First Annual Report (1977)

Administration of the *Toxic Substances Control Act*

U.S. ENVIRONMENTAL PROTECTION AGENCY

FIRST ANNUAL REPORT—1977

ADMINISTRATION
OF THE
TOXIC SUBSTANCES CONTROL ACT

U.S. ENVIRONMENTAL PROTECTION AGENCY

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January 17, 1978

The President
The White House
Washington, D.C. 20500

Dear Mr. President:

I am pleased to transmit to you the Environmental Protection Agency's (EPA) first Annual Report on the administration of the Toxic Substances Control Act (TSCA). This report provides the information required by Sections 30 and 9(d) of the Act, as well as additional information on EPA's activities under the Act.

ORGANIZATION AND STAFFING

In accordance with Section 26(g), EPA has established the position of Assistant Administrator for Toxic Substances. Your appointment of Mr. Steven D. Jellinek to this position was confirmed by the Senate on October 12, 1977. An organizational plan for the Toxic Substances program has been developed and will be approved in the near future. The responsibilities of the Assistant Administrator for Toxic Substances include both the Toxic Substances and Pesticides programs. Because these two programs have much in common, placing them under the purview of a single Assistant Administrator will be beneficial to both of them.

The Assistant Administrator for Toxic Substances also is responsible for promoting Agencywide integration of toxic substances control activities. Toxic chemicals are receiving increasing attention in the Agency's air and water pollution control, drinking water, and solid waste management programs. There is a real need to ensure that the activities of these programs, as they relate to toxic substances that may endanger human health or the environment, are well coordinated.

The Assistant Administrator for Enforcement and the Assistant Administrator for Research and Development, as well as EPA's Regional Administrators, also play important roles in the implementation of the Toxic Substances Control Act. The Assistant Administrator for Enforcement has established a Pesticides and Toxic Substances Enforcement Division. The Assistant Administrator for Research and Development, jointly with the Assistant Administrator for Toxic Substances, is developing an initial plan for research and development in support of TSCA implementation. In each of EPA's Regional Offices, a Toxic Substances Coordinator has been designated, and efforts are underway to integrate toxic substances control activities in the Regional Offices.

In October 1976, when TSCA became law, the Agency's resources allocated specifically for the Toxic Substances program amounted to 45 positions and $7.0 million. In Fiscal 1978, the allocation for TSCA implementation, including research and development, is 319

positions and $27.8 million. Many of the additional positions are already filled; recruitment to fill the others is continuing. Special efforts are being made to recruit toxicologists and other specialists who have the expertise needed to deal with TSCA problems.

STRATEGY

The number of chemicals covered by the Toxic Substances Control Act is very large. Estimates of the number of chemicals produced in the U.S. for commercial purposes range up to 70,000. Estimates of the number of new chemicals introduced annually run as high as 1,000. For the Environmental Protection Agency, the work involved in identifying and assessing human health and environmental risks and in developing and enforcing rules and regulations to prohibit or restrict the manufacture, processing, distribution, use, and disposal of chemical substances and mixtures will be labor-intensive and time-consuming. For the chemical industry, the costs of compliance with EPA's testing requirements and regulatory restrictions could be substantial. Accordingly, it is essential that EPA establish priorities for all its TSCA activities, including testing, monitoring, data-collection, and rulemaking.

A system for establishing priorities will be the heart of EPA's strategy for implementation of the Act. In the near future, the Agency will distribute for public review and comment a draft strategy document now being developed in the Office of the Assistant Administrator for Toxic Substances. This document will outline a priority-setting system in general terms and will also describe the Agency's current thinking about implementation of key parts of the Act. A follow-up document, due to be completed later, will lay out a priority-system in much greater detail; when completed, it also will be distributed for public review and comment.

In developing these strategy documents, the Assistant Administrator for Toxic Substances is consulting people in other EPA programs and is building on the Agency's earlier TSCA strategy development efforts. A preliminary paper was distributed for public review and comment in February 1977. Both before and after its distribution, the Agency held public meetings to discuss TSCA implementation. Meetings were held not only in Washington, D.C., but also in nine other cities around the U.S.

TESTING

Section 30(1) requires that the Annual Report include a list of the testing required under Section 4. Thus far no testing requirements have been issued. Within the Agency, work is underway on the development of standards for carcinogenicity, environmental fate, and ecological effects testing. Preliminary work is underway on standards for teratological and behavioral toxicity testing. As far as possible,

TSCA testing standards will be harmonized with other Federal agencies' and foreign governments' testing standards.

Efforts to identify the chemicals to be covered by the initial testing requirements also are underway. A method of selecting chemicals to be tested—based on their potential impact on human health and the environment—will be an integral part of the system for establishing priorities for TSCA implementation.

Section 4(e) calls for the creation of an interagency committee to recommend testing priorities. In October 1977, this group made its initial recommendations; it recommended various types of toxicological and environmental testing of four individual chemicals and six groups of chemicals. Attachment A is a summary of the recommendations. EPA has one year from the receipt of the recommendations to initiate action to require the recommended testing or to state publicly its reasons for not doing so. As one of its initial steps in assessing the recommendations, the Agency soon will publish proposed rules under Section 8(d); the proposed rules would require chemical manufacturers and processors to submit lists and copies of pertinent health and safety studies already performed with respect to the chemicals covered by the committee's recommendations. EPA is also examining its own files, and asking other Federal agencies to examine theirs, to determine whether such studies have already been performed. Where the recommended types of studies have already been performed in a way that produced reliable results, it obviously would not be desirable to require that it be performed again.

CHEMICAL INVENTORY

Section 8(b) requires the Agency to compile and publish an inventory of chemicals in commerce. Beginning 30 days after publication of this inventory, no person may manufacture or import for commercial purposes a chemical not included in the inventory without submitting premanufacturing notice under section 5. Compilation of the inventory is now underway. An initial inventory, based on information furnished by chemical manufacturers, will be published in late 1978.

In December 1977, the Agency issued rules specifying who is required to report and what information must be reported. Attachment B summarizes the reporting rules. In brief, those chemical manufacturers (including importers) who are required to report will have until May 1, 1978, to report the identity and production volume of chemicals manufactured at each production site during calendar 1977. Chemicals manufactured during the two preceding years also may be reported for inclusion in the inventory. EPA's rules include provisions limiting the reporting requirements applicable to small business and allowing confidentiality claims to be made.

Development of the Agency's 8(b) reporting rules took more time than TSCA provided, largely because of the time required to work out satisfactory ways of dealing with a number of sensitive issues. Questions concerning the applicability and scope of the reporting requirements, treatment of small business, and handling of information subject to confidentiality claims were raised by the chemical industry and other interested parties. EPA took the unusual step of publishing a second set of proposed rules after reviewing the public comments on its initial proposal. In addition, Agency employees involved in developing the rules had many meetings with industry and public interest representatives, officials of other Federal agencies, representatives of foreign governments and international organizations, and other interested parties. Though the decision to publish a second proposal caused a delay in compilation of the inventory, the result was a set of rules that will enable EPA not only to satisfy the 8(b) requirement but also to obtain data needed to begin methodically establishing priorities for attention and action under TSCA.

REPORTING AND RECORDKEEPING

In addition to calling for compilation of an inventory of commercial chemicals, Section 8 authorizes the Agency to obtain other types of information needed for determinations about human and environmental risks. Toward this end, the Agency is authorized to require reporting of data on production, uses, worker exposures, by-products, and disposal methods, as well as existing data on environmental and health effects. The Agency also is authorized to require submittal of lists and copies of health and safety studies and to require maintenance of records on adverse reactions to chemicals. Development of rules for such reporting and recordkeeping is in progress.

Also under Section 8, chemical manufacturers, processors, and distributors are required to furnish information which reasonably supports the conclusion that a chemical substance or mixture presents a substantial risk of injury to health or the environment. The Agency has published proposed guidance indicating what kinds of information should be submitted. Final guidance will be issued after the Agency completes its review and analysis of public comments. Approximately 35 "substantial risk" notices have already been received. Most of them have concerned chemicals already being studied by EPA or chemicals produced in such limited amounts that human and environmental exposure to them is minimal. Some have presented information already available in published literature. All such notices are reviewed in EPA, and copies are routinely distributed to the Occupational Safety and Health Administration, the Food and Drug Administration, and the Consumer Product Safety Commission.

CHEMICAL CONTROL REGULATIONS

Section 30(3) requires that the Annual Report include a list of rules issued during the year under Section 6, which authorizes the Agency to prohibit or restrict the manufacture, processing, distribution, use, and disposal of chemical substances and mixtures, and, in some instances, articles containing chemical substances and mixtures.

Under Subsection 6(e), the Agency is engaged in rulemaking dealing with polychlorinated biphenyls (PCBs), which are a widespread and hazardous environmental contaminant. Proposed rules establishing requirements for PCB marking and disposal were issued in May 1977. Public hearings were held the following month. It is anticipated that final marking and disposal rules will be issued in January 1978.

Subsection 6(e) also prescribes a timetable for phasing out the manufacture, processing, distribution, and use of PCBs, with certain limited exceptions. Proposed rules covering the phase-out and defining exceptions have been developed and are expected to be published in January 1978. Since it will be administratively and legally difficult to enforce the statutory restrictions until the Agency issues final rules defining the terms of these restrictions and the conditions under which exceptions will be made, no implementation action will be initiated until final rules are issued and take effect. It is expected that the final rules will be issued in April 1978. It should be noted, however, that the manufacture of PCBs in the United States has already ceased, and that many producers of items in which PCBs had been used have been switching to substitute materials.

Under Section 6(a), proposed rules prohibiting nonessential aerosol uses of chlorofluorocarbons were issued in May 1977. These rules were developed and issued jointly with the Consumer Product Safety Commission and the Food and Drug Administration. Public hearings were held in August 1977. It is anticipated that final rules will be issued in February 1978.

An investigation of the need for rulemaking is underway with respect to polybrominated biphenyls (PBBs). A few years ago, PBBs were accidently mixed with livestock feed in Michigan and caused extensive harm. EPA is now gathering information on production and uses of PBBs, and on human and environmental exposure to PBBs, in order to provide a basis for determining whether regulatory action is necessary.

RULEMAKING PROCEDURES

Under Section 6(c), the Agency has issued rules establishing procedures to be followed in providing an opportunity for interested persons to present their views on proposed regulations affecting the manufacture, processing, distribution, use, and disposal of chemicals. Among other things, the rules provide for presentation of

testimony to an expert panel and an opportunity for cross-examination to aid in resolving disputed factual issues. In addition, the rules reflect the requirements of Section 6 for issuance by EPA of documentation in support of proposed regulations.

COMPENSATION FOR PUBLIC PARTICIPATION

Also under Section 6(c), the Agency has issued temporary rules under which interested persons may be compensated for certain expenses related to participation in rulemaking proceedings. The temporary rules establish a pilot program related specifically to the forthcoming rulemaking on phasing out manufacture, distribution, and use of PCB's. In accordance with Section 6(c), the rules provide that the Agency may provide compensation for reasonable attorneys' and expert witnesses' fees and related costs of participating if the participant "represents an interest which would substantially contribute to a fair determination of the issues to be resolved" and if either the participant's economic interest in the issues is small in comparison to the costs of participation or the participant would not have the resources to participate if compensation were not granted. Persons who would be regulated by the proposed rules or who represent regulated parties are eligible for compensation, but the aggregate amount paid to such persons may not exceed one-quarter of the total amount paid to all participants.

PRE-MANUFACTURING NOTIFICATION

Section 30(2) requires that the Annual Report include information on manufacturing and processing notices received under Section 5 and on actions taken with respect to such notices. The requirement that manufacturers notify the Agency before manufacturing a new chemical will not become effective until 30 days after publication of the initial inventory of commercial chemicals. As indicated above, it is expected that the initial inventory will be published in late 1978. In the meantime, the Agency is beginning to develop plans and policies for implementing section 5. A Pre-Manufacturing Review Division is being established and will have as its sole responsibility the implementation of section 5. Thus, it will be able to focus its attention exclusively on the important task of identifying and dealing with new chemicals that may present significant hazards to human health and the environment.

PENALTIES

Section 30(4) requires that the Annual Report provide information on judicial and administrative actions completed or pending under Section 16. Section 16 prescribes civil and criminal penalties for violations of certain provisions of the Toxic Substances Control Act and rules issued under those provisions. Thus far, no action has been

initiated under Section 16. Within the Agency, work is underway on the development of rules establishing administrative procedures for assessment of civil penalties.

INDUSTRY ASSISTANCE

In accordance with Section 26(d) of the Act, the Agency has established an Industry Assistance Office to furnish the chemical industry information on implementation of the Act and on requirements applicable to manufacturers and processors. From its inception, the IAO has agressively been reaching out to chemical manufacturers and processors instead of simply reacting to requests for assistance.

IAO's activities have included the development of a mailing list comprising about 37,000 names, of which 26,000 are people involved in manufacturing, processing, and importing chemicals; the remainder are other persons interested in TSCA implementation. Copies of rulemaking notices and other significant documents are distributed via the mailing list. Among other things, IAO has distributed more than 11,000 copies of the Candidate List of Chemical Substances in response to requests. The Candidate List contains the names and CAS Registry Numbers of approximately 30,000 chemicals; it is designed solely to simplify the chemical industry's task when it is reporting the identity of commercial chemicals for purposes of EPA's compilation of the inventory under section 8(b).

Over the past several months, IAO has received an average of 175 telephone requests and 50 letters per week. In addition, IAO staff members have discussed TSCA implementation at meetings of 23 organizations and at nine regional meetings. EPA's Regional Offices have also been quite active in providing information both to industry and the public.

COORDINATION

Section 9(d) requires that the Annual Report include information on actions taken to coordinate TSCA activities with related activities under other Federal statutes, including statutes administered by other Federal agencies.

Of particular note in this respect is the creation of the Interagency Regulatory Liaison Group (IRLG) by EPA, the Consumer Product Safety Commission (CPSC), the Food and Drug Administration (FDA), and the Occupational Safety and Health Administration (OSHA). These four agencies, which play significant roles in protecting human health and the environment from the adverse effects of toxic substances, have entered into an Interagency Agreement to "cooperate with each other as far as is practicable to make the most efficient use of resources, achieve consistent regulatory policy, and improve the protection of the public health and environment."

IRLG working groups are involved in efforts to develop consistent or compatible approaches to testing, epidemiological studies, risk assessment, data management and exchanges, research and development, regulatory procedures, compliance and enforcement procedures, and public education.

Even before the creation of the IRLG, the participating agencies had begun working jointly on specific projects. As indicated above, for example, EPA, CPSC, and FDA are working together on regulating the use of chlorofluorocarbons. With the creation of the IRLG, it is expected that cooperation among the four agencies will increase significantly.

PROBLEMS

Section 30(5) requires that the Annual Report include a summary of major problems encountered in the implementation of the Act. As there are with all new legislation, there have been start-up problems with TSCA; in this case, however, the problems have been somewhat different from those EPA previously has encountered. Unlike most of the other new legislation EPA has had to implement, TSCA did not evolve from previous law. Accordingly, while there already was a small toxic substances program (focused primarily on problem identification and definition) in the Agency at the time TSCA was enacted, the Agency had no actual experience on which to rely. An organization had to be developed. Senior managerial officials had to be recruited. A conceptual approach to implementation of the Act had to be formulated. To varying degrees, all these tasks still are unfinished.

A major conceptual problem that has to be resolved is that of establishing priorities. This is discussed in the section of this report dealing with development of TSCA strategy.

There are, and will continue to be, significant policy and procedural problems related to the Agency's obligations under Section 14, which spells out the conditions under which the Agency is to protect or release information which the chemical industry claims is confidential. A solution has been worked out in the case of the 8(b) requirement for publication of an initial inventory of chemicals in commerce. But there will be other instances in which, broadly speaking, the Agency's obligations to release information to the public and to use information in support of TSCA implementation will come into conflict with its responsibilities under section 14 and the chemical industry's legitimate interest in keeping certain information confidential. Again, this problem is one that will require the Agency's continuing attention.

LEGISLATION

Section 30(6) requires that the Annual Report include such recommendations for additional legislation as the Administrator deems necessary to carry out the purposes of the Act. At this time, the Agency is making no such recommendations.

Respectfully yours,

Douglas M. Costle

FACT SHEET

ALKYL EPOXIDES

TESTING RECOMMENDATIONS:

Carcinogenicity
Mutagenicity
Teratogenicity
Other Chronic Effects
Environmental Effects
Epidemiology

Production, Release and Exposure: Although these compounds are generally used as industrial intermediates, several alkyl epoxides are produced in very large quantities (e.g., ethylene oxide at over 4 billion pounds per year). The vast amounts produced thus raise concerns primarily with respect to workplace exposure. The reactivity of these compounds is such that environmental persistence is not anticipated; however, their reaction products may be of significance.

ALKYL PHTHALATES

TESTING RECOMMENDATIONS:

Environmental Effects

Production, Release, and Exposure: Many of these compounds are produced in large volume, some of them over one hundred million pounds per year. Their use as plasticizers in a wide variety of products results in large volumes of alkyl phthalates reaching the aquatic environment either as wastes from formulating plants or from use and disposal of end products.

CHLORINATED BENZENES, MONO- AND DI-

TESTING RECOMMENDATIONS:

Carcinogenicity
Mutagenicity
Teratogenicity
Other Chronic Effects
Environmental Effects
Epidemiology

Production, Release and Exposure: The chlorobenzenes are produced in large quantities, monochlorobenzene over 300 million pounds/year and ortho- and para-dichlorobenzene approximately 50 million pounds each. These chemicals are widely used in industrial processes, as solvents, and in many consumer products. Therefore, the exposure and potential for hazard is great, particularly in light of their high release rate and anticipated persistence in the environment.

CHLORINATED PARAFFINS, 35-64% CHLORINE

TESTING RECOMMENDATIONS:

Carcinogenicity
Mutagenicity
Teratogenicity
Other Chronic Effects
Environmental Effects

Production, Release, and Exposure: The 1972 annual production of chlorinated paraffins was about 80 million pounds. The use of these materials in a wide variety of household and paint products, as well as adhesives and flame retardants, results in an estimated release rate of about 50 million pounds per year.

CHLOROMETHANE

TESTING RECOMMENDATIONS:

Carcinogenicity
Mutagenicity
Teratogenicity
Other Chronic Effects

Production, Release, and Exposure: The 1974 U.S. production of chloromethane was over 350 million pounds, most of this being used as a synthetic intermediate. However, it is estimated that about 5% of the annual production (over 15 million pounds per year) is released into the environment. NIOSH estimates that the number of workers exposed to chloromethane numbers about 31,000.

CRESOLS

TESTING RECOMMENDATIONS:

Carcinogenicity
Mutagenicity
Teratogenicity
Other Chronic Effects
Environmental Effects

Production, Release, and Exposure: Cresols are produced in large quantities, having a combined U.S. production in 1975 of about 90 million pounds. An annual release rate of about 45 million pounds has been estimated. Their wide use as industrial solvents leads to substantial occupational exposure. NIOSH estimates that roughly two million workers are exposed to cresols. In addition, cresols are used in many consumer products, resulting in a large general exposure.

HEXACHLORO-1,3-BUTADIENE

TESTING RECOMMENDATIONS:

Environmental Effects

Production, Release, and Exposure: Although the most recent (1974) data available indicate that this compound is no longer commercially manufactured in the U.S., it continues to be produced as a waste byproduct of various chlorination processes and is also imported into the U.S. for industrial solvent use. The release of hexachlorobutadiene into the environment has not been quantified, but there is good evidence of widespread distribution in the aquatic environment.

NITROBENZENE

TESTING RECOMMENDATIONS:

Carcinogenicity
Mutagenicity
Environmental Effects

Production, Release, and Exposure: U.S. production of nitrobenzene in 1975 was about 400 million pounds. Its release to the environment has been estimated to be about 20 million pounds annually. Although its predominant use (97 percent of production) is in closed systems in aniline manufacture, nitrobenzene is also an industrial solvent and dye intermediate. General population exposure can arise from environmental release, and from dispersive uses such as perfume in soap; cleaner for woodwork, wood flooring and paneling; ingredient of metal polishes and shoe blacking. Nitrobenzene liquid and vapor penetrate intact skin readily, and the efficiency of vapor absorption by inhalation is high.

TOLUENE

TESTING RECOMMENDATIONS:

Carcinogenicity
Teratogenicity
Other Chronic Effects
Epidemiology

Production, Release and Exposure: Toluene is produced in large quantities with an annual production rate in excess of 5 billion pounds. Because of its widespread use as a solvent, as well as a multiplicity of other uses, toluene has an unusually high occupational exposure (over 1 million workers). Its presence in many consumer products leads to a large general exposure. Toluene is currently being substituted for many benzene-uses and has an annual release rate exceeding 1 billion pounds.

XYLENES

TESTING RECOMMENDATIONS:

Mutagenicity
Teratogenicity
Epidemiology

Production, Release and Exposure: In the aggregate, approximately 8 billion pounds of xylenes are produced each year. Approximately 900 million pounds are released to the environment each year. Mixed xylenes were ranked by NIOSH 13th out of approximately 7000 agents in terms of the number of workers exposed. Xylenes are also used in a wide variety of consumer products, resulting in general population exposures.

Attachment B

QUESTIONS AND ANSWERS ON TSCA INITIAL REPORTING REGULATIONS

Q. *What is the purpose of this regulation?*

A. After publication of the inventory, persons who intend to manufacture any chemical substance not included on the inventory must give EPA premanufacture notification. EPA will use the other information reported to help set priorities and to monitor chemical substances in the environment.

Q. *How do these final reporting regulations compare with those proposed on August 2, 1977?*

A. Like the August 2 proposed regulations, these regulations require reporting by plant site and production volumes for chemical substances manufactured for commercial purposes in calendar year 1977.

The criteria for "who must report" have been slightly modified, but the number of firms required to report should be about the same (an increase of 425 firms).

On the other hand, there are several modifications to reduce the reporting burden to industry.

(1) The definition of intermediate has been modified to exclude fleeting intermediates. Only intermediates which are actually isolated or removed from the equipment in which they are manufactured are to be reported.

(2) Production volumes may be reported in broad ranges, not more specifically as proposed earlier.

(3) Importers are now required to report only bulk chemical substances, and do not have to report the components of articles, and

(4) The definition of "small manufacturers and importers" has been changed from $100,000 total annual sales, 2,000 pounds production, and one plant site, to $5 million total annual sales and 100,000 pounds production of chemical substances.

Q. *How many manufacturing firms will be required to report under these regulations?*

A. About 5400 firms will be required to report, or 8400 sites. This compares with 4975 firms or 7400 sites included in Standard Industrial Classification groups 28 and 2911 that were subject to the reporting requirements as proposed in August. Thus the final regulations are slightly more comprehensive than the August 2 proposal, requiring some 425 additional firms to report. Pulp and paper mills, which were previously exempted, will probably be required to report.

Q. *What manufacturers and importers are required to report for the initial inventory?*

A. All manufacturers who meet the following criteria must report all chemical substances at a plant site if:

(1) Thirty percent or more by weight of the products distributed from the plant site during calendar year 1977 were products within SIC groups 28 (Chemicals and Allied Products) or 2911 (Petroleum Refining Products), or

(2) The total pounds of reportable chemical substances manufactured at the plant site during calendar year 1977 equal one million or more pounds.

In addition, manufacturers must report any chemical substance not reported under (1) or (2) that was manufactured in quantities of 100,000 pounds or greater at a plant site during calendar year 1977.

The reporting requirements for importers are parallel to these, except importers do not report by site.

Q. *When does the reporting period begin?*

A. There are two reporting periods under the final regulations, one for the initial inventory and one for a revised inventory. Only manufacturers and importers may report for the initial inventory. Processors may report for the revised inventory.

Reporting for the initial inventory will begin on January 1, 1978 and extend to May 1, 1978. Most manufacturers of chemical substances, and importers of chemical substances in bulk form, must report concerning chemical substances manufactured or imported for commercial purposes during the calendar year 1977. Manufacturers and importers may report concerning substances manufactured since January 1, 1975.

Reporting for a revised inventory will begin upon publication of the initial inventory. During this period, processors and users of chemical substances for commercial purposes, and importers of chemical substances as parts of mixtures or articles, may report those chemical substances eligible for, but not included on the initial inventory. The reporting period will last seven months (210 days).

Q. *When may persons who process chemical substances report?*

A. Persons who only process a chemical substance, that is, who buy a chemical substance to use as a raw material in manufacturing another chemical substance, mixture, or article, may report for the revised inventory during the seven-month period after publication of the initial inventory. Processors may then report any substance not included on the initial inventory. In an effort to avoid duplicative reporting, processors are not subject to the initial inventory.

Q. *When will the inventory be published?*

A. At the earliest, the initial inventory will be published in late 1978. The revised inventory, based on additions from processors, users and importers of chemical substances as part of mixtures and articles, will be published in late 1979.

Q. *When will premanufacture notification requirements begin?*

A. Thirty days after publication of the initial inventory, any person intending to manufacture or import in bulk form a chemical substance not included on the inventory must submit premanufacture notification for that substance. Thirty days after publication of the revised inventory, no person may import a mixture containing a chemical substance not included on the inventory. EPA is still considering whether persons who import (some) articles must report with respect to (certain) chemical substances which comprise those articles.

Q. *How do the final regulations define "small manufacturer or importer?*

A. Any manufacturer or importer whose total annual sales are less than $5 million qualifies as a small manufacturer or importer for the purposes of the inventory. The $5 million sales criterion applies to the company, its parent company, and all companies owned or controlled by the parent company taken together. No company is considered to be a "small manufacturer or importer" with respect to any chemical which it produces or imports in quantities of 100,000 pounds or more at one plant site.

This definition of small manufacturer may be used for the inventory reporting regulations only. Future reporting rules under Section 8 will reevaluate the burdens involved and the definition of small manufacturer may be adjusted accordingly.

Q. *How many firms qualify as "small manufacturers" under this definition?*

A. Approximately 4200 firms out of 5400 firms required to report (78 percent) will qualify as "small manufacturers" under these regulations.

Q. *What is the small manufacturer or small importer exempted from?*

A. Small manufacturers and importers are not exempt from reporting information necessary for completion of the inventory. They must report at least the identities of the chemical substances. Small manufacturers are not required to report separately for each plant site. Small manufacturers and importers are also exempt from reporting production volumes. However, no manufacturer or importer is a "small manufacturer or importer" with respect to the chemical substances produced in quantities greater than 100,000 pounds at one plant site.

Q. *What is the total of these regulations?*

A. EPA estimates that the total cost for the industry of complying with these reporting regulations will be $13 million.

Q. *What chemical substances may be reported for the initial or revised inventories?*

A. Any chemical substance within the jurisdiction of TSCA which was manufactured, imported, or processed for a commerical purpose since January 1, 1975, may be included on the inventory.

Q. *What chemical substances are excluded from the inventory?*

A. The following chemical substances are excluded from the inventory and premanufacture reporting requirements:

(1) Substances which are manufactured or imported for use solely as a food, food additive, drug, cosmetic, or device, including substances used solely as intermediates in the manufacture of

those products. These substances are regulated under the Federal Food, Drug, and Cosmetic Act.

(2) Substances manufactured or imported solely for use as a pesticide. Chemical substances manufactured or imported for use as an intermediate in the manufacture of a pesticide are not themselves pesticides under the Federal Insecticide, Fungicide and Rodenticide Act.

(3) Chemical substances manufactured or imported in small quantities for use solely in research or development (any substance manufactured in 1,000 pound quantities or less will be presumed to be manufactured for research purposes).

(4) Any impurity.

(5) Any byproduct which has no commercial purpose.

(6) Other chemical substances that occur incidental to storage; or upon end use of another chemical substance, mixture, or article (such as chemical substances that may occur upon use of flares or batteries; processing of curable plastic molding compounds; application of paints; or upon dying a fabric, for example), as provided in section 710.4(d).

Q. *What information is entitled to confidential treatment?*

A. Any piece of data submitted to the agency may be claimed as confidential. This includes chemical identities.

Q. *How will EPA protect confidential data?*

A. EPA is in the process of developing procedures for handling confidential data. A Confidentiality Task Force is investigating the following: (1) physical security, (2) computer security, (3) employee security (including those of contractors). Under TSCA, there are strong penalities for employees who release confidential data. These procedures will be effective before the initial inventory is published. EPA has inspected Chemical Abstract Services, who will be processing the report forms, and is satisfied that adequate safeguards have been taken.

Q. *Will the general public have access to information collected under the inventory reporting regulation?*

A. Yes. Copies of the inventory and the list of generic names for those chemical substances whose identities are confidential will be available to the public. The inventory will contain only chemical names, but other non-confidential information will be available on request. EPA is working on ways to make all non-confidential data readily available to the public. This includes data such as production volumes, company names, and plant sites.

Q. *How can the public find out about chemical substances whose identities are confidential?*

A. Along with the initial inventory, EPA will publish a list of generic names for those chemical substances whose identities are confidential. Thus the public will have a general idea about the kinds of chemical substances which do not appear on the inventory because of entitlement to confidentiality. In response to a Freedom of Information Act Request, EPA's Office of General Counsel will make a confidentiality determination. If the claim is validated, EPA will deny the request for information. If the claim is not validated, the submitter will be informed of EPA's intention to release the data to the public thirty days prior to its release.

TS-788
UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF TOXIC SUBSTANCES
INDUSTRY ASSISTANT OFFICE
WASHINGTON, D.C. 20460

POSTAGE AND FEES PAID
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EPA-335

THIRD CLASS BULK RATE