EPA's Collection and Verification of Data Under the Toxic Substances Control Act (TSCA)

Section 8 of TSCA provides EPA the authority to require, among other things, certain chemical manufacturers and processors to maintain and report data on designated chemical substances and mixtures (insofar as the data are known or reasonably ascertainable, necessary, and not duplicative). The following list is illustrative of the types of data EPA may collect under section 8(a) of TSCA:

- The common or trade name, chemical identity, and molecular structure.
- The categories or proposed categories of use.
- The total amounts manufactured or processed by categories of use.
- A description of the byproducts resulting from the chemical's manufacture, processing, use, or disposal.
- All existing data concerning the environmental and health effects.
- The number of individuals exposed, and reasonable estimates of the number who will be exposed, in their places of employment and the duration of such exposure.

Using its 8(a) authority, EPA gathers data needed to assess the risks posed by chemicals of potential concern.

Section 8(b) of TSCA requires EPA to compile, keep current, and publish an inventory of the chemical substances manufactured or processed in the United States. EPA uses its section 8(a) data-gathering authority to collect production volume and plant site data to help develop that inventory.

Section 4 of TSCA provides EPA authority to require manufacturers and processors to conduct tests on any chemical substance or mixture (1) that either may present an unreasonable risk to health or the environment, or may result in substantial environmental or human exposure, (2) that has insufficient data and experience upon which to determine its health and environmental effects, and (3) when testing is necessary to develop data to make such a determination. To assist EPA in this effort, section 4(e) of TSCA created a committee known as the Interagency Testing Committee (ITC), made up of members from eight federal agencies,[1] to recommend chemicals that should be given priority consideration for testing. The ITC is to consider production quantities, emissions, exposure levels, health and environmental effects studies, and other factors in making its chemical testing recommendations.

[1]The eight ITC members are appointed one each from EPA, the Department of Labor, Council on Environmental Quality, National Institute for Occupational Safety and Health, National Institute of Environmental Health Sciences, National Cancer Institute, National Science Foundation, and the Department of Commerce.

TSCA Inventory of Chemical Substances

In implementing section 8(b) of TSCA, EPA used its 8(a) data-gathering authority and issued Inventory Reporting Regulations in December 1977 whereby certain manufacturers and importers[2] reported data on chemicals manufactured or imported between 1975 and 1977. For example, they identified the chemical name, the 1977 production volume by range (such as 10,000-100,000 pounds), and the site location. They also designated whether a chemical substance was manufactured or processed within a plant site or distributed for commercial purposes outside a plant site.

The inventory, first published in 1979, contained data on about 63,000 chemicals as of October 1, 1985. (This included about 2,500 new chemicals, manufactured since 1977, that have been added periodically to the inventory.) According to the special assistant to the director, Information Management Division, Office of Toxic Substances (OTS), EPA does not attempt to verify the accuracy of the data received from the chemical industry, but it does review the data for reasonableness and completeness at the time it is submitted and follows up by contacting individual companies, when necessary, to improve the data. EPA has not updated the 1977 production volume and site location data since the initial publication. Therefore, much of the inventory is considered by EPA to be outdated as many chemicals listed may no longer be produced and the production volume and location data may have changed.

Proposed Update of the TSCA Inventory

Recognizing that current data are needed for TSCA regulatory decision making, EPA issued in March 1985 a proposed rule to update the TSCA inventory. Under the proposed rule, manufacturers and importers will be required to provide basically the same data used to establish the initial inventory—chemical identity, plant site, production volume, and whether the chemical is distributed for commercial purposes outside the manufacturing site. In contrast to the initial reporting requirement, the proposed rule requires manufacturers to report precise production data rather than production range and to periodically update that data.

The proposed rule exempts from reporting four categories of substances that were included in the initial inventory, and manufacturers and importers will not be required to report if site-specific production or import volume is less than 10,000 pounds annually. EPA estimates that it

[2]Small manufacturers with annual sales of less than $5 million were required to report only the names of the chemicals they manufactured but not production data unless they manufactured more than 100,000 pounds annually at an individual production site.

will request updated information on approximately 42,000 chemicals, but it could receive information on as few as 15,000 chemicals because of the low-production and other exemptions.

According to the OTS special assistant to the director, EPA plans to issue the final rule updating the TSCA inventory in early 1986 and have the new inventory ready for distribution 3 to 4 months after the data updates are received, probably sometime in 1987. In December 1985 we provided a report[3] on the inventory and its proposed update to the Chairman, Subcommittee on Commerce, Transportation and Tourism, pursuant to his April 24, 1985, letter.

Preliminary Assessment Information Rule

In an effort to obtain additional data necessary to rank chemicals for investigation and to assess chemical risk as well as to support the development of test rules under section 4 of TSCA, EPA in 1980 began developing a series of model rules under its section 8(a) authority to collect information on the production, use, and exposure of selected chemicals. The purpose of the model rules was to provide OTS with a more efficient and effective method to collect data from the chemical industry. Once promulgated, OTS would only have to amend the model rule to identify the additional chemical substances and specific questions that are subject to the rules' reporting and recordkeeping requirements.

One model rule is the Preliminary Assessment Information Rule (PAIR), which was developed to gather basic data needed for preliminary assessment and ranking of chemical substances. PAIR, as proposed on February 29, 1980, would have required chemical manufacturers (including miners and importers) and in some cases processors to report production and exposure-related data on 2,226 chemicals. After the rule was proposed and public comments were received, however, the final rule, issued on June 22, 1982, reduced the number of chemicals to 250 in order to reduce the burden of reporting and to serve only the most immediate needs for EPA's assessment of test candidates. Subsequent amendments to the rule have increased the number of chemicals to 345 as of December 2, 1985, according to the OTS director of the Information Management Division.

The chief of the OTS Chemical Screening Branch said that the usefulness of PAIR data has been limited because of the reduction of chemicals. Since PAIR is used to collect data on only a small number of chemicals,

[3]Environmental Protection Agency's Proposed Inventory Update (GAO/RCED-86-47FS, Dec. 4, 1985).

the official said that the rule cannot be used to rank chemicals for investigation as was originally intended.

Data Collected and Verified Under PAIR

Under PAIR, chemical manufacturers and importers are required to complete a two-page reporting form to the extent that the data are known or reasonably ascertainable. The form requests such data as where a chemical is made and in what quantities, how many workers are potentially exposed during manufacture, processing, and use at the manufacturing plant site, what likely environmental releases exist, and what quantities are used in various categories of uses both by the manufacturer and by the industrial customer.

An OTS project manager in the Test Rules Development Branch, Existing Chemical Assessment Division, told us that manufacturers' reporting under PAIR is "spotty." He said that usually manufacturers provide data on such things as total production volume and the releases to the environment, but they do not provide data on customer uses. According to the OTS project manager, not having this data has not been too detrimental so far, since OTS has primarily reviewed high volume chemicals for which much of the customer uses (exposure) data are already available.

According to the director of EPA's Compliance Division, Office of Compliance Monitoring under Pesticides and Toxic Substances, his office is responsible for determining which chemical companies have not reported or have reported incorrect data under TSCA. Because of limited resources, however, the director and his Compliance Branch chief said that they had little opportunity in the past to verify PAIR data, but they have recently begun to concentrate more on trying to verify such data. That effort, according to the officials, involves only about 40 of the chemicals that were included in the latest PAIR updates to the rule.

Comprehensive Assessment Information Rule

In 1983 OTS conducted an analysis of various data-gathering rules that had been issued and concluded that a comprehensive rule was needed to obtain more precise data from the chemical industry so that EPA could better support assessments of and regulations on chemical substances. In March 1984 a working group consisting of representatives from various EPA offices and other federal agencies that regulate chemicals was formed to develop, under TSCA section 8(a) authority, a Comprehensive Assessment Information Rule (CAIR). The group began in August 1984 to design a reporting form for CAIR data.

In developing the CAIR reporting form, various EPA offices such as the Office of Solid Waste and the Office of Air Quality Planning and Standards, as well as the Department of Transportation, the National Institute for Occupational Safety and Health, the Occupational Safety and Health Administration (OSHA), and the Consumer Product Safety Commission (CPSC), submitted the forms they use to collect data on chemicals. Data elements from those forms were then consolidated into a draft CAIR reporting form. During July 1985, EPA held two public meetings to discuss the draft rule and the draft reporting form.

According to the CAIR project manager, OTS plans to pre-test the CAIR reporting form and has accepted nominations from EPA offices and other federal agencies for chemicals to include in its initial CAIR proposal. EPA plans to send the proposed rule to the OMB early in 1986 for review and comment and to issue a proposed rule by March 1986. EPA plans to spend an estimated $15,000-$20,000 for preliminary system design and a feasibility study during fiscal year 1986. The heaviest expenditures are expected to come in 1987, when the system is in place and the final CAIR rule has been published.

CAIR, similar to PAIR, is a model rule that can be amended each time data are needed on a chemical. EPA states in the Federal Register notice on CAIR that its use of the model rule concept with PAIR shows that it takes less time to obtain data on chemicals. For each CAIR rule amendment, EPA will state who must report (manufacturers, importers, or processors) and what questions on the form must be answered. EPA will limit the request to only those data elements that are of particular interest to the users.

EPA also states in its Federal Register notice that CAIR will be designed to be used not only by OTS but also by other offices in EPA as well as by other federal agencies which develop chemical regulations (such as OSHA and CPSC). Currently, according to the notice, duplicative reporting from companies responding to EPA is a major problem, and current data-gathering efforts are both time-consuming and costly. If the different offices that regulate chemicals use CAIR, EPA states that industry compliance costs will be reduced and relevant data will be obtained more quickly and efficiently.

Data Collected Under CAIR

The data elements that can be collected under CAIR include such things as manufacturer, importer, and processor identification, product identification, physical/chemical properties, production volume and use, distribution, process description, worker exposure, and environmental releases. According to an OTS official in the Chemical Screening Branch, OTS plans to take enforcement action as needed in order to receive good data from the CAIR responses.

Chemical manufacturers, importers, and processors may be required to respond to CAIR data requests. Although processors were not initially required to respond to PAIR, EPA recognizes that without processor information it is difficult to make conclusive statements about the exposure to certain chemicals. In many cases, EPA has found that the number of processors of a chemical often far out number the number of manufacturers.

EPA plans to consolidate all CAIR data into one data base so that all users will be able to determine, before using the model rule, whether the data needed have already been obtained. EPA will also attempt, where possible, to make the CAIR data base compatible with other existing systems and is exploring the possibility of allowing companies to submit completed forms on computer disks.

Usefulness of CAIR

Although EPA envisions CAIR as a comprehensive and consolidated data-gathering system for toxic chemicals, the OTS Chemical Screening Branch chief also recognizes that the success and usefulness of CAIR will depend largely on whether the EPA Administrator supports the effort and on whether the various EPA offices and other agencies use the rule. Since the various offices do not yet know in what form CAIR will be proposed and OMB has not yet approved the rule, uncertainty exists about the effort.

Individual responses to OTS from EPA offices and other federal agencies indicate that CAIR could be used to supplement their individual data-gathering efforts, but it probably would not eliminate what they are now doing to obtain data. For example, EPA officials in OAQPS said that they may use CAIR to obtain data from such companies as degreaser users, solvent users, and gasoline stations, but the office will continue using section 114 letters as its primary data-gathering tool. Further, CPSC reported that since its information needs are product specific, CAIR probably cannot be used to replace its current data-gathering activities. On the other hand, OSHA is enthusiastic about CAIR's potential and plans

to use the system extensively, according to the CAIR working group member from that agency. OSHA, for example, has nominated over 40 substances to include in the proposed rule.

EPA has not yet determined how many chemicals will be included in the initial promulgation of CAIR. The CAIR project manager told us that 224 chemicals have already been nominated for inclusion in the CAIR proposal. He also said that the proposed rule may contain only about 50 to 75 chemicals, but a final decision has not yet been made. Once the form and data review system have been tested and industry becomes familiar with the rule and the reporting requirements, a greater number of chemicals could be added by rule amendments. The chief of the OTS Chemical Screening Branch expects that CAIR will eventually be used to request data on several hundred chemicals on an annual basis and will eliminate the need for PAIR.

According to the CAIR project manager, OTS plans to initiate an aggressive advertising campaign to inform offices of CAIR and how they can use it. The project manager also stated that EPA's Office of Program Policy and Planning will need to ensure that the other program offices in EPA use the rule.

EPA's Collection and Verification of Data Under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA)[1]

Section 102 of CERCLA authorizes EPA to designate as hazardous substances those elements, compounds, mixtures, solutions, and substances which, when released into the environment, may present substantial danger to public health or welfare or the environment. Section 102 also authorizes EPA to establish a reportable quantity (RQ) of release for each designated hazardous substance. EPA's data-gathering authority relating to these provisions is found in section 103 of the act. That section requires persons in charge of vessels or onshore/offshore facilities who have knowledge of a release of a CERCLA-designated hazardous substance in an amount equal to or greater than its established RQ to immediately report the release to the National Response Center.[2] The National Response Center, in turn, is to convey each release notification to all appropriate government agencies, usually the EPA regional office or the Coast Guard district office, for any needed cleanup action. A major purpose of section 103 is to alert government officials to releases of hazardous substances that may require rapid response to protect public health and welfare and the environment.

CERCLA establishes an RQ for each designated hazardous substance at 1 pound for each release, unless or until superceded by other regulations. If a release equal to or greater than the established RQ is not reported as required, criminal penalties may be imposed, upon conviction, on the persons in charge who were responsible for the reporting violation.

According to officials in EPA's Emergency Response Division, Office of Emergency and Remedial Response (Superfund), as of December 1985, there were 705 substances designated as hazardous under CERCLA. All of those substances are also designated or listed as hazardous or toxic under other environmental acts, such as the Clean Air Act, the Clean Water Act, and RCRA; thus, none are original to CERCLA. Each designated hazardous substance has an assigned RQ of from 1 to 5,000 pounds based on a review of available data on such things as the substance's toxicity, ignitability, and/or reactivity. The following section describes the data that EPA collected to assign these RQ levels.

[1]This act is also referred to as "Superfund."

[2]The National Response Center, established under the Clean Water Act, answers the need for a rapid response to oil spills and other releases. It is a centralized reporting system operated by the U.S. Coast Guard.

Assigning RQs to Individual Hazardous Substances

In late 1980 EPA committed to the Congress that it would develop RQs for the CERCLA-designated hazardous substances based on specific scientific and technical criteria. EPA decided in April 1985 to establish RQs by relying on a process already being used under the Clean Water Act. That process uses a five-level scale for reporting aquatic spills. According to EPA, the regulated community was already familiar with those scales. Furthermore, according to an environmental engineer in EPA's Emergency Response Division, the aquatic medium appeared to be the most sensitive for chemical substances and most substances have some aquatic data available.

The five-point scale used for reporting aquatic spills is set at 1, 10, 100, 1,000, and 5,000 pounds. The more hazardous or toxic a substance, the lower the assigned RQ. In other words, a substance with an RQ of 1 pound is considered more dangerous than one with an RQ of 100 pounds.

In setting an RQ level for each CERCLA-designated hazardous substance, EPA employs a flowchart in which certain criteria are assessed such as aquatic, mammalian and chronic toxicity, reactivity, and ignitability. The director of EPA's Emergency Response Division said that the criteria were established after extensive study and review by EPA, the Science Advisory Board, and others.

According to an environmental engineer in EPA's Emergency Response Division, the RQ-setting process under CERCLA is a multistage process in which an EPA contractor first searches available literature on a substance's characteristics (for example, aquatic toxicity). Next, the contractor prepares a background document justifying a recommended RQ based on that literature search. EPA staff review the document to determine whether it adequately supports the recommended RQ level. This review constitutes the RQ verification process, at which time the contractor's recommended actions can be challenged.

In our efforts to obtain information, the EPA environmental engineer told us of one instance where EPA staff had taken issue with a contractor's recommended RQ and were successful in having the final RQ lowered from the recommended level. The contractor had conducted a literature search on phosgene and had subsequently recommended that an RQ of 1,000 pounds be set. EPA staff performed additional research and analysis on the literature on phosgene and generated sufficient data to support an RQ of 10 pounds. The final rule, issued in an April 4, 1985, Federal Register notice, incorporated an RQ of 10 pounds for phosgene. The notice also established RQs for 339 other hazardous substances and