

STATEMENT OF DR. C. BOYD SHAFFER  
ON BEHALF OF THE  
MANUFACTURING CHEMISTS ASSOCIATION  
BEFORE THE  
SUBCOMMITTEE ON THE ENVIRONMENT  
COMMERCE COMMITTEE  
UNITED STATES SENATE  
CONCERNING S. 1478 AND AMENDMENT NUMBER 338  
AMENDING THE  
FEDERAL HAZARDOUS SUBSTANCES ACT

October 1 , 1971

Mr. Chairman and Members of the Subcommittee:

My name is C. Boyd Shaffer . I am appearing as a witness on behalf of the Manufacturing Chemists Association (MCA), a non-profit trade association with 165 United States company members, representing more than 90 percent of the production capacity of basic industrial chemicals within the country.

My professional training is in the field of toxicology, and I am so employed by a major chemical corporation with extensive interests in consumer and medical products, synthetic fibers and plastics, agricultural chemicals and pesticides, and industrial chemicals. I am accompanied by Mr. Taylor Hanavan, an attorney from another MCA member company, who has worked many years with product registration problems, William L. Sutton, M. D., a physician with particular expertise in the protection of industry workers from the hazards of chemical exposures, and Dr. M. V. Anthony, a chemical company vice president with corporate responsibilities for the protection of both health and the environment. If our discussions today should involve points that could be clarified by the input of their experience and knowledge, they will be pleased to place these at your disposal.

The President has recommended legislation (S. 1478) to establish new regulatory authorities for the control of chemicals. This bill together with several amendments, notably one offered by the distinguished acting Chairman of this Committee, was the subject of three days of hearings in early August and continues to be a matter of consideration by this Committee. 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. We commend this Committee for its careful study of both the problem to which the legislation is addressed and its possible solutions.

Since I represent the industry that would be most directly affected by a new law, I am sure that this Committee is deeply interested in our assessment of the magnitude of the problem and our response to the solutions that have been proposed. We are aware of the impact that a law of this nature could have on our operations; hence we have given intensive and thoughtful study to the various legislative proposals as they have appeared, and we 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 reasonably comprehensive 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. 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 a recognition of the comprehensive scope of existing regulation should underlie all of its deliberations on the content of a new law.

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In view of the regulatory statutes already in force, our Association believes 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 all uses of all chemical substances. Therefore, our Association further concludes 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 Senator Spong's amendment that places primary emphasis on protection of health and 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 hypothetical hazards.

As emphasized in President Nixon's August 1971 message to the Congress of the United States, 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

\*Insert specific "cost of compliance" example.

that substances not covered by the Administrator's standards will escape any testing whatsoever. Voluntary testing by manufacturers has been substantial for many years, and may be expected to increase.

You will note that the Administration bill (S. 1478) does not include the concept of mandatory premarket testing of all new chemical substances, or registration or certification procedures. With this we fully concur and we do not favor their inclusion in Amendment No. 338 as proposed by the Chairman.

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 the 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 Admendment 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 one to five 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 doesn't 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 significance 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 Senate Bill No. 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(c) will have to be amended accordingly.
- (2) Of major 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, or 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 Act. 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 amended by eliminating the option of the Administrator 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 or a 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) An area of primary concern to our Association in terms of the cost of and delay in product development is Section 205 which authorizes the Administrator to establish standards for test 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 new 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.
- (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 four years, except that one-half of the members appointed after enactment of the law should be designated to serve one term of two years. Thereafter, one-half of the members of the Board would be appointed every two years. Members of the Board should not be reappointed for consecutive terms.
- (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 regulations 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 any state or local action to impose a "total ban on such use or uses."

As we indicated earlier, we are offering to this Committee an additional list of proposed language changes 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. Although we do not ask that the time of this hearing be devoted to such details, we do feel that, 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 to this Committee as it seeks to formulate a national policy that will maximize the net benefits to our society from a vigorous and creative chemical technology. If there are any questions that you care to ask at this time, I or other members of our delegation would be happy to undertake to answer them.

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