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TOXIC SUBSTANCES CONTROL ACT

EPA's Limited Progress in Regulating Toxic Chemicals

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Mr. Chairman and Members of the Subcommittee:

We appreciate the opportunity to be here today to discuss our work on the Environmental Protection Agency's (EPA) implementation of the Toxic Substances Control Act (TSCA). As you know, over 70,000 chemicals are in use in the United States. Although these chemicals are an important part of our economy, they are often toxic and can have adverse effects on human health and the environment. The Congress passed TSCA in 1976 to obtain more information on chemicals' effects and to control those that present an unreasonable risk.

At the request of this Subcommittee, we are reviewing EPA's efforts to (1) assess the risks of chemicals before and after they enter commerce, (2) control those found to be harmful, and (3) make information on chemicals publicly available. Our testimony today, which is based on the preliminary results of this review, will focus on EPA's problems in implementing TSCA. We would also like to highlight some differences between TSCA and the chemical control laws of three other countries that we visited: Canada, Germany, and Sweden. We will issue a report on the final results of our review within the next few months. That report will discuss these problems in more detail and present options for revising TSCA to improve its effectiveness.

In summary, our work to date shows that:

-- EPA has issued regulations under TSCA to control only nine chemicals during the 17 years since the act was passed. This is primarily because TSCA's legal standards for taking regulatory action are so high that EPA has been discouraged from attempting to regulate chemicals and has given implementation of the act low priority. Extensive use of TSCA is not likely as long as EPA interprets the act as giving preference to dealing with chemical risks under other environmental and health laws. These laws generally provide for limits on emissions and exposures rather than restrictions on chemical production, distribution, and use, as provided for under TSCA.

-- TSCA's chemical information-gathering and control authorities appear comprehensive, but they are difficult to use and are ineffective. Consequently, EPA has assessed the risks of only about 2 percent of the chemicals in use. Furthermore, EPA's review process does not ensure that the potential risks of new chemicals are fully assessed before they enter commerce.

-- Because of its limited resources, EPA may not be able to substantially improve its performance in reviewing the thousands of chemicals in use and controlling those found to be harmful without shifting more of the burden to the chemical industry. This includes compiling data on

chemical effects and exposures and proving that chemicals are safe.

-- While the information collected under TSCA can be helpful to others, such as state health and environmental officials, much of it cannot be disseminated because industry claims that it is confidential to protect trade secrets. EPA has successfully challenged the validity of some of these claims, but does not have the resources to challenge a significant portion. Any changes in TSCA's confidential business information provisions would need to balance industry's needs to protect trade secrets and others' needs for information on chemical risks.

Before elaborating on these points, we would first like to provide some background on TSCA.

BACKGROUND

TSCA authorizes EPA to review the risks of both new and existing chemicals. New chemicals are generally those that have not entered commerce. Once they enter commerce, they are classified as existing chemicals. Chemicals that were already in commerce when EPA's new chemicals review program began in 1979 are considered existing chemicals.

To assess risks, EPA examines both a chemical's toxic effects and the amount of human and environmental exposure to the substance. If EPA finds that a chemical's risks are unreasonable, it can prohibit or limit the chemical's production, distribution in commerce, use, and disposal or take other actions, such as requiring warning labels.

TSCA requires the chemical industry to give EPA a 90-day notice of its intent to manufacture or import a new chemical. This notice is to contain information EPA needs to review the chemical, such as its molecular structure, proposed uses, estimated production or import amounts, estimated exposure, and available test data. TSCA also authorizes EPA to require manufacturers and processors to test chemicals already in commerce or provide other data, such as their production volumes. In addition, manufacturers, processors, and distributors are required to report to EPA any data that reasonably support a conclusion that a chemical presents a substantial risk to health or the environment.

TSCA does not apply to pesticides, tobacco, nuclear material, firearms and ammunition, food, food additives, drugs, and cosmetics. These products are regulated under other laws.

CHEMICAL REGULATION UNDER TSCA

As of May 1994, EPA has issued regulations under TSCA to control only nine chemicals--five existing chemicals and four new ones. Moreover, the regulations were generally limited in scope. Only those for two existing chemicals--polychlorinated biphenyls (PCBs) and asbestos--provided for widespread bans on chemical manufacture or uses. The regulations to phase out the manufacture of PCBs were specifically required in TSCA, and the regulation to phase out almost all products containing asbestos was overturned by a 1991 court decision. The regulations for the three other existing chemicals banned a certain use for two of them and prohibited the third from being disposed of in one manufacturer's waste. EPA has also issued regulations for four new chemicals used in metalworking. These regulations prohibited the mixing of the chemicals with certain other substances because, in combination, they form a cancer-causing substance.

A major reason why EPA has taken very few regulatory actions under TSCA is the act's high legal standards. TSCA authorizes EPA to control chemical risks that are unreasonable. However, while TSCA requires that EPA take the least burdensome regulatory action to protect adequately against unreasonable risk, it does not define what constitutes an unreasonable risk. In the absence of statutory guidance on this, EPA assumes a very high threshold for when it can take action to control a chemical. In effect, EPA believes it must have substantial evidence that the benefits to society of implementing any controls outweigh the costs. This standard is

especially difficult for major controls or restrictions on widely used chemicals because the costs can be extensive and the full range of benefits may be difficult to document. EPA's regulation to phase out asbestos products illustrates this difficulty. Although EPA had considerable scientific evidence of serious health risks and spent several years developing the regulation, the court decided that the agency did not adequately demonstrate that it had chosen the least burdensome alternatives for controlling exposures to asbestos.

Another major reason why EPA seldom takes regulatory actions under TSCA is that the act expresses a preference for TSCA to be used only when other laws are not available. Various other health and environmental laws allow EPA or other agencies, such as the Occupational Safety and Health Administration, to control environmental releases or exposures to toxic chemicals. EPA officials believe that the purpose of TSCA is to fill the gaps in other laws. That is, TSCA should be used to control the production, distribution, use, and disposal of chemicals if other laws cannot be used to reduce the risks. Essentially all the major sources of human health and environmental exposures are potentially covered by the Clean Air, Clean Water, and Resource Conservation and Recovery acts and other laws, such as the Occupational Safety and Health and Consumer Product Safety acts. Thus, EPA or other agencies could issue regulations under one or more of these other laws to reduce the releases or exposures contributing to

essentially all the chemical risks identified by EPA. The major exception is new chemicals. Other environmental legislation and the Occupational Safety and Health Act do not cover chemicals before they enter commerce.

The chemical control law of Canada differs from TSCA in that it establishes a simpler standard for regulatory action, and its relationship to other health and environmental laws is more clearly defined. For example, the Canadian Environmental Protection Act of 1988, which is the major law for controlling toxic chemicals, authorizes the government to control chemicals that are toxic, which it basically defines as chemicals entering the environment in a quantity or concentration, or under a condition, having a harmful effect on the environment or human health. The costs and benefits of control actions are not factors in deciding whether chemical risks are such that action should be taken. Rather, they are factors in deciding which alternative action to take. According to Canadian officials familiar with TSCA, it is easier to control chemicals under their standard than under the unreasonable risk standard in TSCA.

In Germany, the major focus of the chemical control law is to classify and label chemical products on the basis of their toxicity. In addition to determining the labeling of a chemical, classification is the starting point for risk assessment. The classifications also drive downstream legislation concerned with

aspects of risk management, such as worker protection. The risk assessments can result in additional testing or the imposition of certain controls on the chemical, such as use restrictions. Bans or major restrictions on chemicals are rare, especially for existing chemicals, because of the complex process established for taking these actions.

In Sweden, the major focus is also on classification and labeling of chemicals on the basis of their toxicity. Certain mandatory controls are established for each classification category. Use restrictions may also apply, depending on the chemical's classification. Although the Swedish government has banned or severely restricted only a few chemicals, it has established a list of 13 undesirable chemicals, such as lead and mercury, that it wants to eliminate or significantly reduce by the year 2000.

CHEMICAL REVIEW UNDER TSCA

In requiring EPA to review new chemicals, TSCA recognizes that the best time to assess the risks of chemicals is before they enter commerce and can cause harm. EPA's authority to review the risks of existing chemicals is also important for two reasons. First, about 62,000, or 86 percent, of the approximately 72,000 chemicals in the TSCA inventory were in commerce when the new chemical review program began in 1979 and have not been reviewed as new chemicals.

Second, the risks of a new chemical can change once it enters commerce and becomes an existing chemical. More may be learned about its toxicity, or exposures to the chemical can change as the amounts produced or how the chemical is used changes.

Review of New Chemicals

TSCA does not require routine chemical testing, and the chemical industry performs limited testing on new chemicals. In a 1990 study, EPA found that 51 percent of premanufacture notices did not include any test data on toxicity, physical chemical properties, and environmental fate. The data that were provided frequently consisted of studies on short-term health effects.

Because sufficient test data are generally not available for new chemicals, EPA uses a method known as structure activity relationships analysis to predict chemicals' health and environmental effects. This method relies on test data from chemicals with similar molecular structures. In 1993, EPA completed a study in which the agency's predictions using this method were compared with actual test results for new chemicals in the European Community. Although EPA's predictions were highly accurate for some characteristics, they were often inaccurate for many others. For example, the predictions on biodegradation agreed with the test data for 93 percent of the chemicals. However, EPA had only a 63-percent accuracy rate in predicting vapor pressure,

an important factor in determining the amount of potential exposure to a chemical. Both EPA and European Community officials considered this accuracy rate too low to adequately characterize chemical risks.

Another uncertainty limits EPA's assessments of risks posed by new chemicals. EPA uses the manufacturers' or processors' estimates of anticipated production volumes and uses of the chemicals to estimate potential exposure. However, actual production volume and chemical uses can change substantially once EPA's assessment is completed and the chemical enters commerce.

In Canada and Germany, the government also reviews new chemicals before they enter commerce. However, unlike the U.S. practice, these countries require manufacturers to test the chemicals and submit the results, along with exposure-related information, to the government at the beginning of the review process. Manufacturers conduct additional testing as the volume of production increases. On the other hand, Sweden's Act on Chemical Products places the main responsibility on chemical manufacturers and importers to assess the risks of both new and existing chemicals and provide adequate information on environmental and health effects to chemical users. These assessments are subject to government review.

Review of Existing Chemicals

EPA has made little progress in reviewing chemicals in commerce. Under its existing chemicals program, EPA has reviewed the risks of about 1,200 substances, some 2 percent of the about 62,000 chemicals that were in commerce when the new chemical review program began in 1979. Not all of these chemicals are the same priority for review. For example, EPA states that about 14,000 of these may be of concern because of their large production volumes and chemical structures. However, EPA officials estimate that the agency can review only 20 to 30 existing chemicals per year, given its current level of resources. And, as we previously pointed out, EPA may need to review chemicals again as their production increases or new uses are found for them.

For existing chemicals, EPA is responsible for compiling available information on the chemicals' effects and exposures. This effort is time-consuming and resource-intensive, and complete data are often not available, especially for exposures. EPA must use various models to estimate or project the amounts and types of exposure, and the results are uncertain. Basic exposure-related information, such as the volume of environmental releases, the number of workers exposed to a chemical, and the types of chemical uses, are generally not available, incomplete, or outdated.

To require industry to test or submit additional exposure-related information on a chemical, EPA must issue a rule. Such an effort can be lengthy and costly. For example, TSCA authorizes EPA

to require industry to test an existing chemical if the agency finds that the chemical may present an unreasonable risk or may result in significant human or environmental exposure. According to EPA, issuing a test rule for a chemical can take as long as 24 to 30 months and cost the agency from $68,500 to $234,000. The testing, which does not begin until the rule is issued, can take from a few months to a few years to complete. Since the testing program began in 1977, EPA has issued 30 test rules covering 121 chemicals. In addition, EPA has entered into negotiated test agreements or consent agreements for the testing of 59 more chemicals.

The other countries that we visited place more of the burden on industry for the review of chemical risks. As previously stated, Sweden's Act on Chemical Products places the main responsibility on manufacturers and importers to assess chemical risks. In Canada and Germany, the government is responsible for assessing the risks of existing chemicals. However, it is easier for the govenment to obtain the chemical information that it needs. Germany is implementing a 1993 European Community directive that requires member countries to carry out a systematic review of existing chemicals. For these reviews, chemical manufacturers and importers have to compile and report certain data. The government may require industry to provide additional data (which could involve performing additional testing) during the assessment process. Under the Canadian Environmental Protection Act, the

government can require industry to provide additional chemical data without having to issue a rule.

CONFIDENTIAL BUSINESS INFORMATION

Recognizing the need to protect trade secrets, TSCA allows chemical manufacturers, processors, and distributors to claim information submitted to EPA as confidential. Under the act, EPA is responsible for protecting the data that contain trade secrets or financial information from unauthorized disclosure. Federal employees and contractors who need the information to carry out their official duties are authorized access to confidential data.

Making confidentiality claims under TSCA is a simple procedure. Claims do not have to be substantiated, and TSCA does not establish a penalty for filing a false claim. Although TSCA limits the information in health and safety studies that can be protected as confidential to data that disclose manufacturing processes or portions of a chemical mixture, the act broadly defines what constitutes a study. Thus, unless data relating to a chemical's effects on public health and safety are contained in what is obviously a study, EPA finds it difficult to prevent industry from claiming confidentiality and limiting public access.

A large portion of the TSCA information EPA receives is claimed as confidential. For example, a 1992 study found that more than 90 percent of premanufacture notices for new chemicals contained some information claimed as confidential. Although EPA officials believe that much of this information is not proprietary, the process of challenging the claims is resource-intensive and EPA has challenged only a small percentage of the claims. As a result, EPA must expend considerable effort to protect large amounts of confidential data. In addition, the data cannot be disseminated to others, such as state officials who have responsibilities for health and environmental protection. EPA would also like to make the information available as part of an overall strategy to use public information and education as a means to control the use of toxic chemicals.

The other countries that we visited also allow industry to make confidentiality claims. However, these countries generally specify more types of data that cannot be claimed as confidential. While health and safety studies are the only type of data on which TSCA restricts confidentiality claims, Canada generally does not allow claims on data such as chemical uses and safe handling procedures. Exposure data are confidential in Germany, but claims are generally not allowed for information such as the chemical's trade name, physical chemical properties, precautionary and emergency measures, and toxicological tests results. Sweden is more restrictive in that it generally limits claims to chemical

identity and some business aspects, such as the volume of production.

CONCLUSIONS

TSCA is a unique piece of environmental legislation. Whereas other environmental laws, such as the Clean Air and Clean Water acts, generally deal with chemicals as pollution by establishing how much can be released to the environment, TSCA potentially provides the means to take up-front or preventive actions through restrictions on chemical production, distribution, and use.

However, EPA has taken few actions under TSCA to control toxic chemicals because it is extremely difficult for the agency to demonstrate that a chemical presents an unreasonable risk under the standards of evidence required by the act. Furthermore, EPA officials responsible for implementing TSCA do not believe that the act gives them a clear mandate to control more than a few chemicals that cannot be addressed through other health or environmental laws. Moreover, EPA's experience in implementing the act has shown that gaps often exist in the data needed to assess the risks of both new and existing chemicals and that obtaining the needed data places a heavy burden on EPA, given available resources.

As EPA emphasizes its efforts to protect human health and the environment by preventing pollution, TSCA's emphasis on prevention

continues to have potential to provide EPA with a valuable tool to achieve this objective. In addition, EPA would like to make more information on chemical risks publicly available as part of a strategy to involve the public more in its pollution prevention efforts. Industry's confidentiality claims, however, limit the amount of data that can be released. Our report on TSCA's implementation will provide some specific options for revising TSCA in these areas.

In continuing our work for the Subcommittee, we will be looking at ways to make TSCA a more effective statute. In doing this, we will be considering three broad matters:

-- First, whether setting a clear goal for TSCA and expectations for what EPA is to achieve under the act is desirable. Key to this would be clarifying whether TSCA is to be used as a backstop when other laws are lacking or whether TSCA is to play a more prominent role in controlling toxic chemicals.

-- Second, whether to continue to hold EPA responsible for assessing and proving chemical risk, or whether to shift the burden to manufacturers to assess and demonstrate chemical safety. Also of concern is whether to modify the threshold for taking regulatory action under TSCA.

Approaches used by other industrial countries could be looked to as models for how to proceed in this regard.

-- Finally, given the sheer number of chemicals in use today, whether both government and industry should focus their resources on those chemicals that, based on their toxicity, production volumes, and potential exposure, present the highest risk to human health and the environment.

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Mr. Chairman, this completes our prepared statement. We would be happy to respond to any questions that you or other Members of the Subcommittee may have.