts are not equipped to handle. Provisions for private enforcement of Government policy by citizens' suits would add unnecessary complications in an area already complicated by overlapping laws. The prime requirement of coordination will be difficult in itself. Adding new citizens' suits will make coordination even more difficult if not impossible.

Eighth, regulating of a chemical under the proposed legislation should preempt any State or local regulation of the chemical.

Ninth, the legislation should insure that not all uses of a new chemical are barred in instances where a test requirement is applicable to just one or a few uses.

Tenth, imports should be regulated in exactly the same manner as domestically produced chemical substances.

Finally, mandatory certification of new or existing chemicals should not be required.

We believe that incorporation of these proposals is essential to achieve the goal of reasonable regulation of chemicals to prevent hazards to health and environment. We would be delighted to review these in detail with the committee or its staff. We urge their adoption.

I would now like to introduce Mr. Roland Derby who has a short statement.

Senator SPONG. All right, Mr. Derby.

Mr. DERBY. I am Roland Derby, president of Nyanza, Inc., of Ashland, Mass. I appreciate the opportunity to express the concern of a small company about the impact of unnecessary testing and regulation of chemical substances.

My company operates two plants. We employ 250 people. Our approximate annual gross sales are $16 million. About 50 percent of our sales are dyes for the textile and related industries.

My company wholly endorses the statements of SOCMA and the Manufacturing Chemists Association. We support their proposals.

In the dye industry we are constantly developing new products. Our business depends upon our ability to find new products to meet special needs.

About 20 percent of Nyanza's dye sales are of products that were not sold 5 years ago. I estimate that we investigate 20 to 30 new formulations per year, and 10 to 20 of these are commercially marketed.

Companies which manufacture chemicals for the pharmaceutical and other industries also depend upon ingenuity in product development. I believe that the smaller companies which produce chemicals for other industries make substantial contributions to our health, economic, and social well-being. We also make an essential contribution to efforts to enhance the environment.

Mr. Joseph Koschak stated before this committee that a drawback of low phosphate detergents is their adverse effect on compounds which make cloth fire retardant. He suggested that the answer is improved fire-retarding chemicals.

Our company may have to develop several new dyes to meet this requirement. In addition, new flame retarding chemicals which do not adversely affect the other desirable properties of fabrics are badly needed. These are among our current projects. Without such improvements, action to prevent harm to the environment may actually jeopardize consumer safety.

We also are developing dyes that are resistant to new detergents. This type of product is necessary to avoid consumer resistance to other new products which are offered as being environmentally safer than existing products.

Adoption of mandatory certification or failure to prevent the imposition of unnecessary testing requirements or restrictions could severely curtail or eliminate our research and development efforts and our business.

Our gross sales of a new dye product that sells well average $20,000 a year. A dye that brings in $500,000 a year in gross sales after extensive market development would be a rare success.

We simply would not be able to continue our research and development efforts if we faced certification requirements or indiscriminate testing that cost $5,000, $10,000, or $15,000 per product. A $100,000 test expense would be unthinkable.

A more important deterrent to development of new products would be the delay. Much of our business is oriented to solving specific problems of our customers. In most cases they would not and could not wait for months but would seek alternative solutions using existing products, and I suspect we would lose much of our business for established products. Our capacity for solving particular problems with new products is the basis for the business relations that bring in orders for old products.

I do not believe that elimination of the small chemical company is necessary to achieve the purpose of the legislation. I hope that the committee would not permit it to happen.

Senator SPONG. Thank you very much.

Mr. Bissinger, in your statement, you describe the authority of the Food and Drug Administration and of the Department of Agriculture to control any dangerous substances in food. You seem to imply that because of this, the need for legislation of the type under consideration here is diminished. Isn't that a bit like saying we need not control mercury pollution, because the FDA will find it in swordfish, or we need not control pesticides, because the FDA will find all residues in food, or that we need not regulate PCB, because the Department of Agriculture will find it in chickens. I am sure you will agree that the control of dangers of this sort must go beyond the mere looking at food.

Mr. BISSINGER. Well, I think that is perfectly true. I think that as a primary consideration you have to look at the end use for which the product is intended.

If something is intended as a pesticide, you obviously have to meet the requirements of that law. But if somebody takes a pesticide and uses it for some purpose for which it was never intended, that would not come within the scope of the pesticide law and the legislation which you have mentioned is important in avoiding health hazards from unintended uses.

I don't know whether that is responsive to the question or not.

Senator SPONG. Well, it is to a degree.

Do you have anything further you would like to say?

Mr. BISSINGER. I think you have to look at the end use that is contemplated. Some of the problems arise when products are used for purposes for which they were never intended. But this is primarily occurring in the consumer area.

This is why I was trying to make sure that the consumer is not unduly exposed to any one of a number of possible products which, in his inexperienced hands, might cause problems. It may never have been intended for the consumer to begin with.

Senator SPONG. Does this happen in industrial areas as well as in consumer cases?

Mr. BISSINGER. I don't believe so. In the chemical industry we are dealing with people who are knowledgable in the properties of these particular products. Based on the state of knowledge and the scientific art, they take whatever precautions are reasonably necessary to protect the people in their factories.

Senator SPONG. How about the PCB's in the chickens now?

Mr. BISSINGER. As I understand, the PCB's got into the chickens because somebody was using the PCB's in a heat exchanger. The device leaked, and the PCB leaked from a closed system on to the chickenfeed.

Now, I would think the manufacturer of the checkenfeed might have detected that, but apparently did not. The manufacturer shipped out the product. The chickens were unable to determine that there was anything wrong with it, and they ate that material.

Senator SPONG. In your statement, you explain why you feel intermediates should not be covered by the legislation. You say that intermediates are covered in all respects now by existing law with respect to workers in plants, solid waste disposal, and the transportation of intermediates, and your case is convincing.

However, the fourth area of coverage, that of air and water effluent limitations, leaves some questions.

Mr. Fri, Deputy Administrator of the Environmental Protection Agency testified on August 4 that the air and water pollution control laws may not be adequate in this respect.

I quote:

> Whenever possible, EPA intends to use effluent authorities to control toxic substances. Section 112 of the Clean Air Act provides for Federal hazard emission standards from new and existing sources. Under the Administration's proposed amendments to the Federal Water Pollution Control Act, effluent limitations would be established for toxic substances. Nevertheless, some toxic chemicals would either not be sufficiently controlled, or would elude control by the traditional approach.
>
> For example, some substances are emitted in such small quantities into the air or water that they cannot be readily controlled.
>
> For others, monitoring technology is inadequate to detect their presence in a media, while still others only become a problem at the point of disposal.

Mr. Fri apparently disagrees with your assessment that the air and water pollution laws are adequate to prevent the discharge of certain toxic substances. His remarks extend to toxic substances generally, in addition to the intermediates, which concern you.

Would you care to respond to his testimony?

Mr. BISSINGER. Well, this is the first time I have heard his testimony. But I am not so sure that we are in disagreement on the nature of the problem. If you know what a toxic substance is, if you can identify it, and if you know what the permissible limits are, then I don't think you have any problem under existing legislation.

But if you are dealing with something that no one knows is toxic, you have a philosophical problem there of saying, "We want to control the toxic substance." The question is: What is toxic and what is not?

You may have very small quantities of these materials. First you have to be able to find out that they are there. There have been new techniques developed over the past several years, scientific testing methods, which allow detection of very small quantities. I am talking in terms of parts-per-billion, which is a very minute amount of material.

You have another step to go through. You have to demonstrate that the presence of that material, even in those minute quantities, is toxic. And to determine toxicity requires some subjective appraisal of a particular material.

So I think, generally, if we know that the material is toxic, regulations can be adopted under existing air and water pollution control law. But if you do not know the material is toxic, I do not know how the EPA can write a regulation to limit the use of a substance, the objections to which are not known or identified.

Senator SPONG. I realize that was a rather lengthy quote that I threw at you if you had not read it before. We will submit it to you and you may want to make some further comment on it.

Mr. BISSINGER. We would be glad to. I just thought you were entitled to a prompt response.

Senator SPONG. I gather that for the most part you agree with the statement that Mr. Fri made, but I think it is rather lengthy and it bears on the whole problem. And I want you to have an opportunity to respond in depth.

Mr. BISSINGER. Thank you very much, sir.

Senator SPONG. In order to clarify what I see is the intent of amendment 338, permit me to comment on your observations concerning premarket clearance of test results with EPA.

First, with respect to your feeling that it is unnecessary for EPA to certify all new chemicals, the definition of chemical substance under amendment 338 excludes those substances with no environmental or public health significance which I presume would eliminate a large number of chemical substances from coverage under this bill.

Second, you say that the costs and delays would multiply because certification would be required for a number of formulations of the same chemical with a number of uses of each formulation.

For the most part, a number of uses of the same formulation could be cleared with a single certification. As the number of uses broadens, then additional requirements would be made under the protocols of section 203.

This is not to say that all of these uses could not be covered by a single certification. You say that a dozen different formulations of a similar nature might have to be certified.

It is true that certification would be required for each of these different formulations. If you will note, section 203 of the amendments, the protocols are for classes of material.

If these different formulations fall within the same class, then separate tests would not have to be run and certification of these additional formulations would be a rather routine matter.

Mr. BISSINGER. We can agree with an intent to limit the testing to areas which are reasonable. We are not taking the position that no testing of any kind should ever be required.

There is a basic problem when testing requirements are discretionary. You get into a gray area, where knowledge about the toxicity of a material or its potential hazards to the environment is not that clean cut. It does not fall into nice black and white areas.

It could happen that an administrative agency, in an attempt to protect itself, would lean over backwards to require extensive mandatory testing, where in fact such testing, with proper scientific inputs, is unnecessary.

Senator SPONG. Dr. Shaffer expressed the same fear when he testified. I would like for you also to have a look at that definition that is used; and if you have any further suggestions with regard to that, we would be very pleased.

Mr. BISSINGER. There is another aspect of this, just thinking of it offhand. If there is an opportunity for scientific people to be involved in the formulation or the establishment of test standards before they are issued, I think you get more meaningful results. Otherwise, industry is faced with a proposed regulation and is put in the awkward position of apparently objecting to it, or of seeming to be in favor of pollution.

I am hopeful that we can have better cooperation between the scientific and industrial fraternity and Government people in achieving the objective which we all want: protection of the people and the environment.

Senator SPONG. Thank you.

Mr. Derby, would you anticipate that all, none, or part of your presentation would fall under the definition of chemical substance in

amendment 338? That is, can it be demonstrated that they do not have environmental or public health significance?

This relates to what we have just been talking about.

Mr. DERBY. New dyes, for example, would probably fall under this classification. These are new chemical substances, but in many cases, they are prepared from previous products which might have been cleared. They are designed in many cases to meet new requirements, such as different detergents, flammability tests, and things like that.

In my own opinion, they are probably not significantly different from what we have made before, as discussed in the SOCMA testimony. However, these would be new chemicals and could be subject to test requirements.

Mr. KLIEVER. Senator, may I make a point here; especially in connection with the MCA proposed amendment on test protocols? The amendments which MCA have proposed as to selectivity of tests are intended to accomplish what you wish to accomplish by definition of "chemical substance."

It seems to me the important point is the question of whether the problems involved in requiring the EPA to affirmatively issue a list of this sort are in excess of what would be gained by that type of a procedure, as opposed to accomplishing the goal through reasonable criteria for whether—and the extent to which—to establish tests for a particular class of chemicals. Your definition, like certification, would require affirmative EPA action.

And that is the point to which, in response to your question, we will address ourselves in supplementary remarks.

Senator SPONG. We would appreciate that. Mr. Derby, I take it you are uncertain as of the moment whether all, none, or some of yours would fall under this?

Mr. DERBY. I would say that is correct; yes.

Senator SPONG. We thank you, gentlemen, very much for your testimony this morning.

The hearings will stand adjourned subject to the call of the chairman.

(Whereupon, at 11:13 a.m., the hearing was adjourned.)

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