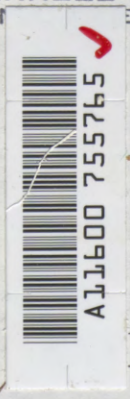

TOXIC SUBSTANCES CONTROL ACT OVERSIGHT

HEARINGS

BEFORE THE

SUBCOMMITTEE ON ENVIRONMENTAL POLLUTION

OF THE

COMMITTEE ON IRONMENT AND PUBLIC WORKS

UNITED STATES SENATE

NINETY-FIFTH CONGRESS

SECOND SESSION

JULY 20, AND 21, 1978

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TOXIC SUBSTANCES CONTROL ACT OVERSIGHT

THURSDAY, JULY 20, 1978

U.S. SENATE,
COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS,
SUBCOMMITTEE ON ENVIRONMENTAL POLLUTION,
Washington, D.C.

The subcommittee met at 10:35 a.m., pursuant to notice, in room 4200, Dirksen Senate Office Building, Hon. Edmund S. Muskie (chairman of the subcommittee) presiding.

Present: Senator Muskie.

OPENING STATEMENT OF HON. EDMUND S. MUSKIE, U.S. SENATOR FROM THE STATE OF MAINE

Senator MUSKIE. The committee will be in order.

I take it we all had difficulty moving around the city this morning.

I am pleased to open this first 2 days of oversight hearings on the implementation of the Toxic Substances Act of 1976.

This has been a week of learning for myself and other members of the Subcommittee on Environmental Pollution. Last Tuesday, we held informative oversight hearings on the implementation of the Safe Drinking Water Act of 1974.

Today, we continue our education by opening hearings on another act which was shifted from the Commerce Committee's jurisdiction to the Environment and Public Works Committee as a result of the Senate reorganization in 1977.

The Toxic Substances Control Act is a long and complicated piece of legislation which took 6 years of deliberation to enact. Close congressional oversight will now be required to insure that the intent of the act is carefully followed.

Until the enactment of the Toxic Substances Control Act (TSCA), controlling the threat of toxic chemicals was confined to reacting to products already available and in use. The new law, however, has filled in some of the gaps of other Federal laws dealing with toxic materials allowing EPA to require premarket testing and other clearances before a product can be marketed.

The scope and nature of this attempt has inherently led to complications in the act's implementation.

We are here to discuss some of these problems today.

EPA has been given broad authority to prevent potential cancer-causing substances from reaching human populations and their environments. But the Agency will be required to develop a program and a set of regulations based on many "unknowns."

—A collection of terms in the law must be spelled out before any regulations can be effectively promulgated.

—An inventory list of manufactured chemicals is still to be developed from the more than 70,000 different chemicals now in production. With paperwork growing, EPA has already missed two major mandated deadlines.

—There remains a vast difference of opinion concerning how much the testing of chemicals will cost industry.

—EPA has yet to decide how much information will remain confidential in the premanufacture notification of chemicals printed in the Federal Register.

I am hopeful some of those testifying here today and tomorrow will shed some new light on these and other questions which remain unanswered.

For the law to become effective, both the $113 billion American chemical industry and public interest groups must be willing to find some common ground as regulations are developed.

The EPA, the Consumer Product Safety Commission, the Food and Drug Administration, and the Occupational Safety and Health Administration all focus on various aspects of the toxic substances issue. Each agency has differing objectives and administers different statutes, and there is a possibility that duplication could result from the various jurisdictions.

I was pleased to see that President Carter has instructed the Council on Environmental Quality to develop an interagency program to eliminate duplication and gaps in the research and collection of data on toxic substances.

The law was passed more than 18 months ago. Is the public more protected now from harmful toxic materials than it was when the act was passed? There is little evidence to indicate that the answer to that question is "Yes." The slowness in the development of regulations has meant that no direct controls have been placed on toxic chemicals.

At the turn of the century, most deaths in the United States resulted from infectious diseases such as pneumonia and tuberculosis. Today, however, the leading causes of death are heart disease and cancer—what most experts believe to be diseases directly related to environmental factors. One of the most significant facts in the rise of the cancer death rate has been the increased exposure to industrial chemicals at work, in the air and in the water.

The Toxic Substances Control Act, alone in a vacuum, cannot be expected to remedy all the problems associated with environmental health hazards. Other important environmental laws, including the Safe Drinking Water Act, the Clean Water and Clean Air Acts, must dovetail with the toxic substances law to attack the problems on several fronts.

I am especially interested in the relationships between the Toxic Substances Control Act and other environmental laws, and look forward to learning more about their interaction here today.

So I open these 2 days of hearings aware of the need to abate the spread of toxic chemicals into our environment, but anxious to hear what the witnesses have to say about the status, the problems, and the goals, of the Toxic Substances Control Act.

I would like to welcome as our first witness Steven Jellinek, the Assistant Administrator for Toxic Substances of the Environmental Protection Agency.

STATEMENT OF STEVEN JELLINEK, ASSISTANT ADMINISTRATOR FOR TOXIC SUBSTANCES, ENVIRONMENTAL PROTECTION AGENCY

Mr. JELLINEK. Thank you, Mr. Chairman. I am happy to be here for the first oversight hearing by this committee on the Toxic Substances Control Act. I have a rather detailed prepared statement. With your permission, I would like to summarize it for efficiency's sake.

Senator MUSKIE. I have two observations. Sometimes summaries prove to be longer than printed statements.

Mr. JELLINEK. I have a written summary.

Senator MUSKIE. Sometimes summaries ignore important points that ought not to be overlooked.

Mr. JELLINEK. It is at your pleasure.

Senator MUSKIE. With those two statements, of course your full statement will be printed in the record. (See p. 39.)

Mr. JELLINEK. One of the major concepts underlying the Toxic Substances Control Act (TSCA) is that the health and environmental hazards stemming from our society's heavy reliance on commercial chemical substances reach into virtually every nook and cranny of modern life. Nothing we touch, smell, consume, or otherwise use throughout a given day hasn't in turn been affected in some way by chemicals.

Relatively little is known about the long-term, chronic effects that result from exposure to many of these chemicals. Under TSCA, however, EPA for the first time has the necessary authority to gather certain kinds of basic information on chemicals, to identify harmful substances, and—when other environmental laws cannot control the specific sources of exposure, which often involve production and use—to control those substances whose risks of injury to public health and the environment outweigh their benefits to society and the economy. Not only can we prohibit the production and use of such chemicals, but we can take a number of other actions to attack the root causes of toxic substances problems in virtually every facet of industry—product development, testing, manufacturing, processing, distribution, use, and disposal. In essence, TSCA enables us to overcome the single greatest obstacle to finding workable and effective solutions to toxic substances problems. That obstacle, of course, is ignorance. Not only EPA's ignorance, but the public's, as well.

I assure you that we take these enormously difficult and complex responsibilities very seriously.

We have set a number of short- and long-term objectives for implementation of TSCA aimed at building a strong, viable program for the future, while vigorously addressing the very real and pressing chemical-related problems we face today. These objectives are summarized in my prepared statement. Also, for the subcommittee's information, I am submitting copies of an EPA document, entitled "Implementing the Toxic Substances Control Act: Where We Stand," which summarizes what we have accomplished in meeting these objectives.

Under TSCA, EPA will assign highest priority to those substances that pose the greatest risk as a function of both toxicity and exposure. Chemicals that may produce chronic or irreversible health effects such

as cancer, birth defects, and gene mutations will take higher priority than those that produce acute effects such as eye and skin irritations. Similarly, substances that are widely dispersed in the environment and that may significantly disrupt ecosystems will take a higher priority than those that threaten individual species other than man.

We already have taken, or are in the process of taking, a number of actions to gather the kinds of basic information we need to determine priorities for various chemical regulatory actions. Late last year, for example, we promulgated rules under sections 8(a) and (b) to compile an inventory of chemical substances and to learn which substances are manufactured where and in what quantities.

Domestic manufacturers and importers of chemical substances had until May 1, 1978, to report the initial inventory information to EPA. About 50,000 reporting forms were submitted to EPA covering some 125,000 substances. Once we have sorted out duplications in reporting among various companies that make the same substance, we expect that the actual number of commercial chemicals listed on the published inventory could be as high as 70,000. We project that the inventory data will be processed by the end of this year, and that the initial inventory itself will be published early next year.

Publication of the inventory will trigger TSCA's section 5 premanufacture review program, which I shall discuss later.

Guidance we have published under section 8(e) provides another channel through which we can identify and address significant problems.

This guidance encourages manufacturers to establish an internal reporting procedure to insure that EPA will expeditiously receive any new information that reasonably supports the conclusion that a chemical substance may present a substantial risk to health or the environment. We have already received over 200 substantial risk notices. Because many relate to issues that fall within other statutory jurisdictions, a number of these have been referred to other EPA programs or other Federal agencies for further study and possible action.

The authority to require chemical manufacturers and processors to undertake testing under Section 4 is another important tool we can use to get information about chemicals. In designing an overall approach to testing requirements under TSCA, we plan to rely largely on a tiered set of standards; that is, the need for long term, more definitive, more costly tests will be determined from the results of short-term relatively simple screening tests, together with other factors such as the extent of exposure.

The section 4(e) Interagency Testing Committee has submitted two sets of recommendations to EPA regarding 18 chemicals and classes of chemicals identified for priority testing consideration.

We have solicited public comment on these recommendations, and, under section 8(d), we have promulgated rules requiring all chemical manufacturers and processors to submit lists and/or copies of any unpublished health and safety studies already performed on substances recommended in the committee's first report last October. We plan to propose similar rules for the second set of Interagency Testing Committee recommendations.

We are especially concerned about the quality of test data submitted to EPA under TSCA. To insure consistently high-quality data, our

testing standards under section 4 will incorporate standards for good laboratory practices consistent with those developed by the Food and Drug Administration (FDA).

Development of the section 5 premanufacture review program is EPA's most critical current activity under TSCA. Any person intending to manufacture or import a new chemical substance must submit a premanufacture notice to EPA at least 90 days before introducing the substance into commerce.

Any chemical substance not included on the inventory of substances compiled under section 8(b) will be considered "new." The premanufacture notification requirements become effective 30 days after publication of the inventory.

EPA is planning to propose rules governing reporting for new chemical substances early this fall. We also are developing nonmandatory testing guidelines to insure that industry knows what kinds of evaluations EPA considers minimally necessary to make informed decisions on new chemicals or significant new uses of existing chemicals.

Cooperation on toxic substances control is occurring within the executive branch. In response to the requirement in section 10(b), for example, an Interagency Toxic Substances Data Committee has been formed to establish an efficient system for retrieving toxicological and other scientific data available in Federal Government files.

Last August, the heads of the four Federal agencies primarily responsible for regulating chemical substances—EPA, the FDA, the Occupational Safety and Health Administration, and the Consumer Product Safety Commission—formed the Interagency Regulatory Liaison Group (IRLG).

The principals and their staff representatives are continuing to meet regularly to coordinate efforts in a number of important toxics-related areas.

Finally, EPA fully participates in the Toxic Substances Strategy Committee, chaired by the Council on Evironmental Quality. I expect that Council Member Gus Speth will give you a complete rundown on this group's activities later this morning.

While much of our initial effort in implementing TSCA is aimed at information gathering, we have taken several actions aimed at controlling the production, distribution, use, and disposal of specific chemical substances or classes of substances.

Our first action was to promulgate regulations on the labeling and disposal of polychlorinated biphenyls (PCB's). The second phase of PCB regulations, implementing the ban on manufacture and use in any way other than a totally enclosed manner, was formally proposed on June 7.

In a joint action last March with the Food and Drug Administration and the Consumer Product Safety Commission, we banned most aerosol uses of chlorofluorocarbons (CFC's). EPA now is investigating ways to further reduce CFC emissions, specifically from such nonaerosol sources as air-conditioners, refrigerators, solvents, and foam blowing.

We are also evaluating what regulatory action may be warranted by the risks presented by a number of other important chemicals. Among these are such well-known materials as asbestos, cadmium, benzidine dyes, mercury, lead, arsenic, and trichloroethylene.

Over the next several months, we expect that our review of these and other substances will produce prime candidates for regulation.

This concludes my prepared remarks. I shall be happy to try and answer any questions that you may have.

Thank you.

Senator MUSKIE. You referred to the screening procedure which you are planning to use to determine what chemicals require testing.

Are you confident that a foolproof screening system can be set up that will not permit harmful chemicals to slip through unnoticed?

Mr. JELLINEK. That is an extremely good question. As I stated in my remarks, Mr. Chairman, one of the main problems associated with toxic substances control is that we don't know much about most of the chemicals that are in commerce. In our efforts to develop procedures for identifying chemicals that need testing, we are faced again and again with this lack of knowledge.

I think it probably is going to be difficult, if not impossible, to develop a foolproof screening system. We are trying to develop a screening system that will catch those chemicals that appear to be the most important ones for testing.

In order to do this, we must focus on exposure characteristics. Are the chemicals exposed to various ecosystems? If we don't have definitive information on this, we must rely on other kinds of information, such as production volume. The chemical inventory reporting process I described in my statement will provide production volume information as well as the names of most commercial chemicals used in this country. This information will help us to set rough priorities based on production quantities.

The short answer to your question, though, is that it is going to be just about impossible to develop a truly foolproof system.

Senator MUSKIE. Do you have any procedure for picking up any misses?

Mr. JELLINEK. Yes, we will. As I have indicated, we don't know what many chemicals are used for. Section 8(a) of the act permits us to find out this information from manufacturers and processors. We expect to use the information that we obtain under section 8(a) to develop our priorities for testing chemical substances.

Our first priority is to require testing of those chemicals that we at least know something about. In what volume are they produced? Do we know anything about their use?

Senator MUSKIE. In other words, your screening is not intended to separate on a permanent basis the white hats from the black hats?

Mr. JELLINEK. That is correct. We have the ability to renew our consideration of whether a particular chemical should receive priority attention.

Senator MUSKIE. In your prepared statement in your description of the actions of the Interagency Testing Committee, thus far there appears to be a long period between their testing recommendations and action by EPA to actually require testing. Why would EPA take so long to respond?

Mr. JELLINEK. The law gives us a year to respond but we do not intend to take that much time just because we have got it. The main

reason it has taken us so long to act on the committee's first report is related to why it has taken us so long to do many things. I refer, of course, to the overall process of starting up a new program within EPA to carry out the Agency's responsibilities under the Toxic Substances Control Act.

At the same time we have been implementing many aspects of the law we also have been recruiting staff and trying to develop basic policy concepts. We are not only recruiting staff; in some cases we are recruiting some of our senior managers.

Once we develop a "critical mass" of management and staff, I think these things will come along much faster than they have and there will not be such long delays.

Senator MUSKIE. We have a rollcall vote on the floor. I guess I am going to have to leave and vote. May I suggest when I return, you remain there and we take the other prepared statements so we can be sure to get through them and then we will get to questions in whatever time remains, due to the floor activity at the present time.

So if the other two witnesses, Mr. Speth and Mr. Hayden, while I am gone, come up to the witness table, I will take their statements in order and then we will get to questions, because there are a lot of questions. I would like to be sure we have the prepared statements presented before we get to them.

Mr. JELLINEK. You would like me to stay at the witness table?

Senator MUSKIE. Yes; then maybe we can get an exchange of questions. I will be back as soon as I can.

[Brief recess.]

Senator MUSKIE. I think we better move with reasonable dispatch because it looks like a voting day on the Senate floor.

So, Mr. Speth, as a member of the Council on Environmental Quality, Chairman of the Toxic Substances Strategy Committee, you ought to be able to give us all the wisdom we need.

STATEMENT OF GUS SPETH, MEMBER, COUNCIL ON ENVIRONMENTAL QUALITY, CHAIRMAN, TOXIC SUBSTANCES STRATEGY COMMITTEE

Mr. SPETH. It is a great pleasure to be here. You know I have only a very little wisdom to offer, but what it is, I will get right to. I will just abbreviate my statement, Senator, and move right through it and submit it for the record. (See p. 91.)

The Council on Environmental Quality is involved in a series of interagency committees which are endeavoring to bring the myriad of programs within the Federal Government that relate to toxic substances together in a better coordinated way and to service these programs with common systems, such as data systems, relating to the toxicity of chemicals.

It is about these committees that I would like to talk today.

The first one, as you mentioned, is the Toxic Substances Strategy Committee; the other committees which I will talk briefly about are the Interagency Toxic Substances Data Committee and the Interagency Testing Committee.

We do chair, as you mentioned, the Administration's Toxic Substances Strategy Committee. This is a committee which includes all of the major governmental agencies which have responsibility for regulating toxic chemicals and all the agencies which have responsibility for gathering information and doing research about toxic chemicals.

I will submit for the record the Committee's work plan and its current membership.

[The information follows:]

[6125-01]

COUNCIL ON ENVIRONMENTAL QUALITY

TOXIC SUBSTANCES STRATEGY COMMITTEE

Work Plan

The work plan for the interagency Toxic Substances Strategy Committee is published here for public comment. This committee was established in response to the President's request, in his Environmental Message of May 23, 1977, that the Council on Environmental Quality develop an interagency program to eliminate overlaps and fill gaps in the collection of toxic chemicals data and to coordinate research and regulatory activities affecting them. This committee will serve as the principal forum for the development of Administration initiatives with respect to government-wide toxic substances strategy and policy.

The Strategy Committee, whose membership is printed below as Appendix A of the work plan, is chaired by CEQ and includes representatives of all agencies with responsibilities for research, regulations or policy relating to toxic chemicals and their effects on human health and the environment. These include 16 member agencies, 5 component parts of the Executive Office of the President as official observers, and 1 interagency group (the Interagency Regulatory Liaison Group) as an ex officio member. These agencies carry out toxic substances responsibilities under at least a dozen major Federal statutes (see Appendix B of the work plan). Although many of the concerns of these agencies and their statutory responsibilities are similar, the various activities have often been developed relatively independently of each other. Some of the research, data and regulatory programs are well-established; some are very new or just now being developed. As demonstrated by several current coordination activities, most can provide useful input to one or more of the other programs; however, better and more effective means for such exchange need to be developed and implemented. In some cases, greater uniformity of approach or elimination of duplication is desirable; in other cases there are legitimate scientific, legislative or administrative reasons for multiple approaches, although these are not always fully understood or communicated to those affected.

The Committee is concerned with development of strategic approaches for carrying out Federal responsibilities in a manner that is both effective in achieving protection from the hazards of toxic substances in the environment and in minimizing unnecessary burdens on outside groups affected by Federal actions, the public, and agencies. Specifically, the Committee will take actions and make recommendations relating to Federal programs for the following:

Advancement of scientific and technical understanding of toxic chemicals problems, including research, testing and monitoring;

Data collection, recordkeeping, reporting and exchange;

Utilization of information and research results in regulatory and policy decisionmaking;

Establishment of mechanisms, plans and priorities for Federal response to potential and actual toxic chemical hazards, including regulatory and nonregulatory preventive measures and handling of toxic chemical crises.

In looking at strategies for identifying toxic chemical hazards relating to human health, an initial high priority task will be to develop a government-wide set of general principles relating to carcinogenesis.

The work plan published below covers the activities of the Committee to achieve its objective in 1978. At the end of this period the need for any further activities of the Committee will be re-assessed. Throughout this period the Strategy Committee welcomes and will solicit information and opinions from the general public, legislative bodies, State and local governments, and interested groups and parties such as industries, labor unions, environmental and consumer groups, and the scientific community. Publicly-held informal meetings with representatives of such groups are expected to begin in December. Later meetings, including ones for the general public, will be held to obtain needed information relevant to the various tasks and comments on proposed actions or draft reports.

At this time the Committee welcomes written comments on the work plan, particularly on the following matters:

1. Which of the areas within the scope of the Committee's concerns and work plan should receive the greatest attention (and why), and what are the priority first steps that might be taken?

2. What are realistic expectations of what should and can be accomplished by development of new Federal strategies for alleviation of toxic substances problems? What benefits would accrue? What are the likely barriers to be encountered in undertaking such efforts and how might these best be overcome?

3. What examples of past effective and ineffective Federal approaches to toxic chemical hazards should be especially noted in considering new strategies? (Please be as specific as possible in providing information or in citing studies or other information of which the committee should be aware, especially for sources outside the Federal agencies.)

4. What specific methods of improved communication might be established between Federal agencies (singly or collectively) and the general public or groups such as legislative bodies, State and local governments, industries, labor unions, environmental and consumer groups, and the scientific community?

5. What mechanisms now exist that are particularly effective (or ineffective) in coordinating the toxics-related activities among the local, regional, State and Federal levels, and what improved approaches should be initiated?

6. The Committee believes that it is vital to its success to have wide participation from all interests at issue in the toxic chemical hazards area. Please identify those groups, associations and others of which you are aware that should have the opportunity to participate in this Committee's activities. Please indicate the contact person and address, if available, and your perception of the nature of the interest of the party and the special information or perspective that it might provide to the Committee's deliberation.

DATE: Comments pertinent to this Committee and its activities are welcome at any time, but must be received on or before December 9, 1977, to be of utility in the pursuit of the major initial tasks of the Committee's work plan.

ADDRESS: Comments or requests for further information should be addressed to the Executive Secretary of the Toxic Substances Strategy Committee: Carroll Leslie Bastian, Senior Staff Member for Environmental Health and Toxic Substances, Council on Environmental Quality, 722 Jackson Place NW., Washington, D.C. 20006, telephone 202-633-7107.

GUS SPETH,
Member, Council on Environmental Quality (Chairman, Toxic Substances Strategy Committee).

TOXIC SUBSTANCES STRATEGY COMMITTEE—WORK PLAN

INTRODUCTION

ESTABLISHMENT AND MEMBERSHIP

The President's environmental message of May 23, 1977 established prevention of toxic substances problems as a high priority of his Administration and instructed the Council on Environmental Quality (CEQ) to develop a coordinated interagency Federal program for control of toxic substances:

The presence of toxic chemicals in our environment is one of the grimmest discoveries of the industrial era. Rather than coping with these hazards after they have escaped into our environment, our primary objective must be to prevent them from entering the environment at all.

At least a dozen major federal statutes, implemented by seven different agencies, address this problem in various ways. With the enactment last year of the Toxic Substances Control Act, no further comprehensive federal legislation should be necessary. Now we must inaugurate a coordinated federal effort to exclude these chemicals from our environment.

I am therefore instructing the Council on Environmental Quality to develop an interagency program (1) to eliminate overlaps and fill gaps in the collection of data on toxic chemicals, and (2) to coordinate federal research and regulatory activities affecting them.

Pursuant to the President's directive, the interagency Toxic Substances Strategy Committee has been established to develop a coherent Federal approach. Federal departments and agencies with major policy, research or regulatory responsibilities relating to control of potentially hazardous chemicals have been requested to participate. Members include representatives of the Department of Agriculture (USDA); the Department of Commerce; the Department of Energy (DOE); the Department of Health, Education, and Welfare (HEW), as well as four of its component agencies—Food and Drug Administration (FDA), the National

Cancer Institute (NCI), the National Institute for Environmental Health Sciences (NIEHS), and the National Institute for Occupational Health and Safety (NIOSH); the Department of Interior (DOI); the Occupational Safety and Health Administration of the Department of Labor (OSHA); the Department of State; the Consumer Product Safety Commission (CPSC); the Environmental Protection Agency (EPA); and the National Science Foundation (NSF). Representatives of the Office of Management and Budget (OMB), the President's Reorganization Project (PRP), the Office of Science and Technology Policy (OSTP), the Domestic Policy Staff, and the Council of Economic Advisers (CEA) are official observers. The Chairman of the Strategy Committee and Executive Secretary will be from the Council on Environmental Quality (CEQ).

A list of official members and their designated alternates is attached (Appendix A). Each agency will have one member and one official alternate, both at a high policy-making level. They may invite additional agency personnel to attend meetings of the Strategy Committee (with prior notification to the Executive Secretary) in order to advise on the various broad range of subject areas covered by the Committee. In addition, the lead agency for specific tasks and sub-tasks will request appropriate participation from the various agencies (which may or may not coincide with those participating in the activities of the full Committee). The lead agency should do so in consultation with the Executive Secretary of the Strategy Committee.

SCOPE OF STRATEGY COMMITTEE'S CONCERNS

The scope of the Committee's interests potentially includes those activities that pertain to hazardous or toxic man-made chemicals at every stage of their existence (testing, production, distribution in the environment, use, distribution in commerce, original and ultimate disposal); in the various sectors of the environment (workplace, home, general environment); and their deleterious effects (acute and chronic human health effects, non-human biological and ecological effects, physical/chemical effects such as ozone depletion). For the initial stages of work, concerns relating solely to radiation hazards, to physical and safety hazards, or to exclusively natural substances will be considered to fall outside the scope of the Committee's work, although they may be considered in any cases in which they are closely related to toxic substances concerns. Furthermore, although the adverse health effects from tobacco and alcohol are substantial, issues relating to these substances will not be initially addressed by the Committee. This narrowing of scope is one of expediency and practicality, as well as one of recognition of certain differences between such substances and ones to which exposure is less avoidable. Major statutes containing toxic or hazardous substances provisions within the scope of this Committee's concerns are listed in Appendix B.

OBJECTIVES OF STRATEGY COMMITTEE'S WORK

The Committee will serve as the principal forum for the development of Administration initiatives with respect to government-wide toxic substances strategy and policy. It will focus upon the sufficiency, effectiveness, and coordination of current Federal programs for understanding and addressing toxic substances problems. The Committee will implement appropriate changes in policy and strategy to accomplish its objectives, in such matters as are within its jurisdiction. In other cases it will make recommendations to appropriate decisionmakers, including the President. Actions and recommendations in the various areas of concern will result in written reports on particular subjects. In addition, the Committee will prepare a publicly-available summary report of its activities at the end of one year of effort.

The Committee will review and assess Federal activities relating to the planning, management and analysis of research; data and information gathering and utilization; toxic substances problem identification and prediction; and regulatory and non-regulatory measures for prevention and correction of problems. In doing so, the Committee will analyze specific known problem areas in order to focus on such broader questions as the following:

How should priorities be established for the level of effort and the timing of Federally-coordinated activities relating to particular chemical substances?

What gaps exist in the information base and in basic scientific and technical understanding that are desirable or necessary for rational Federal decisionmaking in regard to prevention and control of toxic chemical hazards? What measures should be taken to fill these gaps?

What unnecessary or undesirable conflict, confusion or duplication exists among the activities of the various agencies engaged in toxic substances-related work? What are the effects of these problems on the efficient use of Federal resources, on the public, and on the parties affected by Federal actions; requirements and regulations? What should be done (e.g. modification of agency missions and responsibility, organizational changes, improved coordination mechanisms) to minimize or eliminate these effects?

For those activities in which multiple or overlapping participation by several agencies is justified, desirable, or unavoidable, what coordination mechanisms exist or should be established to carry out Federal responsibilities most smoothly and efficiently?

Although the principal focus of the Committee's activities will be U.S. domestic strategies, the international dimension of these strategies will be fully considered in each of the Committee's tasks. Assistance will be sought from the State Department and the international affairs staffs of the various agencies in advising the Strategy Committee of the international implications of alternative U.S. strategies. They will also advise on ways by which U.S. policy initiatives can be reflected in U.S. participation in multinational and bilateral discussions of common and global toxics problems. Such advice to the Committee will be on a continual basis as the need arises. In addition, the State Department will be the lead agency for preparing recommendations (for the full Committee's consideration and adoption) of methods by which domestic activities relating to toxic chemicals can best be coordinated with related international initiatives.

Policy options to be adopted or recommended by the Committee may relate to Federal policies, procedures, decisionmaking processes, utilization of resources, organizational structure, and institutional mechanisms, and relationships with the public and with non-Federal groups. Development and review of the detailed documents necessary to implement such recommendations will be handled by the agencies in accordance with normal Federal practices.

RELATIONSHIP OF THIS COMMITTEE TO RELATED INTERAGENCY EFFORTS

1. Interagency Regulatory Liaison Group.

CEQ is encouraged by the recent formation of an Interagency Regulatory Liaison Group (IRLG), consisting of CPSC, EPA, FDA, and OSHA. This group is meeting regularly and frequently to examine common requirements and functions as they pertain to the regulation of potentially hazardous and toxic substances in their agencies and to develop ways to improve present interagency cooperative efforts as necessary. Their goal, in achieving better public health, is to coordinate their efforts in ways that will ensure more effective regulation and will lessen the administrative burden on the regulated industries, the public, and the agencies themselves.

The work of the IRLG and the Federal Toxic Substances Strategy Committee will be closely coordinated and is expected to be mutually compatible. Many of the IRLG activities will implement the objectives for which the Strategy Committee was established. In addition, the detailed work of the IRLG, which is related specifically to those four regulatory agencies, will provide a good background for the broader Federal-wide strategic considerations of the Strategy Committee. For example, the IRLG has agreed to assess research needs in support of regulatory activities, which cannot be fully addressed by the present inhouse capabilities of the four agencies.

2. Other interagency committees.

The Strategy Committee will keep in touch with the activities of relevant interagency groups and utilize their findings and reports wherever possible. Such groups include the TSCA Interagency Testing Committee (established by section 4(e) of TSCA); the *Ad Hoc* Interagency Toxic Substances Data Committee (and its successors); the Interagency Task Force on Environmental Data and Monitoring; the DHEW Committee to Coordinate Toxicology and Related Programs; and other more specialized committees relating to certain types of hazards, data, research or regulatory activities.

3. President's Reorganization Project.

Close liaison will be maintained between the Strategy Committee and the relevant divisions (Natural Resources, Human Resources, and Regulatory Reform) of the President's Reorganization Project (PRP) to avoid duplication of effort and to assure mutually compatible proposals and time schedules. Reorganization proposals which may emerge from the various tasks of the Strategy Committee will be developed in close coordination with the PRP.

DURATION OF STRATEGY COMMITTEE

The Committee is being convened initially for a period to extend through calendar year 1978. After completion of the Committee's initial reports CEQ will determine, in consultation with patricipating agencies, whether the Committee will continue its activities after 1978. In any case, this Committee's purpose will be to develop policy initiatives, not itself to operate programs.

METHOD OF OPERATION OF STRATEGY COMMITTEE

METHOD OF OBTAINING INFORMATION

The Strategy Committee's activities will focus upon three major areas of concern: Research activities, information and data activities, regulatory and non-regulatory approaches.

The Committee will obtain information on these matters from the interested public, from members of the Committee individually and collectively, from the output from tasks and sub-tasks coordinated by assigned lead agencies, and from review of previous relevant studies.

At the onset of its work, a strong effort will be made by the Committee to solicit the views and suggestions of the public and Congress. The Committee will publish its work plan in the FEDERAL REGISTER and invite comments on the scope and emphasis of the Committee's activities and on specific aspects

of the problem that should receive special attention.

Commentators will be encouraged to present their concerns in terms of known problem areas and how improvements might be made in the future, with reference to specific case histories as appropriate.

As work on specific tasks progresses, public meetings will be held for information gathering purposes as needed, and to obtain comments on draft reports and recommendations. Public participation at these stages may also include solicitations for comments in the FEDERAL REGISTER and by direct mailings.

Shortly after initiation of the Committee's activities and publication of the work plan, a series of initial meetings will be held with representatives of industry, environmental and other interest groups, State and local governments, and the scientific community. Appropriate members of Congress and congressional staff will be consulted concerning their perceptions of needs that led to the passage to TSCA and past and current issues affecting the Executive Branch that are associated with TSCA and other legislation. Informal liaison will be maintained with all of these groups throughout the duration of the Committee's activities.

MEETINGS OF THE STRATEGY COMMITTEE

Meetings of the full Strategy Committee will be scheduled by the Chairman. Additional meetings may be requested by any member agency.

ACTIVITIES OF SUB-GROUPS

Lead agencies have been assigned to the various tasks and sub-tasks of the Committee. The lead agency for a task will arrange for appropriate participation by other agencies and schedule the necessary meetings. The lead agency shall consult with the Chairman and/or Executive Secretary of the Strategy Committee concerning agency participation, work plans, timetables, and meetings. CEQ staff will assist the lead agencies in preparation of common formats and instructions for requests for information to the various agencies and in identification of findings from past studies and interagency efforts that are relevant to the tasks.

TIMETABLE

The Committee plans to take actions and to make reports on its various tasks during calendar year 1978, with an overall status report on all of its activities to be issued in the fall of 1978. Substantial progress on many of the tasks is expected by early 1978. The overall timetable of the Committee's activities and status reports will be distributed regularly to participating agencies by the Committee's Executive Secretary after consultation with the agencies involved in the various tasks. Member agencies plan to follow the schedule unless changes to that schedule are adopted by the Committee. Detailed work plans and timetables may also be needed for some of the tasks and will be developed by the lead agency, in consultation with participating agencies and CEQ.

Every effort will be made to meet major milestone targets, but some adjustments in interim deadlines may be adopted in order to provide earlier initial recommendations on priority topics identified in the course of the investigation, prior to completion of the full investigation; or in order to respond to changes in emphasis suggested during the course of consultation with the public; or in order to coordinate with the work of related committees and groups.

INITIAL STRATEGY COMMITTEE TASKS

I. RESEARCH ACTIVITIES

The Committee will examine the research roles of various governmental organizations; identify major areas of research that should be emphasized; determine how areas for priority attention are or should be selected; and recommend a basis and procedure for coordinating and carrying out such research and utilizing the results.

Task 1A. Assessment of research roles and responsibilities (NSF lead). The first step of this task will be for each appropriate Federal agency to submit a report on its existing research priorities and programs of basic, applied and policy-relevant research, testing and monitoring to include the following subject areas:

(1) Dispersion, presence, transport, evolution and accumulation of toxic chemicals in the environment.

(2) Human exposures, including different routes of exposure, and human health effects of toxic chemicals, including individual variations in susceptibility.

(3) Mechanisms of action of toxic effects in man and experimental animals, and the development and testing of animal models that predict human health effects.

(4) Aquatic ecological and environmental effects of toxic chemicals, including effects on sport and commercial fisheries and freshwater or marine flora and fauna.

(5) Terrestrial ecological effects of toxic chemicals, including effects upon individual plant and animal species and upon ecosystems (e.g. agricultural crops, wildlife, grasslands, wetlands).

(6) Mechanisms for the prevention, mitigation or elimination of hazards caused by toxic chemicals.

(7) Impacts of alternative control measures, including socioeconomic effects.

(8) Miscellaneous other research, including programs covering more than one of the above categories, such as studies of the total effects of a given toxic chemical or class of chemicals.

These reports will be prepared according to common formats developed by CEQ staff (in consultation with NSF) and will be of a summary and analytical nature rather than be detailed inventories of individual research items. Topics to be covered concisely in the reports include the following:

Nature of charter or legislative mandate for the research activities;

Current and future research objectives and priorities and how these are established;

Methods for research planning;

Organization for research management;

Description of major research programs (and current and planned levels of effort) and appropriateness and adequacy of these programs;

Methods of funding research and research facilities and the resources available;

Mechanisms for quality control and evaluation of research;

Current and anticipated research management strategic problems;

Assessment of research coordinating mechanisms, within the agency, with other research activities within and outside the public sector;

Recommended mechanisms for research consideration and for linkages between research and regulatory programs.

The Interagency Regulatory Liaison Group will be looking at many of these same issues for its four member agencies. Following receipt of the above information from the IRLG and the other agencies, the lead agency for this task (NSF) with the assistance of other member agencies[1] will pull together the assembled information for each of the eight subject areas listed above and will prepare an analysis of the Federal-wide situation for the full Committee's consideration. This will be the basis for Committee actions and recommendations concerning the adequacy, quality and coordination of Federal research activities relating to toxic chemicals.

Task 1B. Assessment of research activities in context of regulatory and policy needs (Strategy Committee lead, with input from IRLG). Insufficient linkage between regulators and researchers is an often-cited problem that has not been fully assessed. Regulatory agencies (IRLG) will outline their needs for research to support their decisionmaking that present research programs cannot fully address. The Strategy Committee will review its assessment of Federal research programs, roles and responsibilities (Task IA) and evaluate the ability of Federal research programs to meet regulatory and policy needs within a balanced overall Federal research program. The Committee will focus not only upon the provision of needed research and its adequacy but also upon ways to improve the incorporation of the results of such investigation into regulatory decisionmaking. Issues for particular attention include the following:

Present and desirable roles of regulatory organizations versus research organizations in the planning and design of research programs;

Mechanisms for coordination betwen researchers and regulators in both research planning and sharing of results;

Apportionment of research among various sectors of the research community (Federal laboratories, academic institutions, private profit and non-profit institutions);

Balance between short-term and long-term research;

Influence of regulatory timetables upon quality and design of research and its utilization;

Factors affecting the relative emphasis given to research relating to prevention of chemical hazards from entering the environment as opposed to mitigation of existing toxic hazards.

The Committee will establish priorities for improvements needed to carry out its recommendations.

II. INFORMATION AND DATA ACTIVITIES (CEQ LEAD)

The research, recordkeeping, and reporting requirements specified in the Toxic Substances Control Act of 1976 and in related authorities are extensive. These data requirements include information on production, testing, characterization, adverse reactions, exports, employment effects, health effects, and environmental effects. The production of these data involves the responsibilities of more than 32 Federal agencies. Moreover, enactment of TSCA has raised the expectation that now the many diverse Federal activities under various legislation can be coordinated in a comprehensive program.

If timely and accurate data are to be collected with the least possible burden on business, industry, and the public, steps must be taken to coordinate the planning and activities of the major Federal producers and users of chemical data. This coordi-

[1] E.g., OSTP and OMB on general analysis; Commerce on transport, HEW on health effects, Interior on aquatic effects, USDA on terrestrial effects, EPA on prevention mechanisms and impacts of controls, and others as appropriate.

nation will require a comprehensive inventory of what agencies are producing what data, by what means, and for what purposes. In addition, attention must be given to barriers that can impede interagency efforts and exchanges of information. Among those barriers are confidentiality provisions that protect identity and trade secrets; the lack of a standard method for classifying chemical substances and uses; and a lack of standard formats for reporting such items as the results of toxicological and epidemiological research.

Task IIA. Review of options paper on trade secrecy and confidentiality of trade secrets data. This task will be carried out for the Committee by a subcommittee on trade secrets and confidentiality (formerly a part of the Ad Hoc Interagency Toxic Substances Data Committee).

Current laws and practices restricting release of information by Federal agencies to other agencies and to the public and are not uniform. The subcommittee, assisted by CEQ staff, will prepare a report evaluating these laws and practices and presenting options for needed improvements, which will be the basis for the full Committee's actions and recommendations in this area. Issues to be addressed include the current ambiguities inherent in existing law on the definition of trade secret or confidential material, the need for uniform and fair criminal sanctions for disclosure of such information, and the implications of removing certain restrictions on interagency exchange of information.

Task IIB. Assessment of mechanisms for addressing information needs and their impacts (Strategy Committee lead, with input from Data Committee, IRLG and Commerce). The Strategy Committee will have the benefit of a report by the Ad Hoc Interagency Toxic Substances Data Committee (or its successor) concerning the needs of Federal agencies for various types of chemicals-related data; the adequacy of existing Federal data systems to meet those needs; and methods and policies for improved exchange of information among Federal agencies. The IRLG will study the area of reporting and recordkeeping requirements and will make recommendations for necessary follow-up; it will also be working on development of compatible testing standards and guidelines. Following review of these reports and activities, the Strategy Committee (with the special assistance of Commerce) will evaluate the adequacy of current efforts relating to chemicals information. The Committee will also look at the impacts on industry, environmental groups, and other interest groups of the various information requirements and programs.

III. REGULATORY AND NON-REGULATORY PREVENTION AND CONTROL APPROACHES

Federal authority over hazardous chemicals now extends over the entire life cycle of chemical products prior to production through disposal and for the first time permits the development of comprehensive preventive regulatory and non-regulatory strategies. Critical needs for design and implementation of such strategies will be addressed by the Committee, in close coordination with the IRLG. The IRLG has completed a review of statutes including triggering mechanisms and is reviewing mechanisms for regulatory action and suggesting regulatory priorities. In addition, the IRLG will look at gaps and overlaps in Federal labelling requirements. (The Strategy Committee will later determine, based on the IRLG's initial work, what further study is needed, if any, of coordination of labelling regulations or of the efficacy of labelling as a preventive toxics strategy.) The focus of the Strategy Committee's initial effort will be on the following tasks:

Task IIIA. Analysis of Historical Lessons as Background for Strategy Development (Committee/CEQ lead). The Committee with the assistance of CEQ staff will review various case studies that have been carried out by agencies, interagency groups, the National Academy of Sciences or others, which examined the governmental reaction to and handling of potential hazards of specific chemicals. The review will include information gathered in previous agency public hearings and congressional testimony, as well as information collected by this Strategy Committee in its own meetings with the public and representatives of interested groups. These case studies will be reviewed by the Committee for insights they provide into the coordination, uniformity and effectiveness of the current Federal approach to chemical hazards and as input into Committee findings and recommendations on such matters as the following:

Adequacy of mechanisms by which agencies seek out and become aware of potential future hazards at the earliest possible stage;

Methods for coordinated Federal determination of which chemical substances should receive what type and level of attention;

Once a potential hazard is identified for attention, what procedures are appropriate for gathering information on the extent and nature of the hazard and its effects; for planning and coordinating further research needed to fill information gaps; for establishing a proposed timetable and plans for decision-making; for developing policy options and assessing the likely impacts of those options; for considering factors other than health and safety in regulatory decisionmaking (e.g., availability of substitutes, product utility, impacts of regulation on industry, etc.); for obtaining and allocating resources for these activities; and for coordinating activities of multiple agencies;

Adequacy and effectiveness of present methods for involving the public in regulatory decisionmaking, including alerting the public to pending issues and providing for the participation of private citizens, state and local governments, industry, environmental groups, and other interest groups.

Task IIIB. Policies relating to common approaches for risk assessment (CEQ lead). The desirability of common approaches by Federal agencies to the scientific and technical assessment of certain risks is currently receiving increased attention within the Federal Government. It has been observed that differences in approach toward risk assessment among the regulatory and research agencies have posed barriers to effective cooperation in regard to specific substances and have resulted in some confusion in the regulated industries and among the public. Furthermore, the public dialogue concerning chemical hazards, particularly as they affect human health, has frequently been obscured by the lack of distinction made between scientific methods and principles relating to the detection and measurement of potential hazards on the one hand, and the social, economic, political, legislative, judicial and other factors affecting policy and regulatory decisions on what action to take in regard to a possible hazard once it has been identified. There appears to be a need for greater coordination of Federal agency approaches and for better communication of the reasons for these approaches to the public.

The initial high priority task of the Strategy Committee will be to develop a single set of general principles relating to carcinogenesis for government-wide adoption and use. These principles will be brief statements of the generally agreed upon ways that scientists and agency policymakers view the detection of carcinogenic risk, considering the limits of the present state of the art. For example, the principles would cover the appropriateness of the use of animal laboratory studies in predicting human health risk; handling of dose levels in regard to animal studies and extrapolation to various exposure situations; assumptions about dose-response relationships and threshold levels; the role of epidemiological studies, and others.

This is only a first step in addressing strategies relating to risk assessment. The general policies will need to be backed up by development of detailed policies and procedures, across agencies and within specific agencies. A Risk Assessment Work Group of the Interagency Regulatory Liaison Group is working on analysis and development of alternative procedures for characterizing and quantifying human health risks associated with regulated chemicals. This work will be taken into consideration by the Strategy Committee in addressing government-wide strategies and policies. Topics for the Strategy Committee's attention will be further defined following completion of the initial task on carcinogenesis principles and a review of the IRLG's progress at that time. Future efforts may involve attention to mutagenesis and/or teratogenesis in addition to carcinogenesis.

Task IIIC. Review of non-regulatory incentives for chemical substances control (Commerce lead). Opportunities to strengthen or introduce new non-regulatory approaches to encourage voluntary adoption of preventive practices include market disincentives or incentives (e.g., workers' compensation, tort claims), education and training (for workers and users of hazardous chemicals), consulting services (e.g., on test methodologies, control equipment, monitoring methods) and others.

This task will include the analysis of strengths and weaknesses of such mechanisms and the development of recommendations as to what measures are needed and what form they should take. This effort will be closely coordinated with and make use of the work on non-regulatory incentives being developed by the DOL–OMB task force on occupational health programs, the Interagency Regulatory Liaison Group, the Regulatory Reform Division of the President's Reorganization Project, and research projects of the various agencies.

Task IIID. Recommendations for handling of crisis chemicals (EPA lead). Recent events such as the Kepone and PBB incidents highlight the need for establishing a means for responding to unanticipated but inevitable chemical crises. This task will include identification of the long- and short-term needs for dealing effectively with such crises and an assessment of the adequacy of present Federal programs in meeting these needs.

Recommendations will be developed with respect to (1) mechanisms for mobilizing the diverse Federal resources currently available for assessing, abating, and preparing for contingencies and (2) the need for new authorities, interagency agreements, or other coordinating mechanisms to establish a responsive Federal program.

7/20/78

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A status report is being prepared on the Committee's activities. It will be available by the end of this year and it will cover our initial analyses and the resulting actions and recommendations.

At that time, the decision will be made as to whether the Committee will continue beyond the end of this year.

Because of the Committee's timetable, draft subcommittee reports are just now being completed for submission to the full Strategy Committee. At this time, we haven't reached any conclusions, but I can certainly describe to you the issues which the Committee is now addressing.

In the research area, we are carrying out an analysis of all the research that is being done within the Federal Government to support toxic chemical regulation. We are looking to see if the research is related to regulatory needs and if it is responsive to those needs. That work is being carried out with a lot of assistance from the National Science Foundation.

I don't want to suggest we are doing an indepth job of looking at all the various research programs, but we are trying to get a general overview of the type of research that is being done and its relationship to regulation.

We have also recently begun looking at an analysis of the restraints on recruiting and hiring scientists in Government and on making scientific personnel available to work in the regulatory agencies.

In the area of data and information, a subcommittee of the Strategy Committee is developing consistent Federal policies for handling trade secrets and confidential information. The objectives are to remove impediments to the use of information by agencies in decisionmaking and to the exchange of information among agencies and to permit access to data by private parties with the right to know while at the same time affording adequate protection for legitimately confidential information.

The subcommittee is analyzing existing Federal laws and practices, and we expect to recommend both administrative and legislative changes to overcome the problems that we are finding which inhibit the sharing of this vital information.

The three issues in particular that we are addressing are the sharing of confidential information among agencies and between agencies and contractors; rulemaking using a record containing confidential information; and the handling of health, safety and efficacy data.

The issues that have been identified for possible subsequent analysis include the sharing of this information with the States, the disclosure of data to employees, and the disclosure of medical records for epidemiological study purposes.

The related task of evaluating data needs and coordinating data systems of more than 30 Federal agencies into one comprehensive program is being done for the Strategy Committee by an independent permanent body as I mentioned earlier, the Interagency Toxic Substances Data Committee, and I will be speaking about the Data Committee here in just a moment.

Another area of Strategy Committee work relates to regulation directly. We are sponsoring a study by the Environmental Law Institute to examine case histories of past Federal actions to control

toxic substances. The final Environmental Law Institute report is expected this week for review.

The Strategy Committee will also review the efforts of the Interagency Regulatory Liaison Group which I think Mr. Jellinek mentioned earlier. Four principal toxic substance regulatory agencies have come together and are trying to coordinate their regulatory strategies, and we will be looking at how that is doing and reporting to the President and to the public on that as well.

One particular thing that we are looking at in the regulatory area is the developing of a government-wide policy on cancer principles, the principles that are used to assess cancer risk. How do you know a particular substance is carcinogenic and how do you assess that risk?

Fortunately, most chemicals don't have significant adverse effects in amounts that are normally found in the environment and to which people are exposed. But the state of knowledge on how best to assess those that pose an unreasonable risk is imperfect and fraught with questions of scientific and social judgment that are often inextricable.

As the first step in addressing this problem, the Strategy Committee is developing a common set of principles for use, government-wide, for identifying carcinogenic substances and identifying their impact on health. This effort is one of three closely related efforts going on within the executive branch.

The Strategy Committee's work is being carried out at a very broad policy level. The Committee will develop principles which cover how carcinogens should be defined, how much reliance can be placed on animal tests in predicting risks to humans, appropriate animal species to be used in testing, and types of tumors and other lesions used to identify carcinogenic effects.

Once these principles are agreed to by the Committee—and incidentially, a considerable agreement has been achieved over the past several decades by scientific organizations and advisory groups as well as by the government policymakers in this area—CEQ plans to issue a public information document that explains these matters in lay terms in order to enhance public understanding and improve the quality of public debate.

A related effort is that of the IRLG. The IRLG is preparing more detailed guidelines on how to perform cancer risk assessment for use by agency scientists and policymakers.

Finally, each of the regulatory agencies will develop procedures for using cancer risk assessment in their particular regulatory decisions under the procedures and laws of its program.

As you know, the Occupational Safety and Health Administration is currently involved in 2 months of public hearings over its proposed rule for classifying carcinogens in the work place, and the Consumer Product Safety Commission has an analogous process underway. EPA has been involved in this effort for some time.

Another task in which the Strategy Committee is involved is the development of a plan of action for handling chemical spills and other environmental emergencies involving toxic substances. EPA is conducting a complex study involving several interagency task groups. Certain health aspects are being considered by HEW. These analyses will be the basis for the Strategy Committee's attention to the many aspects of chemical emergencies: scientific and technical information,

financing and legal responsibilities and authorities, resource management, public information, contingency planning, cleanup and disposal and other things which the Chairman has been intimately involved in over the years. We are working within a legislative framework which is a very good one, and we are looking to see how to get the most out of that framework and if there are any improvements we can recommend to you.

The second committee in which the Council is heavily involved is the Interagency Toxic Substances Data Committee. Under section 25(b) of the Toxic Substances Control Act, CEQ is required to coordinate with other Federal agencies in studying the feasibility of establishing a standard classification system for chemical substances, and second, a standard means for storing and for obtaining rapid access to information repecting these substances.

The Interagency Toxic Substances Data Committee was jointly established and is jointly chaired by EPA and CEQ to carry out this purpose and other data purposes associated with implementing the Toxic Substances Control Act.

I will submit for the record the charter of this committee and its membership list.

The principal attention of the Data Committee is currently being devoted to the adoption of a standard chemical classification system and a chemical substances information network, which has been the subject of intensive study by the Council, EPA, HEW, Department of Commerce and other agencies.

Section 25(b) of the act, as I mentioned, requires CEQ to report to Congress on the feasibility of the classification and data system within 18 months of the effective date of the enactment of the act.

The report is being submitted to Congress today and I will include a copy for the record.

In a few weeks we will have multiple copies of a published version for distribution to other interested persons. The principal finding of the report is that on the basis of the studies which have been conducted, the Council has concluded that both the standard Federal chemical classification system and an information storage and retrieval system are feasible and desirable.

In the words of the letter which we forwarded to Congress today, the time is appropriate for the Federal Government to proceed toward Government-wide adoption of a uniform system for identifying individual chemical compounds in order to provide unambiguous identification of these compounds and accurate communication of information about them; and

Second, to proceed with interagency collaboration in the design and implementation of a chemical substances information network.

Several means of classifying chemical substances for various purposes are discussed in the report and recommendations are made for further development of some of these. The basic classification system that is recommended for required use as a standard chemical identifier for chemicals and mixtures in Government files is the Chemical Abstracts Service Registry number. The CAS numbering system is presently in widespread use and has over 4 million chemical substances having more than 6 million names. CEQ has negotiated with Chemical

Abstracts and its parent organization, the American Chemical Society, a set of mutually agreeable terms and conditions to serve as a model for future expanded use within the Government of the CAS system.

The study of chemical information needs looked at over 220 Federal agency data systems containing data relevant to toxic substances assessment. Many of these are data banks presently designed to meet only very narrow specific needs or they are duplicative of other data sources or they are difficult to use in terms of extracting relevant information.

A blueprint has now been proposed and accepted in principle by the Interagency Data Committee to develop a loosely coupled network of data bases, including all Federal and many private data systems both existing and planned or proposed for development. The network would be composed of a directly linked series of core data bases plus a series of noncore data bases which are referenced by the core system.

Data included in the network would include all aspects of chemical substances—chemical properties, production characteristics, use characteristics, occurrence of chemicals in the environment and human exposure information, information about health and environmental effects, and standards and regulations affecting them.

Once this system is in place, Mr. Chairman, we will have for the first time a comprehensive Government-wide network that will contain all of the information that is available about hazardous chemicals and what they are doing to health and to the environment, and it will be available in a form which people can use. It is anticipated that the establishment of the network will contribute greatly to the more effective utilization of all of the information that is available.

The development of this network will be evolutionary. Development of some components is already completed or underway and the status of these activities is discussed in the report to Congress; but implementation of such a network is not a trivial task and ultimate design of the network is not yet fixed, and it may require as long as a decade to develop and implement completely all aspects of it.

Numerous technical, managerial and resource issues are not yet resolved and probably many have not yet been posed. We believe at the Council that the task is sufficiently important to be pursued vigorously despite the anticipated difficulties.

My testimony goes on, Mr. Chairman, to discuss the Interagency Testing Committee which refers chemicals to EPA for testing, and I gather that Mr. Jellinek's testimony also talks about the Testing Committee.

The Council is one of the eight statutory members of the Committee, and I will just submit that portion of my statement for the record.

Thank you.

Senator MUSKIE. Thank you very much, Mr. Speth.

Mr. Hayden.

STATEMENT OF ROBERT HAYDEN, LEGISLATIVE REPRESENTATIVE, UNITED STEELWORKERS OF AMERICA

Mr. HAYDEN. I welcome this opportunity to offer some thoughts and some reactions to the implementation of the Toxic Substances Control Act. The United Steelworkers of America has had a deep commitment

to TSCA because of the critical importance it can have in protecting the health of our members as a supplement to OSHA.

The United Steelworkers of America represents a very large portion of the workers in the chemical industry. Their health interests are directly and obviously connected to TSCA. But the protections provided by a strong toxic substances program do not apply to just the chemical industry. In practically every industrial worksite potentially toxic substances are continually being introduced into the worksites. TSCA, thus, reaches just about all of our 1¼ million members throughout the metals, mining and other industries.

After having worked in support of the legislation for so many years during its evolution in Congress, it is frustrating for our union to witness such a slow implementation pace. But, on the other hand, knowing the lengthy, complex and contentious legislative history behind the law leads to some appreciation of the pressures under which EPA is operating in putting the law into action.

I am privileged to be serving as a member of the EPA Administrator's Toxic Substances Advisory Committee. From that vantage point, I have observed what I think is a good faith effort to develop a broad, coordinated policy framework rather than jump into immediate testing and regulatory actions based on ad hoc policy decisions.

Labor's yardstick for measuring TSCA, both the legislation and the implementation, has always been how it coordinates with OSHA and how effectively it fills gaps in the type of protection that OSHA can provide. Thus, from our perspective, TSCA is most important in the area of first, information gathering, that is, finding out what chemicals are being used where and the degree of worker exposure.

Second, testing; OSHA has no authority to require that manufacturers conduct health effects testing;

Third, premanufacturing control; this is probably the most important area to us. OSHA is structured to deal with existing hazards, not to take preventative action with new products or new processes. From a health standpoint, it obviously is far preferable to prevent new sources of occupational illness rather than to regulate only after disease becomes manifest in the work force.

From a regulatory standpoint, it should be far easier to prevent the placement of a hazardous process than to force the reshaping or withdrawal of a process after substantial capital has become committed, and after jobs and customers have become dependent upon it.

For the most part, it is still too early to pass judgment on EPA's performance in these areas because policies are still being formulated. But policy developments are moving rapidly now, particularly with regard to premanufacture authorities, and critical decisions are near at hand.

It is most appropriate, therefore, that these oversight hearings be conducted at this time to explore the directions in which those policy decisions might go. I would like to direct my remarks to several areas where some of the more important of these policy decisions have been, or are being made.

Under the requirements of the statute, the first major task to be undertaken by EPA was the establishment of the initial inventory of existing chemical substances. The inventory is of major significance for two main reasons. It marks the first time that we will have a com-

prehensive base of information on the universe of chemicals to which we are subjecting ourselves and the environment.

One of the things that became evident during the development of the TSCA legislation was that without the new law, there was no way to find out the types and magnitude of chemicals that are in use. The inventory will compile that information for the first time.

According to Assistant Administrator Jellinek's comments before the most recently advisory committee meeting, some 121,000 substances have been reported. There are duplications among these, however, and EPA estimates that the actual inventory will be composed of about 70,000 unique chemicals.

The second major significance of the inventory is that it is the basis for determining what is a new chemical, and thus subject to premanufacture review. By definition, any substance not on the inventory is a new substance.

Hence, a builtin incentive existed for chemical manufacturers to make sure that the inventory is thorough so that their product would not needlessly be subjected to the special procedure and scrutiny which will be applied to new substances.

The statute required that this initial inventory be completed rather rapidly because the premanufacture review procedure could not be activated until the inventory was in place. Yet EPA is late with the inventory, forcing delay in the preventative, premarket mechanism.

The statute required the inventory to be published in November 1977. The inventory is now expected to be published more than a year later, at the end of 1978 or beginning of 1979. The delay is regrettable but, at least to some extent, probably necessary. It was necessary in that the inventory got off to a bad start due to overly restricitve policy options that were chosen at the outset, and which had to be corrected midcourse.

The agency's initial policy was to collect only chemical identifications in the process of compiling the inventory. In contrast, labor and environmental groups urged that additional information, such as quantities produced, production locations and number of workers exposed also be collected at the same time.

We argued, unsuccessfully at first, that such information was necessary to make a meaningful data base for setting priorities for testing and regulation and for responding quickly to emergency situations.

While this additional information could possibly be obtained at some unspecified later date through section 8(a) authority, it made no sense not to obtain it at the outset when it could most easily be integrated into the data system, and since it would mean only the most minimal increased burden for companies who would be filling out inventory forms anyway.

Furthermore, the statute exempts small firms from section 8(a) reporting requirements. Therefore, unless this additional information could be incorporated into the initial inventory, it would never be obtainable from small chemical firms.

It was not until the appointees of the Carter administration and Mr. Jellinek arrived at the agency that this policy was turned around. The preparations for the inventory regulations were stopped, and ultimately reproposed and promulgated so as to in clude the submittal

of information on production quantities and production locations (but not worker exposure).

Even with the changed policy in the new administration, though, we did not succeed on the small business issue. Under the final rules small firms are not required to report volume or location. EPA estimates that this will not be a significant loss since under this definition of small business—not more than $5 million in annual sales, and more than 100,000 pounds, of any one chemical—only firms representing 4 percent of the production volume and 6 percent of employment in the chemical industry will be exempt.

Nonetheless, it exempts a surprisingly large number of establishments—80 percent of all chemical firms—and means that we will never get this information from these many small, but possibly very hazardous, small chemical shops.

Once the inventory is published at the end of this year, now new substance can be manufactured without EPA being given at least 90 days prior notification. The agency is at a critical point right now in determining what its policies will be on the types of information it will want to see in the notifications, and how it will respond to that information—or to the absence of the information.

The policy advances that have been made in this area, I think, constitute the most important and probably the most controversial development that has occurred in TSCA's implementation.

For 6 years, the Congress was deadlocked over the issue of whether there should be universal premarket notification, or whether the advance notifications should apply only to a limited, preselected group of substances. Early during the congressional debate the concept of minimal premarket testing for all new chemicals was given up as politically impossible.

The final version of the bill did, of course, contain the universal premarket notification requirement. But when hard thinking began to occur on how to premarket authorities would be implemented, both the agency and the industry realized that certain types of minimal testing would have to be conducted on every new chemical.

Without submitting at least basic testing information, the industry would run the risk of EPA moving to withhold the new product from the market under section 5(e) on the basis that sufficient information is not available to determine unreasonable risk. The general feeling that seems to have emerge within the industry is that this type of uncertainty would be the worst possible situation, and thus EPA should set forth a policy on what type of information would be sufficient as part of a premanufacturing notice.

It should be emphasized that the guidelines would not be mandatory, and manufacturers could ignore them when they submit their premarket notices. Doing so, however, would increase the risk they run of having EPA determine that insufficient information exists on the new substance, and that marketing would be held up.

EPA is in the process now of determining those guidelines. The controversy springs not so much from the emergence of the guidelines concept, but from the details of that guidelines—what types of effects should be examined for which reasons.

The subject is still very much a moving target within EPA, so it is hard to make a firm evaluation. It seems, however, that the agency is moving in the right direction. EPA seems to be on the track of fixing a very broad "base set" of effects for which tests should be conducted and which can give preliminary or predictive information for all important risk forms, and of paring back on the base set only where it can be shown that a particular risk is not relevant to a particular new substance.

The base set should not be limited by nonrisk factors. EPA's background circular on the issue, dated July 7, 1978, lists as examples of inappropriate limiting factors the costs of the tests, the size of the company and production volumes exclusive of exposure consideration.

In other words, small volumes but with worker exposure should be fully tested. According to EPA's Draft Guidance for Premanufacture Notification dated July 13, 1978, the health effects that must be examined under the base set would include acute toxicity, subchronic toxicity and the potential for chronic effects, birth defects and reproductive effects, and genetic and cancer potential.

If EPA remains on this course, it is likely to come under two types of pressures. One is to narrow the initial base set so that fewer effects are examined at the initial stage, possibly through tier testing schemes which have more limited tests in their first tiers than EPA has in its base set.

The second pressure will be in making the guidelines overly flexible, and allowing unjustifiable deviation from them. EPA has thus far felt that narrow initial tiers are not adequate to be predictive for all types of risks and, therefore, has suggested the broader base set.

As for flexibility within the base set, the July 7 paper mentioned a moment ago indicates that EPA's current intention is to require well justified, risk assessment associated reasons for any deviation from the guidelines.

However, flexibility necessarily implies the use of subjective decisions and it is impossible to know for certain how EPA will apply its own criteria. This is an area which may be appropriate for close congressional oversight. Overflexibility would make the whole guideline exercise ineffective.

We feel it is imperative to make sure that the initial testing is broad enough to indicate whether or not longer range testing should be conducted for any type of health risk.

For instance, a new substance being introduced into the workplace may result in very low, yet very long-term exposure to workers. Therefore, testing must be conducted not only for acute effects, but also to determine whether there might be chronic effects which might raise the need for EPA or OSHA regulation.

Similarly, workplace exposure always means the possibility of exposure to women of child bearing age and, hence, should lead to testing for human birth defects.

The best way of assuring that adequate testing will be done for the new substances is to rely on section 4 test rules rather than discretionary guidelines under section 5. To a certain extent, this can be done, and EPA maintains that it ultimately intends to do so, through establishing test rules for categories of chemicals. However, this is likely

to be a long way off and it is unlikely that all chemicals could ever be fully covered.

The testing issue, whether through standards or guidelines, seems to raise two lines of complaint from industry. The larger companies are likely to say that the problem is not one of affordability, but of necessity. They can pay for the testing, but they feel that in many cases the testing is a waste of time.

We feel strongly that we must start with the assumption that in every case the broadest possible testing must be done. EPA cannot make its determination of "unreasonable risk," and OSHA cannot make its determination of health protection, unless they know the full range of the risks.

If a manufacturer is to escape testing for a particular type of risk, he must be under a strict burden to show that the substance will not result in any possibility of that type of risk occurring.

The smaller companies, on the other hand, are likely to stress that they cannot afford to conduct a broad range of tests as contemplated under EPA's base set. I have no idea whether this claim is true or not But if there is some truth to it, we cannot let that fact override the scientific fact that certain information is needed to make scientific determination on the existence or nonexistence of risk.

If economic adjustments must be made, it should not be to lower the test requirements, but to make economic or testing aid available to those companies for which the testing is financially impossible. I urge that the Congress fully investigate whether such aid might be necessary and, if so, how it might be applied.

It would be far cheaper for society to assist in some of the testing than to incur further health and other social costs which are sure to result if we fail to do adequate testing. The cost of prevention is far preferable to the cost of compensation.

The premanufacturing section of the law, section 5, raises another very large issue—confidentiality. Section 14A prohibits from public disclosure any proprietary information EPA obtains from manufacturers.

In establishing the inventory, EPA found around 2 percent of the chemical identities were claimed to be confidential, and provisions were made to keep them out of the public's reach and away from competitors.

The situation takes on mammoth proportions in premarket notifications, however, EPA estimates that in the neighborhood of 80 percent of all notifications will be claimed as trade secrets. The manufacturers claim that in a premarket situation, chemical identity of the new product is especially sensitive information.

On the other hand, section 14(b) says that the confidentiality protection will not apply (with certain exceptions) to health and safety studies that are submitted to EPA. The testing which EPA hopes all manufacturers will conduct for new chemicals under the premanufacturing testing guidelines fall within the definition of health and safety studies.

Thus, if the test guidelines are compiled with, and if it is determined that the tests are meaningless to the public without the specific chemical identity, the act might seem to require that the companies' confi-

dentiality claims are to be overridden. A policy of releasing the information to the public, as a result, could discourage the companies from complying with the test guidelines.

In other words, we could see a conflict not only between trade secret claims and the public's need to know, but also between two public needs—the public's need to know and the public's need for companies to conduct adequate premarket testing.

I am not prepared at this time to offer a solution to this dilemma. Numerous suggestions have surfaced, however, including allowing restricted access to the confidential information by groups with a bona fide interest in health investigation rather than market competition—similar in concept to EPA's solution to a somewhat analogous problem with the inventory—use of generic names which are generic only to the extent necessary to mask the critical part of the chemical identity, and maintenance of full confidentiality but on the condition that additional health and safety data be developed and submitted to EPA.

It is important that Congress be aware that this could be a major problem for labor unions and environmental and health groups in their efforts to monitor EPA's and OSHA's use of premarket information to prevent occupational and public health hazards.

Finally, Congress should be aware that international pressures have begun to materialize to have the United States relax the TSCA program, and these pressures are likely to build in the future.

In other environmental programs, like OSHA and the Clean Air Act, the industrial process is regulated. To the extent that process control has an impact on international commerce, it is to give an incentive for our producers to move to countries with lesser requirements.

TSCA, on the other hand, regulates the product, not a process, whether it is produced overseas or domestically. Countries which export chemical products to the United States are becoming concerned that the stringency of the U.S. law will harm their export market.

The member nations of the European Economic Community are currently considering a proposed chemical control law of their own, which is much less stringent than the TSCA. European countries have voiced an interest in "harmonizing" the United States and European toxic control systems. I fear that what they mean is lowering the controls to the lowest common denominator.

We must prevent such a curbing of our effort, and the best way to remove the pressure is to work with the other nations to help them raise their own efforts closer to ours. The OECD is a possible international vehicle for doing this.

Recently, the OECD initiated a program for bringing together experts on six phases of toxics control. We ought to work seriously with this program to assure that it will move in the direction of bringing about the highest possible control efforts by industrialized nations.

We are approaching 2 years since the enactment of the toxic substances law. We would have expected to see testing and regulatory procedures in operation by now. But they are not in operation. This time lapse would indicate a poor record indeed but for the fact that some very significant developments have been taking place as EPA picks its way through the complex law toward a base of coordinated operating policies.

One source of delay was that the change in administration came just as TSCA was beginning to gear-up. The initial delay turned out to be beneficial as initial policy decisions on the inventory were changed for the better.

The time has also been marked by the laying of significant policy groundwork in the premarket area, particularly with regard to testing guidelines which are expected to lead to at least minimal testing for almost all new chemicals. If these guidelines do not become so flexible as to be meaningless, the long wait for implementation may have been worthwhile.

As far as we in labor are concerned, the biggest test of worth will be found in the manner in which TSCA can help OSHA's efforts. The two programs must be coordinated not only in section 9 situations, where regulatory overlaps are dealt with but should be coordinated throughout the entire information gathering and testing functions as well.

OSHA and the National Institute for Occupational Safety and Health both sit on the Interagency Testing Committee, and thus have a formal avenue for input into TSCA testing priorities. But information must also flow in the other direction.

EPA must make sure that provisions are in place to channel pertinent information on workplace exposures and potential hazards to OSHA on a regular basis. This must apply to premarket information as well as information on existing substances.

We will be watching closely EPA and OSHA's performance in this area of information flow and coordination to see how well the toxic substances program lives up to its potential of being a significant force in protecting workers' health.

Thank you, Mr. Chairman.

Senator MUSKIE. Well, you all seem to be satisfied with the ground work that is being laid for action. The question still arises when are we going to get action.

Could I ask a question this way: Are there no chemicals that need immediate regulation?

Mr. JELLINEK. Mr. Chairman, we think that there are some chemicals that need immediate regulation under TSCA. We are busy right now trying to identify those chemicals, and to build a solid case for regulating them.

We are looking at a whole series of chemicals to identify which ones we can regulate without having to wait for the results of an information or testing regulation to come in. What we are trying to do is apply some "seat-of-the-pants" priority setting, so to speak. We are looking at chemicals that pose generally indisputable health risks so we will not have to develop new information to determine whether those chemicals present unreasonable health or environmental risks. We are looking at chemicals that we known have high exposure, that may be ubiquitous in the environment, and that might have a number of different uses.

We also are looking for chemicals that have not been adequately or effectively regulated under existing laws. Over the next few months and into the next couple of years we will come up with a number of presently used chemicals that will be the targets of regulatory action under TSCA.

Senator MUSKIE. What you seem to be saying is that the urgent more obvious regulation will take place with delays up to two years.

How long is it going to take the rest of your system to begin impacting on chemical production?

Mr. JELLINEK. The process that we are involved in now on the regulatory side is to identify candidates for regulation. Once we have identified the candidates, our proposed regulatory actions must then go through the normal EPA rulemaking process. This generally involves proposals and final rules with a number of opportunities for public comment in between.

Once we start a regulatory action, it probably will take as much as a year or so to get a final regulation out. If we identify a chemical this fall, for example, the final regulation might not be out until next fall.

We are starting from scratch though, on chemicals we don't know anything about. We have to develop much of the basic information ourselves; it could take several years, in some cases, because we have to wait for the health effects information to be developed, then we have to analyze it, and, finally, we have to decide how to regulate the chemical.

Senator MUSKIE. What is the time frame involved with what might be generally regarded as the most obvious chemicals needing regulation as soon as possible?

Mr. JELLINEK. Within 1 to 2 years. We are looking at 10 to 20 chemicals right now. We intend to identify a number of them for regulatory action over the next 8 to 9 months. For any given one, it probably will take a year or so to complete the standard regulatory process. If it takes as little as a year, it probably would be a record by past EPA standards.

Senator MUSKIE. I am not sure that is accurate. I think with respect to the clean air and clean water law, regulations have been put in place within the timetables mandated. You are operating outside the timetables that were mandated in the law now.

When will your first regulation take place?

Mr. JELLINEK. Well, we already have taken regulatory action on two: chlorofluorocarbons and polychlorinated biphenyls (PCB's). And, we will be identifying others beginning this fall. As I said, that means the regulatory process would be complete sometime next year, probably late next year for those we identify this year.

Senator MUSKIE. Are there other candidates like PCB's that could result in regulation in a shorter time frame than a year?

Mr. JELLINEK To be perfectly candid, I think that the requirements of the Administrative Procedure Act and the general process of building an effective regulatory case would make it extremely difficult for us to regulate any existing chemical in less than a year, unless we determine, of course, that there is an imminent hazard. Under section 7 of TSCA, we have the authority to act immediately if an imminent hazard is identified.

Once the premanufacture notification and review process under section 5 begins, we will be regulating new chemicals almost continuously. If we decide that either we do not have enough information to make a risk assessment on a new chemical or that there is a problem with it, the regulatory process becomes relatively much faster. I expect that

over the course of the next year we will make a number of decisions on new chemicals that will be regulatory type decisions.

Senate MUSKIE. What does risk assessment mean with respect to chemical substances which constitute a health hazard?

Mr. JELLINEK. The statutory test under TSCA is one of unreasonable risk. If the agency determines that the chemical poses an unreasonable risk to health or the environment, there are a number of regulatory tools we can use against that chemical.

What that means is that we have to go through a risk benefit assessment. We have to determine that the health or environmental risk outweigh the economic or social benefit of the chemical.

Senator MUSKIE. Does that mean you are going to try to establish thresholds, cost-benefit ratios, risk-benefit ratios?

Mr. JELLINEK. No. At this point, we don't think we have either the experience or the knowledge to do that. In fact, we question whether, as a policy matter, it is a good idea to do that.

We are going to try to identify the risks on the one hand and the benefits on the other, and then make a judgment. In many cases it will be a subjective judgment.

We will try to be as objective as possible however. We will try to quantify risks as much as possible and to quantify benefits as much as possible, but we don't think we will be able to compare them necessarily on equal terms. For example, we are not going to try to put a dollar value on a human health risk.

The agency has some experience in the risk benefit area through the pesticide program which has a similar statutory test.

Senator MUSKIE. Now, the burden, then, is on EPA to prove unreasonable risk rather than on the manufacturer to prove there is an acceptable risk?

Mr. JELLINEK. That is generally correct.

Senator MUSKIE. Is that the way it ought to be?

Mr. JELLINEK. First of all, I think we ought to let the act operate a little more to see how it works.

As we interpret Congress intent, we are not dealing with wastes, not dealing with residuals, not dealing with byproducts of an industrial process, as is the case with the Clean Water Act and Clean Air Act.

Under TSCA, EPA must deal with products that someone in society believes have some utility, some intrinsic benefit themselves. While there may be some problems and some undesireable side effects with some of these substances, before the agency can take an action against a product, we ought to take a look at the benefits and crank those benefits into its decisionmaking process. I think that is basically a good idea when you are dealing with a product that to someone has some social utility. Whether or not that proves to be overly restrictive in dealing with what we think are real problems and real risks, remains to be seen.

If it does, we will come back to this committee for further help and guidance.

Senator MUSKIE. With respect to premarket testing, you have a 90-day period, I understand.

Mr. JELLINEK. Yes.

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Senator MUSKIE. You view that as a reasonable amount of time to fully test for the risks?

Mr. JELLINEK We think we are going to have a tough job ahead of us. It is going to present a very tough challenge.

Senator MUSKIE. If you are not able to reach a definitive analysis of risk in 90 days, what happens? Does the manufacturer proceed with manufacture?

Mr. JELLINEK. It is extendable to 180 days for good cause. If we don't take an action within that time period, then the product goes on the market.

Senator MUSKIE. Can you prohibit the manufacture of the product until you are fully satisfied?

Mr. JELLINEK. If we are not fully satisfied that we have enough information with which to make a decision, we can attempt to delay the manufacture of the product. But we would have to do is go to court to force a delay. We can not do that by simply issuing an administrative order.

If we believe that the product poses an unreasonable risk, based on the information available, we have two venues of redress. If we want to ban the product altogether, we have to go to court.

If we want, however, to do something short of banning it—if we want to restrict its use, for example—we can undertake an expedited administrative rulemaking which does not require immediate court action. In these cases, too, Congress has laid down some stringent timing requirements for EPA.

Senator MUSKIE. What kind of testing is involved in evaluating the risks to humans of a chemical substance?

Mr. JELLINEK. A whole series of tests relating to the kind of health and environmental effects that Congress was concerned about——

Senator MUSKIE. Does it involve tests on humans?

Mr. JELLINEK. No.

Senator MUSKIE. Tests on animals?

Mr. JELLINEK. Yes; tests on animals and tests on bacteria and invertebrates.

Senator MUSKIE. Ninety days appears to be a very short period to do that.

Mr. JELLINEK. Well, we have 90 days in which to evaluate the test results that industry presents to us. Industry has as long as they need to perform the tests beforehand that they think are necessary.

Senator MUSKIE. And they submit the results to you?

Mr. JELLINEK. They submit the results to us and we analyze them.

Senator MUSKIE. So you assume there would be some testing of effects before submitting the report to you?

Mr. JELLINEK. Yes.

Senator MUSKIE. But it is not mandated?

Mr. JELLINEK. It is not mandated.

Senator MUSKIE. So you may be presented with some on which no test has been done.

Mr. JELLINEK. If such a case arises, we think we will have a prima facie case of not having enough information upon which to base a decision. If we have to take such a case to court, are are confident most judges will agree with us. We think industry is going to do the recommended testing prior to submitting their premanufacturing notices.

As Bob Hayden said in his testimony, that is one reason we think industry has shown such interest in the development of section 5 guidelines. And that is why even though we cannot —through prior rulemaking—require industry to perform section 5 testing, we are trying to help them decide what kinds of test data EPA will need to make decisions by coming out with testing guidelines for new chemical substances.

As a practical matter, we think there is going to be a lot of testing done in this area.

Senator MUSKIE. Mr. Hayden's testimony expresses concern over the need to use the toxic substances program to assist in protecting workers in the workplace. EPA appears to be quite cautious in this area. Is that a correct assessment? If so, why?

Mr. JELLINEK. I don't think that is quite correct, Mr. Chairman. We are working closely with the Occupational Safety and Health Administration (OSHA) at just about every level. Administrator Costle and Assistant Secretary of Labor Bingham have an extremely close working relationship.

We meet regularly with OSHA staff and we intend to find out what OSHA's needs are at every step of the way as we develop our program under TSCA.

Frankly, we think TSCA's information authorities, testing authorities, and premanufacture authorities are going to provide as much help to OSHA as they will to EPA in carrying out our various regulatory responsibilities.

Senator MUSKIE. Are you planning to collect information on worker exposure?

Mr. JELLINEK. Yes; we are.

Senator MUSKIE. You will do it and not OSHA?

Mr. JELLINEK. Generally speaking, yes. We will do that as an integral part of the information we are going to systematically collect on new chemicals. And we develop information rules on existing chemicals, we have the authority to do so in ways that OSHA does not.

Mr. HAYDEN. If I could add a quick word there, we have never perceived TSCA as a mechanism for setting a workplace exposure standard, that clearly should be the role of OSHA. We want just one agency in the workplace.

The trigger that OSHA uses for setting the health standard is quite different from what TSCA uses. It is based on whatever is needed to protect the health rather than unreasonable risk.

We insisted all though the legislative involvement that OSHA recommend exclusive jurisdiction for setting workplace exposure standards, but there is the need for EPA to provide that information to OSHA so OSHA can make those standards.

Senator MUSKIE. In premarket testing, how will you handle the case where it may not provide accute effects but exposure to employees of low-level exposures?

Mr. JELLINEK. The premanufacture testing guidelines we are working on are designed to provide test data that will give us an indication of probable chronic health effects, as well as accute health effects. We will take appropriate action whenever we receive these kinds of data.

Senator MUSKIE. Now, you described your testing guidelines for new chemicals as nonmandatory. Are there ways in which a statutory authority can be improved?

Mr. JELLINEK. Once again, this is an area where we prefer to have a little more experience with the law before we make any suggestions for amendments. However, there is a connection between the section 4 testing authorities and section 5. Although we cannot require testing under section 5 for all new chemicals, if we have a testing rule under section 4 and a new chemical falls into a category that we have asked to be tested under section 4, then by law that new chemical must meet the testing requirements specified in the section 4 testing rule.

One of the things we are working on and hope to propose late this year are our first testing rules under section 4. These will include rules for testing categories of chemicals as well as individual substances.

Just for discussion's sake let's say that all chlorinated hydrocarbons must undergo these series of tests. That means any new ones that come along and are subject to the premanufacture notification provisions of section 5 will have to first undergo the section 4 tests.

So the act gives us the discretion to identify what we think are potentially hazardous existing chemical classes and to require testing of them as well as of any new chemicals that fall into that same class.

Senator MUSKIE. Have you received any criticism about your proposed testing guidelines?

Mr. JELLINEK. So far we have gotten what I would say is constructive criticism. We have just completed a draft of the section 5 guidelines, though, and I don't think either the industry or the environmental public interest groups have had a chance to sink their teeth into them.

We expect we will be receiving some more vigorous criticism, soon, however.

Senator MUSKIE. Could you describe the rulemaking authority you have, or do not have, under the premanufacturer review program?

Mr. JELLINEK. That gets to the heart of this issue of testing. We can not require testing under section 5 so we are limited to issuing nonmandatory guidelines. Conventional "legislative" rulemaking under section 5 is restricted to identifying the basic information that industry must submit with their premanufacture notices.

One of the concerns we have about TSCA is that we do not have general rulemaking authority for the act as a whole. There are a number of issues that we think we could deal with more effectively if we had the ability to issue "legislative" regulations, rather than interpretive rules under the act. I would expect that if we come back to Congress anytime soon for help, that would be a likely area which would be high on the list.

Senator MUSKIE. In an effort to understand the complexity of the problem and how it cuts across several EPA programs, I would like to ask about Kepone, which is clearly a toxic substance. How would TSCA apply to Kepone today?

Mr. JELLINEK. Kepone was a pesticide, and pesticides are excluded from TSCA's jurisdiction. So the short answer to your question is that TSCA would not have applied to kepone.

But let's say there is an industrial chemical, nonpesticide, that poses similar problems. First of all, under the TSCA section 8 inventory, we would know about the existence of every chemical produced in the country, where it is produced, and in what volume it is produced.

One of the things that we expect to do with the inventory, to the extent that we are not restricted by the need to maintain data confidentiality, is to share information on where chemicals exist and in what volumes they are produced with OSHA and with our EPA regional offices, and, of course, to some extent with the States. So that in a Kepone-like situation, where one of the major problems was the effects on workers, OSHA would know and will know, once our inventory is published, about every chemical that is manufactured in this country, where it is produced, and in what volume it is produced. That will give OSHA an opportunity to identify whether work or health standards are being adequately met in particular plants.

The other major problem that we ran into with Kepone of course, was the water pollution problem. They were dumping it in violation of the Federal Water Pollution Control Act.

By virture of the chemical substances inventory, our regional offices will now know in the case of high volume chemicals where these chemicals are being produced and in what amounts. And they will be able to do some creative surveillance to find out if chemicals are getting into the air or water, based on the knowledge that we will be able to provide through the inventory.

Through other TSCA authorities, such as our information and testing authorities, if OSHA or our regional offices believe there is more they need to know, then we have the authority to get further information. And, of course, the TSCA section 5 premanufacture notification requirements will keep us informed of new chemicals before they come on to the market.

Senator MUSKIE. You publicly stated the inflationary impact of TSCA would be very slight. Can you elaborate on that point?

Mr. JELLINEK. We think that the major impacts in these early years of implementing TSCA are going to result from our information gathering efforts and testing requirements.

We have tried to add up the costs of everything that we think we are going to require, and we just don't believe that these costs will involve the kind of multibillion-dollar impacts that some of EPA's other regulatory programs result in. That is No. 1.

No. 2, we are not necessarily dealing with the total industry. We are dealing with an individual product or a series of products, very often not produced by every single chemical company—as a matter of fact, most are produced only by one or two or a small number of companies. The impact of our actions is going to be on individual companies and on individual products, not necessarily industrywide.

Therefore, we think that the impact of any discreet action will be relatively small. Now, cumulatively, I think we could have a fairly significant impact. I think the cumulative impact of some of EPA's earlier regulations has probably also run into the hundreds of millions. But the impact of any individual rule or regulation or regulatory action under TSCA should not run into the billions or even the hundreds of millions.

Senator MUSKIE. Small businesses have expressed great concern about the cost of testing chemicals. Do you see that as a problem? Do you think EPA should pay for the cost of testing new products?

Mr. JELLINEK. I think that is a potential major problem. One of the things we don't know, frankly, is to what extent small companies are involved in creating new chemicals.

I think we are going to find this out over the next year or so. But to the extent that a small company is extensively involved in creating new chemicals, they are likely to be burdened more severely, obviously, than big companies by our regulations.

We are very concerned about this. On the other hand, we are finding it difficult to develop a scientific or policy rationale that says companies of a certain size should be excused from performing certain tests strictly on economic grounds.

If a small company is developing a chemical that has potentially wide exposure and that could be dangerous, then we think as a scientific and policy matter, we need to know what those potential results are, even if the company is small.

Bob Hayden raised the possibility of some kind of assistance. I think that EPA—and I assume I would speak for the administration on this point—is not ready at this time to agree that any kind of Government assistance is needed.

But we need to get a better handle on this issue over the next couple of years because we are very sensitive to the problems of small business.

Senator MUSKIE. Could I ask Mr. Speth this question? Can you give us an estimate of the number of chemicals which might be recommended for testing each year?

Mr. SPETH. Mr. Chairman, as you know, TSCA permits the Testing Committee to designate chemical substances and mixtures for priority testing which may not exceed 50 on the list at any one time. There have been two Testing Committee reports which have been submitted this year, which together have designated 8 chemical substances and 10 categories of substances. And when you get into numbers in a category, and especially when talking about organic compounds, it is very hard to get a precise fix on what the real numbers are.

In the original Testing Committee submission, there were a series of listings. For example, just to give you an example of what I am talking about, alkyl phthalates is a category of chemicals and can theoretically include a great number of chemicals, depending on what you count. The Committee is only concerned with chemicals in commercial production, however, and recommended for testing only those alkyl phthalates in high production (for example, 10 million pounds per year or more) which currently includes about six.

And cresols, this was another one that could include a number of things. It is had to get an absolute number. The Committee's definition of the category included three substances, I expect that the Testing Committee will continue to make the kind of submissions periodically to EPA that it has.

When you see 8, 9, 10 things on the list, it looks like it is not very long, especially when you see numbers like 70,000 chemicals in an inventory. However, these are often categories, and the number of chemicals could be quite numerous in some cases or could increase with the addition of new substances into commercial production.

Senator MUSKIE. Now, under section 311 of the Clean Water Act, some 300 chemicals have been evaluated and listed as hazardous.

Has your committee made use of the analytical techniques developed under section 311 for purposes of identifying potential toxic chemicals under TSCA?

Mr. SPETH. Well, I am sure there has been coordination between the people doing those two efforts. I think the responsibilities of the two are quite different, though. I am sure, for example, under 311 you are interested primarily in chemicals of known hazard that might be shipped or used in bulk and susceptible to spill into waters, and this kind of thing. The Testing Committee's primary responsibility is to determine those substances that, while the use characteristics are extremely important, we need to know more information about them in order to determine their possible hazard.

As for whether the two lists are comparable in size, I don't know whether the Testing Committee has done this, to really elaborate how many precise chemicals there are if you list everything that is included in the categories that have already been submitted, I could get that information for you. [Mr. Speth subsequently submitted for the record the estimate that the October 1977 listing of 4 substances and 6 categories included about 41 substances altogether.]

Senator MUSKIE. Mr. Jellinek made the point that most of these chemicals have a useful purpose or they wouldn't be submitted for manufacture. Of the 70,000, what proportion might you guess would have side effects that would require regulation?

Mr. SPETH. I wouldn't have the vaguest idea how to answer that. I could try to get some of our technical people to come up with an answer on that. But I doubt if they could either, really, given the state of knowledge about these chemicals right now.

Senator MUSKIE. Should one assume that they all have that possibility?

Mr. SPETH. As you know, Senator, too much salt or too much sugar can be harmful; it varies so much. It depends on what effects you look at. If you look at cancer, I think there is a mythology that if you have enough of a substance it can cause cancer. With the growing awareness that particular substances such as hair dyes and saccharin do cause cancer, people are beginning to say, well, everything causes cancer and maybe we can't worry about it at all because it would bring our civilization to a halt, or something.

In fact, it turns out that only a very small percentage of substances have been found to cause cancer. Of those which have been tested for carcinogenicity, which are often only those chemicals which are suspect, it is considerably less than has been tested. I think it is around 5 percent. So cancer causing capability in a product is a rare property. And the belief that everything will cause cancer is quite erroneous.

Senator MUSKIE. You are attempting to define harmful effects and categorize them, measuring the 70,000 chemicals against your definition of harmful effects, like too much salt?

Mr. SPETH. As you know, I think that is definitely part of the Testing Committee's work; they are looking at the various possible harmful effects. Obviously, as was mentioned here earlier today, some acute effects such as irritation of the skin or the eyes are less important in the activities that we are discussing here today than long-term chronic effects from materials that can accumulate in human or animal tissues.

Senator MUSKIE. Do you have a list of effects that are acute, chronic and otherwise that you could put together?

Mr. SPETH. Yes; I am sure that material could be made available to the committee and we will submit it for the record.

Senator MUSKIE. I think that would be useful. I assume that such a list would be under constant review as you proceed?

[Mr. Speth supplied the following information:]

TYPES OF EFFECTS CONSIDERED BY THE TSCA INTERAGENCY TESTING COMMITTEE

Carcinogenicity.
Mutagenicity.
Teratogenicity.
Other Chronic Effects (e.g., effects on various specific organs such as liver, kidneys, heart, lungs; systems such as cardiovascular, renal, neurological; and behavioral effects).
Environmental Effects.
In addition, specific consideration is given to any types of epidemiological studies in humans which may have been conducted or should be recommended to EPA.

Mr. SPETH. There is one thing I would like to add to your question, Mr. Jellinek, about inflation. It is obviously an extremely serious problem that both Congress and the administration want to address, and in every way we can.

The Council of Environmental Quality with EPA cooperation and assistance has done a series of studies over the years of the inflationary impact of the air and water programs that are now in full swing, and having major financial consequences.

And what those studies have indicated is that the inflationary impact, well, that projected for this year, for example, is about 0.5 percent, and it has been less in previous years.

The range is usually between 0.3 and 0.4. I don't think anybody would advocate eliminating all of these pollution or toxic chemical control programs. What is usually discussed is the possibility of shaving off some of the costs, and if you recognize that even some people who would like to shave off a great deal would only shave off what would be a fraction, a third or a quarter of those total costs, you are talking about a fourth, say, of 0.5 percent.

So in aggregate national terms, you are talking about maybe 0.1, 0.2 percent in an inflationary period where 7 to 10 percent might occur. Also, these figures do not address the fact that benefits result from these programs. including potential deflationary benefits, such as a reduction in health costs.

I think it is helpful to bear that kind of information in mind when assessing the inflationary consequences of these programs.

Senator MUSKIE. Mr. Hayden, in your testimony, you mentioned the international pressures which are building to relax U.S. toxic substances laws. Is there any pressure aboard to enact stronger laws from a group such as yours or are these international forces all for stopping them?

Mr. HAYDEN. I don't know of any programs or proposals that are stronger than ours. Mr. Jellinek has had some direct conversations with some Europeans. He may know of some.

From all the efforts I have seen, their efforts are less stringent than ours. So really if we harmonize we have to bring ours down to their level.

I think it is extremely important to work with the governments and the industries and the labor unions within other nations to have all them realize what we are doing here and how we can solve the problems, to put in place more stringent approaches and try to get them to come along to that higher level of performance.

Senator MUSKIE. What domestic effect would substantial losses of imports of chemical products have? Will the jobs of union members be affected?

Mr. HAYDEN. I really couldn't say. I suppose TSCA could be looked on as a benefit as a nontariff barrier that will help industry in the United States, but I don't know. I don't know of any study that has been done to find out what the effect would be in terms of lost foreign suppliers.

Senator MUSKIE. The New York Times recently ran an article on the American steel industry saying it was besieged by Federal regulation and pollution control requirements. Will the implementation of the Toxic Substances Control Act further besiege the industry, and possibly be used as a reason for further price increases?

Mr. HAYDEN. I don't know that implementation of the act could be used as a justification for price increases. Certainly they have used the regulatory burdens as one reason for the raising of prices.

I think that raises a subject that I feel we should state that is, our union has not felt that environmental, or OSHA standards should be relaxed with regard to the steel industry. The steel industry is having a very difficult time right now in terms of some of the plants which have not been modernized over the years and are vulnerable to imports and to economic downtrends.

But those problems would exist whether there were environmental standards or OSHA standards or not. The removal of those standards wouldn't change the situation.

Senator MUSKIE. You mentioned on page 5, the exemption of small firms who reported the volume of their production and location sites. That exemption, I take it would cover 80 percent of all chemical firms. Is that a serious problem?

Mr. HAYDEN. That is information which EPA estimated would be the effect, 80 percent of the firms, which means there are a lot of very small chemical companies in existence.

Many of those, I am sure, are extremely hazardous. You mentioned Kepone. That is an example of very small business.

I don't know if it would fit in the inventory's definition of small business or not, but in terms of employees it is small business. I think it is important that regardless of the size of the company that we need to obtain better information.

Mr. JELLINEK. I would like to clarify slightly the situation regarding the chemical inventory and small businesses. First of all, no manufacturer is exempted from reporting the fact that he manufactures a chemical.

Businesses with under $5 million net sales were exempted from detailed reporting of production volume for chemicals they manufacture and from reporting their location with the exception that if they manufacture a chemical in excess of 100,000 pounds, then they did have to report that volume.

So as a practical matter, they were exempted from reporting production volumes lower than 100,000 pounds. We think this was a reasonable exemption, and that we can live with that in terms of our regulatory responsibilities because we will know the fact that the chemical is being manufactured by that company and we will know the fact that it is under 100,000 pounds. It would be nice for us to know it was 10,000 or 50,000 pounds. But we don't think this is crucial just now and it will save these small companies from some of the burdens of reporting.

Senator MUSKIE. How would that affect the Kepone situation?

Mr. JELLINEK. I can't say for sure, but I think that Kepone was produced in over 100,000 pounds. I don't know whether that company had more or less than $5 million in net sales. But in any event, that chemical would have been reported if it met the criteria.

Senator MUSKIE. Gentlemen, is there anything else you would like to say before we break up?

Mr. SPETH. Just one thing, Mr. Chairman. I would call your attention to the way that two of these Committees that I mentioned address this problem of relating the work that is one under TSCA to the needs of the Occupational Safety and Health Administration.

The OSHA representatives sit on the Testing Committee and so get to have their say in the substances that are put to EPA. Also, EPA is mandated under section 10(b)(1) of TSCA to establish a committee, and that is that Interagency Data Committee which I mentioned to you earlier. One of the responsibilities of that Committee is to be sure that the information that is developed under TSCA is relevant to the needs of OSHA in its work.

Senator MUSKIE. Thank you very much, Mr. Jellinek.

Mr. JELLINEK. I would like to thank you, Mr. Chairman, I have enjoyed this session. I hope that when we get together again, perhaps; next year or sooner, we will have more real progress to report on under the act.

Senator MUSKIE. I just will make this final statement, that I think there will be people impatient to see the beginning of the regulation for what people regard as the obviously harmful chemical substances.

I would hope that you have that in mind. I would not let the establishment of the process take such high priority as to inhibit you from moving to act in areas where action is clearly needed.

I know that is a generality that you don't always find it easy to deal with. But I think that word of caution ought to be added. Thank you all very much.

[Whereupon, at 12:40 p.m., Thursday, July 20, 1978, the subcommittee was recessed, to reconvene subject to the call of the Chair.]

[Prepared statements submitted for the record follow:]

STATEMENT OF THE HONORABLE STEVEN D. JELLINEK
ASSISTANT ADMINISTRATOR FOR TOXIC SUBSTANCES
U.S. ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE
SUBCOMMITTEE ON ENVIRONMENTAL POLLUTION
COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS
U.S. SENATE
JULY 20, 1978

Mr. Chairman and distinguished Members of the Subcommittee:

Thank you for this opportunity to review the Environmental Protection Agency's (EPA) progress in implementing the Toxic Substances Control Act of 1976 (P.L. 94-469).

Mr. Chairman, one of the major concepts underlying the Toxic Substances Control Act (TSCA) is that the health and environmental hazards stemming from our society's heavy reliance on commercial chemical substances reach into virtually every nook and cranny of modern life. Nothing we touch, smell, consume, or otherwise use throughout a given day hasn't in turn been affected in some way by chemicals.

Relatively little is known about the long-term, chronic effects that result from exposure to many of these chemicals. Under TSCA, however, EPA for the first time has the necessary authority to gather certain kinds of basic information on chemicals, to identify harmful substances, and--when other environmental laws cannot control the specific sources of exposure, which often involve production and use--to control those substances whose risks of injury

to public health and the environment outweigh their benefits to society and the economy. Not only can we prohibit the production and use of such chemicals, but we can take a number of other actions to attack the root causes of toxic substances problems in virtually every facet of industry--product development, testing, manufacturing, processing, distribution, use, and disposal. In essence, TSCA enables us to overcome the single greatest obstacle to finding workable and effective solutions to toxic substances problems. That obstacle, of course, is ignorance. Not only EPA's ignorance, but the public's, as well.

I assure you that we take these enormously difficult and complex responsibilities very seriously. With jurisdiction over as many as 70,000 commercial chemical substances manufactured or processed in up to 115,000 establishments nationwide, TSCA's mandate to protect public health and the environment from unreasonable chemical risks will not be achieved overnight. However, we have set a number of short- and long-term objectives for implementation of TSCA aimed at building a strong, viable program for the future, while vigorously addressing very real and pressing chemical-related problems we face today. These objectives may be summarized as follows:

- Develop the organization and staff necessary to carry out EPA's responsibilities under the Act
- Define methods for assigning priorities to chemical substances requiring investigation or regulation

- Gather information on the production, use, exposure, and other basic characteristics of important chemicals
- Develop testing standards for health and environmental effects of concern, and issue rules requiring testing of selected substances or classes of substances
- Establish a program for premanufacture notification and review of new chemical substances
- Regulate the production, use, distribution, and/or disposal of selected substances or classes of substances
- Develop a coherent Agency-wide approach to toxic substances
- Work toward consistent international approaches to toxic substances control

For the Subcommittee's information, I am submitting copies of an EPA document, entitled Implementing the Toxic Substances Control Act: Where We Stand, which summarizes what we have already accomplished in meeting these objectives.

EPA is working on an implementation strategy for TSCA that will describe our program in more detail. One of our most important reasons for doing so is to give the chemical industry the chance to apply the same or similar principles and priorities to its own planning, decisonmaking, and internal scientific reviews.

We fully recognize that TSCA implementation can contribute to protection of public health and the environment not only through specific rules and regulations, but also through its general influence on the industry to seek less hazardous substances for the marketplace, or to develop acceptable use and exposure limitations to mitigate risks.

I now would like to describe the major actions taken thus far to implement TSCA and some of our plans for the future.

There was only a skeleton toxic substances program within the Agency when Congress enacted TSCA in October 1976. Between Fiscal Year 1977 and Fiscal Year 1978, the Agency's authorized toxic substances staff--which includes abatement and control, enforcement, and research and development--nearly tripled, from 112 to 314 positions. The President's budget for Fiscal Year 1979 proposes that staffing dedicated to TSCA increase 82 percent, for a total of 573 positions.

The number of TSCA-dedicated staff authorized for the Office of Toxic Substances in Fiscal Year 1978 is 196. This compares with 96 positions in Fiscal Year 1977 and 432 requested for Fiscal Year 1979.

The organization of the Office of Toxic Substances includes four Deputy Assistant Administrators, three of whom are responsible for TSCA implementation through the Offices of Chemical Control, Testing and Evaluation, and Program

Integration and Information. The fourth Deputy Assistant Administrator, responsible for the Office of Pesticide Programs, carries out the Agency's responsibilities for regulating pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act. Warren Muir, a Ph.D. chemist and former Senior Staff Member at the President's Council on Environmental Quality, is the Deputy Assistant Administrator for Testing and Evaluation; Marilyn Bracken, who holds the Ph.D. in public administration and is a former Department Head with the MITRE Corporation, is the Deputy for Program Integration and Information; and John DeKany, who has a Masters in engineering and was former Director of the Emission Control Technology Division of EPA's Mobile Source Air Pollution Control Program, is the Deputy for Chemical Control. These three Deputy Assistant Administrators have been with the program since the first of the year. Edwin Johnson, who holds Masters degrees in public administration and economics, continues in the position of Deputy Assistant Administrator for Pesticide Programs. In addition, we have almost completed the recruitment and selection process for eight Division Directors to assist the three TSCA-related Deputy Assistant Administrators. However, only three of these Division Directors have actually reported for duty as of today.

We expect significant improvements in our ability to carry out both TSCA and FIFRA to result from the Administrator's decision early this year to transfer the Office of Pesticide Programs to the Office of Toxic Substances. Many of our responsibilities under TSCA closely resemble those under FIFRA. Both programs regulate chemical substances that may pose unreasonable risks to human health and the environment. And many of the scientific, economic, and other considerations involved in assessing risks and benefits and in choosing appropriate control actions are common to both programs. In the area of hazard assessment, for example, our goal is to make optimum use of the scientific expertise available in both programs. Similarly, by integrating our efforts, we hope to be able to make better use of common support staff for data processing, monitoring, analytical chemistry, and a wide range of other technical and administrative services.

In addition to the program integration under way within the Office of Toxic Substances, an EPA Toxic Substances Priorities Committee has been established to attempt to develop Agency-wide toxics strategies and to set priorities for controlling toxic substances under each of EPA's authorities. I chair this Committee, which includes the Office of Toxic Substances' four Deputy Assistant Administrators and senior representatives from other components of the Agency, including the air and water pollution control programs.

Under TSCA, EPA will assign highest priority to those substances that pose the greatest risk as a function of both toxicity and exposure. This means we are going to concentrate on the most important problems--problems whose actual or potential magnitude present the greatest threats to public health and the environment.

For example, chemicals that may produce chronic or irreversible health effects such as cancer, birth defects, and gene mutations will take higher priority than those that produce acute effects such as eye and skin irritations. Similarly, substances that are widely dispersed in the environment and that may significantly disrupt ecosystems will take a higher priority than those that threaten individual species other than man.

We already have taken, or are in the process of taking, a number of actions to gather the kinds of basic information we need to determine priorities for various chemical regulatory actions. Late last year, for example, we promulgated rules under sections 8(a) and (b) to compile a list of chemical substances and to learn which substances are manufactured where and in what quantities. Final rules governing industry reporting for this inventory were issued in December 1977. Domestic manufacturers and importers of chemical substances had until May 1, 1978, to report the

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initial inventory information to EPA. About 50,000 reporting forms were submitted to EPA in response to the inventory regulations, covering some 125,000 substances. Once we have sorted out duplications in reporting among various companies that make the same substance, we expect that the actual number of commercial chemicals listed on the published inventory could be as high as 70,000. Although considerable work on this project remains ahead for contractor and Office of Toxic Substances staff, we are sticking to our estimates that the inventory data will be processed by the end of this year, and that the initial inventory itself will be published early next year.

Once these inventory data are available, we will be in a position to begin selecting chemical substances and classes of chemical substances for further attention based on their production volumes. Also, publication of the inventory will trigger TSCA's section 5 premanufacture review program, which I shall discuss later in this statement. The inventory data also will be useful in responding to emergency situations and quickly identifying possible sources of exposure to specific chemical substances.

Guidance we have published under section 8(e) provides another channel through which we can identify and address significant problems. Specifically, this guidance encourages manufacturers to establish an internal reporting procedure to insure that EPA will expeditiously receive any new information that reasonably supports the conclusion that a

chemical substance may present a substantial risk to health or the environment. We have already received over 200 substantial risk notices. Because many relate to issues that fall within other statutory jurisdictions, a number of these have been referred to other EPA programs or other Federal agencies for further study and possible action.

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The authority to require chemical manufacturers and processors to undertake testing under section 4 is another important tool we can use to get information about chemicals that is not currently available to EPA or other regulatory agencies. Before enactment of TSCA, few chemical substances in commerce had been tested for chronic, long-term effects. For many substances, additional testing will be necessary to enable EPA to fulfill the objectives of TSCA. In designing an overall approach to testing requirements under TSCA section 4, we intend to obtain the information we need without imposing needlessly burdensome costs or tying up personnel and facilities with excessive testing requirements. Therefore, we plan to rely largely on a tiered set of standards--that is, the need for long-term, more definitive, more costly tests will be determined from the results of short-term, relatively simple screening tests, together with other factors, such as the extent of exposure.

The section 4(e) Interagency Testing Committee has submitted two sets of recommendations to EPA regarding 18 chemicals and classes of chemicals identified for priority testing consideration. We have solicited public comment on these recommendations, and by October 1978 we will either initiate action to require testing for the first 10 Committee recommendations or explain our reasons for not doing so, as TSCA mandates. We have until April 1979 to respond to the second set of eight recommendations.

Under section 8(d) we have promulgated rules requiring all chemical manufacturers and processors to submit lists and/or copies of any unpublished health and safety studies already performed on substances recommended in the first Interagency Testing Committee report. In general, we plan to review results of tests already performed before requiring manufacturers and processors to perform additional tests. We plan to propose similar rules for the second set of Interagency Testing Committee recommendations.

We are especially concerned about the quality of test data submitted to EPA under TSCA. To insure consistently high-quality data, our testing standards under section 4 will incorporate standards for good laboratory practices consistent with those developed by the Food and Drug Administration (FDA). As you know, recent investigations have indicated that data developed on a significant number of pesticide chemicals by a major independent testing

laboratory may be unreliable. These investigations highlight the importance of quality control in the development of test data.

Development of the premanufacture review program is EPA's most critical current activity under TSCA. As provided in section 5, any person intending to manufacture or import a new chemical substance must submit a premanufacture notice to EPA at least 90 days before introducing the substance into commerce. Any chemical substance not included on the inventory of substances compiled under section 8(b) will be considered "new." The premanufacture notification requirements become effective 30 days after publication of the inventory.

EPA is planning to propose a rule governing reporting for new chemical substances early this fall. These rules will specify the types of information to be included in premanufacture notices. We also are developing non-mandatory testing guidelines to insure that industry knows what kinds of evaluations EPA considers minimally necessary to make informed decisions on new chemicals or significant new uses of existing chemicals. These guidelines, along with the section 4 testing standards, will in many cases permit chemical companies to take adequate action on potential chemical hazards on their own without EPA intervention.

The United States' policy on testing and review of new chemical substances has significant ramifications for international chemical trade. Accordingly, we are working

closely with the Organization for Economic Cooperation and Development (OECD) and the European Communities (EC) to develop consistent, compatible methods and requirements for evaluating new chemical substances. In addition, we expect to work closely with the World Health Organization in a new program to evaluate chemicals and to develop assessment methods.

Cooperation on toxic substances control is also occurring, of course, within our own government. In addition to the Interagency Testing Committee required under section 4, TSCA either implicitly or explicitly requires other forms of close coordination among Federal agencies. In response to the requirement in section 10(b), for example, an Interagency Toxic Substances Data Committee has been formed to establish an efficient system for retrieving toxicological and other scientific data available in Federal government files, and to insure that data collected under TSCA are easily accessible, with proper safeguards, to other agencies responsible for regulating various aspects of toxic substances.

Last August, the heads of the four Federal agencies primarily responsible for regulating chemical substances--EPA, the FDA, the Occupational Safety and Health Administration, and the Consumer Product Safety Commission--

formed the Interagency Regulatory Liaison Group (IRLG). The principals and their staff representatives are continuing to meet regularly to coordinate efforts related to testing standards, epidemiology, risk/benefit assessment, information sharing, research planning, regulation development, compliance and enforcement, and interagency communication and public education on toxic substances.

Finally, EPA fully participates in the Toxic Substances Strategy Committee, chaired by the Council on Environmental Quality. I expect that Council Member Gus Speth will give you a complete rundown on this group's activities later this morning.

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Now I would like to turn to the subject of chemical regulation under section 6. While I have mentioned that much of our initial effort in implementing TSCA is aimed at information gathering, we have taken several actions aimed at controlling the production, distribution, use, and disposal of specific chemical substances or classes of substances. Our first action was to promulgate regulations on the labeling and disposal of polychlorinated biphenyls (PCBs). The second phase of PCB regulations, implementing the ban on manufacture and use in any way other than a totally enclosed manner, was formally proposed on June 7.

In a joint action last March with the Food and Drug Administration and the Consumer Product Safety Commission, we have banned most aerosol uses of chlorofluorocarbons (CFCs). EPA now is investigating ways to further reduce CFC emissions, specifically from such non-aerosol sources as air conditioners, refrigerators, solvents, and foam-blowing.

We also are evaluating what regulatory action may be warranted by the risks presented by a number of other important chemicals. Among these are such well-known materials as asbestos, cadmium, benzidine dyes, mercury, lead, arsenic, and trichloroethylene. Over the next several months, we expect that our review of these and other substances will produce prime candidates for regulation.

In the case of cadmium, which has been found to cause chronic kidney damage and possibly other adverse effects, the Administrator has already initiated an informal effort with the Secretary of Defense to limit non-essential military uses of cadmium electroplating. We have found that industry-wide requirements for cadmium-electroplated hardware are largely rooted in Department of Defense and General Services Administration specifications, many of which may no longer be justified by strict military needs.

And with respect to asbestos, in addition to our general review of the need for regulation under TSCA, we are putting together a plan to assess and deal with a specific problem arising from past use of asbestos in ceilings of

schools and other public buildings. As the ceilings deteriorate, asbestos can be released into the air inside such buildings. Although some surveys have been made, the extent of this problem is still not known. We are trying to determine how widespread this problem may be, and to develop a plan for dealing with it. An EPA contractor is evaluating a number of materials that have been suggested for use in coating ceilings to prevent asbestos emissions. This and other possible remedies may provide practical ways for asbestos producers to cooperate in solving this particular asbestos problem. If it cannot be solved through voluntary remedial actions, regulatory action probably will be necessary, as it would be in the case of cadmium.

We have encouraged extensive participation by industry, environmental, labor, and other groups in the development of regulations under TSCA. Development of the inventory reporting regulations, for example, involved 18 public meetings between December 1976 and October 1977. Further, EPA will run a pilot program to fund public participation in rulemaking in connection with the proposed PCB ban regulations.

As a final comment on our implementation of TSCA, I would like to mention our research and development program for Fiscal Years 1978 and 1979. Assistant Administrator for Research and Development Stephen Gage and I have agreed on an $8-million program involving research in the areas

of health and ecological effects, transport and fate, analytical methods, and industrial processes. A key objective is the development of rapid, reliable, and economical testing procedures that can be used as screens in assessing chemical health and environmental risks. In addition, the Office of Research and Development will provide technical support in monitoring and other areas. This component of the program will involve $2.4 million in Fiscal Year 1979.

This concludes my prepared remarks. Thank you.

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUL 20 1978

OFFICE OF TOXIC SUBSTANCES

Implementing the Toxic Substances Control Act:

Where We Stand

Mandate

- TSCA gives EPA authority to identify and control harmful chemicals: those already in commerce and new chemical substances prior to their commercial manufacture

- Responsibilities under TSCA include:

  -- Requiring industry to provide information about the production, distribution, use, exposure, and health and environmental effects of chemicals

  -- Requiring industry to test potentially harmful chemicals for health and environmental effects

  -- Controlling chemicals that pose an unreasonable risk to health or the environment

Scope

- As many as 70,000 chemical substances are currently in commerce

- Perhaps 1,000 new chemical substances will be introduced into commerce annually

- Characteristics of U.S. chemical industry:

  -- Annual sales exceeded $112 billion in 1977

- -- Chemical and allied products account for approximately 6 percent of the Gross National Product

- -- An estimated 115,000 establishments involved in manufacturing and/or processing chemical products are affected by TSCA

- -- The U.S. Chemical and Petroleum Refinery industries employ about 1.6 million persons -- the 170 largest companies account for over 80 percent of total industry employment

- -- The United States maintains a traditional trade surplus in chemicals, amounting to around $6 billion in 1975, 1976, and 1977

Budget for TSCA

- FY 78 budget for toxic substances abatement and control is $22.9 million; $41.6 million requested for FY 1979; as contrasted with $7 million in FY 1977

- FY 78 budget for toxic substances enforcement is $2.3 million; $4.6 million requested for FY 1979; as contrasted with $0.2 million in FY 1977

- FY 78 budget for toxic substances research and development is $3.6 million; $10.5 million requested for FY 1979; as contrasted with $1.4 million in FY 1977

Implementation Strategy

- Key elements EPA considers fundamental to TSCA strategy in the early stages of implementation:

  - -- Defining priorities for selection of chemical substances for early action

  - -- Using actions under TSCA to further effective control of toxic substances under other laws

  - -- Encouraging actions by industry, beyond the actions directly required by regulation, to minimize risks from chemicals

- -- Administering the several provisions of TSCA in a coherent, integrated way

- -- Considering the total risks of toxic substances, including global risks

- Basic objectives of initial TSCA implementation activities include:

  - -- Developing the organization and staff necessary to carry out EPA's responsibilities under the Act

  - -- Defining methods for assigning priorities to chemical substances requiring investigation or regulation

  - -- Gathering information on the production, use, exposure, and other basic characteristics of important chemicals

  - -- Developing testing standards for health and environmental effects of concern, and issue rules requiring testing of selected substances or classes of substances

  - -- Establishing a program for premanufacture notification and review of new chemical substances

  - -- Regulating the production, use, distribution, and/or disposal of selected substances or classes of substances

Organization and Staff

- EPA is developing several major new systems critical to implementation of TSCA:

  - -- Mechanisms for effective review of new chemical substances under section 5

  - -- Data systems for efficient retrieval

  - -- Toxic Substances Priorities Committee, including senior representatives from other components of EPA

- TSCA Abatement and Control staff in the Office of Toxic Substances currently numbers about 180 persons
  - -- 221 positions authorized for FY 78 (includes 31 in Regions), plus 6 for management
  - -- 428 requested for FY 79 (includes 46 for Regions), plus 50 for management
  - -- 99 actual for FY 77
- Enforcement has approximately 15 positions at Headquarters and another 18 in the Regions
  - -- 48 positions authorized for FY 78
  - -- 85 requested for FY 79
  - -- 3 actual in FY 77
- Research and Development is nearly full staffed as FY 78 positions were reprogrammed from other ORD programs
  - -- 45 positions authorized for FY 78
  - -- 60 requested for FY 79
  - -- 10 actual for FY 77

Determining Priorities

- A major immediate objective is to develop a systematic method for selecting chemical substances for investigation or for regulatory action under TSCA
- In all decisions, risk will be determined by considering both the toxicity of a substance and its estimated exposure
- Chemical substances that may produce chronic health effects will take higher priority than those that produce acute effects

- -- EPA will emphasize those whose effects are either irreversible or slowly reversible and debilitating: e.g., oncogenic, mutagenic, teratogenic, and neurotoxic effects

- -- With respect to cardiovascular, respiratory, immunological, dermatological, and reproductive effects, EPA will determine priorities based on the severity and irreversibility of the effects

- EPA will rely on validated test methods that are generally accepted by scientists

- EPA will give high priority to the environmental effects of substances that are widely dispersed into the environment and either indirectly threaten human health, affect commercially important species, or significantly disrupt ecosystems

Information Gathering Under Sections 8 and 12

- Initial inventory reporting regulations were promulgated in December 1977 under TSCA section 8(a); deadline for reporting was May 1, 1978

- Objective of the inventory is to compile a list of chemical substances as required by TSCA section 8(b) and to establish a profile of the chemical industry (what substances are manufactured where and in what quantities)

  - -- The inventory is expected to be published early in 1979

  - -- Premanufacture notification program under section 5 will begin 30 days after publication of the initial inventory; covers all new chemical substances manufactured or imported (in bulk) into the United States

  - -- Processors may add to the inventory during special 210-day reporting period following publication of the initial version early next year

- EPA is analyzing several options for reporting requirements in the near future, in order to obtain necessary information at various stages of hazard assessment and regulatory development

- EPA is planning to propose general rules for reporting production, use, byproducts, exposure and other information under section 8(a); after the general rules are promulgated, EPA would apply them in subsequent rules to individual substances

- Under section 8(c), EPA is planning to propose a general rule requiring recordkeeping for allegations of significant adverse reactions to health and the environment

- EPA published final rules on July 18, 1978, under section 8(d) to require industry to submit results of relevant health and safety testing already performed on chemicals included in ITC's first report (October 1977)

- Final policy guidance on section 8(e), reporting of substantial risk information, was published on March 16, 1978

- Preliminary guidance on section 12(b), notification of export of PCBs and CFCs, was published on June 7, 1978; a final policy statement on section 12(b), which will supercede the preliminary guidance, will be published soon

- EPA is developing an integrated data system for information on chemical substances; there will be full public access to all nonconfidential information, and confidential business information will be strictly protected

Testing

- Testing standards under TSCA section 4 will be directed at specific characteristics and effects, including oncogenicity, teratogenicity, mutagenicity, and other chronic effects, as well as environmental fate, persistence, and ecological effects

-- These standards will be as consistent as possible with those already developed by EPA under the Federal Insecticide, Fungicide, and Rodenticide Act

-- To assure quality test data, the standards will include rules for Good Laboratory Practices that will be modeled after those used by FDA

-- The first standards -- oncogenicity and other chronic effects -- will be proposed this fall; others will follow throughout 1979

- Through separate rules, the section 4 testing standards will be applied to specific chemicals and groups of chemicals

-- These rules will be issued periodically once the testing standards are in place; the first such rule will be proposed late this year or early next year

-- Chemicals and groups of chemicals subject to testing rules will be based on recommendations from the section 4(e) Interagency Testing Committee, EPA's own chemical selection process, and other sources

- Interagency Testing Committee's (ITC) initial report to EPA (October 1977) recommended that priority consideration be given to requiring testing of four individual chemicals (chloromethane, hexachloro-1,3-butadiene, nitrobenzene, and toluene) and six groups (alkyl epoxides, alkyl phthalates, chlorinated benzenes, mono- and di-, chlorinated paraffins, cresols, and xylenes); by October 1978, EPA must initiate action to require the recommended testing or explain why it is not acting

-- EPA will propose testing rules directed toward the effects to be evaluated; the rules will apply to various substances, as appropriate

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- Second Interagency Testing Committee's report issued April 10 -- recommends priority testing consideration for another four individual chemicals and four groups of chemicals: acrylamide, aryl phosphates, chlorinated naphthalenes, dichloromethane, halogenated alkyl epoxides, polychlorinated terphenyls, pyridine, and 1,1,1-trichloroethane; by April 1979, EPA must initiate action or explain its reasons for not doing so

Establishment of Premanufacture Notification

- EPA will publish testing guidelines under section 5 identifying the information it considers necessary to evaluate the risks associated with various classes of chemical substances
- Development of a system for reviewing premanufacture notification is under way in anticipation of the beginning of notification early in 1979 (30 days after publication of inventory)
- Rules for "significant new uses" will follow development of premanufacture notification requirements

Regulation of Chemical Substances

- PCB marking and disposal rules were promulgated February 17, 1978
- PCB regulations implementing the statutory ban on manufacture and use in any way other than totally enclosed manner were proposed June 7, 1978
- Regulations on aerosol uses of chlorofluorocarbons were promulgated March 17, 1978, in a joint action with the Food and Drug Administration and the Consumer Product Safety Commission
- EPA is investigating ways to further reduce chlorofluorocarbon emissions by controlling non-aerosol uses (e.g., air conditioners, refrigerators, solvents), although eventual regulation will be under the Clean Air Act not TSCA

- Ongoing reviews of high-volume, high-toxicity chemicals will produce other candidates for regulation over the next several months

- EPA will run pilot program to provide funds for public participation in rulemaking in connection with PCB ban regulations

State Cooperative Agreements

- $1.5 million is available in FY 78 and FY 79; it will be provided to States under cooperative agreements with EPA

- Funds will be used in a few States for priority programs for chemical risks for which EPA is unable or not likely to take action

- Criteria for these funds are being developed and will be proposed shortly; award of funds is expected in the first half of FY 79

Industry Assistance Office

- Established in January 1977, as required by section 26, to provide technical and other non-financial assistance to industry on TSCA requirements, compliance measures, and Agency policy

- Actions to date:

  -- Letters

     + Over 500 Congressional inquiries answered, plus approximately 500 routine letters (majority from industry) received monthly

     + During the 4-month inventory reporting period, the letter average increased to 3,000 per month with requests for reporting forms and instructions

     + Grand total: 19,500 letters over a 19-month period

-- Telephone calls

+ A toll-free number installed in January 1978 has been used to handle 6,050 calls

+ Approximately 3,750 other telephone requests for assistance have been received

+ Grand total: 9,800 phone calls over a 19-month period

-- Seminars/meetings

+ Planned and helped conduct 32 TSCA inventory training seminars in 28 cities between February 27 and March 17, 1978; more than 3,000 industry representatives reached

+ More than 775 meetings with trade associations and industry representatives held (about 10 per week over a 19-month period)

Relations With Other Agencies

- Interagency Regulatory Liaison Group (IRLG)

  -- Was formed by EPA, FDA, OSHA, and CPSC in August 1977 to facilitate their combined effectiveness in conducting chemical control activities

  -- Eight working groups have been formed on (1) regulatory development, (2) testing standards and guidelines, (3) information exchange, (4) risk assessment, (5) methodologies for epidemiological studies, (6) coordination of enforcement and compliance strategies, (7) research needs, and (8) interagency communication and public education

  -- The results of these specific initiatives, which are currently ongoing, will be used to develop coordinated and integrated approaches in these areas

-- In addition, the four agencies have begun to coordinate their activities in the 10 Federal Regions

- Sections 10(b)(1) and 25(b) Interagency Toxic Substances Data Committee (ITSDC)

  -- Charge is to establish an EPA system for collection, dissemination to other Federal agencies, and use of data under TSCA

  -- Basis will be EPA/CEQ survey of Federal agencies' toxic substances data needs and systems last year

  -- About 18 Federal agencies invited to participate

  -- Serves as mechanism for coordinating Federal toxic substances regulatory reporting and recordkeeping requirements

- TSCA Interagency Testing Committee

  -- EPA is a member and provides support as required under section 4(e)

  -- Purpose is to recommend chemical substances for priority consideration for testing under TSCA

  -- Initial recommendations made in October 1977 and April 1978

  -- Recommendations will be revised at least every 6 months; list not to exceed 50 entries at any given time

Conclusions

- By end of FY 1979, all aspects of TSCA program will be in operation -- although not each at full capacity

  -- Priorities are being set to direct implementation

- Initially more emphasis will be placed on obtaining and analyzing information than on writing specific control regulations

  -- Information is needed for nonregulatory control and for regulation under other authorities as well as under TSCA

- FY 1979 will concentrate on

  -- Premanufacture notification system

  -- Making priority-setting and information systems operational

  -- Developing testing standards and regulations

  -- Conducting hazard assessments

  -- Promulgating reporting and recordkeeping requirements

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

AUG 14 1978

OFFICE OF TOXIC SUBSTANCES

Honorable Malcolm Wallop
United States Senate
Washington, D. C. 20510

Dear Senator Wallop:

I am pleased to furnish you the enclosed answers to your questions about the Environmental Protection Agency's implementation of the Toxic Substances Control Act. I am enclosing several copies to facilitate distribution to other members of the Subcommittee.

I regret that you were unable to attend the recent oversight hearing and look forward to discussing TSCA activities with you on other occasions.

Sincerely

Steven D. Jellinek
Assistant Administrator
for Toxic Substances

Enclosures

ARE THERE A SUFFICIENT NUMBER OF TESTING FACILITIES? WHAT WILL BE THE INDIVIDUAL AND AGGREGATE COSTS OF MANDATORY TESTING?

It is apparent that when it is fully implemented the Toxics Act will demand a substantial increase in the number of testing facilities or the number of people involved in testing.

Question #1: Does EPA have any estimates of the number of facilities and qualified experts which will be required to meet this increased demand?

Answer #1: EPA is required to consider the availability of testing facilities and qualified personnel in implementing the testing provisions of TSCA. The need for testing facilities and qualified personnel cannot be estimated until the testing requirements themselves have been specified in more detail--i.e., which tests and for how many chemicals EPA will require testing. The first few testing rules under TSCA will not have a significant impact on the availability of testing facilities and personnel. Rather, it is the cumulative impact of TSCA testing requirements over the next few years that must be estimated and considered. This is the subject of a comprehensive study currently in the development stage. The results of this study probably will be available late next year or early in 1980.

In the interim, the Agency is considering this question in relation to individual rulemaking activities in order to assure that adequate capacity exists to perform the required

tests. For example, the Office of Toxic Substances is currently examining the question of the availability of testing facilities and personnel as part of the economic analyses of the pesticides guidelines and of the premanufacturing notification rules.

Question #2: Has EPA estimated the probable cost of testing per chemical, as well as the probable total cost?

Answer #2: Testing costs obviously will depend on how many and what types of tests are required. Testing requirements will not be the same in all cases. Even more important is the fact that testing requirements will be selectively, not universally, imposed, as explained in response to other questions. Accordingly, it is not possible to estimate total testing costs related to TSCA implementation. Testing costs and their economic impact will be estimated and analyzed with respect to each testing rule before it is promulgated. As for the cost of individual tests, it can range from a few dollars for simple tests needed to define basic chemical and physical properties, to $200,000 or more for a lifetime test in animals. The Agency's strategy is to make as many judgments as possible on the basis of simple and inexpensive tests, but it clearly will be necessary to require long-term testing of chemicals that may pose significant risks to human health and the environment.

Question #3: What is the likely impact of these additional costs on the economy?

Answer #3: As a matter of Agency policy, EPA conducts analyses of the costs and economic impacts of all major regulations. Testing requirements are no exception to this policy. Although no testing requirements for chemicals have yet been promulgated, when they are, their costs and impacts will have been evaluated.

Question #4: Are these additional costs likely to have a chilling effect on the development of new products or new uses of existing products, both of which will require testing?

Answer #4: There is a possibility that required testing of new chemicals and significant new uses of existing chemicals will have an effect on research and development and commercialization of new products. The Agency is aware of this and will be sensitive to these types of effects throughout development of the TSCA program. The approaches being taken in the development of testing rules and guidelines for premanufacture testing will tend to soften the impact. These approaches are described response to the question on testing costs.

On page 11 of his prepared testimony, Mr. Hayden discussed what he saw as a potential conflict between two public needs: the need to know and the need for adequate premarket testing of chemicals. His contention is that the conflict between these two could create a disincentive for premarket testing by chemical manufacturers.

Question: Could you provide your comments on this?

Answer: There is an apparent conflict in TSCA's provisions respecting confidentiality (e.g., Section 14(a), Section 5(d)(2)), and Section 14(b) concerning health and safety studies. Further, we recognize the possibility that the release of chemical identity as a part of health and safety studies might deter industry from performing such studies. For the following reasons, it is probable that this will not be the case:

- Whether or not a manufacturer complies with EPA's nonmandatory premanufacture testing guidelines, he is required by the Act, specifically by section 5(d)(1)(B), to submit with his premanufacture notice all test data in his possession or control. Thus, unless a manufacturer performs no testing whatsoever, he will be submitting some health and safety studies to EPA. The industry's concern, is that chemical identity will be revealed and thus make trade secrets available to competitors. Accordingly, if EPA were to reveal the identity of chemical substances for which health and safety data are submitted, it will have the same impact on a manufacturer whether he submits one or a dozen health and safety studies.

- Quite apart from EPA's requirements or recommendations, the chemical industry commonly performs some testing of new chemicals, including health and safety testing, for its own purposes. Thus, as explained above, unless a manufacturer performs no testing whatsoever, there will be no particular reason to refuse to perform the tests recommended by EPA while performing others.

- In any event, EPA's preliminary proposals call for protecting the confidential identity of chemicals for which health and safety data are submitted. In accordance with TSCA, generic names will be used in public notices of the receipt of premanufacturing notices, except where more specific identification is required by the public interest. A major issue still to be resolved, one which the Agency takes quite seriously, is how the chemical industry's interest in confidentiality can be served while the public interest in having an opportunity to participate in evaluating new chemicals and monitor EPA's evaluation process also is served.

WHAT IS EPA'S PROGRESS IN COMPILING THE INVENTORY OF PRESENTLY MANUFACTURED CHEMICALS?

As you probably know all too well, EPA should have published inventory list of chemicals manufactured or processed in the United States last November, but failed to do so. It has been said that the principal reason you missed the deadline was that you changed course in mid-stream because you disagreed with the approach taken by the previous Administration.

Question #1: Would you explain first why you felt free to ignore a deadline which was mandated by the law and, secondly, why you missed the original deadline. Is it correct that you disagreed with the approach of the earlier Administration?

Answer #1: EPA's initial proposal was designed primarily to satisfy the explicit requirement for compilation of a list of chemicals manufactured or processed in the United States; chemicals not included in the list are subject to the premanufacturing notification requirement. Thus, it would have ignored the implicit statutory mandate to begin assembling information on chemicals already in use--information needed to begin identifying existing problems requiring EPA action under the Toxic Substances Control Act. EPA's final rules were far more efficient in that they asked the chemical industry to provide in one package information that otherwise would have required at least two submittals.

Question #2: When do you now expect to have completed the inventory list?

Answer #2: The Inventory Reporting Regulations call for two reporting periods; the first began January 1, 1978, and ended May 1, 1978. In that period, manufacturers and importers were required to submit reports. Those reports are now being processed and the data used to prepare an Initial Inventory, which is scheduled to be published in early 1979. Thirty days after its publication, the pre-manufacture notification provisions of TSCA will become effective.

Meeting this schedule allows about six to eight months for checking, correcting, and processing reported information for up to 150,000-175,000 nonunique chemical substances, and a month or so for layout and printing. Each stage of this process--from receipt and through to collation for layout and printing--requires personnel to cope with establishing unique chemical identities for an estimated 70,000 unique chemical substances. EPA and the Chemical Abstracts Service (CAS), which maintains the most extensive known collection of chemical identities, are cooperating closely to ensure the reliable and consistent chemical identification, definition, and nomenclature for these substances.

The most difficult problem entails processing reports for some 34,000 chemicals of unknown or variable composition

which do not have a standard name or CAS Registry Number. The volume of reports of chemicals of this nature is about three times what was originally anticipated by EPA. The processing of such chemicals is a tedious, labor-intensive effort that must be carried out by highly skilled, thoroughly trained chemists. The number of chemists involved in this work must be kept relatively small so that EPA's policies for identifying complex chemicals will be consistently applied. This consistency is essential to make the Inventory as accurate and useful as possible.

Finally, the term "initial" inventory requires an explanation. The first publication of the Inventory will be called "initial" because we will allow a seven month period for processors of chemical substances to check it for any omissions by their manufacturer-suppliers. This two-phase plan means that we have to handle reports from processors only where they know with certainty that the chemicals they use were not reported by any manufacturer of those chemicals, rather than hundreds of thousands of reports from uncertain processors, many of whom would not have known the chemical identities of the substances they purchase. We refer to the second publication of the Inventory as the Revised Inventory.

Question #3: What problems, if any, have you been encountering in compiling the list?

Answer #3: EPA has encountered relatively few procedural problems in compiling the Inventory, but a significant number of technical problems have arisen. Most of these problems are due to the nature of chemicals and the chemical industry, both of which are diverse and complicated. Some of them are due to the special efforts EPA made to facilitate compliance by industry and ensure confidentiality for its submissions.

While EPA accurately forecast the total number of reports, the proportion of complex chemical substances has been much larger than expected. Many of these substances are difficult to identify, making it hard for EPA to evaluate these reports and create reliable descriptions for Inventory. EPA will need to consult frequently with the submitting companies in order to clarify the description of substances and establish their specific identities. In most cases, when the specific identity of a substance is claimed confidential, our chemists are providing assistance and guidance in the development of a suitable generic name for publication in the Inventory.

Also, there are critical distinctions which have been difficult to make except on an individual basis but which determine whether a substance is excluded by definition.

For example, we required reporting on substances but not "mixtures;" manufactured chemicals but not "naturally-occurring" substances; and intentionally made chemicals but not incidental formations.

Regarding confidentiality, which we recognize as critical and normal in business, we instituted some special procedures which have proved time-consuming for EPA although they have facilitated compliance by industry. For example, many importers know only the trade names of substances they import, and many manufacturers know only the trade names of reactants they use in making a substance. The confidential link between the chemical identity and the trade name of imported substances will be maintained. In other words, we include the specific name supplied by the foreign manufacturer on the inventory, but will not reveal the relationship to the U.S. importer. A similar, but more complex situation exists when a manufacturer uses a substance known only by its trade name as a reactant in making a substance he is reporting. Obviously, he cannot report the specific identity of his product unless the identity of the trade named reactant is known. Some 1,600 of these cases have been identified so far. If the two manufacturers cannot negotiate an agreement which will permit the reporting of the specific identity, EPA will request the manufacturer of the trade named reactant to divulge its identity to EPA. We will use this information to prepare a specific name for the reported product, and enter it on the inventory in such a way that the link between the trade name and its identity will not be divulged.

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HAS INDUSTRY COOPERATED IN IMPLEMENTING THE ACT?

The Toxics Act has assigned a very difficult task to EPA: you must protect the public and the environment without smothering free enterprise with excessively burdensome regulations. Obviously, this requires the help and cooperation of all concerned parties.

Question #1: To put it very bluntly, have you found the industry to be cooperative?

Answer #1: For the most part, the chemical industry has been very cooperative. Representatives of numerous companies and trade associations have attended our meetings and submitted constructive comments on our proposed regulations. Most companies reported before the May 1 deadline for the chemical inventory and were conscientious in filling out the report forms. There have been a few isolated exceptions to this cooperative posture, including, for instance, filing of frivolous confidentiality claims in connection with the inventory reporting.

Question #2: If a chemical is not included on the inventory of substances presently manufactured in the United States, it will be treated as a new substance. As a new substance, much more stringent testing and other standards must be met when the product is placed on the market. Obviously, this creates an incentive for manufacturers to rush products into the marketplace immediately. Have you seen a flood of new chemicals coming into the market? Do you believe these new products have been adequately tested?

Answer #2: It is certainly possible that some manufacturers have pushed substances through research and development and test-marketing more quickly than they normally would

in order to make them eligible for inclusion on the Initial Inventory. It should be noted, however, that the development of new chemical substances generally takes many years and cannot always be expedited. In any event, the Agency does not now have information that would enable us to determine the extent to which new chemicals currently are being introduced. After the completion of the inventory, it may be possible to perform a retrospective analysis of the introduction of new chemicals during this period.

WHY HAS EPA EXPANDED THE SCOPE OF THE INFORMATION SOUGHT IN THE INVENTORY:

The first inventory reporting regulations were proposed on March 9, 1977, but on August 8 of that year you re-proposed the regulations. The re-proposal significantly expanded the amount of information which manufacturers and importers must submit. It now includes the identity of the chemical substance; the site of manufacture; and, the location of other manufacturing sites. We have been told that, in addition, you will later collect information on the use or uses of the specific substance.

Question #1: Exactly what information are you collecting and why? To what uses do you intend to put this information?

Answer #1: The information EPA has collected includes company identity, chemical identity, site-specific production data (in ranges rather than exact figures), whether manufacture is site-limited, and whether the chemical is imported. The fundamental purpose is to generate the inventory of chemicals required by section 8(b). In addition, one of our major objectives is to identify, those chemicals in commerce, that should have priority for assessment and action under TSCA. An important step in this process is to identify those chemicals which are produced in greatest quantities. In addition, site-specific production data will provide a locator in the event a substance is identified as imminently hazardous and will reveal patterns of concentrated production which could pose high exposure problems in specific locations.

Question #2: Industry has complained that you have expanded the statutory concept of inventory so vastly that it will cost $130 million to collect the information you want. Do you have any comment?

Answer #2: EPA has seen no hard evidence to support this figure ($130 million), although reporting costs to industry may have exceeded our original estimate of $14.3 million. It is probable that some of these "costs" are not exclusively attributable to the Agency's requirements. A number of chemical companies have indicated that, while compiling the data required by EPA, they also redesigned their information systems and undertook other activities that will be of continuing benefit to them but were not essential to comply with EPA's requirements. The high estimates may reflect inclusion of the costs of such activities, even though such costs cannot properly be attributed to EPA's rules. In addition, many firms now have, for the first time, a complete inventory of the chemical substances they manufacture, production sites, and production volumes.

ARE THE WORKING AND STAFFING CONDITIONS AT EPA FRUSTRATING IMPLEMENTATION OF THE ACT?

With the passage of the Toxics Act, I suspect there was quite an increase in the demand for professionals such as toxicologists. Both EPA and the industry are competing for the same people, but industry probably has more freedom in hiring individuals than EPA.

Question #1: How many of the slots which are authorized have you actually filled to date and how long does it take you to fill a slot?

Answer #1: At the time the Toxic Substances Control Act was passed, there were about 45 persons employed in EPA's Office of Toxic Substances. The staff currently numbers about 190 and will be double that number in FY 79. An aggressive recruiting effort has been initiated and is continuing. In the professional categories, it takes an average of about four months to complete the hiring process. In certain disciplines, such as toxicology, pharmacology, and pathology, there is, of course, competition from industry.

Question #2: What are other working conditions in the Toxics program like? Obviously, if you are short on people, work may not be finished as soon as it should be. Is a personnel shortage slowing the program? Have you received complaints about your slowness in processing information?

Answer #2: There are some areas in TSCA implementation where having larger numbers of experienced people over the past 18 months obviously would have speeded up our progress. In this respect, a more expeditious hiring process would have helped. It also has been necessary to develop an organizational structure and deal with many fundamental policy issues, all of which takes time.

Insofar as working conditions are concerned, the major problem at the moment is the lack of sufficient office space. The Office of Toxic Substances is already quite crowded and cannot continue growing without additional space. EPA is working closely with the General Services Administration to resolve this problem.

Thus far, TSCA implementation has not reached the point at which the time required to process data could have a substantial impact on the chemical industry. There may have been some complaints about slowness in responding to inquiries, but, to my knowledge, that has not been a major problem. The Industry Assistance Office, established in accordance with section 26(d) has done a remarkably effective job in making information available on a timely basis.

IS THERE EVIDENCE THAT SOME MANUFACTURERS ARE FLEEING THE UNITED STATES TO AVOID OUR MORE STRINGENT ENVIRONMENTAL AND REGULATORY LAWS

I have read reports recently of a study done by a Mr. Barry Castleman, who has apparently concluded that the manufacture of some hazardous products is being exported to Third World countries in order to escape regulatory laws in the United States.

Question #1: In your experience in implementing the Toxics Act, have you seen any evidence of such an exodus? If so, can you provide us with some specifics?

Answer #1. I have seen no evidence that the manufacture of hazardous products is being exported to Third World countries in order to avoid our regulatory laws.

Question #2: Do you believe there are provisions in the Toxics Act which could encourage the kind of problem Mr. Castleman described? If so, what are they?

Answer #2: While I have not seen Mr. Castleman's study, there may be some provisions in TSCA that could encourage the type of problem you have described. Section 4, Testing of Chemical Substances and Mixtures, could have this effect. A company could avoid testing of intermediate chemicals (but not the final product itself) by setting up production outside the U.S. and importing the final product into the U.S. Section 5, Premanufacturing Notification, could likewise be confined to the product imported into the U.S. and not intermediate chemicals. Section 6 regulations concerning by-products of manufacture could be ignored, as could some section 8 reporting and recordkeeping rules. However, this is all speculative and since the final product would still be subject to TSCA requirements, I do not think a company would have a great deal to gain by proceeding in this manner. At this time, I have seen no evidence that TSCA is causing the export of production and employment from the U.S.

SHOULD THERE BE A MECHANISM TO COMPENSATE INDIVIDUALS FOR INJURIES SUFFERED FROM INCIDENTS INVOLVING TOXICS?

As you may know, this Subcommittee has recently approved S. 2900, which is commonly referred to as the "superfund" bill. In part, S. 2900 establishes a system to compensate persons who are injured by discharges of hazardous materials. The bill does not address the issue of personal injuries, however, just economic loss. Many of the more widely publicized incidents have involved toxic substances.

Question #1: Is it your experience that persons injured by incidents involving toxic substances are compensated in a timely and complete fashion? Do you believe there is a need for a system of compensation?

Answer #1: EPA has virtually no data as to the extent of timely and complete compensation of persons injured in toxic substances incidents. It is often said, however, and easily imaginable, that there are many cases where compensation is neither timely nor complete. There is no doubt that an improved compensation system is a desirable goal. I am not sure whether a Federal compensation system is needed or whether reform of the judicial system would more efficiently and effectively serve this purpose.

Question #2: If the Congress were to create a compensation mechanism, should it be linked to the Toxics Act or kept separate?

Answer #2: It should be possible to devise a compensation scheme that is not linked to TSCA, at least administratively. In any event, EPA has no particular expertise in this area and probably would not be the best agency to administer such a program.

Question #3: Do you believe we know enough about the whole area--the types of injuries which are inflicted, the extent of damages and other considerations--to construct a compensation scheme?

Answer #3: No, I believe we do not know enough yet to construct a compensation scheme. There are a number of problems in designing a compensation system. For instance, such schemes work best when there is an immediate, clear cause-and-effect relationship (e.g., worker safety or oil spills). With toxic substances, however, there is often a long latent period between exposure and effects which makes it difficult to establish cause-and-effect relationships.

WHAT IS THE IMPACT OF THE ACT ON SMALL BUSINESS?

When you appeared before the Committee last September for your confirmation hearings, we discussed how you would define small business for purposes of implementing the Toxics Act.

Question #1: Have you yet defined what is a small manufacturer for purposes of the Act? If so, what is the definition?

Answer #1: Small business must be defined for purposes of both section 8(a) and section 26(b) of the Act. Small manufacturers and processors are exempt from compliance with section 8(a) recordkeeping and reporting requirements. In addition, under section 26(b), small businesses cannot be required to pay a fee in excess of $100 when submitting data under sections 4 or 5. EPA is not planning, at this time, to implement section 26(b). Thus, the question of what constitutes a small business for section 26 purposes is not being addressed.

EPA has not yet set a permanent definition of "small manufacturer or processor" for section 8(a). But, we are in the process of developing that definition. EPA did promulgate a one-time definition of "small manufacturer or processor" for the purpose of the Inventory rules. While TSCA did not exempt small manufacturers and processors from reporting for the section 8(b) list of chemicals in

commerce (the Inventory), it did exempt them from other section 8(a) reporting requirements that were promulgated at the same time. EPA defined a small manufacturer or processor, for the latter reporting rules only, as a business with less than $5 million per year in sales (except no manufacturer was considered small with respect to any chemical substance manufactured at one site in quantities greater than 100,000 pounds per year).

Question #2: Specifically, what has EPA done to lessen the burden of this Statute on small businesses, which are almost certainly less able to sustain the requirements of this program than the industry giants?

Answer #2: As discussed above, small manufacturers and processors were exempt from some aspects of the Inventory Reporting Requirements. The other rules EPA has issued under TSCA concern polychlorinated biphenyls (PCB's) and chloro-fluorocarbons. There have been no exemptions from these regulations for small businesses. TSCA does not authorize small business exemptions from regulations affecting the production, use, and disposal of chemicals. It does require specific consideration of small business impacts, and where such impacts would be significant but could be mitigated without compromising the effectiveness of a particular regulation, the Agency will try to do that.

Question #3: Related to this issue is what kinds of testing requirements EPA will impose generally. Since testing of a product is a fairly expensive undertaking, will required testing have the result of eliminating small companies or small volume chemicals? Could broad scale testing have the effect of killing off promising and responsible new companies or products?

Answer #3: EPA recognizes that testing can be expensive. For that reason, the Agency intends to take an approach which would minimize testing requirements, particularly requirements for long-term animal testing.

In setting up its testing standards under section 4, for example, the Agency plans to rely as much as possible on a hierarchical approach, in which relatively simple short-term tests would be undertaken first and results evaluated, together with other relevant data, before the more elaborate and expensive long-term testing is initiated. In some instances, depending on the results of short-term tests, on the uses being made of a chemical, on the extent of human and environmental exposure, long-term testing would not be necessary. Because the extent of such exposure often is directly related to production volume, and because small companies frequently are the producers of small-volume chemicals, this approach will tend to mitigate the burden imposed on them.

An analogous approach is being taken with respect to testing of new chemicals for which section 4 rules do not exist (which will be true for most new chemicals for some time to come). In this case, the Agency is planning to issue nonmandatory testing guidelines identifying the types

of testing that should be done to permit EPA (and manufacturers) to make a reasoned judgment on possible risks. In the section 5 guidelines, the Agency plans to indicate by example the circumstances under which some tests might not be necessary.

For both existing and new chemicals, of course, the Agency will avoid requiring testing that would simply duplicate testing already performed.

Another factor that will tend to soften the impact of testing requirements on small companies is the provision in section 4 that allows the Agency to grant an exemption from a testing requirement to a manufacturer whose chemical is the same as a chemical being tested by another manufacturer. The one granted the exemption is, of course, required to reimburse the one doing or sponsoring the testing. Such reimbursement will have to cover a fair share of the testing cost, which, under the Act, is to depend in part on relative market shares for the chemical in question and relative competitive positions of the companies involved. Where a chemical to be tested is produced by both large and small companies, or even by many small companies, this cost-sharing arrangement should reduce the economic impact on the small companies.

TESTIMONY OF GUS SPETH, MEMBER,

COUNCIL ON ENVIRONMENTAL QUALITY

Before the

SENATE SUBCOMMITTEE ON ENVIRONMENTAL POLLUTION

OF THE COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS

July 20, 1978

Mr. Chairman,

It is with great pleasure that I appear before this subcommittee for your first hearings on the Toxic Substances Control Act (TSCA). The Council on Environmental Quality is a strong advocate of the need for comprehensive toxics substances regulation, and we are particularly pleased to be in a position of reporting favorably on aspects of TSCA's initial implementation.

The principal involvement and interest of CEQ in TSCA, both before and after the passage of the Act, has been in the following three areas: (1) improving the data base necessary for making informed judgments about chemical hazards and for choosing the appropriate preventive strategy; (2) providing the legislative framework for taking appropriate regulatory action for the more serious potential hazards; and (3) developing a federal-wide coordinated approach to chemicals. This involves the meshing of TSCA objectives and activities with programs under 18 other pieces of major regulatory legislation conducted by 6 agencies. Several dozen more agencies have research or data responsibilities relevant to chemical hazards.

CEQ pursues these general interests and the specific responsibilities assigned to it under TSCA primarily through participation in interagency activities. The principal groups

which I would like to talk about with you today are the Toxic Substances Strategy Committee, the Interagency Toxic Substances Data Committee, and the TSCA Interagency Testing Committee. I shall also refer to the work of the Interagency Regulatory Liaison Group (IRLG), in which CEQ has a great interest although is not itself a member.

TOXIC SUBSTANCES STRATEGY COMMITTEE

Work Plan and Membership

The Toxic Substances Strategy Committee was formed last year by CEQ in response to the instruction in the President's 1977 Environmental Message that CEQ develop an interagency program "(1) to eliminate overlaps and fill gaps in the collection of data on toxic chemicals, and (2) to coordinate federal research and regulatory activities affecting them." The Strategy Committee is composed of 17 member agencies with toxics research, regulatory or policy responsibility, with observers from Executive Office of the President agencies. I chair the Strategy Committee; most of the members are at the Assistant Secretary level.

We do not see the Strategy Committee as a permanent mechanism to coordinate all of these diverse activities, some of which can perhaps be handled more effectively by smaller, more specialized groups. The Committee therefore adopted a one-year initial work plan to focus on several

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critical matters. I will submit for the record the Committee's work plan and current membership. A status report is to be prepared by the end of 1978 that will cover the Committee's initial analyses and resulting actions and recommendations. At that time a decision will be made as to whether the Committee will continue beyond 1978. Because the Committee's timetable is such that draft subcommittee reports are just now being completed for submission to the full Strategy Committee, at this time I have no conclusions to report, but I can describe the issues that the Committee is addressing.

Research

The Strategy Committee's work on research includes analysis of types of research being conducted, research management, unmet research needs, and evaluation of how well federal toxics research supports federal regulatory and policy needs within a balanced overall program. As part of this work, a survey of toxics-related research being conducted by all federal agencies is just being completed. That survey includes both quantitative information for each agency about the FY 1977 dollar level of programs in 8 toxics research categories and qualitative information about how research is planned, coordinated and managed, and how research results are evaluated and disseminated. Final analysis is being completed by the National Science Foundation, which led this

part of the Strategy Committee's effort, and their report is expected shortly. The Strategy Committee has also recently begun an analysis of the constraints in recruiting and hiring scientists in government and in making scientific personnel available for work on regulatory issues.

Data

In connection with the Committee's work on data and information coordination, a subcommittee is developing consistent federal policies for handling trade secrets and confidential data. The objectives are to remove impediments to the use of information by agencies in decisionmaking and to the exchange of information among agencies, and to permit access to certain data by private parties with a right to know, while at the same time affording adequate protection for legitimately confidential information. This subcommittee is analyzing existing federal laws and practices and is expected to recommend both administrative and legislative changes. Issues that have been addressed to date include (1) sharing of confidential information among agencies and between agencies and contractors; (2) rulemaking using a record containing confidential information; and (3) handling of health, safety, and efficacy data. Issues which have been identified for possible subsequent analysis include sharing of data with states, disclosure of data to workers,

and disclosure of medical records for epidemiological study purposes.

The task of evaluating data needs and coordinating the data systems of more than 30 federal agencies into one comprehensive program is being done for the Strategy Committee by an independent permanent body, the Interagency Toxic Substances Data Committee, which I'll be talking about in a moment.

Regulation

To assist the Strategy Committee in considering new regulatory and non-regulatory control strategies, CEQ sponsored a study by the Environmental Law Institute to examine case histories of past federal actions to control toxic substances. The final ELI report is expected this week for review. The Strategy Committee will also review the efforts of the IRLG in improving the coordination, consistency and effectiveness of the current federal approach to regulating specific chemical hazards.

Risk assessment is a critical component of regulatory decisionmaking. Because of the growing realization of the difficulties in establishing priorities for addressing the hazards of the 70,000 or so chemicals currently in commercial production or the ones soon to be introduced, risk assessment is receiving increased attention by the private and public sector. Fortunately, most chemicals do not appear to cause

significant adverse effects in the amounts normally found in the environment and to which people are exposed. But the state of knowledge of how best to assess those that do pose "an unreasonable risk of injury to health or the environment" (in the words of TSCA) is imperfect and fraught with questions of scientific and social judgment that are often inextricable.

As a first step in articulating federal risk assessment strategies, the Committee is developing a common set of principles for use government-wide for identifying carcinogenic substances and evaluating their impact on human health. This effort is one of three closely related efforts going on within the Executive Branch. The Toxic Substances Strategy Committee is operating at the broadest policy level. The Committee will develop principles which cover how carcinogens should be defined, how much reliance can be placed on animal tests in predicting cancer risk to humans, appropriate animal species to be used in testing, the types of tumors and other lesions used to indicate a carcinogenic effect, and whether safe exposure levels can be established for carcinogens. Once these principles are agreed to by the Committee -- and incidentally, considerable agreement has been achieved over the past several decades by scientific organizations and advisory groups as well as by governmental

policymakers -- CEQ plans to issue a public information document that explains these matters in lay terms in order to enhance public understanding and improve the public debate.

A second related effort is that of the IRLG. The IRLG is preparing more detailed guidelines on how to perform cancer risk assessments for use by agency scientists and policymakers.

Finally, each regulatory agency will develop procedures for using cancer risk assessments in their particular regulatory decisions under the procedures and laws of their programs. As you know, the Occupational Safety and Health Administration is currently involved in two months of public hearings over its proposed rule for classifying and regulating carcinogens in the workplace. The Consumer Product Safety Commission has recently issued a policy statement on how it plans to classify substances for their potential carcinogenic risk and what regulatory action is likely to take place as a result. CEQ regards these and similar efforts as very important to the successful implementation of the objectives of TSCA and other closely related chemical hazard legislation.

Another task of the Strategy Committee is the development of a plan of action for handling chemical spills and other

environmental emergencies involving toxic substances. EPA is conducting a complex study involving several interagency task groups; certain health-related aspects are being considered by HEW. These analyses will be the basis for Strategy Committee attention to many aspects of chemical emergencies -- scientific and technical information, financial and legal responsibilities and authorities, resource management, public information, contingency planning, clean-up and disposal, interagency coordination, and the roles of state and local governments and industry. The EPA study includes a survey of emergency response capabilities of the 50 states plus a more in-depth analysis of 11 states; it also includes 9 case studies of actual emergencies that have occurred and the responses to them.

International Toxic Substances Strategies

Although most of the Strategy Committee tasks are focused on domestic policies, the State Department is a member for the purpose of ensuring that the Committee considers the international policy implications of domestic decisions and for recommending ways in which domestic toxic substances policies can best be reflected in the many international activities in which the United States participates. For these and other purposes of coordinating the international aspects of toxic substances among the many

federal agencies, the State Department chairs a Subcommittee on toxic Substances of the interagency Committee on International Environmental Affairs.

Further Work

Our staff will be pleased to keep you informed of further progress of these efforts as we move toward completion of our 1978 report to the President and plans for follow-up on the recommendations. Throughout the work we have been soliciting comments from industry, environmental groups, states and others. We anticipate further discussions and public review of findings in the late summer and fall.

INTERAGENCY TOXIC SUBSTANCES DATA COMMITTEE

Committee Charter

Now let me turn to the Interagency Toxic Substances Data Committee and related responsibilities of CEQ under TSCA. Section 25(b) of TSCA requires CEQ to coordinate with other federal agencies in studying the feasibility of establishing (1) a standard classification system for chemical substances and (2) a standard means for storing and for obtaining rapid access to information respecting such substances. The Interagency Toxic Substances Data Committee was jointly established and is jointly chaired by CEQ and EPA for several purposes: (1) to carry out CEQ's responsibilities under Section 25(b); (2) to carry out EPA's responsibilities under Section 10(b)(1) of TSCA, which requires EPA to establish an interagency committee to coordinate the

the use by other federal agencies of information collected by EPA under TSCA; and (3) to perform several other functions related to the creation of effective toxic substances data systems that are responsive to the needs of both federal and nonfederal users. I will submit for the record the notice of charter, membership and meetings of the Data Committee.

Data Report to Congress

The principal attention of the Data Committee is currently being devoted to the adoption of a standard chemical classification system and a Chemical Substances Information Network, which have been the subject of intensive study by CEQ, EPA, HEW, the Department of Commerce and other agencies. Section 25(b) of TSCA requires CEQ to report to Congress on the feasibility of the classification and data systems within 18 months of the effective date of enactment of TSCA. The report is being submitted to Congress today, and I will include a copy for the record. In a few weeks we will have multiple copies of a published version for distribution to other interested persons.

The principal finding of the report is that on the basis of the studies that have been conducted, CEQ has concluded that both a standard federal chemical classification system and an information storage and retrieval system are feasible and desirable. In the words of the transmittal letter, "(T)he time is appropriate for the government to proceed toward (1) government-wide adoption of a uniform

system for identifying individual compounds to provide unambiguous identification of these compounds and accurate communication of information about them, and (2) interagency collaboration in the design and implementation of a Chemical Substances Information Network."

Standard Chemical Classification System

Several means of classifying chemical substances for various purposes are discussed in the report and recommendations are made for further development of some of these. The basic classification system that is recommended for required use as the standard chemical identifier for chemicals and mixtures in government files is the Chemical Abstracts Service (CAS) Registry Number. The CAS numbering system is presently in widespread use and currently includes over 4 million chemical substances having more than 6 million names. CEQ has negotiated with CAS and its parent organization, the American Chemical Society, a set of mutually agreeable terms and conditions to serve as a model for future expanded government use of the CAS system.

Chemical Substances Information Network

The study of chemical information needs looked at over 220 federal data systems containing data relevant to toxic substances assessment. Many of these are presently designed to meet only very narrow specific needs, or are duplicative

of other data sources, or are difficult to use in terms of extracting relevant information. A blueprint has now been proposed and accepted in principle by the Interagency Toxic Substances Data Committee to develop a loosely coupled network of data bases, including all major federal and many private data systems, both existing and planned or proposed for development. The network would be composed of a set of directly linked core data bases plus a group of noncore files which are referenced by the core system. Data included in the network would cover all aspects of chemical substances -- chemical properties, production, use, occurrence in the environment and human exposure, health and environmental effects, and standards and regulations affecting them. The network would be designed to meet multiple needs and to be flexible to evolve as the unique data requirements of the many users evolve.

It is anticipated that the establishment of the network will contribute greatly to the more effective utilization of available knowledge and will eventually result in the reduction of overlapping industry reporting requirements. Improved sharing of information among different sectors such as federal agencies, states, industry, universities, private research groups, and international information systems is also an objective of the network.

Development of the network will be evolutionary. Development of some components is already completed or underway. The status of these activities is discussed in the report to Congress. But implementation of a Chemical Substances Information Network is not a trivial task. The ultimate design of the network is not yet fixed, and it may require as much as 10 years to develop and implement it completely. There are numerous technical, management, and resource issues to be resolved, probably many yet to be posed. Development of the network will require a level of cooperation and coordination among agencies that is virtually unprecedented. We at CEQ believe that the task is sufficiently important to be pursued vigorously despite the anticipated difficulties. We are encouraged by the interest and commitment of the Data Committee, which will be responsible for coordinating the continuing work and developing future initiatives.

TSCA INTERAGENCY TESTING COMMITTEE

Mission and Early Work

Another committee that has had to face the problems caused by gaps and insufficiencies in available data concerning chemical substances is the TSCA Interagency Testing Committee. The ITC is the committee established by Section 4(e) of TSCA to recommend to EPA chemical substances and mixtures which should receive priority consideration for promulgation

of testing rules to determine their hazard to human health or the environment. CEQ is one of the eight statutory members of that committee.

In its first 18 months of activity, the ITC was able to develop procedures and policy criteria that have enabled it to carry out its responsibilities effectively. The ITC developed a logical selection strategy for identifying a manageable list of chemicals for its initial consideration. The ITC developed a scoring and ranking system for making a preliminary judgment of which of those chemicals should receive further attention on the basis of their production volume, environmental release, occupational exposure, and general population exposure. The Committee then further reduced the number of chemicals for consideration by eliminating substances that were already under regulation or judged to be well characterized for regulatory purposes, substances covered by testing requirements under other legislation, certain natural products, and essentially inert materials.

The resulting "Preliminary List" was published for public review and comment. A further scoring and ranking step took into consideration chemical structural similarity to substances of known hazard, the existence or absence of data on effects, and the extent to which testing might

result in data useful for predicting health or environmental effects. A more detailed review of the resulting 80 substances has to date resulted in the designation of 8 individual substances and 10 categories of chemical substances in the two ITC reports to the EPA Administrator of October 1977 and April 1978. As required by statute, the Committee is continuing its review process and will report to EPA every six months.

Data Problems Encountered by ITC

The Interagency Testing Committee should be commended for the reasonable and expeditious manner in which it has carried out its responsibilities to date, considering the serious data limitations under which it has been operating. During this period before the results of the TSCA-mandated inventory are available, it is not even known how many chemicals are in current commercial production. Little information is available on the uses of chemicals or their pathways in the environment that determine potential exposures. Data on health and environmental effects are either missing entirely from the scientific literature or are scattered throughout a maze of data sources which reveal little about the relative quality of the data and which are not readily accessible. At every stage in the ITC's screening, scoring and evaluation process, large numbers of chemicals had to be deferred from consideration at least temporarily because of lack of sufficient information.

Many of these problems can be expected to be corrected at least partially as the reporting and testing provisions of TSCA are implemented and as public and private chemicals data systems are improved and coordinated. Other difficult policy issues with which the ITC has been faced will have to be resolved soon in a preliminary manner but are also expected to evolve with increased experience. One such question is what should be the criteria for establishing priorities for testing among tens of thousands of substances; e.g., what weight should be given to production and exposure, to characteristics of chemicals that make them suspect, to evidence of risk that we do have on some substances or to the need for developing data on those about which we know the least.

CONCLUSION: PRIORITY SETTING FOR CHEMICALS

There are two possible extremes to priority setting for chemicals, whether it be for further testing and research or for regulatory purposes. The one extreme would be to put all available private and governmental resources into addressing known problems of the most serious concern and only turn to consideration of the other substances once we have dealt with the identified hazards. The other extreme is to give equal attention to all chemicals, at least until sufficient research and data are available to reach some judgment about their relative priorities in terms of potential hazards. The first approach is the crisis mentality

that too often has characterized government efforts in the past, that of dealing with a chemical problem only after it has become front-page headlines. The second approach, of studying everything before doing anything, sounds fine in theory but seldom works in practice -- the comprehensive study is so resource and time consuming that it never keeps pace with the occurrence of the serious hazards it is supposed to prevent.

CEQ believes that a combined approach is essential, and that such a combination is made possible by the legislative framework established by TSCA and by the current strategies being developed by individual federal agencies and interagency groups. Attention is finally being paid to building the information base for more effective preventive environmental health measures in the future, while at the same time the resources of the federal government are being mobilized to begin to take action on a number of significant known hazards. CEQ looks forward to continuing to participate in these important activities. Thank you.

TOXIC SUBSTANCES CONTROL ACT OVERSIGHT

FRIDAY, JULY 21, 1978

U.S. SENATE,
COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS,
SUBCOMMITTEE ON ENVIRONMENTAL POLLUTION,
Washington, D.C.

The subcommittee met at 10:10 a.m., pursuant to recess, in room 4200, Dirksen Senate Office Building, Hon. Edward S. Muskie (chairman of the subcommittee) presiding.

Present: Senator Muskie.

Senator MUSKIE. We will resume our hearings on the Toxic Substances Control Act.

We are delighted to have this morning an impressive panel made up of Ms. Jacqueline Warren, Environmental Defense Fund; Richard E. Heckert, Du Pont Co., representing the Manufacturing Chemists Association; Donald E. Ellison, manager, government and industry relations, Virginia Chemicals; Ralph Engel, Chemical Specialty Manufacturers Association.

If you will proceed in the order I named, we will get the hearing underway.

STATEMENT OF JACQUELINE WARREN, ENVIRONMENTAL DEFENSE FUND

Ms. WARREN. Thank you. I would like to express my appreciation for having a second opportunity in 3 days to come before this committee and present our views. I am a staff attorney for the Environmental Defense Fund and I have been working on the Toxic Substances Control Act since before it was passed. I was also very recently appointed to the EPA Administrator's Toxic Substances Advisory Committee.

The Environmental Defense Fund is a nonprofit environmental organization of approximately 45,000 members who are dedicated to finding scientifically sound solutions to the Nation's environmental problems. EDF has been involved in administrative, legal and legislative efforts to control exposure to toxic and particularly cancer-causing substances in the environment, and has participated in regulatory proceedings concerned with toxic chemicals.

EDF scientists and lawyers worked for the passage of the Toxic Substances Control Act and have monitored EPA's implementation of the statute since it was passed in October 1976. We appreciate this opportunity to present our views on EPA's efforts to carry out Congress intent that chemicals which present unreasonable risks of injury to health and the environment be regulated.

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Although it has been almost 2 years since TSCA was passed, the first year of implementation was significant principally for the lack of meaningful efforts to develop a regulatory program. An Assistant Administrator for Toxic Substances was not officially appointed until October of 1977, and the program was also understaffed and underfunded.

Since Mr. Jellinek took over, some of the difficulties besetting the Office of Toxic Substances have been resolved. Nevertheless, EPA's implementation of TSCA to this very day can only be described as slow, cautious, and tentative.

The Agency's hesitant approach to dealing with existing problem chemicals in particular does not bode well for the establishment of a major regulatory effort to reduce human and environmental exposures to known hazards in the foreseeable future.

Yet, it was repeated disclosures about adverse human effects from exposures to asbestos, Kepone, vinyl chloride, benzene and many other hazardous chemicals which moved Congress finally to enact legislation designed to regulate the chemical industry as a whole.

To the Agency's credit, implementation of TSCA has been carried out in a very open and public manner. There have been numerous public meetings at which representatives of the chemical industry, environmental groups and labor have been able to express their views on a large number of EPA's proposed regulations and approaches.

The Agency has promulgated regulations to develop the inventory of existing chemicals under section 8(b), has issued guidance for the immediate reporting of information indicating a substantial risk to health or the environment under section 8(e), has published regulations under section 8(d) for submission of data on the substances recommended as high priority candidates for testing by the Interagency Testing Committee, has established a pilot program for reimbursement of public interest intervenors in proceeding under section 6 and has developed procedures for protecting the confidentiality of sensitive business information.

In addition, efforts are well underway to develop rules and guidlines to govern compliance with the premanufacturing notice provisions of section 5, which will go into effect 30 days after the inventory is published in early 1979.

Most of these efforts are aimed at establishing a procedural framework for the operation of various statutory provisions. They will provide information for creation of a data base containing a profile of the chemical industry. When the inventory is published, EPA will know who is manufacturing which chemicals in what amounts and at what locations.

A very substantial enlargement of EPA's knowledge about the nature and activities of the chemical industry will be the principal result. The latter result was not achieved without significant efforts by environmental and labor organizations to persuade EPA that an initial information-gathering undertaking was necessary to support as well as to identify the need for future regulatory actions.

EPA's original plan had been to request only the names of chemicals produced in the United States in the past 3 years and nothing more—not even the names and addresses of the manufacturers. The acquisi-

tion of information essential to implementation of TSCA would have been deferred for the indefinite future.

Although we unsuccessfully urged EPA to request information on the use of the chemicals as well, the data base being established will provide the basic information to support regulatory actions which we hope will be forthcoming. The absence of use information, however, severely handicaps the Agency in determining what are "significant new uses" of existing chemicals which should be subject to section 5 premanufacturing notification.

EDF's principal criticisms of EPA's performance so far in implementing TSCA, in addition to the generally reluctant approach which has characterized the actions which have been taken, are the following:

1. *The Agency has paid very little attention to its regulatory authority under section 6.*—TSCA is both an information-gathering and a regulatory statute. Section 6 contains authority for EPA to deal appropriately with a broad range of toxic chemicals problems.

Thus, the Agency can impose mere notification of the existence of a risk, to geographic or quantity limitations on particular uses of a substance, all the way to a complete prohibition on manufacture, processing, distribution in commerce, use and disposal. This authority has been used only sparingly so far by EPA, and the Agency shows few indications of any inclination to embark upon a vigorous program of regulating existing hazards.

Soon after his appointment, Administrator Costle announced at a public meeting that EPA would investigate and take appropriate regulatory action upon a list of 15 chemicals of concern. The list included arsenic, asbestos, benzene, cadmium, mercury, and tris, to name a few.

In the 16 months that have passed since that statement was made, no visible action has been taken on any of the substances on the list. In fact, in response to specific requests by EDF that discrete regulatory actions be taken with respect to tris-treated garments and asbestos in interior ceiling coatings, EPA has done nothing.

In the instance involving tris, EDF asked EPA to initiate a rulemaking to require that tris-treated children's garments known to be in the distribution network be labeled as containing tris. The General Counsel's Office of the Consumer Product Safety Commission had expressed the opinion that the Commission lacked clear legal authority to impose such a requirement after the garments had left the manufacturer's control.

Despite the cooperation promised by creation of the highly touted Interagency Regulatory Liaison Group, EPA apparently made only low-level contacts with CPSC about the problem posed by the presence of an estimated 100 million tris-treated garments in existence after the ban on further use of tris to flameproof children's sleepwear.

No action was ever taken and our most recent information indicates that half the garments have been exported while half remain in existence in the United States. None of these garments contains any label or other indication that it contains tris, which was banned because it poses a cancer risk to humans—especially small ones.

EPA's inability to deal with the asbestos in ceiling coatings provides a second example. The problem of asbestos in interior air due to

deterioration of asbestos-coated ceilings and other structural components is a matter of serious public health concern.

Asbestos coatings were widely used in schools and public buildings from 1957 through the late 1960's for decorative, acoustical and fireproofing purposes. Recent evidence indicates that deteriorating ceilings may be releasing hazardous levels of asbestos into the interior air of as many as 10,000 schools around the Nation. All of the ceilings of the Yale architecture building were recently replaced because of this problem.

EPA's response to EDF's requests—and they were only requests; so far we have not filed a petition on this—for action has been equivocal. The Agency is reluctant to use its section 6 authority because the regulatory provisions are "untested" and "uncertain."

The possibility of a voluntary program to identify problem buildings and perhaps prompt local action to apply sealant or else replace the ceilings has been suggested by EPA. At times it has appeared that the Agency preferred to study the entire asbestos problem and arrive at a grand solution rather than to address discrete, manageable and perhaps imminently hazardous current situations now.

Apart from these two so far unsuccessful attempts to prompt regulatory actions under section 6, we are aware of no other pending regulatory actions that were not mandated by the statute (PCB's) or a coordinated interagency effort (chlorofluorocarbons).

Even the Agency's actions to control the disposal of PCB's which were specifically banned by section 6(e) of TSCA, have been marked by hesitation and half measures. Section 6(e) imposes a flat prohibition on the manufacture and distribution of PCB's according to a phased 2½ year time schedule.

EPA published regulations covering the labeling and disposal of PCB's in February 1978. Unfortunately, those rules do not cover articles and mixtures containing less than 500 ppm of PCB's, such as small electrical capacitors, waste oil and sludges. The exclusion of smaller items containing PCB's will leave unregulated the disposal of an estimated 80 million pounds of PCB's.

This is a very significant amount when one considers that all of the environmental contamination by PCB's that has occurred so far has been due to the discharge of 120 million pounds of PCB's. The quantity left wholly unregulated is equal to 67 percent of that amount. EPA recently proposed a second set of regulations concerning the phaseout of PCB's which propose to lower the cutoff from 500 to 50 ppm. While such a reduction represents an improvement, the general thrust of those proposed rules is to permit the use of PCB's in other than closed systems for periods as long as 5 years into the future.

EPA's whole approach to implementing and enforcing the ban on PCB's has been questionable. Section 6(e)(2) states that effective January 1, 1978, "no person may manufacture, process or distribute in commerce or use any PCB in any manner other than a totally enclosed manner."

This provision should have ended all discharges of PCB's into publicly owned treatment works as of last January 1. Direct discharges of PCB's into water were banned under section 307 of the Clean Water Act effective in February 1978.

However, because EPA had not issued regulations defining "totally enclosed manner," the Agency published a notice in the Federal Register on December 30, 1977 stating that section 6(e)(2) would not be implemented—that is, enforced—until after publication of the regulations defining "totally enclosed manner" and providing for exemptions.

By clearly stating that the law would not be enforced, EPA destroyed any possibility of voluntary compliance by companies whose process could in no way be considered "totally enclosed." Those regulations were expected to be effective by July 1, 1978; in fact, they have just been proposed and will probably not be promulgated before the end of the year. Such a cavalier interpretation of TSCA as EPA displayed in this instance is inconsistent with Congress intent in including a specific ban on PCB's in the statute, is contrary to the public interest, not to mention public health, and should not be tolerated in the future.

It is, however, indicative of EPA's approach to its responsibilities under the regulatory as opposed to the information-gathering provisions of the statute.

2. *EPA appears to have no sense of its mission in implementing TSCA.*—Since TSCA was passed, EPA has been attempting to articulate a strategy for implementation.

Various draft "strategy" documents have been circulated for public comment, but no clear strategy has yet emerged. The absence of a clear articulation of the direction in which the Agency intends to move has adversely affected all of the implementation efforts EPA has so far undertaken.

For example, because the Office of Toxic Substances lacked a clear idea of what use the inventory might serve in carrying out the Agency's TSCA responsibilities, the initial inventory proposals were narrow and short sighted.

Since the chemical industry has consistently advocated the narrowest possible interpretations of the law, strong media and other pressure upon EPA officials by citizens groups and labor unions was necessary to move EPA toward a broader perspective, to ask for the information on name of company, quantity of chemicals, site of production.

Throughout the deliberations about what the inventory should contain, EPA played the role of a neutral arbitrator of the disagreements between the chemical companies on one side and the environmental protection advocates on the other.

The Agency appeared to have no views of its own or sense of its role in carrying out Congress intent. This attitude has been apparent in other areas of EPA's jurisdiction in recent years, but never as blatantly as in the development of the inventory regulations.

As one who attended most of the public meetings, it was often the case on disputed issues that EPA semed to be taking a head count of the industry and environmental representatives to resolve the issue, and the tally was usually 50 to 3. It is our belief that EPA has an affirmative mandate under TSCA to regulate unreasonably hazardous chemicals in the environment, and that that responsibility requires positive actions by the Agency to address existing chemical hazards and to prevent the introduction of new ones.

We are hopeful that the assumption of jurisdiction over TSCA by this committee will result in a firm reminder to EPA of its obligations under the statute.

Problems which may require legislative solutions

Given the very slow pace of EPA's implementation of TSCA, it is not yet clear whether the administration mechanisms created by the statute or workable, feasible and fair. Specific suggestions for legislative adjustments should therefore await EPA's attempts to use those mechanisms and see how well they function.

One change that might be appropriately considered, however, is the addition of a general rulemaking provision. The size, complexity and variability of the chemical industry virtually guarantee that situations will arise which cannot be adequately addressed by the specific procedures set forth in TSCA.

It is surprising that Congress enacted a major regulatory statute without including authority for the Administrator to enact whatever rules are necessary to carry out the provisions and objectives of the law.

An example of an instance in which the absence of such authority may cause difficulties is the asbestos problem described above. Because the reporting provisions of the statute are addressed only to persons who manufacutre, process, or distribute chemical substances, EPA may be unable to identify the buildings which contain presently or potentially hazardous asbestos-coated ceilings.

It may be possible to reach those persons through the subpena power of section 11(c), but the issuance of subpenas involves formal legal process and is far more complicated than issuing requests for information under general rulemaking authority.

Other as yet unanticipated problems are certain to arise as TSCA is implemented and will require general rulemaking authority to resolve. For this reason, EDF urges this committee to give serious consideration to enactment of general rulemaking authority in TSCA.

I understand that such a provision was appended to the Senate bill on indemnification of victims of toxic substances incidents. But the House has taken no action. I would urge this committee to consider that again next year.

A second area of great concern is that of access by the public to information considered to be confidential by the companies. Section 14(b) of TSCA provides that health and safety studies, which are very broadly defined, must be disclosed to the public. Such studies have traditionally been claimed as confidential by the chemical, pesticide, drug and other industries.

In order to facilitate independent scientific review by outside parties and to permit intelligent monitoring of EPA's decisions on particular chemicals, Congress specified that such information must be disclosed.

EPA is now being urged by the chemical industry to withhold the name and chemical identify of chemicals submitted for premarket notification when health and safety studies of those chemicals are requested.

The tension between the public's right to know whether the chemicals they may be involuntarily exposed to are safe, and the chemical companies' commercial interest in keeping that information confidential, was recognized in the statute and resolved in section 14(b).

If the chemical identities are withheld when health and safety studies are released, the independent review function is effectively defeated. Our scientists insist that they cannot evaluate a study when they do not know what chemical was tested, nor can they bring to bear any other knowledge about related chemicals which might suggest that further testing is necessary before the chemical is commercially marketed.

To highlight the importance of this particular controversy, I might point out EPA is estimating that 80 percent of the chemicals submitted for premarket notification will be claimed as confidential and would therefore be withheld under the approach that is being advocated by the chemical industry.

There are ambiguities in the provisions of section 5 and, indeed, throughout TSCA which raise unresolved confidentiality issues. If EPA is unable to resolve them in a manner which serves the public health protective purposes of TSCA, a legislative solution may be required.

Apart from the two areas of concern outlined above, however, EDF believes that legislative changes would be premature at the present time.

We appreciate this opportunity to express our views on EPA's implementation of TSCA and would be pleased to be of any further assistance to the committee in the future.

Senator MUSKIE. Thank you very much, Ms. Warren. As is custom, I think we will take all the statements first before we take questions.

Mr. Heckert.

STATEMENT OF RICHARD E. HECKERT, SENIOR VICE PRESIDENT, Du PONT COMPANY, REPRESENTING MANUFACTURING CHEMISTS ASSOCIATION, ACCOMPANIED BY ROBERT BONCZEK

Mr. HECKERT. Mr. Chairman, members of the subcommittee, my name is Richard E. Heckert. I am senior vice president of the Du Pont Co. I am appearing here today on behalf of the Manufacturing Chemists Association, a nonprofit trade association representing more than 90 percent of the production capacity of basic industrial chemicals within this country.

I am pleased to appear here today to present our views on EPA's implementation of TSCA. I am quite familiar with this act and the deliberations preceding its enactment. During these deliberations, I chaired a special MCA committee which was the lead industry liasion group working directly with the relevant congressional committees, their members and staffs, and EPA to develop a reasonable toxic substances law.

This subcommittee should also bear in mind in addressing its oversight function the fact that TSCA will have an immense effect on the basic industrial chemical industry and, thereby, on the industrial economy as a whole.

Last year sales of basic and industrial chemicals and allied products reached $114 billion. This is less than 10 percent of our gross national product, which is nearing the $2 trillion mark. However, chemical products pervade the remaining 90-plus percent of the

economy. And it would be impossible for this remaining segment to provide for the Nation's needs without our 10 percent.

Before turning to our specific comments regarding implementation of some of the key provisions of the statute, I would like to say a few words about the industry's overall view of TSCA. Congress debated the scope of authority to be granted EPA in the area of toxic substances control for many years. The chemical industry devoted an unprecedented effort to obtain legislation that was both reasonable and effective. MCA supported the present law because it has the potential to satisfy both objectives.

There is no doubt that the present law contains ample authority to protect human health and the environment from unreasonable chemical risks. TSCA provides EPA with broad authority to regulate the chemical industry. It allows the Agency to require manufacturers to conduct time consuming and expensive tests which may take up to 4 years and cost $600,000 or more per chemical or to ban or limit manufacturing, processing, and distribution of a chemical. However, the question of whether the statute is, in fact, a reasonable one can only be answered on the basis of EPA's administration. For example, EPA has the authority to prohibit manufacture of a chemical if it finds that manufacture of the chemical presents or will present an unreasonable risk to health or the environment. Clearly, the exercise of such discretion can have an enormous impact on the industry. It may result in the loss of a product line or, in some cases, close down a business. Where prohibiting manufacture is the only way to protect against an unreasonable risk, MCA supports such action. However, where there are less burdensome, yet equally effective methods available to abate the risk, excessive regulation is not in the public interest. Congress recognized this fact, and in section 6 clearly requires EPA to use the least burdensome authority adequate to protect health and the environment.

In summary, success in achieving the health and environmental protection goals set forth by Congress depends on a reasonable approach towards policymaking and regulatory implementation. The key is a reasonable balance reflecting scientific and economic considerations consistent with preventing unreasonable risks to health and environment. Indeed, Congress recognized the need for such balance as reflected in the statement of findings, policy and intent contained in section 2 of the act which directs EPA to implement TSCA ". . . in a reasonable and prudent manner, and . . . consider the environmental, economic, and social impact of any action . . . ." This section also requires that the act be ". . . exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation . . . ." I cannot overstate the importance of EPA's adhering to this theme as it implements TSCA.

Now, if I may turn to some specific actions EPA has taken to implement sections of the act. At the outset, I would like to compliment EPA for its positive and constructive program of seeking outside comments. We urge EPA to consider fully industry's comments. We feel that such a dialog is essential to effective implementation of the act and encourage its continuation.

Since January 1, 1977, EPA has been developing the organizational capability to effectively administer the statute. Although programs

have been adequately funded, the shortage of qualified personnel, particularly with scientific training, has been a limiting factor. Nevertheless, several major regulatory actions have been taken. EPA issued regulations for the compilation of the inventory of existing chemicals, the labeling and disposal of polychlorinated biphenyls and the phaseout of nonessential propellant uses of chorofluorocarbons. In addition, the Agency undertook the development of a major enforcement policy with respect to the notification of substantial risks under section 8(e). In response largely to industry's concerns, the Agency began and has just recently completed an overhaul of its internal procedures for the handling of confidential business information.

Generally, the Agency has moved judiciously on these issues and has encouraged public participation. The final product in most cases has reflected the comments provided by those who participated in the regulatory process. However, there have been some major differences of opinion between EPA and the industry regarding statutory interpretation. These experiences have led to a concern that the congressional requirement of reasonable and prudent administration is not being followed. Specifically, we are concerned about EPA's actions in the following areas:

—Section 8(b) inventory reporting;
—Section 8(e) substantial risk notification;
—Implementation of the premature notification requirements, particularly with respect to testing for new chemicals; and
—Priority testing of existing chemicals.

The inventory list of existing chemicals described in section 8(b) will be used to determine whether a chemical is a new substance and, therefore, subject to EPA premanufacture review. EPA could have compiled this list from existing sources permitting industry to supplement if necessary. However, EPA decided to produce the list by requiring submissions from chemical manufacturers. EPA proposed regulations and was on schedule to meet the statutory deadline. However, just prior to promulgation of a final rule, the Agency announced that it had changed its approach to reporting and would repropose its reporting rule. Instead of acquiring only that information necessary to compile the chemical substance inventory, EPA decided to expand the scope of its regulation to encompass other chemical production data, specifically, the volume and site of production.

The decision to expand the reporting regulation to include acquisition of data not relevant to the inventory has delayed the publication of the chemical substance inventory and, therefore, the start of premanufacture notification. It has also increased the total cost of reporting to industry. For Du Pont, the false start in compiling the inventory caused a needless expenditure of $700,000, raising the total cost of inventory reporting from $1.3 to $2 million.

More importantly, MCA is concerned about the ability of EPA to utilize in a cost-effective way the extensive production volume and site data that was reported for the approximately 70,000 chemicals submitted for the inventory. Since the objective of a data base is to provide the background for regulatory decisions, it is essential that the data be relevant and accurate. Due to changes in levels of production and product turnovers, much of the data so obtained will be of limited significance at the time of use.

Section 8(e) requires that a chemical manufacturer, processor, or distributor notify EPA immediately if he obtains information that reasonably supports the conclusion that a chemical presents a substantial risk to health or the environment unless he has actual knowledge that EPA has already been adequately informed.

Although no administrative action was necessary to implement this provision, EPA began a major effort to draft reporting guidelines. EPA's first draft of reporting guidelines extended the scope of section 8(e) well beyond that intended by Congress. EPA's interpretation not only placed a reporting obligation on both chemical manufacturers and their employees, regardless of ability to assess substantial risk information, but also extended the notification requirements to chemicals used for product research and development. The final version of the Agency's 8(e) policy statement reduces the impact on employees by limiting the obligation to those employees "capable of appreciating" substantial risk information and relieving them of liability if they act in accord with an employer's compliance program. However, the ambiguity of the phrase "capable of appreciating" to describe the employees covered still generates confusion concerning the scope of an organization's reporting program. This confusion, coupled with the possible imposition of criminal sanctions for failure to report, can be expected to stimulate unnecessary reporting. Indeed, an examination of the 8(e) submissions to date includes notices of effects not amounting to substantial risks. Such overreaction may lead to administrative delays and possibly divert EPA attention from true substantial risk situations.

These experiences have convinced many within the industry that the implementation of TSCA will be far more difficult and costly than originally believed. The strategies that are adopted by EPA over the next few years in implementing two key provisions—premanufacture notification and testing—will be critical to the chemical industry. It is, therefore, imperative at this juncture to reaffirm the congressional intent that administration proceed in a reasonable and prudent manner.

There has been some concern that EPA is heading toward a more rigid view of the premanufacture notification provisions than intended by Congress. Congress rejected the premarket certification approach that would allow EPA to require testing for all new chemicals. However, EPA has been engaged in developing what it calls "testing guidelines."

Ostensibly, these guidelines would set forth what EPA considers the minimum level of testing for any given chemical. While MCA believes such guidelines could serve a useful function, it is opposed to the arbitrary imposition of a rigid set of testing requirements for all new chemicals irrespective of structure, use, exposure, and hazard potential. Industry concern over testing guidelines was prompted in June when an EPA document containing the Agency's concept of a base set of tests was released to representatives of the German Government and chemical industry. More recent statements from EPA indicate that the base set of tests is not intended to apply to all chemicals but that it in fact is expected to be flexible depending on such factors as the physical and chemical properties of the substance, its

use, exposure, and production volume. Although these statements have eased our concerns somewhat, we encourage EPA to inject as much flexibility as possible in its approach to chemical testing.

The preliminary report of the Conservation Foundation panel on testing guidelines supports MCA's position for a tiered or hierarchical approach to testing. A technical panel composed of representatives from academic institutions, public interest organizations, industry, and Government agencies recommended that such a tiered approach using a logically consistent series of tests be employed in the testing of chemical substances. If I may quote from the report:

> We believe that this is a more cost-effective and scientifically acceptable approach than any requirement which does not provide for a sequential assessment of potential risks. The requisite number of tiers of testing for a particular chemical substance will be determined by factors such as the type and extent of potential exposure of humans and the environment to the chemical substance.

There have been some concerns expressed regarding EPA's ability to evaluate whether a new chemical may present an unreasonable risk without having the results of the full base set of tests. This fear is unjustified. A multitiered approach to testing in which the extent of testing for a particular chemical is determined by factors such as the type and extent of potential exposure of humans and the environment will provide EPA with adequate information to conduct a risk assessment. Moreover, since the statute provides EPA with authorities that can be used to track the development of a new chemical EPA can insure that a risk assessment based on limited use or exposure does not become invalid. For example, reporting rules may be imposed where necessary to obtain changes in production levels, exposure, or the manner or method of disposal into the environment. The ability to require premanufacture notification for significant new uses of existing chemicals allows EPA to evaluate the risk potential associated with a different use. We feel it would be more effective and efficient for EPA to exercise these authorities rather than depending on excessive premanufacture testing.

During the legislative consideration of the testing provisions of the statute, there was much testimony presented regarding the shortage of qualified personnel in toxicology and related disciplines and testing laboratories. This situation has not improved significantly. The Conservation Foundation recently reported to EPA that, "About 1,000 additional professional toxicologists are needed to meet the immediate demand, a 20 percent increase over the present work force."

In order to assist EPA in setting priorities for the testing of existing chemicals, Congress established an interagency committee to provide recommendations to the administrator. The recommendations are to be in the form of a list which, in the words of section 4(e) "may not at any time, exceed 50" substances. We do not take issue with "50" as being inviolate. The report recognizes the list may be less. In establishing this quantitative restriction, Congress recognized toxicological resource limitations and the need to focus on problem chemicals. In effect, this requirement is a caveat to insure that these resources are not so strained that the whole system breaks down.

The interagency committee's recommendations represent an avoidance of the letter and intent of the statute by including a number of

broad categories or classes of chemicals. In several cases, the number of individual substances in a category is enormous and enlarges the list far beyond 50 substances. The intergency committee's recommendations do not serve the priority-setting function intended by Congress. Consequently, MCA believes it is important for all concerned that EPA obtain a refined list designating a workable number of problem chemicals in line with the statutory directive.

In closing, I would like to reemphasize that our fundamental concern is that EPA use reasonable cost-effective programs to achieve the statutory objective of adequate protection of health and the environment. I emphasize that this concern is not with cost but cost effectiveness which does not minimize the commitment to protect health and the environment. In supporting the enactment of TSCA, MCA recognized that additional economic burdens would be placed on the chemical industry. However, we question the investment of industry and Government resources in activities which do little or nothing to improve the quality of life and health in the United States.

I wish to thank the subcommittee for allowing me the opportunity to express our views this morning and to add that NCA will continue to provide constructive participation in the administrative process of implementing TSCA and will stand ready to assist and inform this subcommittee regarding TSCA. I would be pleased to answer any questions.

[Mr. Heckert supplied the following comments and responses to written questions:]

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DUPONT
REG. U.S. PAT. OFF.
ESTABLISHED 1802

E. I. DU PONT DE NEMOURS & COMPANY
INCORPORATED
WILMINGTON, DELAWARE 19898

SENIOR VICE PRESIDENT

July 31, 1978

The Honorable Edmund S. Muskie
Chairman,
Subcommittee on Environmental Pollution
145 Russell Senate Office Building
Washington, D.C. 20510

Dear Mr. Chairman:

I would like to thank you for the opportunity to testify on July 21 at the oversight hearings on the Toxic Substances Control Act. I would also like to add to the record some thoughts on two points you raised in your opening remarks on July 20, 1978.

The first pertains to your point on timing: "Is the public more protected from harmful toxic materials than it was when the act was passed? ...The slowness in the development of regulations has meant that no direct controls have been placed on toxic chemicals."

The "direct controls" of Section 6(a) remain unused due not to slowness of regulation, but rather because toxicology has not yet shown an unreasonable risk which has not already been regulated under other authority. There has been no slowness in toxicology. The nation's laboratories are fully utilized and are being expanded.

Second, in your next paragraph, you mentioned environmental causes of cancer, particularly "...the rise of the cancer death rate (associated with) the increased exposure to industrial chemicals at work, in the air, and in the water."

The age-adjusted cancer death rate in the U.S. has been increasing very slowly -- about 0.2% per year for the last 20 years. Many experts have stated that all of the increase can be accounted for by cigarette smoking. The American Cancer Society reports that the

incidence of cancer is actually declining on an age-adjusted basis. Diet is generally considered to be associated with about half of all cancer. Add another 35% from cigarettes, liquor, and sunlight, and 10% for heredity and viruses, then the remaining industrial contribution is put in better perspective.

If industrial chemicals were a major cause of cancer, one would expect to find higher cancer rates among chemical workers. Du Pont has been keeping track of employee death rates and illness rates from the major diseases for over 20 years. Our employees and pensioners who have or have had both occupational exposures at work and community exposures at home, have lower death rates than the general public from all causes of death in general and cancer in particular up to age 75, after which they are the same as those of the general public.

My objective in writing you is to be helpful, to present facts that are often overlooked. I am not trying to minimize industry's responsibility for controlling pollution and providing a safe workplace. I do feel, however, that overemphasis on industry's part of the problem can mislead the public by raising expectations which cannot be fulfilled. The prevention of cancer is a problem for all of us, not just industry.

Sincerely yours,

R E Heckert

R. E. Heckert

DUPONT
ESTABLISHED 1802
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INCORPORATED
WILMINGTON, DELAWARE 19898

SENIOR VICE PRESIDENT

August 29, 1978

Mr. Curtis A. Moore
Minority Staff
Committee on Environment and
Public Works
4210 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Mr. Moore:

Mr. Donald M. Clark, the Manufacturing Chemists Association's Legislative Representative for the Environment, has forwarded to me your list of questions, on behalf of Senator Stafford, relevant to MCA testimony which I presented before the Senate's Committee on Environment and Public Works.

Attached is a copy of our response to each primary question including comments relevant to each subquestion.

Thank you for this opportunity to provide my views on various areas of interest to you. If I can be of any further assistance, please do not hesitate to contact me.

Sincerely yours,

R. E. Heckert

REH:amk
Attachment

Q. DOES TSCA MERELY REQUIRE AS A MATTER OF LAW ACTIONS THAT WERE BEING UNDERTAKEN VOLUNTARILY BEFORE ITS PASSAGE?

A. For years prior to enactment of TSCA, it has been Du Pont's policy to continually evaluate each product to determine whether it could be made, used, and/or disposed of safely. In accordance with this policy, products were tested to the extent appropriate following a tiered-hierarchical approach based on a product's physical and chemical properties, potential exposure, production volume, etc.; marketing decisions were made on the basis of test results; and customers were voluntarily supplied with all pertinent information that would assist in using and disposing of Du Pont products safely and in an environmentally acceptable manner.

We assume the question relates primarily to premarket testing of chemicals. Whether TSCA would require testing beyond what industry would otherwise do depends on a reasonable approach by EPA to policymaking and regulatory implementation of testing requirements. If, as we have recommended, EPA adopts a reasonable approach to premanufacture review of new chemicals recognizing the concepts of tier testing and sequential assessment of risk, the testing burdens would be relatively comparable to what industry did prior to TSCA. On the other hand, if a rigid base set of tests for all new chemicals was to be required, the testing programs would be far in excess of what would be considered appropriate in the absence of TSCA.

Q. HOW MANY SUBSTANCES HAVE THE COMPANIES SOUGHT TO BE PROTECTED AS CONFIDENTIAL AND WHAT HAS THEIR EXPERIENCE WITH EPA BEEN?

A. The number of confidentiality claims made by any individual company varies greatly depending on the need for confidential treatment for chemical identity, production volume, site location, etc. These data items may involve highly sensitive confidential business and trade secret information invaluable to competition if disclosed, e.g., disclosure of plant site and production volume of an intermediate could reveal process information.

Only EPA would be in a position to provide statistics as to the number and kinds of substances sought to be protected as confidential in industry's 8(b) inventory filing. We are aware, however, that the Polaroid Corporation is seeking judicial relief to provide additional protection for some of its photographic chemicals. In summary, considering the commercial significance of reportable information and based on Du Pont's experience with claims for confidentiality, we believe that the number of such claims must have been substantial. To date, no EPA rejection of such claims has been brought to our attention.

Q. WHAT ARE EXAMPLES OF CHEMICALS OR PRODUCTS WHICH WOULD NOT HAVE BEEN MARKETED IF TSCA HAD BEEN IN PLACE?

A. Except for PCB's, expressly banned under Section 6(e) of TSCA, we know of no example of an industrial chemical which

would necessarily not have been marketed if TSCA had been in place. Even if certain specific uses may present an unreasonable risk, other uses may not do so, e.g., nonessential fluorocarbon propellant uses versus fluorocarbon refrigerants. On the other hand, if alcohol or tobacco were not subject to a TSCA exemption, neither would be likely to survive the Section 5 premanufacturing review.

TRIS contains chemically active bromine atoms sometimes associated with carcinogenicity. If nothing were known about the toxicity of TRIS, and it was under consideration today for marketing as a sleepwear flame retardant, its premanufacture toxicity testing would be likely to include an Ames-type, short-term bacteria test often used as a screening test for possible carcinogenicity. If a positive result was obtained, it would trigger other short-term testing or cause a developmental chemical to be abandoned. Confirmation by other short-term assays would indicate the need for long-term testing for carcinogenicity and skin permeability in animals as well as tests of its fastness in fabrics in order to assess whether it could safely be used in sleepwear, data which would be essential for any EPA risk assessment under TSCA.

When TRIS was being developed, the Ames test was not in use and much less was known about chemical carcinogenicity than now.

Q. HOW MUCH TESTING SHOULD BE REQUIRED?

A. The testing for any particular chemical should follow a tiered or hierarchical approach determined by considering such factors as the substance's physical and chemical properties, proposed uses, potential human and environmental exposure, and projected production volumes (see also the answer to question 1).

EPA's "base or reference set" of tests could take over three years to conduct and could readily cost in excess of $500,000. Additional long-term tests could extend the time and increase cost substantially. The concept of "broadest possible testing in every case", as urged by one witness, without regard to the properties of the chemical, its uses, exposure, etc., would be a needless waste of critical scientific and economic resources resulting in decreased technological innovation contrary to the express intent of Congress in Section 2 of TSCA.

If, in the absence of data, use of a chemical presents an unreasonable risk of injury to health or the environment, it should be tested as appropriate, irrespective of whether the manufacturer is a large or small company. Reimbursement raises entirely different issues. If testing were required under a Section 4 rule, a small business would share the testing cost burden with other manufacturers or processors. Even if the chemical subject to the Section 4 rule were a new chemical, the small manufacturer could obtain reimbursement from those who

begin manufacture within a five-year period. This is in sharp contrast to the non-reimbursable costs of any testing done to support a Section 5 premanufacturing submission. However, where testing may be needed to support a premanufacturing submission for a new chemical substance, the tiered-testing or hierarchical approach that we have urged EPA to adopt would permit in many cases a spreading of the test costs over an extended period of time as additional uses or increases in potential exposure may require. Such an approach would allow the initial use of a chemical to pay for the additional testing which might be appropriate for broader use.

Q. DO THE COSTS IMPOSED BY THE TOXICS ACT ULTIMATELY RESULT IN VASTLY GREATER SAVINGS BY DETECTING AND PREVENTING THE MARKETING OF HARMFUL PRODUCTS?

A. The detection of carcinogenic effects through testing does not necessarily mean that a product would not be marketed. Arsenic, benzene, and asbestos are examples of critical industrial products that may be carcinogenic at certain levels of exposure but, under proper exposure controls, can be used without unreasonable risk. This is recognized in current OSHA carcinogen regulations or proposals for these products.

An extensive battery of tests for every chemical is not "good business or common sense" for the reasons noted in the response to Question 4. Before TSCA was enacted, responsible segments of the chemical industry conducted whatever tests that seemed

necessary and appropriate to support the safe use, handling, and disposal of their products. Since we believe we were acting responsibly prior to TSCA, Du Pont's budget for toxicology studies has not increased as a result of TSCA's enactment.

In general, under common law rules of negligence, a manufacturer could be liable for failing to test his product adequately and failing to warn the user of the hazards associated with use. The nature and extent of such liability, of course, would depend on the facts of each case.

Q. HOW SHOULD "UNREASONABLE RISK" BE DEFINED FOR PURPOSES OF IMPLEMENTING THE TOXICS ACT?

A. The Act has no definition of unreasonable risk, but the statute does provide criteria that must be considered in any determination of unreasonable risk under Section 4 for a testing rule or under Section 5 for regulatory controls. We do not believe that the "burden of proving that there is no risk associated with a new product" should be placed on industry. The concept of no risk imposes a negative burden of proof which cannot possibly be met.

Q. TIMELY IMPLEMENTATION OF THE ACT--ARE THE STATUTORY DEADLINES REASONABLE?

A. EPA has missed several key statutorily mandated TSCA deadlines to permit the time required to develop implementation strategies and proposals which EPA believes are reasonable. While

we disagree sharply in several areas as to EPA's concept of reasonableness, we would concur that hasty decisions on procedures and policies based on statutory time frames that do not permit orderly development of meaningful cost-effective regulatory programs are not helpful. New Congressional deadlines would not seem to be needed in most cases.

Q. WILL THE TOXICS ACT CAUSE R&D OR TEST MARKETING ON NEW PRODUCTS TO BE EXPORTED ABROAD IN ORDER TO AVOID U.S. REQUIREMENTS?

A. A decision by a U.S. manufacturer to locate a facility abroad would depend on a number of factors, including the possibility of cost savings achieved through more lenient government regulations. If the premanufacture review requirements in the U.S. are more stringent than in foreign countries, it is conceivable that manufacturers would find it advantageous to introduce a product in a foreign market to assess its commercial viability. Studies of the impact of the 1962 amendments to the Federal Food, Drug and Cosmetic Act have blamed the cost and delays of FDA approval of new drug applications for the decrease in introduction of new drugs in the U.S. as compared to the European countries.

We are not aware that this phenomenon is taking place in the chemical industry. However, we caution EPA against imposing unnecessarily burdensome premanufacture review requirements to ensure that innovation within the U.S. remains strong.

Q. IS THERE EVIDENCE THAT SOME MANUFACTURERS ARE FLEEING THE UNITED STATES TO AVOID OUR MORE STRINGENT ENVIRONMENTAL AND REGULATORY LAWS?

A. We have seen only press reports of Mr. Barry Castleman's study referred to in your sub-question and have no specific comments other than to note that his suggestions would seem to be based on the overall impact of all environmental laws including the Occupational Safety and Health Act and not just TSCA. If TSCA is reasonably interpreted and administered, we would not anticipate any drastic pattern of shifting of manufacturing outside of the United States due to TSCA requirements.

Q. ARE THERE A SUFFICIENT NUMBER OF TESTING FACILITIES? WHAT WILL BE THE INDIVIDUAL AND AGGREGATE COSTS OF MANDATORY TESTING?

A. There are not a sufficient number of testing facilities if testing is to be required in the scope and manner now under consideration by EPA. This is why Du Pont has urged Congress before TSCA enactment and EPA afterwards to limit testing requirements to priority risks rather than overburdening existing testing resources with nonpriority situations. As noted in the answer to Question 4, using even the base set proposed by EPA may cost in excess of $500,000 per chemical. If additional long-term studies are required, the total testing cost for any one product could exceed $1,000,000. The broadest possible testing concept noted in Question 4, if required for every new chemical substance and significant new uses of existing

chemical substances without regard to chemical properties, uses, etc., would stifle and impede significantly new products and new end-use development. If tier testing based on sequential risk assessment is permitted as we have recommended, this potential impact on new end-use development would be minimized. As the preliminary report of the Conservation Panel on Testing Guidelines notes:

> "We believe that this is a more cost-effective and scientifically acceptable approach than any requirement which does not provide for a sequential assessment of potential risks."

Q. HOW ARE COMPANIES IMPLEMENTING THE TSCA REQUIREMENT THAT "SUBSTANTIAL RISK" CHEMICALS BE REPORTED?

A. Du Pont's Section 8(e) reporting plan will allow an employee either to:

1. report directly to EPA information received which he believes presents a substantial risk or
2. file a report with his supervisor for corporate processing in accordance with the reporting system described in EPA's March 16 Federal Register published Statement of Interpretation Enforcement Policy.

Even assuming the pool of liquid that you noted in the hypothetical you have stated could kill a dozen birds, this fact in and of itself would not require a report under EPA's guides for 8(e) substantial risk reporting. The toxicity of the

liquid to birds might be well known and the number of birds was relatively small. Under EPA's Section 8(e) reporting guides, reportable environmental effects must be widespread and previously unsuspected. If Du Pont did not consider this type information reportable, the employee who initially reported the information to supervision would be advised that he could still report this information to EPA if he chose to do so without risk of job loss or disciplinary action.

The custodial worker in your hypothetical example under established company procedures regardless of Section 8(e), would report the incident to supervision. Further action after immediate physical cleanup and repair of the leak source would depend on the facts of the particular situation.

The authority to discontinue production on a permanent basis lies with general management. However, in the event of a serious hazard, the plant manager has the authority to halt production pending more complete evaluation of the problem or installation of temporary safety measures adequate to provide interim protection.

It has been Du Pont's policy for many years to bring to the attention of appropriate government agencies, such as OSHA, NIOSH, EPA, or FDA, significant health and safety data that it has developed particularly with respect to carcinogen tests. There are also many reporting requirements associated with other environmental laws such as the Clean Air Act and the Federal Water Pollution Control Act. Du Pont's internal communication and reporting procedures that existed prior to TSCA have been more formally defined to meet the specific requirements in EPA's guide for Section 8(e) corporate reporting plans.

Senator MUSKIE. Mr. Ellison.

STATEMENT OF DONALD E. ELLISON, MANAGER, GOVERNMENT AND INDUSTRY RELATIONS, VIRGINIA CHEMICALS INC. ON BEHALF OF THE SYNTHETIC ORGANIC CHEMICAL MANUFACTURERS ASSOCIATION, INC., ACCOMPANIED BY RICHARD HINES, COUNSEL TO SOCMA

Mr. ELLISON. My name is Donald E. Ellison. I am appearing here today on behalf of Virginia Chemicals, Inc., an industrial chemical manufacturer, with headquarters in Portsmouth, Va.

Virginia Chemical has approximately 950 employees and gross sales of about $100 million. I am also appearing on behalf of the Synthetic Organic Chemical Manufacturers Association, Inc., which has 105 members, including both small and large companies. Accompanying me is Richard Hinds, counsel for SOCMA. A list of SOCMA's members is attached to my testimony.

We are pleased to have this opportunity to testify concerning EPA's implementation of the Toxic Substances Control Act.

After a long evaluation, EPA issued its final inventory reporting regulations on December 23, 1977. The regulations were relatively complex and the reporting burden they imposed was considerable, particularly for smaller companies. In large part, this was the result of EPA's decision to require that information on production volume and site of manufacture be submitted for all chemicals at the same time as the information needed to compile the inventory.

The Agency concluded that for purposes of the inventory reporting regulations, a small business was one having annual sales of less than $5 million. Production of any chemical over 100,000 pounds also has to be reported, regardless of a manufacturer's size. We are pleased that in response to the legitimate concerns expressed by small business, EPA did revise its initial proposed definition, which would have excluded virtually no manufacturers. EPA also made certain other changes in its proposed requirements which reduced somewhat the burden placed on small business.

EPA will be required to formulate another definition of "small business" in connection with general reporting requirements issued under section 8(a). As you know, Congress exempted small business from the burden of complying with general reporting requirements other than for chemicals already subject to specific regulatory action by the Agency. We trust that the Agency will keep in mind Congress' express intent to minimize the reporting burden on small business and define "small business" in a manner which will further that congressional intent.

Smaller chemical companies are responsible for a large share of the innovation and new product development which has made the U.S. chemical industry second to none. Under the act, all commercial chemicals developed after publication of the inventory in 1979 will be subject to premanufacturing notification. Companies such as Virginia Chemicals are therefore considerably apprehensive when they hear that EPA is considering requiring a "base set" of tests for new chemicals that could cost as much as $150,000 and in general turning the premanufacturing notification requirement into something resembling

a pesticide registration procedure. I am sure this committee is well aware that very few new pesticides have been developed and registered in the last few years.

A similar approach to the chemical industry as a whole would have devastating results on small companies, many of whom are able to survive in this industry only by their innovative ability. The profit margin on most newly developed chemicals is such that little toxicological and ecological testing can be undertaken before the cost of development becomes too high to justify the economic risks. I might say as an example that we recently developed an intermediate chemical for a small speciality plastic firm. The net profit from that specialty chemical is only $20,000 per year. It would take us more than 7 years to pay back the testing costs for that one chemical before we could begin to realize any return on our investment. And this is not atypical of the products that we handle in our particular company.

If EPA takes a "fail-safe" approach and requires voluminous data on such low volume, low profit items, they simply will not be able to be developed by small companies. It is, therefore, essential that EPA link its data requirements to anticipated exposure. If a new chemical is being produced in small quantities as an industrial intermediate and if there is no reason to suspect that the chemical poses a potential risk from its physical and chemical properties, the amount of expensive toxicological and ecological test data which EPA needs to evaluate the chemical should be quite limited. EPA's draft guidelines, however, call for considerable testing of all chemicals which present "significant human exposure or environmental release." Some clarification of what constitutes "significant" exposure release needs to be made.

The principal impact that the act will have on manufacturers of existing chemicals is the testing requirements to be issued by the Agency under section 4. We are concerned by the interagency testing committee's decision that it has authority under section 4(e) to recommend up to 50 categories of substances for priority testing. This decision conflicts with Congress' decision to give the committee authority to recommend up to 50 chemical substances as candidates for priority testing.

So far, the committee has recommended 10 broad categories and 8 individual substances for priority testing by EPA. EPA has already indicated that it intends to follow suit by issuing rules requiring testing on broad categories of chemical substances. If EPA does proceed in this manner, testing personnel and facilities—which are already in short supply—will soon be unavailable. Such a shortage of testing resources will have a severe impact on innovation because of the inability to test new products. Testing requirements for broad categories of chemical substances could also have a devastating impact on small companies, which may find a substantial part of their product lines subject to extensive testing requirements at the same time.

We believe that both the interagency testing committee and EPA should focus on the need for testing on a chemical-by-chemical basis. In no event should more than 50 individual chemical substances be determined by the committee to be "priority" candidates for testing in any given year.

One issue of considerable concern is the security of the highly confidential information which EPA will be acquiring from many companies as a result of the inventory reporting program and subsequent reporting requirements. EPA has already requested a great deal more data than it can evaluate and use at this time, and has announced its intention to share this information with other Federal agencies, private contractors, and subcontractors. There is also sure to be increasing pressure in the future to make this information available to State governments as well. Since any system for the protection of confidential data is only as strong as its weakest link, we believe that EPA should not release any confidential information to any government agency or contractor unless such an agency or contractor has a security program which is at least equivalent to the one being developed by EPA.

We do urge, however, that EPA work toward cooperative agreements which would allow nonconfidential data to be shared with the States. Such agreements would be likely to reduce the burden imposed by inventory-type reporting requirements which many States have or are considering enacting. My State, Virginia, is an example in that area.

In light of the growing shortage of qualified toxicologists in both the private and public sector, EPA is experiencing great difficulty in hiring enough toxicologists to keep pace with the expanding responsibilities of the Office of Toxic Substances. The toxic substances control program has far too pervasive an impact to allow it to expand into a vast bureaucracy which lacks adequate internal scientific expertise. The Office of Toxic Substances will soon be faced with great numbers of highly technical judgments. The limited availability of trained agency personnel qualified to make those judgments must therefore be considered an important problem which has to be resolved promptly.

The absence of a Federal civil service job category entitled "toxicologist" is a severe impediment to effective recruitment of outstanding toxicologists into EPA and other regulatory agencies. We strongly recommend that EPA increase its efforts to obtain from the U.S. Civil Service Commission a career category and promotion ladder for toxicologists.

We are gratified by the Agency's program to obtain input from interested parties, including industry representatives, at an early stage in their development. We are impressed by the diligence and desire to learn exhibited by the new Assistant Administrator and the staff of the Office of Toxic Substances. We feel that the Agency has generally recognized its responsibility to consider the costs which its regulatory program will impose on the public and the industry and has arrived at reasonable results in many instances. Although we are concerned about certain aspects of the implementation program, and have mentioned some of those concerns today, we hope that the present spirit of cooperation and mutual trust can be maintained in dealing with these and other issues in the future; only by doing so can the legitimate goals of the statute be obtained.

Thank you.

[The list attached to Mr. Ellison's statement follows:]

SOCMA MEMBERSHIP

ACETO INDUSTRIAL CHEMICAL CORP.
ALLIED CHEMICAL CORP.
AMERICAN COLOR & CHEMICAL CORP.
AMERICAN CYANAMID CO.
AMERICAN HOECHST CORP.
ARAPAHOE CHEMICALS, INC., A SYNTEX CO.
BASF WYANDOTTE CORP.
BERNCOLORS-POUGHKEEPSIE, INC.
BIDDLE SAWYER CORP.
BOFORS LAKEWAY, INC.
BORDEN CHEMICAL CO.
BUFFALO COLOR CORP.
CAREY INDUSTRIES, INC.
CARROLL PRODUCTS, INC.
CELANESE CORP.
CHATTEM DRUG & CHEMICAL CO.
CIBA-GEIGY CORP.
CP CHEMICALS, INC.
CROMPTON & KNOWLES CORP.
DAY-GLO COLOR CORP.
DEGUSSA CORP.
DOW CHEMICAL USA
DRAKE CHEMICALS, INC.
DREW CHEMICAL CORP.
DU PONT DE NEMOURS & CO., E. I.
DYE SPECIALTIES, INC.
EAST SHORE CHEMICAL CO., INC.
EMERY INDUSTRIES, INC.
EVANS CHEMETICS, INC.
FABRICOLOR, INC.
FAIRMOUNT CHEMICAL CO., INC.
FIRST CHEMICAL CORP.
FMC CORP.
GAF CORP.
GANE'S CHEMICAL WORKS, INC.
HARDWICKE CHEMICAL CORP.
HARSHAW CHEMICAL CO., THE
HATCO CHEM. DIV., W. R. GRACE & CO.
HERCULES, INC.
HEXCEL, FINE ORGANICS DIV.
HILTON-DAVIS CHEMICAL CO., THE, DIV. OF STERLING DRUG, INC.
HOOKER CHEMICALS & PLASTICS CORP.
ICI AMERICAS, INC.
IMC CHEMICAL GROUP, INC.
INMONT CORP.
KOHNSTAMM, H., & CO., INC.
KOPPERS CO., INC.
LONZA, INC.
M&T CHEMICALS, INC.
MARTIN MARIETTA CHEMICALS, SODYECO DIV.
MAY, OTTO B., INC.
MC&B MANUFACTURING CHEMISTS
MILLIKEN CHEMICAL, DIV. OF MILLIKEN & CO.
MINEREC CORP.
MOBAY CHEMICAL CORP.
MONSANTO CO.
MOONEY CHEMICALS INC.

MORTON CHEMICAL CO.
MUSKEGON CHEMICAL CO. INC.
NICKSTADT-MOELLER, INC.
NYANZA, INC.
OLIN CORP.
OXIRANE INTERNATIONAL
PASSAIC COLOR & CHEMICAL CORP.
C. J. PATTERSON CO., INC.
PENNWALT CORP.
PFISTER CHEMICAL, INC.
PHILLIPS CHEMICAL CO.
PLASTIFAX, INC.
POLAROID CORP.
PPG INDUSTRIES
PROCTOR CHEMICAL CO., INC.
REILLY TAR & CHEMICAL CORP.
SALSBURY LABORATORIES
SANDOZ COLORS & CHEMICALS
SCHOLLER BROTHERS, INC.
SHERWIN WILLIAMS CHEMICALS
SOLUOL CHEMICAL CO., INC.
SOUTHWEST SPECIALTY CHEMICALS, INC.
STANDARD CHLORINE CHEMICAL CO., INC.
STAUFFER CHEMICAL CO.
SUN CHEMICAL CORP.
SYNALLOY CORP., BLACKMAN UHLER CHEMICAL DIV.
TENNECO CHEMICALS, INC.
TOMS RIVER CHEMICAL CORP.
UNION CARBIDE CORP.
UPJOHN CO., THE
VELSICOL CHEMICAL CORP.
VIRGINIA CHEMICALS, INC.
WHITE CHEMICAL CORP.
WITCO CHEMICAL CORP.

ASSOCIATE MEMBERS

ATLANTA CHEMICAL CO., INC.
BRETON ASSOCIATES, INC.
CHASE MANHATTAN BANK, THE
DELPHI MARKETING SERVICES, INC.
NEAL M. DRAPER & ASSOCIATES
ENVIRONMENTAL RESEARCH & TECHNOLOGY, INC.
R. W. GREEFF & CO., INC.
KENNEDY & KLIM, INC.
KOCH CHEMICAL CO.
THE LUMMUS CO.
HOWARD L. MINCKLER & ASSOCIATES
MONKMAN-RUMSEY
ROGER WILLIAMS TECHNICAL & ECONOMIC SERVICES, INC.
WILSON DYE & CHEMICAL DISTRIBUTORS, INC.

STATEMENT OF RALPH ENGEL, PRESIDENT, CHEMICAL SPECIALTIES MANUFACTURERS ASSOCIATION, ACCOMPANIED BY STEPHEN KELLNER, DIRECTOR, LEGISLATIVE AND REGULATORY AFFAIRS, CSMA; GEORGE LOWRY, TECHNICAL DIRECTOR, MONA INDUSTRIES; DR. DAN HARLOW, SCIENTIFIC DIRECTOR, CSMA; AND ROBERT ACKERLY, GENERAL COUNSEL, CSMA

Mr. ENGEL. Mr. Chairman, my name is Ralph Engel. I am president of the Chemical Specialties Manufacturers Association, headquartered at 1001 Connecticut Avenue, Washington, D.C. I am accompanied by Dr. Dan Harlow, CSMA scientific director; Mr. Robert Ackerly, our general counsel, Sellers, Conner & Cuneo; and Mr. George Lowry, technical director of Mona Industries. CSMA has a membership of over 400 firms engaged in the manufacture, formulation, distribution and sale of insecticides, disinfectants and sanitizers, detergents and cleaning compounds, transportation chemicals, and waxes and polishes for household, institutional and industrial uses. CSMA has been actively involved in toxic substances matters beginning with the early legislative development of the Toxic Substances Control Act (TSCA). We have maintained an active role in the implementation activities of TSCA as well as a leadreship position in interpreting TSCA in our industry. We are thus deeply interested in voicing our assessment of TSCA activities during the past 1½ years. We thank you for the opportunity.

Our general assessment of the implementation of TSCA to date is that EPA has acted to stretch the language of the act in some respects beyond its plain and clear language and congressional intent.

In particular, we point to the Agency's final rules for the implementation of section 8(B) inventory. This section requires the administrator to develop ". . . a list of each chemical substance which is manufactured or processed in the United States." (Emphasis added). Section 8(A), on the other hand, which requires a separate rule promulgation, gives the Administrator authority to require "companies to maintain . . . and submit to the Administrator such reports, as the Administrator may reasonably require . . .". We believe that the intent of the act was for all companies, regardless of size to comply with section 8(B) by reporting only the name of the chemical substance, while those companies not exempt under the small business definition were to report section 8(A) information such as production volume.

The final EPA implementation of the inventory reporting under section 8(B) went beyond the simple list and included information which should have been obtained under section 8(A) reporting. In reality, EPA combined section 8(A) and section 8(B), presumably to avoid some of the small business exemptions provided by Congress in section 8(A). The final rules, which were promulgated to implement section 8(B) required more than a mere listing of chemical substances manufactured in the United States, as called for by section 8(B).

The rule rather required extensive reporting by both large and small business, including the name of the chemical substance, its site(s) of manufacture, the manufacturer's name, production volume and whether or not the chemical substance was site-limited.

This marked deviation from the congressional intent of minimizing reporting by small business is reflective of a generally perceived at-

titude of the Agency that it should exercise its recordkeeping and information gathering authorities to fulfill any and all data needs felt by other regulatory agencies which were granted statutory access to data generated under TSCA. This focus on data collection is at the very real expense of what should be the Agency's principal focus: The control and regulation of "toxic chemical substances."

A further indication of the "data collection syndrome" and transgression of statutory authority can be gleaned from the section 8(B) inventory proposal of last August when the Administrator sought to establish a small business definition which would have only excluded businesses of $100,000/year sales or smaller. Such a firm would generate, using a 5–6 percent profit from sales average, only $5,000 to $6,000/year profit. Thus, the "exclusion" would effectively exclude no firm from reporting, thereby providing the Administrator with still more data not intended by Congress for collection by EPT.

Another example of EPA over-extending statutory authority and congressional intent existed in proposals for implementation of section 8(E), substantial risk reporting.

The language of the act states, in part:

> Any person who manufactures, processes, or distributes in commerce a chemical substance or mixture . . . and who obtains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment shall immediately inform the administrator . . .

The policy proposed by EPA was that "any person who manufactures, processes" . . . be defined as any individual employee of a company capable of appreciating the risk. The language of the act "any person who manufactures . . ." and so forth had a clear intent that a company must report since the company is the "manufacturer, processor, or distributor" and so forth.

Again, we commented extensively on this interpretation of TSCA by EPA. We noted that in the joint explanatory statement of the Congressional Conference Committee, the following language appeared:

> Subsection (E) requires manufacturers, processors, or distributors in commerce of a chemical substance or mixture as well as their liability insurers to inform the administrator when they receive information which supports the conclusion that such substance or mixture causes or contributes to an unreasonable risk of injury to health or the environment. Such persons are relieved of such requirements when they have reason to believe that the administrator has been adequately informed of the risk.

"Such persons" in the paragraph refers to "manufacturers, processors, or distributors in commerce of a chemical substance" which precede it in the same paragraph. There is no indication that "such persons" was intended to include all employees and officers of a corporation as EPA had concluded in its statement of interpretation and enforcement policy for section 8(E). Indeed, the common interpretation of "manufacturers, processors, or distributors in commerce" would be the corporate entity.

The Agency, apparently recognizing its inability to hold all individual employees liable as persons under section 8(E), amended their original proposal so as to include only those employees . . . "capable of appreciating the significance of . . ." the risk, a position

that we believe is still outside the authority of the Administrator under section 8(E).

However, it is a fact. We have recited the details of these specific implementations to illustrate our belief that EPA has, in these initial TSCA actions, not followed the clear language of the act nor congressional intent. It rather has adopted the posture of an advocate so as to effectively assume a position which precludes proper administrative practice and goes beyond the mandate from Congress that the act be carried out in a reasonable and prudent manner. It is an act that requires reasonableness and prudence.

It is difficult for regulators to fully understand the absolute importance of protecting trade secret and confidential information owned by the regulated company. Growing industry concern for the continuing confidentiality of sensitive business data was heightened considerably by the additional data required by the final inventory reporting rules.

Confidentiality of business information is of critical concern to the chemical specialty industry. This industry exists by being able to focus on particular needs and problems and developing small volume but critically important chemicals as solutions to these problems.

As such, this ability to define the needs and develop commercial chemicals to fill these needs is the essence of our industry's existence. The market information developed in the conduct of our business must be kept confidential if our member companies are to exist and to continue to serve these needs; otherwise, we are open to unfair competitive intrusion by companies both foreign and domestic. Some few companies are not willing to spend the time and money to isolate, identify, and test innovative chemicals to answer these problems; they can use other companies' confidential information to gain quick market entry.

CSMA believes that the Agency has become much more aware recently of industry concerns for security of confidential data and the staff has conscientiously attempted to be responsive to these concerns. However, a major problem still exists and arises from the fact that the development of TSCA security regulations for the treatment of confidential information submitted to EPA under TSCA has not been subject to Agency rulemaking.

In November 1977, CSMA presented a statement at an EPA public meeting concerning submission of confidential business information under TSCA. The CSMA statement—attached hereto as exhibit I (p. 146) was intended to make the Agency aware of its responsibilities under TSCA and to insure the safety of confidential and trade secret information by urging rulemaking for the entire TSCA security program.

On January 18, 1978, EPA published proposed regulations setting forth procedures for dealing with requests for information under the Freedom of Information Act (FOIA) and made certain proposed modifications so that FOIA regulations would conform to requirements of TSCA. These proposed regulations apply only to public requests for disclosure of data submitted to EPA under TSCA and do not encompass the total security scheme within the Agency for the protection of confidential data submitted to it under TSCA.

In comments on the January proposal, CSMA again called for the Agency to develop a total security program. We noted that provisions

in the proposed regulations failed to deal with the consequences, deterrents, and remedies for wrongful inadvertent disclosure of confidential data by Federal employees and employees of contractors and subcontractors. A proposed amendment of January 18 to current regulations would extend penalities for willful, improper disclosure of confidential data to contractors and subcontractors and their employees.

While CSMA strongly supports this extension, we believe that such penalties should also reach instances of inadvertent disclosure. They hurt as bad.

Wrongful disclosure of trade secret and confidential business information, whether willful or inadvertent, results in the same detriment to a submitting firm. Industry faces unmitigated risks in submitting information valuable to competitors and costly to the submitter to develop or generate. Absent effective measures to protect the integrity of confidential business information and trade secrets, the net effect will be to discourage research and development. And we have seen examples of that in other industries.

It is disappointing to us that while the Agency chose to publish proposed rules on January 18 under the Freedom of Information Act, it declined to publish proposed rules relative to its own security provisions under TSCA for the Agency maintenance of confidential business information submitted to it. Instead, the EPA has chosen to regard these very important regulations as being "internal procedures" not subject to rulemaking. These "internal procedures" have been distributed to the public and the Agency has invited comment on them. However, the problem is that absent formal rulemaking, no Agency record is available for review by the district court to determine whether or not these "final procedures" are arbitrary and capricious. As important as these security provisions are, they should be subject to rulemaking, especially in view of the use of rulemaking for the January 18 Freedom of Information Act regulations.

Because of the alleged security procedure defects, the trade secret issues are already starting to reach the judiciary. On June 22, 1978, the Polaroid Corp. was successful in obtaining a preliminary injunction enjoining enforcement of EPA inventory reporting information for use of 20 chemicals which are critical to its process and of very high value to its competitors until adequate confidentiality regulations and procedures have been adopted by EPA. In the opinion, the court expresses concern over the failure of TSCA—except in one instance—to provide notice to the submitter of the EPA's intention to release to the public the manufacturer's data if it falls within the confidentiality exemptions. Without prior notice of EPA intention to release the data, the manufacturer is deprived of opportunity to resort to legal action to protect the confidential status of the trade secret information.

In short, the court in granting a preliminary injunction found Polaroid had a reasonable likelihood of establishing that in the absence of standards for release of information and of notice and opportunity for hearing and judicial review:

(1) Release of information under section 14(A)(1), 14(A)(2), 14(A)(4), and 14(E) of TSCA may constitute deprivation of property without due process of law, and

(2) The release of information under section 14(A)(2) constitutes taking of property for public purposes without compensation.

It should be clear, therefore, that the confidentiality question raised and the potential major consequences for all industries of premature, willful or inadvertent release of confidential and trade secret information demand the highest standards of Agency and judicial review.

Another concern of our industry is the commingling of independent statutes. As a result of the recent incorporation of the office of Pesticide programs into the Office of Toxic Substances, there is some concern within the industry that regulation and registration of pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) will become tangled in the broader TSCA statute.

There is a similar concern among other portions of the industry that the Agency may attempt to mold TSCA, using FIFRA as the mechanism, into a licensing type statute. While we realize the need to streamline administration of Agency functions, we believe that EPA must not commingle administrative functions of these two statutes. Congress must impress upon the Agency the importance of each of these statutes being separate pieces of legislation designed to regulate different segments of the chemical industry.

Mr. Chairman, I am aware of your interest of hearing from an industry representative and should like to ask your permission to have Mr. George Lowry, technical director of Mona Industries, address this subcommittee concerning the impact of TSCA on small business. Mr. Lowry's company is truly a small chemical company with about $10 million in annual sales. I am sure he can give this committee some additional insight into the implementation of TSCA. Thank you.

STATEMENT OF GEORGE LOWRY

Mr. LOWRY. Thank you, Mr. Chairman, for this opportunity.

In enacting TSCA, Congress was very much aware of the impact that this broad-based statute would have upon small business and attempted to minimize its burdens. EPA thus far has implemented final regulations for inventory reporting and is currently developing section 5 premarket notification proposed rules. In both of those instances, the Agency actions, either enacted or proposed, will negatively impact upon small business.

As previously noted by Mr. Engel, the initial small business exclusion under section 8(A) which would exempt small businesses from reporting information other than a mere inventory list has been circumvented by the final inventory regulations. The small business definition, even though modified by EPA to $5 million annual sales, still produces an extraordinary economic reporting burden on small business. These same businesses are already feeling the heavy pressure of governmental regulation from many statutes and agencies.

In commenting on this small business exclusion, CSMA solicited and received a number of cost estimates for compliance with the proposed expanded inventory reporting. We note the following company profiles as examples:

Example 1—A. Approximately $1 million annual sales. B. Twenty-six employees. C. Estimated cost of compliance is $5,000–$6,000 or 10 percent of annual profit.

Example 2—A. Approximately $10 million annual sales. B. Sixty-two employees. C. Estimated cost of compliance is $40,000 or 7.75 per cent of annual profit.

Example 3—A. Approximately $100 million annual sales. B. Nine hundred and fifty employees. C. Estimated cost of compliance is $250,000 or 0.05 percent of annual profit.

By way of contrast, the Small Business Administration defines a small business in this industry as one having 500 or less employees.

From this information we believe that an inverse relationship exists between the size of the company and the percentage of profits estimated to be spent on the inventory. The smaller the company, the greater the percentage of profit consumed. With data such as this and with additional data relating size of company to availability of computers and full time regulatory personnel, CSMA recommended that the small business definition be set at $30 million annual sales for the inventory reporting requirement. We were unsuccessful.

We are concerned that future interpretations by EPA of other sections of TSCA will impose additional major burdens not intended by the act upon small business. Indeed, this concern has been expressed by other interested parties, and I would like to quote from a letter from the Industrial Union Department of the AFL–CIO, to Chairman Magnuson of the Senate Appropriations Committee, on May 10, 1978:

> We were the first to tell you that small businesses needed help—not from demagogues but from the Appropriations Committees of the Congress of the United States—in meeting the OSHA requirements. We are the first to tell you that the TSCA program has the same need.

The section 5 premarket notification regulations applicable to new chemicals and significant new uses currently under development by EPA present similar small business problems. The growth, vitality and actual existence of small specialty chemical companies depends on our ability to develop and rapidly market products which will solve specific problems; often the development of these new chemicals require many hours of intensive research coupled with toxicity testing, pilot plant and engineering studies and development of manufacturing procedures. Much of our research efforts are directed toward developing products with reduced toxicity and greater efficacy. Volumes are frequently small in terms of tonnage.

The extensive testing requirements now being considered by EPA for implementation of the section 5 premanufacture notice present a major impact to the existence of the small specialty chemical manufacturer.

From our first look, the probable cost of even the base set studies being considered for section 5 would preclude the development of most new products in our industry. Obviously, in an industry such as ours, where the average life of a product is 10 years, without the continual addition of new products, small chemical companies cannot remain in business.

Speaking specifically for Mona Industries, another concern we have is with the section 5 requirement that the premarket notification notice be published in the Federal Register. Currently, only a generic description of the chemical substance would be required.

However, some pressure is being applied claiming that this is not satisfactory. If a Federal Register notice were to reveal the exact

chemical identity of a chemical substance, it would remove any technical edge we might have and enable our competitors to offer the same product without the need for extensive research and testing and other overhead.

The growth of small companies in the Nation as a whole has been based on the opportunity to capitalize on innovative ideas. Only by preserving confidentiality can a small company justify innovative research, remain viable and dynamically contribute to this country's prosperity.

Mr. ENGEL. Mr. Chairman, we thank you and the subcommittee for the opportunity to testify. We believe the subcommittee should hold this type of hearing periodically so that both the Agency and the industry can bring forth potential problems in administration of this vital statute. It is one that requires a prudent approach, along with a spirit of cooperation. Thank you very much.

[The attachment to Mr. Engel's statement follows:]

EXHIBIT I

STATEMENT OF

STEPHEN KELLNER

DIRECTOR

LEGISLATIVE AND REGULATORY AFFAIRS

CHEMICAL SPECIALTIES MANUFACTURERS ASSOCIATION

AT AN EPA PUBLIC MEETING

CONCERNING SUBMISSION OF CONFIDENTIAL

BUSINESS INFORMATION UNDER TSCA

NOVEMBER 18, 1977

CHEMICAL SPECIALTIES MANUFACTURERS ASSOCIATION
1001 CONNECTICUT AVENUE, N.W.
WASHINGTON, D.C. 20036

I AM STEPHEN KELLNER, DIRECTOR OF LEGISLATIVE AND REGULATORY AFFAIRS FOR THE CHEMICAL SPECIALTIES MANUFACTURERS ASSOCIATION. CSMA APPRECIATES THIS OPPORTUNITY TO PRESENT OUR VIEWS WITH RESPECT TO ISSUES RAISED BY EPA'S NOTICE OF NOVEMBER 7th CONCERNING SUBMISSION OF CONFIDENTIAL BUSINESS INFORMATION.

AS A REPRESENTATIVE OF A LARGE CHEMICAL TRADE ASSOCIATION, I MUST ADVISE THAT THERE IS SERIOUS AND IMMEDIATE CONCERN WITHIN THE BUSINESS COMMUNITY WITH RESPECT TO THE GRADUAL EROSION OF THE STATUS OF DATA HERETOFORE CONSIDERED TO BE TRADE SECRET AND CONFIDENTIAL MATERIALS AND WITH THE PROTECTION, IF ANY, AFFORDED SUCH DATA WITHIN MANY GOVERNMENT AGENCIES AND WITH THEIR CONTRACTORS AND SUBCONTRACTORS.

THE PROTECTION OF TRADE SECRET AND CONFIDENTIAL MATERIAL WITHIN GOVERNMENT AGENCIES AND THEIR INDEPENDENT CONTRACTORS STRIKES AT THE VERY HEART OF THE FREE ENTERPRISE SYSTEM. OVER THE PAST FEW YEARS, WE HAVE WITNESSED THE EROSION OF TRADE SECRET PROTECTION AND AS A DIRECT RESULT, THE DECLINE OF RESEARCH AND DEVELOPMENT. ABSENT FIRM AND UNQUALIFIED TRADE SECRET PROTECTION REGULATIONS IN THIS INSTANCE, WE WILL SEE THE LACK OF FURTHER INCENTIVE AND THE LOSS OF A VERY IMPORTANT NATURAL RESOURCE. EPA MUST RECOGNIZE THE NEED FOR PROTECTION OF TRADE SECRET AND CONFIDENTIAL DATA SUBMITTED BY CHEMICAL MANUFACTURERS TO THE AGENCY UNDER PROVISIONS OF TSCA IF THE MANUFACTURER'S COMPETITORS ARE NOT TO GAIN UNFAIRLY FROM TIME AND FINANCIAL COMMITTMENTS EXPENDED IN DEVELOPING A CHEMICAL PRODUCT.

THE QUESTION OF PROTECTION OF TRADE SECRET AND CONFIDENTIAL DATA WITHIN FEDERAL AGENCIES AND THEIR OUTSIDE CONTRACTORS IS NOT NEW TO CSMA. THREE YEARS AGO, CSMA URGED THE CONSUMER PRODUCT SAFETY COMMISSION TO PROMULGATE BY RULE,

REGULATIONS FOR THE INTERNAL SECURITY OF PRODUCT FORMULATION DATA WHICH WAS ORDERED BY CPSC TO BE SUBMITTED BY MANUFACTURERS IN RESPONSE TO A PRODUCT INGREDIENT SURVEY.

CSMA ALSO SOUGHT RULEMAKING FOR REGULATIONS CONTROLLING THE FLOW OF TRADE SECRET MATERIALS WITHIN CPSC'S OUTSIDE CONTRACTOR AND ITS VARIOUS SUBCONTRACTORS. AFTER NEGOTIATIONS WITH THE COMMISSION FAILED, CSMA FILED SUIT IN THE U.S. DISTRICT COURT FOR THE DISTRICT OF COLUMBIA. PERHAPS THE PRIMARY ISSUE IN THIS CASE IS THE RIGHT OF THE OWNERS OF TRADE SECRET DATA REQUIRED TO BE SUBMITTED TO CPSC TO HAVE AN OPPORTUNITY UNDER THE ADMINISTRATIVE RULEMAKING PROCESS TO SUBMIT COMMENTS ON SECURITY PROCEDURES THEREBY STRENGTHENING THE VERY SECURITY PROCEDURES INTENDED TO PROTECT THE OWNERS DATA. AT ISSUE ALSO, IS CSMA'S FIRM CONTENTION THAT THE SECURITY PROCEDURES OF OUTSIDE CONTRACTORS CHARGED WITH RESPONSIBILITY FOR COLLECTING, COMPILING AND OTHERWISE HANDLING TRADE SECRET MATERIALS LIKEWISE MUST BE SUBJECTED TO MINIMUM STANDARDS DERIVED THROUGH THE RULEMAKING PROCESS.

IN THE CASE OF THE CONSUMER PRODUCT SAFETY COMMISSION, BEFORE THE REQUIRED SUBMISSION OF PRODUCT FORMULARY DATA, THERE WERE NO FORMAL PUBLISHED SECURITY PROCEDURES FOR STORAGE, COLLECTION AND USE OF THE INFORMATION WITHIN THE AGENCY. NOR WERE THERE ANY PROCEDURES, OR FOR THAT MATTER, CONTROL OVER THE INDEPENDENT OUTSIDE CONTRACTOR WHO WAS CHARGED WITH THE RESPONSIBILITY OF REDUCING THE HARD DATA TO COMPUTER TAPES AND SUBMITTING THE TAPES BACK TO THE CONSUMER PRODUCT SAFETY COMMISSION. IN FACT, IT IS CSMA'S CONTENTION THAT THE AGENCY DID NOT EVEN KNOW THAT THE CONTRACTOR WAS USING SUBCONTRACTORS TO ASSIST IN THE PROCESSING OF THE DATA. IT WAS NOT UNTIL AUGUST 31, 1976, ABOUT A YEAR AFTER THE CSMA LAW SUIT WAS FILED, THAT THE COMMISSION PUBLISHED ITS SECURITY PROCEDURES IN THE FEDERAL REGISTER. DESPITE GOVERNMENT COUNSEL'S PROMISE TO THE COURT THAT FORMAL

RULE-MAKING PROCEDURES WOULD BE IMPLEMENTED, NO SUCH OPPORTUNITY FOR COMMENT WAS AFFORDED AFFECTED PARTIES. THE NET RESULT WAS THE UNILATERAL ISSUANCE OF THE AUGUST 31 CPSC SECURITY PROCEDURES. I SHOULD POINT OUT THAT THESE INADEQUATE CPSC PROCEDURES ARE THE VERY SAME PROCEDURES WHICH THE TASK FORCE HAS STATED IT WILL CONSIDER IN DEVELOPMENT OF EPA REGULATIONS. A SECURITY EXPERT, IN AN AFFIDAVIT FILED WITH THE CSMA BRIEF, STATES THAT THE COMMISSION'S SECURITY PROCEDURES AS PUBLISHED IN AUGUST 1976 ARE SERIOUSLY DEFICIENT AND HE OFFERS SOME ALTERNATIVES. I WOULD BE PLEASED TO PROVIDE THIS AFFIDAVIT FOR THE TASK GROUP'S CONSIDERATION.

UNFORTUNATELY, LIKE THE CPSC PROGRAM, THE EPA TENTATIVE FORMAT HAS ONE BASIC GLARING DEFECT; IT ATTEMPTS TO SEGREGRATE SECURITY PROCEDURES OF THE CONTRACTOR FROM THOSE OF THE AGENCY. IN ESSENCE, IT IS A PIECEMEAL POLICY UNDER WHICH THE AGENCY IS GOING TO ATTEMPT TO WEAVE A TIGHT SECURITY PROGRAM. WE DO NOT BELIEVE THIS IS POSSIBLE OR PROPER. ON THE BASIS OF THE INFORMATION SET FORTH IN THE NOVEMBER 7th NOTICE, IT WOULD APPEAR THAT THE CONTRACTOR, CAS, WOULD BE RECEIVING HARD DATA AND COMPILING IT FOR ULTIMATE TRANSFER BACK TO THE AGENCY WITHOUT ANY DULY PROMULGATED SECURITY PROCEDURES OR AT THE VERY BEST, UNDER PROCEDURES WHICH WE AT PRESENT HAVE NO IMMEDIATE KNOWLEDGE OTHER THAN AN ASSURANCE BY THE AGENCY THAT THEY ARE UNDER CONSIDERATION. AS THE CONTRACTOR WILL BE RECEIVING HARD DATA AND THE PROCEDURES WHICH WILL GOVERN THE CONTRACTOR APPARENTLY WILL RELATE ONLY TO COMPUTER SECURITY, THERE IS AN IMMEDIATE VOID UPON RECEIPT OF THE HARD DATA BY THE CONTRACTOR.

ADDITIONALLY, WHAT THE EPA GRANTS WITH ONE BREATH, IT TAKES AWAY WITH ANOTHER. WE ARE TOLD THAT THE INFORMATION RECEIVED UNDER THE INVENTORY REPORTING REGULATIONS WILL GO DIRECTLY TO AN EPA OFFICE AT CAS. CAS IN TURN, WILL PROCESS THE HARD DATA AND IT IS ESTIMATED THAT PROCESSING WILL TAKE 6

TO 8 MONTHS AFTER THE INITIAL REPORTING PERIOD. NEXT, IT IS STATED THAT EPA WILL NOT BEGIN ROUTINE ACCESS TO ALL THE INVENTORY DATA UNTIL THE END OF THE PROCESSING PERIOD. HOWEVER, THEN IT IS EXPLAINED THAT EPA IS CONSIDERING PROVIDING ACCESS TO A PORTION OF THE INFORMATION AS IT IS PROCESSED TO SEARCH FOR SPECIFIC INFORMATION ABOUT A SPECIFIC CHEMICAL OR SPECIFIC COMPANIES. SUBSEQUENTLY, WE ARE ASSURED THAT ACCORDING TO THE PROCESSING RATES AT CAS, EPA ANTICIPATES THAT SECURITY PROCEDURES WILL BE FINAL BEFORE THIS PROCEDURE WOULD BEGIN. FINALLY, WE ARE TOLD SHOULD ANY OTHER TSCA INFORMATION BE OBTAINED IN THE INTERIM, PROCEDURES WOULD BE SPECIFIED FOR ITS HANDLING. THESE STATEMENTS ARE NOT CONSISTANT NOR DO THEY PROVIDE ANY SOLACE FOR AN INDUSTRY WHICH IS EXTREMELY VULNERABLE TO ECONOMIC DAMAGE RESULTING FROM DISCLOSURE OF TRADE SECRETS.

THE BASIC PROBLEM WITH THE APPROACH AS OUTLINED IN THE NOVEMBER 7th NOTICE IS THAT IT IS A PIECEMEAL, UNCOORDINATED ATTEMPT TO INSURE THE INTEGRITY OF THE MOST IMPORTANT DATA THAT INDUSTRY MIGHT EVER GENERATE. THE OWNERS OF SUCH TRADE SECRET DATA HAVE AN ABSOLUTE RIGHT TO THE GUARANTEE OF ITS SAFETY AND SECURITY OR IT SHOULD NEVER BE SUBMITTED. CSMA MEMBER FIRMS BELIEVE THAT ANYTHING LESS THAN A COMPLETE AND OPEN RULE-MAKING PROCEDURE FOR THE ENTIRE TSCA SECURITY PROGRAM IS INSUFFICIENT. THIS NOT ONLY INCLUDES EPA'S INTERNAL PROCEDURES BUT THE CONTROL AND THE BASIC PROCEDURES TO BE IMPOSED ON ANY CONTRACTOR OR SUBCONTRACTOR WORKING WITH THE AGENCY UNDER THE TOXIC SUBSTANCES CONTROL ACT.

IN CSMA'S COMMENTS FILED SEPTEMBER 16, 1976 CONCERNING THE AUGUST 2nd INVENTORY REPORTING REQUIREMENTS, THE ASSOCIATION MADE IT VERY CLEAR OF OUR CONCERN FOR SECURITY. WE STATED:

> "... WE NOTE THAT THE AGENCY HAS PRODUCED PROPOSED REGULATIONS AND DRAFT FORMS FOR COLLECTING CONFIDENTIAL DATA BUT HAS NOT AT THIS TIME PROMULGATED RULES FOR PROTECTING THE CONFIDENTIALITY OF THIS DATA UNDER TSCA. IT IS WHOLLY INAPPROPRIATE FOR THE AGENCY TO REQUEST AND RECEIVE CONFIDENTIAL DATA WITHOUT PROPER PROCEDURES FOR PROTECTING SUCH DATA."

ACCORDINGLY, CSMA REQUESTED THE AGENCY TO PROMULGATE REGULATIONS FOR THE PROTECTION OF ALL CONFIDENTIAL DATA. THE ASSOCIATION ALSO GAVE A FIRM COMMITMENT TO WORK WITH THE AGENCY TO DEVELOP AN ACCEPTABLE SECURITY SYSTEM FOR THE PROTECTION OF CONFIDENTIAL DATA SUBMITTED UNDER TSCA.

EPA ITSELF RECOGNIZES THE OBLIGATION TO PROTECT TRADE SECRET DATA. IN THE REPUBLICATION OF THE INVENTORY REPORTING PROPOSED REGULATIONS, THE AGENCY CITES SECTION 14 OF TSCA WHICH MAKES IT CLEAR THAT IF EPA DETERMINES INFORMATION IS EXEMPT, UNDER 5 U.S.C. 552 (b)(4), IT MUST BE KEPT CONFIDENTIAL BY EPA. MOREOVER, SECTION 2 (b)(3) OF THE ACT STATES THAT "AUTHORITY OVER CHEMICAL SUBSTANCES AND MIXTURES SHOULD BE EXERCISED IN A MANNER AS NOT TO IMPEDE UNDULY OR CREATE UNNECESSARY ECONOMIC BARRIERS TO TECHNOLOGICAL INNOVATION WHILE FULFILLING THE PRIMARY PURPOSE OF THIS ACT TO ASSURE THAT SUCH INNOVATION AND COMMERCE IN SUCH CHEMICAL SUBSTANCES AND MIXTURES DO NOT PRESENT AN UNREASONABLE RISK OF INJURY TO HEALTH OR THE ENVIRONMENT." ACCORDINGLY, CSMA BELIEVES THAT THE GENERAL APPROACH AS OUTLINED IN THE NOVEMBER 7th PROPOSAL SHOULD BE MODIFIED TO INCLUDE THE ENTIRE SECURITY SCHEME BOTH WITHIN EPA AND FOR THE USE OF OUTSIDE CONTRACTORS AND SUBCONTACTORS. ABSENCE SUCH UNIFORM APPROACH AND ADMINISTRATIVE PROMULGATION OF COMPREHENSIVE SECURITY REGULATIONS, NO CONFIDENTIAL INFORMATION SHOULD BE SUBMITTED BY MANUFACTURERS EITHER TO EPA, CAS, OR ANY OTHER ENTITY DESIGNATED BY THE AGENCY.

WITH RESPECT TO ANY SECURITY PROCEDURES, PROMULGATED FOR THE AGENCY OR CONTRACTORS, WE HAVE HEARD BEFORE THE COMMENT THAT SUCH SECURITY SYSTEMS COULD NOT BE DISCLOSED BECAUSE THAT INFORMATION IN ITSELF IS CONFIDENTIAL. IT IS INDEED IRONIC THAT KNOWLEDGE OF THE VERY SYSTEM UNDER WHICH INDUSTRY DATA IS TO BE KEPT IS DENIED TO INDUSTRY UNDER THE GROUNDS THAT IS IS CONFIDENTIAL. WE DO NOT NECESSARILY NEED THE KEYS TO THE SAFE, BUT WE ARE ENTITLED TO KNOW HOW THE SAFE IS TO BE LOCKED AND GUARDED. IN ESSENCE, PARTICIPATION IN THE DEVELOPMENT THROUGH RULEMAKING OF THE GENERAL STANDARDS BY WHICH THE AGENCY AND OUTSIDE CONTRACTORS ARE TO KEEP CONFIDENTIAL AND TRADE SECRET INFORMATION IS THE NECESSITY . THE AFFIDAVIT WHICH I PREVIOUSLY MENTIONED, SHOWS THE CONTRIBUTIONS EXPERT PERSONS OUTSIDE THE AGENCY CAN RENDER IF PERMITTED THE OPPORTUNITY TO PARTICIPATE IN THE RULE-MAKING PROCESS.

THE NOVEMBER 7th NOTICE DOES NOT GIVE DETAILS AS TO THE COMPOSITION OF THE TSCA DATA SECURITY TASK FORCE. HOWEVER, IT WOULD BE BENEFICIAL TO ALL CONCERNED IF INDUSTRY WERE REPRESENTED ON THIS TASK FORCE. WE REQUEST, THEREFORE, THAT THE AGENCY APPOINT INDUSTRY REPRESENTATIVES TO SERVE ON THE TASK FORCE TO ASSIST THE AGENCY IN IMPLEMENTATION OF ITS TOTAL SECURITY SYSTEM.

IN ADDITION TO THE SPECIFIC ISSUES RAISED BY THE AGENCY IN THE NOVEMBER 7th NOTICE, WE OFFER THE FOLLOWING POINTS FOR CONSIDERATION:

(HEADINGS REFER TO THOSE IN 42 FED. REG. 57984.)

C. DOCUMENT CONTROL

- o SHOULD FILES CONTAINING CONFIDENTIAL INFORMATION BE OF A SPECIAL COLOR TO FACILITATE DOCUMENT CONTROL?

D. EMPLOYEE CONTROL

- o SHOULD EMPLOYEES HAVING ACCESS TO CONFIDENTIAL DATA BE BONDED?

E. TRANSMISSION OF DATA

- o SHOULD FIELD OFFICES HAVE ACCESS TO DATA AND, IF SO, HOW SHOULD IT BE CONTROLLED?

F. ACCESS AND DISTRIBUTION PROCEDURES

- o WHAT CONSTITUTES AN EMPLOYEE'S "NEED TO KNOW"?

G. FURNISHING INFORMATION TO OTHER FEDERAL AGENCIES

- o WHAT KIND OF CONFIDENTIAL DATA, IF ANY, SHOULD BE FURNISHED TO OTHER FEDERAL AGENCIES?

H. FURNISHING INFORMATION TO CONTRACTORS

- o SHOULD CONTRACTORS BE BONDED?
- o SHOULD PROVISIONS BE WRITTEN INTO EPA CONTRACTS CALLING FOR PENALTIES TO BE IMPOSED UPON OUTSIDE CONTRACTORS FOR INADVERTANT OR NEGLIGENT RELEASE OF DATA?
- o SHOULD THERE BE CONTROLS ON TIME SHARING OF COMPUTERS?
- o SHOULD THERE BE RESTRICTIONS ON THE USE OF SUBSONTRACTORS?
- o SHOULD THERE BE LIMITATIONS ON REMOTE TERMINAL ACCESS?
- o SHOULD EPA SEEK THE OPINION OF AFFECTED PARTIES CONCERNING CONTRACTOR CANDIDATES PRIOR TO SELECTING A CONTRACTOR WHO WILL HAVE ACCESS TO TRADE SECRET DATA?
- o SHOULD CONTRACTORS BE AUDITED FOR COMPLIANCE WITH SECURITY REGULATIONS? IF SO, SHOULD RESULTS OF AUDITS BE MADE PUBLIC?

WE APPRECIATE THIS OPPORTUNITY TO SHARE OUR VIEWS WITH YOU AND WE OFFER OUR FIRM COMMITMENT TO WORK WITH THE AGENCY TOWARD THE DEVELOPMENT OF A TOTAL SECURITY SYSTEM CONSISTANT WITH THE MANDATE OF TSCA.

Senator MUSKIE. Now you have heard each other. Do you have any comments to make about any of the testimony presented by other members of the panel?

Ms. WARREN. I would like to speak briefly to the issue of small business. I was involved in the efforts to pass the Toxic Substances Control Act and there was sentiment in one House to exempt small business completely and the other House not to.

There are compromises which have small businesses in for some and out for others. The fact of the matter is a lot of the innovations come from small business. If they produce the bulk of the new chemicals, they are the ones that produce the new PCB's and so forth.

The exemption from testing those chemicals should not be the appropriate way to deal with this. The way to do it is to have some mechanism to handle the expense. I don't know whether I understood them correctly here today to suggest that because these companies find the testing requirements onerous, therefore the chemicals should not be tested. I think that defeats the purpose of the act.

Senator MUSKIE. Any other comments?

Mr. ENGEL. Mr. Chairman, I gave no indication that any company is indicating they want nothing to do with testing. I think the question really becomes rational testing relative to the type of product that we are talking about and not just a bevy of base tests which every company has to perform of every product which can't be met financially.

Therefore, useful products are going to be terminated because no one can perform the tests indicated. But no one is indicating from our industry that no testing should be done.

Senator MUSKIE. Well, that leads to a rather obvious question, it seems to me. Is there any disagreement with the suggestion made that every chemical ought to be fully tested for its potential for toxicity? Who should mandate it, or who should perform the test? You gentlemen are in the chemical business. You represent an industry that has introduced, according to the figures we have, 70,000 chemicals into our environment and into our society.

And I am simply asking is there any challenge to the suggestion that chemicals, those now being used, if they have not been adequately tested, ought to be fully tested with respect to their toxic potential?

Mr. HECKERT. If I may respond to that, I think that it is an admirable goal and in practice we may come closer than is currently perceived.

Senator MUSKIE. Who comes closer?

Mr. HECKERT. I am talking about society today. We may have come closer to the goal of adequately testing chemicals than is currently perceived. Let me support that position with some observations.

We have been dealing with many of these 70,000 chemicals for a long time. We know a great deal about their acute toxicity. In many cases, where there is reason to believe because of chemical structure or because of widespread exposure, toxicological evaluations have been made.

So either through the experience of manufacture and selling them for decades or having evaluated them in the laboratory, we have a reasonable toxicological handle on a large number of these 70,000 materials.

Clearly the 1960's and the 1970's led to some very unpleasant surprises for our industry and for the population as a whole. At the beginning of the 1960's, conventional wisdom in Government, academia, medical circles and in industry was that there were very few chemical products that were carcinogens. Fifteen years has made a big change.

The fact is that during the period in which the law was being developed, industry has not been sitting on its hands. We responded to this new information just as you would hope we would.

We began increasing our testing capability and working on test methods. We began this effort by carefully analyzing the materials we produced in large amounts or to which the public is widely exposed in order to identify those that ought to receive priority testing. We now are working on that list.

Therefore, the fact that EPA has not yet promulgated any rules under section 4 of this law does not in any way suggest that the Nation's resources for testing chemicals aren't fully engaged in dealing with the problem.

Senator MUSKIE. I think I would challenge that, when you say fully engaged. And then you appear on this panel, and urge that small business, as yet not fully defined, somehow be exempted from the discipline.

I have to conclude that small business is not fully engaged in examining toxicity potential of many of the chemicals which they introduce in the stream. If they are, then why is it so burdensome to require that they share the information with us that they report? And for those laggards, and I assume there are laggards—they ought to be brought into line.

But you say the challenge is being fully met now.

Mr. HECKERT. I am not saying the challenge is being fully met. I am saying we are using all the capabilities we have to deal with the problem.

The toxicology testing capability of this country is very distinctly limited. There simply aren't enough toxicologists, pathologists and medical doctors to do more evaluations than are currently being done.

However, industry is responding to this. We have established a Chemical Industry Institute of Toxicology in North Carolina. Most of the large companies have doubled their capacity to run tests or perhaps installed entirely new facilities for toxicological evaluation. The small companies are contracting this work out, for the most part, because they simply can't internally develop that capability.

All of the skilled people in this country who can make these assessments are currently engaged in making them.

Senator MUSKIE. Now the question really is whatever the resources are, that they are effectively organized to identify the risks wherever they exist. And I get the impression from all of the panel members that they exist. With respect to small businesses, however defined, the risk is so minimal that the burdens of being part of this program are too great to impose.

Mr. HECKERT. I don't think that is the industry's position. Before turning the mike over to those who represent the smaller companies, let me just cite MCA's position.

MCA has never taken the position that a chemical should be exempt from evaluation by virtue of size or commercial significance. We have said that the resources of the country should be used initially to evaluate high priority chemicals. There are enough chemicals that require priority attention around so that now is not the time to be overly concerned about testing materials that don't receive widespread human or environmental exposure. In essence, it is a question of prioritization.

I think you made an excellent observation when you said our key concern now is are we working with the proper priorities.

Senator MUSKIE. Of course, priorities apply to this as most other fields. Those toxic materials which have already been identified ought to get our first attention.

Does that mean that in the meantime we don't take preventive steps with respect to toxicity potentials of which we are now unaware, which may provide the surprises of the seventies? You are not really saying to me, are you, that we have been using the 70,000 chemicals, all of them, for decades? Aren't they being introduced at the rate of thousands per year?

Mr. ELLISON. Many of those, sir, are chemicals that are in the same family of chemicals that we have been using for many, many years. There is not that much of a change in the chemical structure.

Being a relatively small company—not a small one by EPA's definition, but at least a company that is probably better able to do testing than the small companies—we have done a lot in this area to try to figure out which of our chemicals may have toxicological problems or may have environmental problems. What we as a chemical industry are really asking for when we say limit the testing is let us establish the priorities and then work on the toxicological environmental testing, to the extent that we have testing facilities. As an example, I recently visited the Chemical Industry Institute of Toxicology at Research Triangle Park in North Carolina. They are helping us look into areas that need more testing information.

We, at Virginia Chemicals, have also done extensive literature research, trying to compile as much information as we can about physical toxicological and ecological effects of our chemicals to help us determine areas where we need to do additional testing. We are also looking at the exposure of our employees and the exposure to our chemicals in the marketplace. Those chemicals that seem to have a deficiency in testing information would be the ones that would seem to make sense to test first in any priority system.

If we are given a request by EPA to do—if I may be facetious—tests with green rats and next week we are given a request by OSHA to do testing with purple rats and then another agency with yellow rats, we are not using the testing facilities in the way we should.

We should make sure we have all the information together, we have a recognized protocol, and we are asking the types of questions that really need be asked and spend our money and use the limited testing facilities to do that and only that type of testing.

Senator MUSKIE. I can't really quarrel with that objective. But I hear on the one hand an argument that with respect to public employees, employed by TSCA, that the inadvertent disclosure of information should be subject to penalty, confidential information; and

yet, with respect to corporate entities' employees, individual employees, however involved they may be in the manufacture of toxic materials, however much information they may have about the toxicity of materials, shouldn't be subjected to the mandates of the law.

Now what kind of a double standard is that? The public employees should be punished for inadvertent disclosure of material, but the provision of information should be limited to the neutral corporate entity and shouldn't be brought to bear upon high officials or individuals or employees of companies who are in possession of information.

You know, I find that a very difficult double standard to understand, if what you are saying to me is truly the view of this panel.

This committee did not produce this law. We have been given jurisdiction over it by virtue of the reorganization of the committees of the Senate. And I am trying to understand what this law is about, what it was intended to do, whether it is a tool for progress in dealing with the problem or an obstacle to progress in dealing with the problem, whether the attitude of those regulated is positive or negative, whether it is their intent to use the law to block progress or to advance it.

What I have always tried to stimulate in legislation for which I am responsible is a mutual effort, a cooperative effort, between the regulated and the regulators that serve the public interest.

But here I get testimony from the public interest advocate which says that the Agency is too neutral, that it is not an advocate in the sense of working to advance the public interest. And then I get testimony from the rest of you to the contrary, that it is too advocacy-minded and that it apparently is seeking to harass people in the industry.

I understand the problems of small business. I come from a States which has only small business. We don't have any big business. We used to want big business. The attitude seems to be changing.

But in any case, we understand there is a difference. But the fact is, isn't it, gentlemen, that many of the new products, much of the innovative thrust of the private sector is coming from so-called small business. That is where a lot of it happens. I would imagine it happens in the chemical industry. I see it happening in my State, and even my State doesn't have a viable industrial base. I see it happening. Small businesses are building there, with new ideas. So I assume it is happening here.

Now in the last testimony we heard we were told that they do engage in some toxicity testing. So they are using some and making some effort.

Shouldn't we be seeking, and we are going to bungle and stumble toward a standard before we finally find one we can live with that deals with the problem, but shouldn't we be striving under this program to establish a standard for testing that small and large businesses alike can meet? They ought not to be excluded because they are small or ought not to be assumed they are doing it because they are big, should they? I mean it is the business of an agency of this kind, which has this charge of responsibility of protecting the public interest, to make sure that interest is protected.

Now I find some of your interpretations of the law really nit-picky. Now if the list of chemical substances was intended by Congress to

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include only the name, why even Congressmen are bright enough to know they could have said name instead of list. I have never encountered such a narrow interpretation of congressional intent.

Shouldn't the information obtained be relevant to the objective to be served? Are you really telling me that the production and volume of a chemical has nothing to do with public exposure to it and thus the risk that may be entailed? Are you saying that the site of manufacture is irrelevant to the generation of risk?

I mean, there is a lot of other information that the agency is not now seeking that it seems to me is relevant. Are we trying to narrow the information base, the relevant information base upon which the agency is asked to accept this public responsibility?

What would be the public attitude if any agency inadvertently permits a toxic material to be dispersed throughout the environment? What penalty and who will pay?

Obviously the confidentiality of proprietary information is important in our society, and it has been for 200 years and will continue to be. It is a difficult balance to strike there. But it seems to me there is a great deal of inflexiblity here disclosed this morning.

I raise these questions as my first exposure to the issues, and I am challenging you because these are the questions that occur to me. I am not ready to write a law today. I don't expect to write one this month or even this year. But I am telling you my attitude has been slowly evolving under this testimony.

Mr. HECKERT. Mr. Chairman, may I respond to some of your concerns. I would like to make a few observations to help clarify the issue.

Certainly all of this type of information is necessary for EPA to make intelligent decisions. Information to make risk-benefit decisions should be made available to EPA.

However, the initial list of commerical chemicals was to be compiled for the singular purpose of differentiating old chemicals from new ones. Our point is that in implementing this particular section, EPA really took on a different mission. Now it may be a useful mission, but it is a different mission.

Information regarding volume and production site may be obtained by the agency under the act. EPA can ask us how much we make, where we make it, and anything else they need to know about health and safety evaluations in order to make risk assessments. So there is no lack of ability to obtain information under the toxic substances law.

Senator MUSKIE. If that is the case, what is wrong with including it in the inventory?

Mr. HECKERT. It simply provides them with more information than they need. It will deteriorate rather rapidly. Remember this is a one-time snapshot picture of the production of chemicals in the United States. Five years from now it will be very different.

Senator MUSKIE. It seems to me it would be an ongoing inventory.

Mr. HECKERT. That has occurred to us and I am sure to the Agency, and it probably will be. Again, it is an expansion of the authority granted under the law.

Now with respect to the list of 50 priority chemicals. I do take exception to your thought that the priority list could include or should include categories rather than just individual materials.

EPA has the very difficult job of deciding just what the most crucial problems are in the chemical industry. The list of 50 was to help them focus on those chemicals which the experts in Government thought were most in need of testing.

Now when you tell me categories are going to be included, I have to respond that if you give me 50 categories, I can list almost every chemical in the world. Therefore, including categories simply doesn't help the Agency to prioritize.

Senator MUSKIE. On the other hand, if you limit it to 50 specific chemicals, how long will it take you to get through 70,000?

Mr. HECKERT. But that is not the purpose of that section. It is simply to help them focus on chemicals that require priority testing. Testing of other members of that 70,000 goes on constantly. The priority list is not intended to define the only activities of the Agency, but simply the high priority activity of the Agency.

The list of 50 was to help them sort out, with the best counsel and advice they could get from all other branches of Government, the 50 key problem chemicals.

Senator MUSKIE. Nobody in EPA, as far as I know, is objecting to starting with the list of 50. Our objection is to the proceeding beyond that, the method that EPA is using, to assemble information with respect to the next priority or the next priority.

Shouldn't you begin with a total understanding, a total picture, of what the chemical injection is into our society? I mean, obviously most of them, through the testimony I get up to now, they will prove to be useful, nontoxic chemicals.

Mr. HECKERT. I agree with you, Senator. I think the "quantity information" is supportable. I think the production site information is probably not that useful. The point is that information is generally available from other sources.

Senator MUSKIE. If it is generally available, why this sticky business of resisting this particular pursuit of it?

Mr. HECKERT. We are not. We have already complied.

Senator MUSKIE. You. But what about the other witnesses here this morning?

Mr. HECKERT. Our concern is not really with these sections of the law except insofar as EPA's implementation of them indicates a rather expansive view of the law. If this view is carried over into sections 4, 5 and 6, it will be troublesome.

The fact is that the costs and inconvenience associated with compiling the inventory will be incurred only once, unless there is a new rule promulgated. Therefore, that is not a serious ongoing issue. However, the manner in which the inventory was compiled indicated a problem that we may have in the implementation of this law.

Senator MUSKIE. I remind the panel in last year's Water Act, the provisions dealing with toxic substances, we identified 65 families of chemicals, exactly the same issue.

It has been a long time since I studied chemistry. I would certainly not claim to be a chemist. But it seems to me that is not an unfamiliar way of analysis. You don't start with the basic elements? How many are there now, a 100 or so? I think there were about 90 when I was in high school or maybe 80.

Mr. HECKERT. We are discovering them all the time.

Senator MUSKIE. Yes. So I don't approach this from the point of view of anyone presuming to know anything about chemistry. But I know you fellows are extremely ingenious in your laboratories, in the exercise of your intelligence and experience, in developing new combinations of old chemicals, revising them, changing them to meet new needs and new consumer requirements. That has been a great service, I think, to the American standard of living.

All we are trying to do here is to organize an effort to eliminate the danger. You know, you talk about the chemicals, that toxicity is already of concern. There is only one on this panel who has mentioned it this morning—asbestos, tris, arsenic, benzene, cadmium, mercury. Nothing has been done about them.

How about urging a little priority action by EPA to deal with those, or do you have some problems about that?

Mr. HECKERT. We have no problem with that. That is old information. Industry by and large has dealt with those problems.

I think when you consider the asbestos problems, you are talking about what to do with towns with old city halls as well as a lot of other questions. Should EPA get into that area?

Senator MUSKIE. Shouldn't it? How about the tris problem? No labeling? No adequate labeling, according to the testimony.

Mr. HECKERT. I assume that was based on the assessment of risk.

Ms. WARREN. That is absolutely not correct. It was based on their feeling they might not be able to track the garments down through the distribution network. So they decided not to do it.

Mr. HECKERT. Would you tell me what the risk is?

Ms. WARREN. The risk is based on evidence that tris comes out of the garments, that it passes through the skin when the garment is wet, and that tris is carcinogenic, when tested in laboratory animals, and poses a risk to infants.

Mr. HECKERT. I understand the mechanism. What is the risk to the American public?

Ms. WARREN. They would be purchasing the garments. They can't tell whether it has tris in it or not. If they decide they don't want to buy garments that have tris, they couldn't tell from the label when it only says polyester.

Mr. HECKERT. We are talking about the material in inventory. What is the risk to the American public of consuming the remaining material in inventory?

Ms. WARREN. The same risk as if they were still producing it. Every time an infant wears one of those garments and tris passes through their skin, they have a renewed risk of exposure to a carcinogen.

Mr. HECKERT. What is that risk?

Ms. WARREN. I can supply that. I am not here to debate the risks. I am willing to rest on the assessment of the agency that banned it.

Senator MUSKIE. My question, as a member of the committee which is charged with the responsibility of this bill, is you tell me, you gentlemen, that we ought to be concentrating on a relatively small list of 50, with the risk to the public of a high order to be dealt with.

I mean when I ask you about this, are these 6 included on your list of 50, or aren't they? I would like to know.

Mr. HECKERT. Mr. Chairman, that list of chemicals has dealt with I think if you will check one by one the regulations that exist relating to each, the process is already well along the way.

Senator MUSKIE. By whom?

Mr. HECKERT. By the country as a whole—industry, Government, regulatory agencies. Benzene is not a surprise.

Senator MUSKIE. How about the rest of the 50?

Mr. HECKERT. Arsenic is not; tris is not.

Senator MUSKIE. Haven't you said to me that this agency ought to be working with that list of 50——

Mr. HECKERT. Sorry.

Senator MUSKIE [continuing]. Before it begins to burden industry——

Mr. HECKERT. No.

Senator MUSKIE [continuing]. And forgetting information about others?

Mr. HECKERT. No, sir, that is a misunderstanding.

Senator MUSKIE. It certainly is.

Mr. HECKERT. Let me start at the beginning. The list of 50 was put into the bill to permit the expertise of Government to suggest to EPA which materials were in most need of attention under the Toxic Substances Control Act.

Now that function is only accomplished when a specific list of 50 compounds is passed along to EPA. It is revisable. As soon as some chemicals are tested, additional ones can be added to the list. It is an ongoing priority list that has to be a part of the administrative process, along with all the other aspects of the law. So it is just a little piece of the total.

Senator MUSKIE. Are you saying the agency ought to consider only 50 at a time?

Mr. HECKERT. No, sir, I am saying that the Agency should consider that 50 with any revisions and at the same time administer all of the other sections of the law and deal with all of the other problems in the country at a rate which they can manage.

Senator MUSKIE. Shouldn't they then, in order to determine the rate at which they should manage, first full inventory the problem?

Mr. HECKERT. There is no question that they should inventory the problem to the best of their ability. Unfortunately, after they have compiled 70,000 chemicals by name, after they have looked at production information, after they have brought in their experts to cull through these files and see what is in them, we still have the problem that we don't know enough about the relation of chemicals to cancer, EPA should deal with those materials structurally related to materials known to cause cancer, or assume that there might be some others among those materials to which the human population has wide exposure, and require testing of those materials that are related one way of another to those two categories.

Senator MUSKIE. You are not saying that cancer is the only risk intended to be dealt with.

Mr. HECKERT. Indeed not. In fact, I would like to make the observation that if we solve the problem of the industrial chemical contribution to carcinoma in this country, even if we eliminate that completely, and we make no progress on the other causes, it is unlikely that you will be able to see the inflection in the curve.

The industrial contribution to cancer isn't that much of the total problem. It is important and has to be dealt with. It is unconscionable to hurt people when we know there are ways to avoid it.

Senator MUSKIE. As I say, 70,000 chemicals is a big job. This argument reminds me of the argument I get against sunset legislation in the Senate. It is too big a job. If we try to review on a continuing schedule 1,200 programs, it is too big a job. Congressional committees can't handle it. They won't have time to create new laws if we take up all the time reviewing old laws. It is a very similar argument I am hearing this morning. It is too big a job.

Mr. HECKERT. It is an enormous job and a complicated law. EPA needs all the help and sympathy it can get from both environmentalists and industry. We really do want to see them succeed.

Our arguments, our concerns, boil down to this: The provisions of the law were very carefully worked out in 6 years of negotiations in the halls of Congress between industry, the environmentalists, and all other interested parties.

The authorities given were carefuly considered. What we produced was admittedly an incredibly complicated law, but one that was really rather thoughtfully done from start to finish.

I agree with Ms. Warren about one aspect of EPA's administration. I would like to see them play that law right down the middle; in other words, literally follow the intent of Congress as best they are able to determine it from the words, the guidance they get from the law itself, and from supporting documents.

I think it is regrettable that too often they act as arbiters between environmentalist positions and industrial positions. Congress designed an approach which was reasonable, measured, and in our view can be administered reasonably in terms of the effect on the economy and still accomplish its purpose. But we really hope that EPA still stick to the letter and intent of the law and will work toward that end.

Now I have to assume that the environmental groups, the responsible ones, feel the same way.

Ms. WARREN. Sir, may I speak for the environmental groups myself, please?

Senator MUSKIE. Sure.

Ms. WARREN. There are statements I want to respond to.

Senator MUSKIE. I am only a neutral party. [Laughter.]

Ms. WARREN. First of all, the principal purpose of this statute is to prevent unreasonable adverse effects or injury from chemicals. The statute provides that economics must also be taken into account in a reasonable way.

But the bottom line is that unreasonable risks must be prevented and eliminated. I think the testimony here today has shown again that the industry is advocating the most narrow interpretation of the law that is possible.

The argument has been raised about whether categories as opposed to individual substances should appear on the list of 50. The list of 50 chemicals or 50 chemical categories was developed by representatives of the Government's leading health and science agencies, who have suggested we do not know enough about them and should be testing further. They are not the high priority items we are already concerned about.

Section 25 of the statute says that any action authorized or required to be taken by the Administrator under any provision of the act, with respect to a chemical substance or mixture, may be taken respect to a category of chemical substances.

So there is no question that there is a good legal basis for addressing categories as opposed to individual chemicals.

The same kind of narrow interpretation goes to the use of the section 8(a) reporting authority along with the inventory EPA has the authority to require submission of additional reports under section 8(a). They also can compile an inventory under section 8(b). They did it at the same time under both authorities. Had they only gotten the list of names and then gone industrywide shortly after that for all of the other information, the chemical industry would have been here screaming that.

"They just aked us for all of this first information. Here they come back again asking for more." It is unlikely EPA is going to go industrywide, soliciting information from the whole chemical industry, ever again asking for the same kind of information. More likely, EPA has said they will choose selected chemicals and regulate them and get further information from the relevant industries with respect to the individual chemicals. But there is no way they could get the whole industrywide picture without asking the question throughout the industry.

Another example involves the substantial risk notice under section 8(e). The purpose of that is to keep information which indicates a risk to humans or the environment from being buried in a file drawer somewhere. If the obligation is on anybody who is capable of appreciating the significance of the information, that person has an obligation with criminal liability attached to it to see that that information gets to EPA.

We have had many instances in the past of studies indicating risk that sat in a drawer until the men who worked, for example, with DBCP became sterile. Animal studies indicating sterility from exposure to DBCP were in existance at that time.

The same thing happened with Kepone—by the way, produced by a small company. In that case there were animal studies indicating a risk from exposure, but nothing was done about it until the men who worked with Kepone began shaking and suffering motor nerve damage. Yet that information didn't come out until people in a position to know that information existed were required to get that information out.

I don't quite understand why the chemical industry is resisting the obligation to report substantial risk information to EPA. It is an important obligation and Congress knew what it was doing when it put it in the statute. I don't think EPA's interpretation of section 8(e) is beyond what Congress intended in including that language.

Senator MUSKIE. What I am willing to assume at this stage is that business representatives are understandably concerned with costs, as is their business; that interest groups are understandably concerned primarily with the results to be served, the public interest results, and that is their business. My interest is in seeing to it that the Agency, which in my judgment has moved cautiously, maybe overly cautiously, not lose sight of the fact that they exist for the purpose of dealing with the problem.

I would hope that we find ways to establish the necessary information base with all of the relevant information. I am not interested in piling up excessive files. As chairman of the Budget Committee, I have to find the money to pay for excessive files. But I want to make

sure that we get the essential information about problems of whose existence we are unaware. I mean, with respect to the toxic substances of which we were aware when this bill became law, we didn't need this kind of a law to deal with them. We could have prohibited them directly by law.

But what we wanted to do was establish a procedure which would minimize the possibilities of surprises like some of these in the sixties and seventies being repeated; because chemicals, I assume, are entering the society and the economy at a faster pace all the time.

Would you agree with me on that?

Mr. HECKERT. No.

Senator MUSKIE. They are not?

Mr. HECKERT. No; about the same.

Mr. ELLISON. Mr. Chairman, I have really no problems with your concern when you say essential chemicals need be looked at. I think we are doing that. We have no problem with EPA progressing at a reasonable pace, as long as there are toxicological laboratories and sufficient toxicologists to make intelligent scientific decisions.

I think the reason why we may appear to be overly concerned and stressing some points that may bother you is that we look at FDA and the slowdown of drug applications. The chemical industry, also, notices the far larger number of drugs that have been introduced earlier overseas compared to the United States because of excessively cumbersome regulations in the United States. Mind you, many of those regulatory are important, and it may have been important for FDA to do some of the things they did do but many experts agree our drug regulations are restricting new and useful drugs from being available to American patients.

We also see what is happening under FIFRA. I used to work in EPA. I know EPA has more pesticide information than they can ever effectively process. I would rather EPA ask for current information and review the current information to establish priority items.

So we are requesting that EPA be allowed to implement regulations at a reasonable pace. The chemical industry is concerned because of other pieces of the legislation that have been passed. We are certainly not trying to disregard our responsibility. We will continue to be responsible and concerned citizens.

Senator MUSKIE. It is all a positive attitude of what we can do with it. I think if we watch each other, as obviously we are, that we can achieve that result.

I don't sense any great pressure for changing the law right now. I certainly don't feel any sense of urgency. I might 6 months from now, as I get more fully exposed to what is happening and what ought to be happening. I won't be reluctant to suggest changes if I feel they are necessary.

But I think we are still on the learning curve. I hope the learning curve begins to rise a little more rapidly here so we can begin to get the benefits of this new experiment. And I think from understanding your preoccupation with cost and overregulation, which is a business syndrome these days, and I understand why, I nevertheless sense a positive attitude about the objectives of this law. I would hope I am right in sensing that.

Mr. ELLISON. Yes.

Mr. HECKERT. You are.

Mr. ENGEL. Yes.

Senator MUSKIE. And we are going to get a positive, cooperative attitude developed here.

I must say Ms. Warren's attitude—she has testified twice now in 1 week before this committee—I think is a constructive one, too. She has to raise the signals that her responsibility requires her to raise. She does it I think very constructively and knowledgeably.

So I think we need this kind of monitoring; this committee must do its work and the agency must do its work and the Congress must provide the resources. We found with clean air and clean water laws a shortage of the laboratory skills, the scientific skills, the health knowledge, that was essential to measure the impact on the environment. So we have got to expand that base, too.

But we will try to do it. And every time you come here, I am going to ask the sharpest questions I can to every one of you. That is my job.

With that, I know we haven't exhausted the possibility of debate and confrontation, but I think we have used up all the time that is available. I thank you all.

[Whereupon, at 12 noon, the subcommittee recessed, to reconvene subject to the call of the Chair.]

[A statement from the Polaroid Corp. and the American Chemical Society follows:]

STATEMENT OF POLAROID CORPORATION FOR SUBMISSION TO THE ENVIRONMENTAL POLLUTION SUBCOMMITTEE OF THE SENATE ENVIRONMENT AND PUBLIC WORKS COMMITTEE OVERSIGHT HEARINGS ON THE ENVIRONMENTAL PROTECTION AGENCY'S IMPLEMENTATION OF THE TOXIC SUBSTANCES CONTROL ACT

July 21, 1978

While Polaroid Corporation firmly supports the salutary purpose of the Toxic Substances Control Act (TOSCA) "to regulate chemical substances and mixtures which present an unreasonable risk of injury to health or the environment," it believes that the Act in its present form fails to provide due process safeguards for the discharge by the Environmental Protection Agency (EPA) of the Act's mandate to preserve the confidentiality of trade secrets submitted to EPA.

To date EPA has not promulgated final regulations to protect the security of confidential information submitted under TOSCA. Further, the issuance by it of proper regulations on that subject will not be possible unless and until TOSCA's provisions requiring EPA to safeguard confidential data have been amended to include due process safeguards or to authorize EPA to issue formal regulations to that effect. Only if such amendments are made can EPA's confidentiality regulations, when issued, satisfy constitutional requirements.

Faced with a filing deadline under TOSCA and no prospect of the promulgation of regulations prior to that deadline,

Polaroid commenced an action in the United States District Court for the District of Massachusetts seeking a declaratory judgment that it not be required to submit information on twenty of its most vital chemicals, constituting invaluable trade secrets, prior to EPA's issuance of adequate confidentiality regulations (Polaroid Corporation v. Costle, Civil Action No. 78-1133-S).

In a Memorandum and Order handed down by Judge Skinner on June 22, 1978, the District Court enjoined EPA from disclosure of any confidential information submitted to it by Polaroid until the further order of the Court. The Court requested the parties to submit briefs specifically addressing the following questions: (1) whether a disclosure by EPA under the disclosure provisions of TOSCA's section 14 constitutes deprivation of property without due process of law under the Fifth Amendment or a taking without just compensation; and (2) whether such provisions of TOSCA's section 14 as are found to be violative of due process can be saved by judicial engrafting of due process standards and procedures or whether TOSCA, in its present form, must be considered by the Court in its entirety and if certain provisions thereof are found to violate due process requirements, TOSCA, as an entire Act, must be held to be in violation of the Fifth Amendment.

The disclosure provisions of TOSCA's section 14, other than 14(a)(3), provide for the disclosure of submitted information without notice to the submitter. A corporation which may have invested millions in developing secret, proprietary chemicals, processes or other information, has a vital interest in the protection of that secret information in any required transfer thereof by EPA. Without notice that a request for the information has been made to EPA, the submitter is deprived of an opportunity to assert its rights with respect to any such transfer and to insure that the confidentiality of any information so transferred be preserved. The absence of a requirement of such a notice to the submitter before the secret information is to be released by EPA makes TOSCA's disclosure provisions, in their present form, violative of the due process clause of the Fifth Amendment.

The absence of general, substantive rule-making authority for section 5 of TOSCA coupled with the publication provisions of section 5(d) raises an equally serious constitutional question. The publication of the identity of all new chemicals to be manufactured without provisions for exceptions would result in unnecessary and improper disclosure of vital trade secret information and may constitute a taking of property without compensation.

The constitutional questions raised by TOSCA in its present form are serious. Congress should obviate this serious constitutional problem by amending TOSCA to provide the required due process safeguards and to prevent unconstitutional takings of property or by giving to EPA substantive rule-making authority with respect to all of its provisions so that EPA will be in a position to satisfy constitutional requirements in its final regulations.

Respectfully submitted,

POLAROID CORPORATION,

By Its Attorneys,

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American Chemical Society

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President-Elect, 1977
President, 1978

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August 24, 1978

The Honorable Edmund S. Muskie
Chairman
Subcommittee on Environmental Pollution
Committee on Environment and Public Works
United States Senate
Washington, D.C. 20510

Dear Senator Muskie:

The American Chemical Society has consistently supported the goal of the Toxic Substances Control Act (TSCA), to protect human health and the environment. Prior to the passage of the Act, the ACS worked with the Congress to help formulate law that could achieve this goal, and at the same time have the flexibility to recognize the great diversity in properties of chemical substances, as well as the scale and nature of the manufacture, use, and disposal of chemicals.

The Society has been, and is, concerned about the possible impact of unnecessarily restrictive and demanding regulations; regulations that do not serve to attain the goals of the Act, and produce an excessive burden upon industry, as well as upon laboratories involved in testing, academic research, and training. Such a burden could increasingly inhibit research and development, and seriously curtail innovation in this country. Small companies, organizations that are frequently highly innovative, could be particularly impacted by unduly restrictive regulations. Also, unnecessarily expensive procedures will inevitably result in higher costs to the public.

Subsequent to the passage of the Act, the ACS has participated actively in the public process of implementation. The observations and comments that we are conveying to you are based on our own experiences with the Office of Toxic Substances (OTS). The Society has found the staff at OTS to be open in their deliberations, and the documents that they have written to be generally clear and readable. The thoroughness of these proposed regulations has obviously been aided by the staff's active effort to obtain assistance from the scientific community in the evaluation of the scientific bases for these regulations. However, since the Society's comments are prepared, reviewed and approved by voluntary groups from within its membership, we have experienced difficulties in meeting the stated time requirements for comments and often have to request extensions. When dealing with documents of a rather lengthy, detailed nature, which may request rather specific information, the Society has generally found the comment period to be too short. We believe that comment periods need to be realistic in relation to the particular document that is under consideration.

The problem involved with any regulatory process can be extremely complex. For example, if a regulation under TSCA is to be effective, it must have credibility with the scientific community by being consistent with current scientific knowledge, and with the general public by serving the public good. The regulatory process also must be selective. Even if the entire scientific resources of the nation were to be devoted to toxicilogical testing, only a relatively small portion of the large number of known substances could be subjected to a complete sequence of toxicological tests within the next ten years. From the standpoint of continuing innovation, part of the nation's scientific resources should be devoted to the extension of knowledge and the testing of new compounds, even at a reduced level of activity.

The law provides the Administrator of EPA with the flexibility to use judgement. In fact, it is the intent of the Act that the Administrator carry out the provisions of TSCA in a "reasonable and prudent manner." The American Chemical Society is prepared at the request of EPA, to assist in identifying chemists and chemical engineers who possess specific capabilities in areas relating to the implementation of TSCA. The Society also is proud of the resources which our Chemical Abstracts Service has provided to the Agency in the compilation, storage of, and access to the great mass of data needed for the implementation of the Act.

The ACS has continually recognized that the central element both in the Law and the implementation activities is the concept of "unreasonable" or "substantial" risk. Our concern for both the present and future health and welfare of the American people is not inconsistent with the realization that some level of risk must be accepted in any activity including those involving chemicals and chemical processes. The Society therefore urges EPA to take a balanced view of proposed regulations during its administration of various phases of the Act, and applauds EPA's attempt to be flexible in its approaches.

The capacity of the scientific community to carry forth the research and testing that will be required under the Act is severely hampered by the limited number of scientists who have acquired the necessary competence in toxicology, pathology, and other related sciences. We therefore again recommend that the Congress as well as EPA support the expansion of education and training at the graduate level in these essential disciplines in order to meet the needs of the Act.

In general, the American Chemical Society has been pleased with the manner in which the early implementation phases of TSCA have been handled by the Environmental Protection Agency; EPA has not always agreed with our recommendations, but it has always given the Society a fair hearing. The ACS welcomes the opportunity to continue participating constructively in the implementation of the Act, and we appreciate this chance of transmitting our views to your Subcommittee for the oversight hearing record on the Toxic Substances Control Act.

Sincerely yours,

Anna J. Harrison

Anna J. Harrison