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TOXIC SUBSTANCES CONTROL ACT

Preliminary Observations on Legislative Changes to Make TSCA More Effective

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Mr. Chairman and Members of the Subcommittee:

We appreciate the opportunity to again participate in the Subcommittee's deliberations on reauthorization of the Toxic Substances Control Act (TSCA). At your May 17, 1994, hearing, we discussed the Environmental Protection Agency's (EPA) problems in implementing certain provisions of TSCA.[1] We said that 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 a low priority. Furthermore, EPA has interpreted the act so that it gives preference to using other health and environmental laws that do not have the full range of controls offered by TSCA. Moreover, gaps often exist in the data needed to assess chemicals' risks, and obtaining the needed data places a heavy burden on EPA, given available resources. Industry claims that much of the data that are collected is confidential, limiting the dissemination and usefulness of the data to federal and state organizations with health and safety responsibilities.

This and our earlier testimony are based on our ongoing work, being performed at the request of this Subcommittee, to review EPA's efforts to assess the risks of chemicals before and after they enter commerce and to control those that are harmful. This work includes a comparison of TSCA's provisions with those of chemical control programs implemented in Canada, Germany, and Sweden. As you have requested, we will focus today on our preliminary observations on legislative changes to improve EPA's implementation of TSCA. A final report on the details of our review and options for revising TSCA will be provided to this Subcommittee when our work is completed in September 1994.

In summary, although TSCA contains information-gathering and regulatory authorities that are essential to an effective chemical control program, EPA has achieved few results under the act. In completing our work for the Subcommittee, we are reviewing a number of options for revising TSCA that could (1) strengthen EPA's ability to regulate harmful chemicals, (2) improve the reliability of EPA's new chemical reviews, (3) accelerate EPA's progress in reviewing existing chemicals, and (4) increase the dissemination of information on chemical hazards. TSCA could also be revised to become a more comprehensive toxics statute by incorporating provisions aimed at reducing the overall use of toxic chemicals.

We would now like to highlight these options.

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[1]Toxic Substances Control Act: EPA's Limited Progress in Regulating Toxic Chemicals (GAO/T-RCED-94-212, May 17, 1994).

STRENGTHEN EPA'S ABILITY TO REGULATE HARMFUL CHEMICALS

Governments at all levels are under increasing pressure to address the public's concerns about pollution and public expectations for a cleaner environment. Much of this attention is now focused on toxic pollutants because of their potentially serious health and environmental effects. As both government and industry look for ways to respond to the public's demands, it is increasingly evident that achieving substantial progress in dealing with toxics will require a comprehensive approach that addresses the life cycle of chemicals from their manufacture and distribution in commerce to their use and eventual disposal or release to the environment. Conventional pollution abatement strategies typically involve only certain pollutants at one stage of generation and at a readily identifiable source. Exposures and releases to the environment can occur during any or all stages of a chemical's life cycle, and all stages need to be examined. In some cases, the most appropriate way to deal with a toxic chemical may be to not produce it in the first place.

Although TSCA can be an important part of a comprehensive toxics control program, the act's authorities have not been used effectively when EPA has considered how to address toxic chemical concerns. One of our preliminary observations is that TSCA authorities could be used more effectively if the act were on more of an equal footing with other environmental laws. Another is that TSCA could be made less burdensome to use by allowing EPA to regulate a chemical on the basis of a finding that the chemical presents a significant risk to human health or the environment, without having to demonstrate that the risk is also unreasonable based on comprehensive analyses of the costs and benefits of regulating the chemical.

Clarify TSCA's Role and Relationship to Other Laws

TSCA's role--that is, how and under what circumstances EPA can use the act to deal with toxic chemical concerns--has long been controversial within EPA and among Members of Congress, the regulated community, and environmental organizations. The major point of contention has been whether TSCA should be a comprehensive "umbrella" statute aimed at regulating all unreasonable risks from chemical exposures or whether it should be a gap-filler to address chemical risks that cannot be controlled under other statutes.

TSCA does not clearly articulate what the act is to achieve through its regulatory authorities. In addition, section 9 generally requires that other environmental laws be used to address the risk posed by a chemical, if the EPA Administrator determines that such laws can eliminate or sufficiently reduce the chemical's risk. EPA has generally interpreted this section to mean that TSCA is not a comprehensive chemical control statute and should be used primarily to fill gaps in the authorities of other laws, such as

the Clean Air, Clean Water, and Occupational Safety and Health Acts. While these other laws can control environmental releases and certain exposures to chemicals during their production and use, they do not offer the flexibility provided in TSCA to control the production, distribution, and use of the chemicals themselves.

In our view, there are at least two possibilities for using TSCA as a more comprehensive chemical control statute. EPA could provide a different interpretation of the statute or the statute itself could be revised to remove references to other environmental statutes, leaving the EPA Administrator free to use TSCA whenever he/she believes it is necessary to reduce risks. Using TSCA in a more comprehensive manner would make control actions under the act an option in EPA's deliberations on how best to deal with toxic chemical concerns--either through TSCA, one or more of the other laws, voluntary actions by industry, or a combination of these approaches. This would give EPA a cost-effective way of controlling pollution other than by placing restrictions on industry at the end of the pipe.

Establish a New Framework for Taking Action

To regulate a chemical under TSCA, EPA must show that the chemical presents or will present an "unreasonable" risk. To determine whether the risk is unreasonable, EPA assesses the chemical's risks and performs analyses to weigh the benefits of controlling the chemical against the economic and social costs of any contemplated regulations.

This test of reasonableness has been very difficult for EPA because of the complexity and amount of evidence required to demonstrate that the benefits to human health and the environment outweigh the economic and social costs of controlling or banning the use of a chemical. According to EPA, the nature of scientific assessment is such that it must make extrapolations to determine both human and environmental risks, and uncertainties always exist. However, the introduction of doubt means that EPA may fall short of TSCA's threshold of sufficient proof to substantiate claims of unreasonable risk. Because of TSCA's legal standards, EPA has issued regulations under TSCA to regulate only nine chemicals.

EPA's 1989 regulation to phase out almost all products containing asbestos illustrates the difficulty of demonstrating unreasonable risk. In that case, EPA had considerable scientific evidence of serious health risks and spent several years developing the regulation. Nevertheless, the Fifth Circuit Court of Appeals decided in 1991 that the agency had issued the regulation on the basis of insufficient evidence.

In contrast to TSCA, the Canadian Environmental Protection Act separates the process of deciding whether to control a chemical from the process of determining what appropriate control action to take. The act authorizes the government to control chemicals that

are toxic, which are defined as those entering the environment in a quantity or concentration, or under a condition, having a harmful effect on the environment or human health. Determining whether a chemical is toxic and should be controlled is based on an assessment of the chemical's risks. Costs and benefits are then considered as factors in deciding what control actions to take, rather than in deciding whether chemical risks should be addressed.

A similar two-step process could be established in TSCA. For example, EPA could be required to determine whether a chemical presents a significant risk on the basis of several factors, including the chemical's toxicity, production volume, releases to the environment, and exposures. For those chemicals found to pose a significant risk, EPA would determine the most cost-effective actions to take to adequately reduce the risks. The agency would have the flexibility to select actions--whether under TSCA, other laws, or voluntary agreements--by considering their cost-effectiveness in reducing risks. In effect, costs and benefits would not be factors in deciding whether to reduce risks; they would be considerations in selecting a course of action to deal with the risks.

IMPROVE EPA'S REVIEW OF NEW CHEMICALS

TSCA does not require routine chemical testing, and industry performs only limited testing on new chemicals. Because sufficient test data are generally not available, EPA uses a method known as structure activity relationships analysis to predict new chemicals' health and environmental effects. This method, which relies on test data from chemicals with similar molecular structures, is highly accurate in predicting some chemical characteristics but is often inaccurate for other important characteristics.

To provide better data, TSCA could require manufacturers to perform basic tests for new chemicals and additional tests when production for the chemicals reach certain levels. This would increase the burden on both the manufacturers and on EPA, which would have to review the test results and related information to determine the chemicals' risks. These burdens could be reduced if TSCA were revised to allow EPA to review chemicals before they enter the marketplace, rather than before they are manufactured. Many chemicals at the premanufacture stage are never marketed.

Require Basic Testing of New Chemicals

A 1993 study comparing EPA's predictions using structure activity relationships analysis and actual test results for new chemicals in the European Union[2] showed that EPA performed poorly in predicting some characteristics, such as physical chemical

[2]Formerly the European Community.

properties. For example, 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 Union representatives considered this accuracy rate to be too low to characterize chemical risks.

TSCA currently 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 certain information that EPA needs to review the chemical, such as its molecular structure, proposed uses, estimated production amounts, estimated exposure, and the results of any testing that has been conducted. The Congress could revise TSCA to require manufacturers to perform certain minimum tests and submit the results to EPA with their premanufacture notices. To reduce industry's testing costs, the act could require that only certain basic tests be performed initially and that more extensive testing be done when a chemical's production reaches certain levels. Only a small percentage of chemicals would likely reach these levels and require the additional testing. Such an approach is used by Canada and countries belonging to the European Union.

Industry's costs could be reduced further by requiring testing for only those chemical effects or characteristics, such as vapor pressure, for which the 1993 study showed that structure activity relationships analysis did not perform well. In addition, some chemicals may not need to be tested. EPA currently provides a very limited review of certain types of new chemicals that agency officials believe pose little risk because of their chemical structures.

EPA, at the conclusion of its review of the premanufacture notice, could designate the additional testing to be performed. Once the testing is completed, the manufacturer would submit the results to EPA. At that time, the manufacturer could also update key information in the premanufacture notice, including any new uses and estimated exposures to the chemical. Currently, to require reporting on significant new uses, EPA has to issue rules on a chemical-by-chemical basis, which is costly and burdensome.

Minimize Burden by Requiring Notices When New Chemicals Are Marketed

TSCA currently requires manufacturers to submit information to EPA on chemicals that they intend to manufacture and market, but that have thus far been produced only under controlled conditions in the manufacturers' research and development laboratories. In contrast, European Union countries do not require manufacturers to submit a notification, including their test data, until a chemical has been manufactured and is ready to be marketed.

In her May 17, 1994, testimony to this Subcommittee, the EPA Assistant Administrator pointed out that, since 1979, about half of the approximately 19,000 premanufacture notices that EPA reviewed were for chemicals that never entered the marketplace. She pointed out that reviewing all of these notices--about 2,000 annually--is a continuous challenge to the agency. Revising TSCA to have EPA review new chemicals only when they are ready to be marketed could increase EPA's efficiency.

This change could also help minimize industry's testing and reporting costs. Industry would have to prepare fewer notices than it currently does, and a requirement for certain initial tests, if included in TSCA, would apply to fewer chemicals.

ACCELERATE THE REVIEW OF EXISTING CHEMICALS

In addition to requiring the review of new chemicals, TSCA authorizes EPA to review the risks of chemicals already in commerce. 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. EPA has reviewed only about 1,200, or 2 percent, of these substances under its existing chemicals program. While TSCA specifically requires the review of new chemicals within a certain period, the act contains no explicit requirement for reviewing existing chemicals. Consequently, EPA historically has given higher priority to reviewing new chemicals. Furthermore, while industry is responsible for collecting and submitting to EPA the data needed to review new chemicals, EPA must assume the burden of initiating existing chemical reviews and collecting the necessary data.

Establish Goals and Priorities

To put the existing chemicals program on a more equal footing with new chemical review, TSCA could be revised to set some specific deadlines or targets for the review of existing chemicals. Providing such a goal would establish a clear national policy and focus EPA's and the chemical industry's efforts on completing the reviews.

However, even with such a goal, it would likely take many years to review the large number of chemicals that comprise the TSCA inventory. Thus, some means of setting priorities would be necessary to ensure that risks to health and the environment are addressed in an appropriate and timely manner. According to EPA, only about 16,700, or 23 percent, of the 72,000 chemicals in the TSCA inventory are of concern because of their production levels or chemical structure. This number is still large, and EPA would need flexibility to focus the agency's and the industry's resources on those chemicals that, based on their toxicity, production volumes, and potential exposure, present the highest risk to human health

and the environment. This could be accomplished by setting out chemical review priorities in TSCA or by requiring EPA to implement a process to develop such priorities.

Other industrial countries have recognized the importance of systematically reviewing their existing chemicals. A 1993 European Union directive, for example, requires member countries to participate in a systematic review process for existing chemicals. The European Union plans to focus at first on high production chemicals and to periodically develop priority lists of chemicals for member countries to review.

Shift Some of the Burden to Industry

Although establishing priorities would help EPA to focus its efforts on the most serious chemical risks, the agency still may not be able to substantially improve its performance in reviewing the thousands of chemicals in use without shifting to the chemical industry more of the burden and cost for developing and compiling data. EPA now is responsible for compiling and analyzing the available information on chemicals' effects and exposures. Because few data--especially on exposures--are often available, EPA uses various models to project or estimate information, such as the amounts and types of exposures. The agency has to issue rules to require testing or to collect additional exposure information from industry. A rule to require testing of a chemical can take as long as 24 to 30 months and cost from $68,500 to $234,000.

One way to shift some of the responsibility to industry would be to revise TSCA to require chemical manufacturers to compile available data on chemicals and submit the results to EPA, as they now do for new chemicals. Under this approach, EPA would identify the types of information required and the reporting format. The agency would also notify the industry in advance of the priority chemicals scheduled for the agency's review within a certain period and the dates when it must submit the information to EPA. EPA would review the information and inform industry of the additional data needed. The 1993 European Community directive requires manufacturers to compile and report certain data on existing chemicals to member countries.

Another option would be for EPA to continue to be responsible for compiling available information, relying primarily on information in its files and in publicly available data bases. EPA could be authorized to more easily obtain information from industry to fill gaps in the data needed to perform assessments of chemical risks. Authorizing EPA to obtain the additional data without having to issue rules, as it is now required to do, could substantially reduce the resources that the agency uses for this purpose. This authority could be limited to chemicals that, at the time, are in the process of being reviewed and to the specific data needed to complete assessments of these chemicals's risks. TSCA

could also be revised to make it easier for EPA to issue these rules. For example, to issue a test rule, EPA must currently demonstrate that insufficient data exist and a chemical may present an unreasonable risk or that significant exposure may occur. Allowing EPA to issue a rule solely on the basis that the information is needed to assess the chemical's risks would require less supporting evidence for the rule.

INCREASE DISSEMINATION OF INFORMATION ON CHEMICAL HAZARDS

Industry claims a large portion of the chemical information that it provides EPA under TSCA as confidential to protect trade secrets. For example, a 1992 study found that more than 90 percent of premanufacture notices for new chemicals contained some information claimed as confidential. Consequently, EPA must expend effort to protect the information against unauthorized disclosure and it cannot be shared with the public and others, such as state health and environmental officials, who are not authorized access to it. The public, for example, may have an interest in information on the risks of chemicals that are produced or used in nearby manufacturing plants. State officials have various responsibilities related to protecting health and the environment from the dangers posed by toxic chemicals. Confidential TSCA information is not available except through the individual companies that submit it.

EPA has been successful in getting industry to voluntarily withdraw confidentiality claims after inquiring about their appropriateness. However, the process is resource-intensive, and agency officials have challenged the validity of only a small percentage of the claims. Although the officials believe, on the basis of the 1992 study and their experience with the data, that the problem with inappropriate claims is extensive, they told us that an increase in their efforts to challenge their validity is unlikely, given limited resources.

To discourage excessive confidentiality claims, EPA is considering various actions, including educating industry on what information may legitimately be claimed as confidential. EPA is also considering other actions, such as revising its regulations to require industry to substantiate claims, having a senior corporate official sign claims, resubstantiating claims at a later date to ensure that confidentiality continues to be necessary, and imposing penalties for filing false claims. While these, if implemented, should reduce the number of inappropriate confidentiality claims, the Congress could ensure that the actions are completed and are permanent by making them specific requirements of TSCA.

Another option would be to revise TSCA to limit the types of information that industry can claim as confidential. For example, TSCA could be revised to prohibit manufacturers from claiming as

confidential such information as a chemical's trade name, physical chemical properties, health and environmental effects, and safe handling and disposal procedures. These types of information would appear to provide the public with data about the potential dangers of chemicals without revealing business information.

Even with these changes, industry could claim a considerable amount of TSCA information as confidential. Federal employees with health and environmental protection responsibilities can obtain access to this information. On the other hand, state officials, who are delegated major responsibilities for implementing federal environmental and occupational health and safety laws, cannot obtain access. The Congress could give EPA the authority to provide access to states that implement satisfactory procedures to protect confidential data against unauthorized disclosure.

TSCA IS NOT A COMPREHENSIVE TOXICS STATUTE

Given the thousands of chemicals in use and the many ways that exposures and releases to the environment can occur, TSCA's chemical-by-chemical and risk-based approach means that the act is unlikely to address more than the most serious chemical risks--even with the types of changes that we have discussed. Consequently, a substantial amount of toxic pollutants will continue to enter the environment.

For example, we reported in February 1993 that hundreds of pollutants, including toxic water and air pollutants, have been identified in environmental laws as harmful and in need of control, but historically these pollutants have not been well regulated by federal and state agencies.[3] In addition to these agencies lacking the resources needed to carry out their regulatory responsibilities, much of the pollution has stemmed from sources that are small and diffuse and difficult to control under existing regulations.

A different approach is to set goals for reducing the use of toxic chemicals overall. Under this approach, legislation could establish national goals for reductions in the use of toxic chemicals and provide EPA with various tools, such as pollution taxes and other economic incentives, to achieve these goals. In our February 1993 report, we concluded that, because of their inherently greater flexibility, market-based incentives can be both a less costly and more effective means of controlling pollution.

Establishing longer-term goals for overall reductions in the use of toxic chemicals could be a useful supplement to TSCA's efforts to review individual chemicals to identify and control the

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[3]Environmental Protection: Implications of Using Pollution Taxes to Supplement Regulation (GAO/RCED-93-13, Feb. 17, 1993).

more serious health and environmental risks. These goals could be established in TSCA if the act were revised to provide EPA with the types of tools it would need to achieve these goals.

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In conclusion, TSCA has not played a major role in EPA's efforts to protect human health and the environment from the harmful effects of toxic chemicals. Although the act contains some unique chemical information-gathering and control authorities, these authorities have proven to be difficult to use. On the basis of our ongoing work, we have discussed our preliminary observations on a number of options for changes in the authorities that could strengthen the act and its role in reducing the risks associated with toxic chemicals. Details on such options will be provided to the Subcommittee in our report, which we plan to issue in September 1994. However, other approaches, such as national goals for reducing the use of toxic chemicals, may be needed to supplement TSCA, if the Congress anticipates a substantial reduction in the amount of toxics that enter the environment. Mr. Chairman, we would be happy to respond to any questions that you or other Members of the Subcommittee may have.

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