

July 1995

TOXIC SUBSTANCES

EPA Should Focus Its Chemical Use Inventory on Suspected Harmful Substances



**Resources, Community, and
Economic Development Division**

B-261203

July 7, 1995

The Honorable Joseph I. Lieberman
The Honorable Harry M. Reid
United States Senate

Little is known about the risks of many of the chemicals to which millions of consumers and workers as well as the general public are potentially exposed. While the amount of exposure to a chemical can vary greatly depending on its use, the Environmental Protection Agency's (EPA) information on chemical use is often scarce, incomplete, or outdated. To obtain the data it needs to assess the risks posed by chemicals, EPA is planning to develop a Chemical Use Inventory.

Concerned about the adequacy of information on chemical risks, you requested that we review EPA's efforts to develop this inventory. On the basis of discussions with your office, we focused our review on (1) determining the extent to which agreement exists on the chemicals and data to be included in the inventory and (2) the status of EPA's efforts to develop the inventory.

Results in Brief

The chemical industry, public interest groups, and other organizations have conflicting views on key issues relating to the Chemical Use Inventory that may be difficult for EPA to reconcile with its own views. EPA and the various organizations and groups differ concerning which and how many chemicals should be included in the inventory, the specific types of data that should be obtained, and the sources of these data. Although EPA has not yet made final plans for implementing the inventory, the agency has proposed collecting general data on chemical use and exposure from chemical manufacturers and importers on up to 12,000 chemicals. However, most organizations believe that the inventory should include substantially fewer chemicals than the number EPA has proposed. Our past work has shown that EPA does not have the resources to effectively compile and analyze information on a large number of chemicals. Therefore, the inventory could be more useful to EPA and other interested parties if it initially focused on a smaller number of the highest-priority chemicals known to present risks to health and the environment and was expanded as necessary. Furthermore, while chemical industry members are concerned about revealing confidential business information that would harm their competitive positions, EPA officials maintain that the

agency will ensure that legitimate confidential business information is protected in the inventory.

EPA officials have made no firm decisions about the specific features of the inventory or how it will be implemented. EPA officials met with representatives of the chemical industry, public interest groups, and others in April 1995 for technical discussions on alternative proposals for implementing the inventory. According to EPA officials, the agency has not yet decided whether to implement the inventory through the regular federal rulemaking process, which may take 2 years or more to complete, or through negotiations with interested parties to facilitate and expedite the rulemaking.

Background

Little is known about the ill effects that many chemicals in commerce might have on the people exposed to them. Adverse health effects result from the chemicals' toxicity as well as the extent of human exposure to them. To fully assess human exposure to a chemical, EPA needs to know the number of persons exposed, the means of exposure, and the amount and duration of the exposure. Actual measurements of exposure for the thousands of chemicals in use are not practicable because of the extensive monitoring equipment and staff resources required. Consequently, EPA estimates the types and amounts of exposure on the basis of a chemical's physical properties and use, the industrial processes used to produce and process the chemical, the production volumes, and the types and amount of the releases of the chemical into the environment.

The Toxic Substances Control Act (TSCA) authorizes EPA to collect information about the hazards posed by chemical substances and to take action to control unreasonable risks by either preventing dangerous chemicals from entering commerce or placing restrictions on those already in the marketplace. Under the act, EPA can control the production, distribution in commerce, use, and disposal of chemicals. TSCA applies to new and existing chemicals; it does not apply to pesticides, tobacco, nuclear materials, firearms and ammunition, food, food additives, drugs, cosmetics, or medical devices.

Information about chemical use is important for estimating potential exposure because the amount of exposure to a chemical can vary substantially depending on its use. However, although EPA officials believe that TSCA provides the authority to collect some data on chemical use and

exposure, the agency's current reporting rules do not require the chemical industry to provide this information.

The Chemical Use Inventory that EPA plans to develop is intended to provide the data on chemical use and exposure that the agency needs to assess risks. EPA envisions the inventory as a data base that will enable the agency to screen chemicals to identify those of highest concern as well as those that are potentially safer and can be substituted for more harmful chemicals in some applications. To implement the inventory, EPA intends to amend the TSCA Inventory Update Rule.

The Inventory Update Rule generally requires chemical manufacturers and importers to report to EPA certain information about the chemicals they produce or import in excess of 10,000 pounds per year. According to EPA officials, the rule covers approximately 9,000 chemicals produced or imported by about 2,400 facilities. The current rule generally requires chemical manufacturers and importers to provide data every 4 years on a chemical's identity, plant sites, and production volume but not on use or exposure. Such chemicals as inorganic substances,¹ polymers, microorganisms, and certain naturally occurring substances are excluded from the rule's reporting requirements. EPA plans to amend the rule in order to gather data on how chemicals are used and to make other changes to reporting requirements.

No Agreement on the Chemicals and Data for the Inventory

Beginning in July 1993, representatives of EPA, the chemical industry, public interest organizations, and other groups interested in information on chemical use met to discuss the agency's proposal for the Chemical Use Inventory. Following these meetings, these groups provided written comments to EPA on key issues such as (1) the chemicals that should be included in the inventory, (2) the types of data that should be obtained, and (3) the sources from which data should be collected. The most extensive comments were received from the chemical industry, public interest groups, and the Consumer Product Safety Commission—the federal agency responsible for protecting consumers from harmful products.

Some of the views expressed by these organizations may be difficult for EPA to reconcile with its own views. Most of these organizations believe that the inventory should address a limited number of high-risk chemicals. While EPA agrees with this position, agency officials believe that the data

¹Generally, inorganic substances are those chemicals that do not contain carbon.

available on exposure are insufficient to identify such chemicals. To develop a more comprehensive data base, EPA has proposed obtaining information on the approximately 9,000 chemicals included under the current Inventory Update Rule plus about 3,000 inorganic chemicals that are now excluded under the rule. Furthermore, the various organizations differ among themselves concerning which chemicals and data should be included in the inventory and which information sources should be used. Members of the chemical industry also expressed concern about revealing confidential business information, saying their competitive positions could be harmed as they provide EPA with data for the inventory.

Number of Chemicals to Be Included in the Inventory

The Chemical Manufacturers Association, representing companies that account for over 90 percent of the U.S. bulk chemical production, has expressed concerns about EPA's proposal for a comprehensive Chemical Use Inventory. The association believes that an inventory as proposed by EPA, including several thousand chemicals, would be overly broad, impose an extraordinary reporting burden on the industry, and present EPA with a significant challenge in information management. The association believes that EPA should narrow the list of chemicals in the inventory by taking into account the chemicals' hazards, production volumes, and potential for exposure.

The Chemical Manufacturers Association is developing a method for identifying high-risk chemicals to be included in the inventory, and it intends to propose this method to EPA. Although this proposal is not yet completed, EPA and association officials generally agree on the concept and the data elements that should be used to identify priority chemicals for the inventory but differ on the screening process to be employed.

The Consumer Product Safety Commission and public interest organizations also provided EPA with their views on the chemicals to be included in the inventory. The Commission generally supports EPA's plans to include the chemicals covered by the Inventory Update Rule, in addition to inorganic substances. However, the Commission believes that EPA should also include polymers, naturally occurring substances, and the chemicals produced by microorganisms, which are currently exempt from reporting under the rule. EPA officials were unable to estimate how many chemicals are included in these three categories. The Commission believes that data are needed on how these types of chemicals are used in order to provide a comprehensive view of the chemicals in products and to identify potential concerns about exposure. Public interest groups did not identify

the specific types or numbers of chemicals to include in the inventory. However, the groups said that the chemicals included should be selected on the basis of factors such as their toxicity and production levels. Such a selection process would limit the number of chemicals in the inventory.

As noted, EPA believes that the inventory should include the chemicals now covered by the Inventory Update Rule, in addition to inorganic substances. Although EPA officials told us that the agency is considering measures to reduce the number of chemicals in the inventory, EPA believes that it is important to include a relatively large number of chemicals in order to gather an appropriate amount of data on chemical use and exposure. These data can then be evaluated to identify the chemicals that pose the greatest risks because of their toxicity and potential for human exposure. EPA also believes that information is needed on a large number of chemicals to ensure that data are available for identifying those chemicals that can be used as substitutes in processes in which more hazardous substances are now used. However, EPA believes that including polymers, naturally occurring substances, and the chemicals produced by microorganisms in the inventory would not add to the usefulness of the data on chemical use and exposure because these chemicals are generally considered to be of less concern than the other chemicals EPA is proposing for the inventory.

EPA acknowledges that a comprehensive inventory will add to the chemical industry's reporting requirements and the agency's data management responsibilities. Although EPA has not yet determined the extent of the inventory's potential effects on its data management burden, the agency is currently assessing the likely impact on the industry of the increased reporting requirements. EPA plans to analyze the inventory's costs to the agency as part of the rulemaking process. EPA officials told us that the agency is considering using thresholds of production volume (for example, amounts above a certain production level) and limited hazard screening to reduce the number of chemicals in the inventory, thereby reducing the reporting and data management burdens.

Although EPA indicates that it needs data on a large number of chemicals, our past work shows that EPA needs to establish some means of setting priorities to ensure that risks to health and the environment are addressed in an appropriate and timely manner.² In this regard, our past work noted that EPA needs to focus the agency's resources on those chemicals that, on

²Toxic Substances Control Act: Preliminary Observations on Legislative Changes to Make TSCA More Effective (GAO/T-RCED-94-263, July 13, 1994) and Toxic Substances Control Act: Legislative Changes Could Make the Act More Effective (GAO/RCED-94-103, Sept. 26, 1994).

the basis of their toxicity, production volumes, and potential for exposure, present the highest risk to human health and the environment.

Although EPA recognizes the advantages of focusing on the chemicals of greatest concern, the agency does not believe that it has the chemical use and exposure data it needs to set priorities for the chemicals to be included in the inventory according to their relative risk. However, our past work indicates that, while EPA may not have complete information to assess chemicals' risks, the agency has enough data on chemicals' toxicity and production volumes from other sources to assess risk. These sources include EPA's reviews of new and existing chemicals and other sources that the agency uses to identify chemicals of concern and to target priority testing, such as those included in the Toxic Release Inventory³ and the TSCA Master Testing List.⁴

While EPA officials acknowledge that the existing data might provide a basis for selecting priority chemicals for the Chemical Use Inventory, they maintain that a more limited inventory focusing only on the most hazardous chemicals would necessarily exclude those that are less harmful, thus preventing EPA from identifying safer substitute chemicals for certain uses. Nevertheless, it is doubtful that EPA could obtain and analyze the information it needs to identify such substitute chemicals in a timely manner. As our past work indicates, EPA reviews only about 100 chemicals a year. At this rate, it would take over a century to review the approximately 12,000 chemicals the agency has proposed for the Chemical Use Inventory. Given EPA's limited capability to review chemicals, it is unlikely that the agency could effectively utilize data on the use and exposure of this large number of chemicals. Therefore, given the need for EPA to set priorities and industry's concerns about reporting burdens, a more moderate approach, at least initially focused on a smaller number of priority chemicals, could be more manageable for EPA and the industry and more valuable for the agency and other interested parties.

Data Types and Sources

The views of chemical industry representatives on the type and sources of data needed for the inventory vary. The Chemical Manufacturers Association believes that if the inventory is to be a reliable basis for determining risk, it must include data on a chemical's users and toxicity as

³The Toxic Release Inventory reports on about 600 toxic chemicals released into the environment, transferred from plant sites, and present in waste from U.S. manufacturing facilities.

⁴The TSCA Master Testing List includes chemicals that, on the basis of available knowledge, EPA believes to be of concern and has designated for priority review.

well as on the conditions under which the chemical is used—for example, whether it is isolated in a sealed environment or is accessible for human exposure.

Although the Inventory Update Rule currently requires reporting only by chemical manufacturers and importers, the Chemical Manufacturers Association believes that chemical processors can also provide the inventory with detailed data on how chemical products are used. Other members of the chemical industry, however, favor limiting the reporting requirements to manufacturers and importers. For example, the Chemical Specialties Manufacturers Association, representing specialty chemical producers, told EPA that including data from processors in the inventory would greatly increase the industry's reporting burden and EPA's data handling requirements.

EPA agrees that the inventory should include data that would allow it to characterize risks. For this purpose, EPA is considering amending the rule to require manufacturers and importers to report data on the number of workers potentially exposed at processing and other sites and on the volumes of chemicals used in different categories of industrial and consumer products. Furthermore, EPA believes that including data from chemical processors might make the inventory more comprehensive and accurate by identifying more facilities that handle toxic chemicals and by providing additional information on workers' exposure. However, EPA acknowledges that including such data would increase the industry's overall reporting requirements and the agency's data management responsibilities. EPA officials told us that the agency currently is not planning to include data from processors in the inventory. Furthermore, although EPA officials recognize the value of obtaining data from the industries that are final users of the chemicals, they told us that TSCA does not provide the agency with the authority to collect such data.

The Consumer Product Safety Commission also provided EPA with its views on the data to be included in the inventory. The Commission told EPA that it needs information on the quantity of chemicals in specific consumer products or categories of products and data to estimate the amount of human exposure to the chemicals in these products. The information that the Commission needs to estimate exposure includes a chemical's function in the product—for example, as a solvent or a pigment; the conditions under which consumers may be exposed to the chemical in the product; and the chemical's vapor pressure or evaporation rate.

EPA officials recognize the value of obtaining data on specific consumer products or product categories. However, as noted above, they believe that obtaining these data would be difficult because the agency lacks the authority under TSCA to collect information from the segments of the industry that are the final users of chemicals. In lieu of this information, EPA proposes to require manufacturers to identify the industrial and consumer uses of the chemicals they produce. However, EPA acknowledges that the quality of the data on end uses that it would receive from manufacturers could be questionable, because these companies may not be aware of all of the final uses of their chemicals.

Representatives of a number of public interest groups also provided their views. Generally, these representatives believe that the inventory should be used to place public pressure on the chemical industry to reduce its use of toxic chemicals. Towards this end, they believe that the inventory should provide data from each chemical production and processing facility on the (1) chemicals flowing into, used in, and emitted from the facility; (2) chemical end-users and purchasers of toxic chemicals; (3) number of workers and consumers handling products; and (4) chemical processors and processes.

Because these groups' concerns focus on individual chemical facilities and their chemical flows, EPA believes that the groups' data needs can best be addressed under the Toxic Release Inventory. EPA is considering revising the reporting requirements for the Toxic Release Inventory in order to obtain site-specific data on industrial facilities' chemical flows. EPA officials told us that the agency will consider the data needs of the public interest groups in its planned revisions to the Toxic Release Inventory's reporting requirements. EPA will not initiate the proposed revisions to this inventory until it completes ongoing efforts to expand the number of chemicals and reporting facilities included in this inventory. EPA expects this effort to take several years.

Industry Is Concerned About Confidentiality of Data

Although EPA, the Consumer Product Safety Commission, and public interest groups believe that the data in the inventory should be made public, members of the chemical industry are concerned that the information they provide might be used by competitors to harm their business positions. The Chemical Manufacturers Association is concerned that reporting data on chemical use would damage companies' competitive positions by disclosing key information about the ingredients of chemical

products, plans for new products, chemical processes, or improvements to processes.

TSCA provides that chemical manufacturers, processors, and distributors may designate the data submitted to EPA as confidential. Information entitled to confidential treatment includes trade secrets and certain commercial or financial information. EPA generally must protect information entitled to confidential treatment from public disclosure.

EPA believes that the number of claims of confidential information made by the industry under TSCA has been excessive and that many of these claims have been inappropriate. Consequently, EPA has recently initiated a number of actions to reduce the number of claims, including proposing regulatory changes to require companies to substantiate their claims. Despite industry's concerns over the public availability of data in the inventory, EPA officials believe that these concerns are insupportable and told us that the agency will fully protect legitimate confidential business information. They also said that EPA will require reporting of data by ranges, in aggregates, or in other ways to avoid claims concerning confidential business information.

Status of EPA's Efforts to Develop Inventory

EPA officials have made no final decisions about the specific features of the Chemical Use Inventory, including the chemicals and data to be included and how the inventory will be implemented. These decisions will be made on the basis of future discussions with the chemical industry and other interested parties.

Although EPA initially planned to implement the Chemical Use Inventory through a regulatory negotiation process, the agency is reconsidering this approach because some parties are reluctant to participate in the process. In this process, the agency would work to resolve differences among chemical industry members, public interest groups, and others before introducing a proposed amendment to the Inventory Update Rule. This approach is intended to facilitate and expedite the normal rulemaking process, in which EPA first proposes a rule and then works to resolve differences among the interested parties. This process can take 2 years or more to complete.

EPA officials met with representatives of the chemical industry, public interest groups, and others in April 1995 for technical discussions on alternative proposals for implementing the inventory. According to EPA

officials, they will continue to work with the interested parties in attempting to identify an approach that will make the inventory most useful to the agency and others.

EPA officials told us that the agency is uncertain whether the restrictions on new regulations and the cost-benefit analysis requirements that are currently under consideration in the Congress will be enacted and, if they are passed, what the exact provisions of the final legislation will be.⁵ Consequently, EPA officials told us that they do not know the effect that these proposed legislative changes may have on the agency's plans to revise the Inventory Update Rule. Although EPA officials are proceeding to further develop technical aspects of new reporting requirements, they have not yet established a specific schedule for implementing the inventory.

Conclusions

EPA is developing its Chemical Use Inventory to obtain the data on use and exposure the agency needs to assess chemicals' risks and to set priorities for its programs for toxic substances. While EPA has made no firm decisions on the specific features of the inventory, the agency has proposed including about 12,000 chemicals. EPA officials maintain that a broad approach will provide the comprehensive information needed to identify those chemicals that pose risks as well as those that can substitute for such chemicals. However, the chemical industry, public interest groups, and the Consumer Product Safety Commission generally believe that the number of chemicals in the inventory should be limited. In our opinion, implementing the inventory on a smaller scale than currently envisioned by EPA, initially covering possibly as many as several thousand of the chemicals suspected to present the greatest risk, would provide key data on chemical use and exposure while limiting the reporting burden on the chemical industry and EPA's data management requirements. This approach would also give EPA the opportunity to assess the data obtained, reconsider the chemicals and type of data included in the inventory, and make any necessary adjustments to its approach.

Recommendation

To ensure that the Chemical Use Inventory provides the data on chemical use and exposure that EPA and other interested organizations need while at the same time minimizing the data management burden on both the

⁵Several bills pending in the Congress would impose restrictions on issuing regulations. For example, S. 343 and H.R. 9 would generally require agencies to conduct cost-benefit analyses before issuing regulations. Other bills, including S. 219 and H.R. 450, would impose a moratorium on many regulatory actions by agencies.

agency and the chemical industry, we recommend that when the Administrator of EPA implements the inventory, the agency begin with a limited number of those chemicals, perhaps as many as several thousand, that are suspected of presenting the greatest risk to human health and the environment. As information is obtained through the inventory, EPA may need to expand the number of chemicals included and/or substitute other chemicals as appropriate.

Agency Comments

We requested comments on a draft of this report from EPA. On May 25, 1995, we met with the Director of the Economics, Exposure and Technology Division in EPA's Office of Pollution Prevention and Toxics to obtain the agency's oral comments on the draft report. During our meeting, this official stated that overall, the report is a well-written description of issues concerning EPA's proposed Chemical Use Inventory. Nevertheless, EPA disagreed with our recommendation as stated in the draft report because the agency did not believe that the inventory should be limited to a few hundred of the most toxic chemicals with the highest production volumes. However, after we discussed the recommendation and clarified that we believe that EPA should initially limit its inventory to as many as several thousand chemicals rather than the proposed 12,000, this official said that the agency would consider our recommendation.

As we discuss in our report, EPA has concerns about limiting the size of the inventory because the agency (1) believes it is difficult to screen high-priority chemicals for the inventory without data on exposure and (2) wants information on a large number of chemicals used in similar applications, or "use clusters," in order to identify safer substitutes. In addition, EPA believes that the agency's risk management capacity should not determine the number of chemicals included in the inventory.

Although EPA officials maintain that they are considering employing limited hazard screening to reduce the number of chemicals in the inventory, EPA believes that a limited set of potential high-risk chemicals cannot be identified without the data on exposure supplied through the inventory. While we agree that risks may not be screened with precision on the basis of data on production volumes only, we believe that this type of information, in conjunction with data on toxicity and other available data, can provide an indication of which chemicals potentially pose the greatest risks. Initial screening of chemicals on this basis could result in a more manageable number of chemicals for which data on exposure could be obtained. Successive screenings on this basis may provide the accuracy

that EPA needs but on a smaller universe of chemicals, which could be expanded as needed.

EPA also believes that data on chemical use and exposure are essential to identifying groups of chemicals used in similar applications, or use clusters. EPA believes that this approach is key to helping the users of the chemicals make informed choices that include consideration of exposures and risks when selecting chemicals for a specific use. As we discuss in our report, EPA believes that the agency needs such information on a large number of chemicals. While including a relatively large number of chemicals in the inventory could provide EPA with the data needed to identify a range of substitute chemicals for a given use, we continue to question the need for, and EPA's ability to effectively manage and utilize, data on as many as 12,000 chemicals. Data on the use of a smaller number of chemicals, perhaps as many as several thousand, would be more manageable for both the chemical industry and the agency and would provide EPA with data on a sufficient number of chemicals to identify use clusters and potential substitutes that are safer.

EPA believes that the agency's risk management capacity should not be the limiting factor in determining the number of chemicals selected for the inventory. Although we agree that EPA's risk management capacity should not be the sole determinant of the number included, we believe that this capacity should be an important consideration in implementing the inventory. Similarly, EPA should consider its data management capacity in deciding how many chemicals to initially include in the inventory. Given that EPA has not yet determined the extent of the reporting burden on the industry or the data management responsibilities of the agency that would result from the inventory, we continue to believe that it would be prudent for EPA to initially include a more limited number of chemicals in the inventory until the agency has determined the value of the information obtained as well as the costs to the industry of providing the data and to EPA of managing it and making it available to interested parties.

EPA provided additional technical comments on our draft report. We have made changes in our report as appropriate to accommodate these comments.

Scope and Methodology

To identify the information needed by EPA, we interviewed EPA officials, including the Director of the Economics, Exposure and Technology Division, Office of Pollution Prevention and Toxics. To obtain information

on EPA's efforts to develop the inventory, we interviewed the Chief of the Chemical Engineering Branch, Economics, Exposure and Technology Division, in EPA's Office of Pollution Prevention and Toxics.

We also reviewed EPA's internal and public documents on the inventory program. To identify the views of the potential users and suppliers of the data in the inventory, we reviewed written comments on the inventory submitted to EPA by the Consumer Product Safety Commission; various public interest, environmental, environmental justice, and labor groups; the Chemical Manufacturers Association; the Chemical Specialties Manufacturers Association; other chemical industry representatives; and some individual chemical manufacturing and processing companies.

We conducted our review between April 1994 and May 1995 in accordance with generally accepted government auditing standards.

As arranged with your office, unless you publicly announce its contents earlier, we plan no further distribution of this report until 10 days after the date of this letter. At that time, we will send copies to the Administrator of EPA and the Director, Office of Management and Budget. We will also make copies available to others on request.

Please contact me at (202) 512-6111 if you or your staff have any questions. Major contributors to this report are listed in appendix I.

A handwritten signature in black ink, appearing to read 'Peter F. Guerrero', written over a faint rectangular box.

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