Understanding the Toxic Substances Control Act: The Significance of Reporting and Recordkeeping Requirements

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INTRODUCTION

In 1976 Congress enacted the Toxic Substances Control Act ("TSCA" or the "Act") because of a concern about the effects of toxic chemicals on human health and the environment. This concern arises from the numerous chemicals entering the marketplace that may have carcinogenic (cancer-causing), teratogenic (birth defect causing), and/or mutagenic (genetic damaging) effects. Congressional debate evidenced a need to balance the desire to protect human health and the environment from unreasonable risks due to untested chemicals with the fear of overburdening the chemical industry with testing and regulatory costs that might inhibit innovation.

TSCA supplements sections of existing toxic substance laws, including section 112 of the Clean Air Act, section 307 of the Clean Water Act, and section 6 of the Occupational Safety and Health Act.

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1. 15 U.S.C. § 2601-71 (1988). This article is intended as an introduction to TSCA. For simplicity's sake, subsequent references to TSCA will provide the section number under the Act, but parallel citations to the official code have been omitted.


which already provide some regulatory control over toxic substances.\textsuperscript{8} After several tragic episodes concerning toxic chemicals in the late 1960s and early 1970s,\textsuperscript{9} the government recognized the need to develop a law that would allow administrators to track toxic chemicals entering the environment.\textsuperscript{10}

The Act enables the Environmental Protection Agency ("EPA" or the "Agency") to (1) gather information about chemicals in routine situations as well as in specific instances where potential hazards are involved; (2) promulgate testing requirements; and (3) provide for enforcement methods. TSCA essentially establishes a statutory basis for comprehensive identification and control of chemicals that pose an unreasonable risk to human health or the environment. The Act is vital to the federal government's efforts to regulate toxic chemicals because it supplies the means by which the government obtains much of its information about the effects of new and existing chemical substances. TSCA also enables the government to require safety testing before allowing a significant new use of a chemical or its introduction into the environment. Because the government relies so heavily on the Act to require chemical producers, manufacturers, and importers to disclose information, the penalties for noncompliance with reporting and recordkeeping requirements are stiff.

TSCA is one of the federal government's most powerful regulatory

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9. Several experiences illustrate the consequences of the lack of testing programs prior to TSCA. During the 1960s, widespread contamination of food, water, and soil by certain highly toxic compounds of organic mercury came to the public's attention. In 1975, vinyl chloride was linked to a rare form of cancer discovered in a number of workers exposed to the chemical. An OSHA standard on vinyl chloride set a permissible link at one part per million, but not before three decades of workers had been exposed to much higher levels. TSCA was enacted largely in reaction to existing policies and practices that effectively used human beings as guinea pigs for untested chemicals. \textit{Id.} at 282-283.

10. \textit{Id.}
and enforcement tools in the quest for pollution prevention. The Act forces the regulated community to "self-regulate," providing a means by which the government may collect information necessary for the promulgation of regulations. For these reasons, TSCA which warrants serious consideration.

In light of the Agency's motivating goals, TSCA has three main regulatory features. First, the Act provides an inventory mechanism for EPA to acquire sufficient information to identify and evaluate potential hazards from chemical substances. Second, the Act provides for ongoing regulation of the production, use, distribution, and disposal of toxics chemical substances. Finally, the Act establishes strict requirements for reporting hazards so that the Agency will be notified and can respond quickly.

THE STATUTORY SCHEME: AN INITIAL OVERVIEW

A review of the statutory scheme demonstrates how TSCA implements the goals set forth by Congress in 1976. In the more stringent and restrictive sections of the Act, TSCA utilizes a precautionary approach, applying specific regulatory standards to a substance that carries a reasonably foreseeable "substantial" risk of harm through exposure.11 The Act allows the EPA to require testing of both old and new chemical substances to which the public or the environment may be exposed.

The Information-Gathering Process

As a logical, if somewhat daunting, first step, section 8(b) of TSCA requires EPA to compile an Inventory of all existing chemicals in

11. Regulation is triggered by risk of harm, not necessarily actual damage. For example, in the premanufacture review process the EPA must determine that the chemical may pose an "unreasonable risk" of harm before the Agency can restrict manufacture or import pursuant to its power under the Act. Similarly, in section 8(e) reporting, an incident must be reported if it involves a "substantial risk" of harm. From Microbes to Men: The New Toxic Substances Control Act and Bacterial Mutagenicity/Carcinogenicity Tests, 6 Envtl. L. Rep. (Envtl. L. Inst.) 10,248 (1976) [hereinafter New Toxic Substances Control Act].
commercial use in the United States. The Inventory Update Rule which the Agency issued in 1986\(^1\) requires recurring reporting every four years so that the Agency may maintain current data on production volume, plant site, and site-limited status of the substances.

Next, section 5 of TSCA, "Manufacturing and Processing Notices," forms the basis of EPA's regulation of new chemicals introduced into commerce, and keeps the Inventory current. Under section 5's provision for premanufacture notice and review process ("PMN"), a company must notify EPA at least ninety days prior to commencement of production or importation of a new chemical. Significant new uses of a chemical already inventoried trigger PMN requirements as well. If a manufacturer deliberately fails to issue a required premanufacture notice, EPA may impose heavy penalties and even may subject the violator to criminal prosecution.\(^3\) If no exemption or exclusion provided under section 5(h) is available from the PMN requirement (for example, low volume, research and development, test marketing, or polymer exemptions), then the ninety day premanufacture review period begins.

**Testing Requirements and the Prevention of Hazardous Situations**

Once the PMN process has begun, section 5 of the Act requires that EPA determine whether the chemical poses an "unreasonable risk" of injury to human health or to the environment. The Agency, pursuant to its power under section 4 of the Act, may require that the manufacturer conduct additional tests. All manufacturers, importers, or processors of the particular chemical bear the costs of such tests. An extensive reimbursement procedure created to prevent repetitive, costly testing

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procedures spreads the costs among manufacturers. If the Agency finds that an unreasonable risk exists, then section 5 empowers the Administrator to restrict the introduction of the chemical into the environment or to ban production and distribution altogether.

If the chemical already exists in the marketplace, EPA may regulate under TSCA section 6, "Regulation of Hazardous Chemical Substances and Mixtures," as well. As in section 5, an unreasonable risk standard governs, and section 4 may demand chemical testing so that EPA may determine if the chemical meets the unreasonable risk threshold. Once EPA makes a determination of unreasonable risk, the Agency has various options. Pursuant to section 5, EPA may prohibit the particular chemical and then allow applications for exemptions to the general ban, as it has done with PCBs; it may limit a certain use of the chemical; or the Agency may impose requirements concerning the method of use, such as labeling requirements.

Recordkeeping and Reporting Requirements

Section 8 of the Act provides recordkeeping and reporting requirements for routine instances, as well as for specific instances, where potential hazards must be reported. Section 8(a) provides the Agency with authority to promulgate recordkeeping and reporting rules as it deems necessary. Pursuant to this section the Agency has created model reporting rules which apply to certain chemical substances (the Preliminary Assessment Information Rule or "PAIR" and the more recent Comprehensive Assessment Rule or "CAIR"). Section 8(c) requires that manufacturers, processors, and distributors keep records of significant adverse reactions to health and the environment alleged to have been

14. Section 4 of TSCA includes a provision which was made to avoid duplicate testing and to compensate persons who run tests for their use by others. The Administrator may charge fees up to $2,500 to defray the costs of evaluating tests under section 26(b). The New Toxic Substances Control Act, supra note 11, at 10,248.
caused by a chemical substance or mixture. Section 8(d) requires that records of health and safety studies be kept and submitted to the Administrator. Section 8(e) requires manufacturers, processors, and distributors to use their subjective judgement and to report information that constitutes "substantial risk". Section 8 reporting enables the Agency to obtain and disseminate information needed to set priorities and perform risk assessments that may be national in scope.

Enforcement

Section 15 of TSCA lists actionable violations. Section 16 authorizes the imposition of both civil and criminal penalties for such violations. The Agency may assess civil penalties on a per day basis, with each day constituting a separate violation. Imprisonment of up to one year may be imposed for knowing and willful failures to conform to any provision of section 15.

Section 7 of the Act provides enforcement for the EPA by allowing the Agency to obtain a court order for seizure or recall of a substance that is "imminently hazardous". However, the Agency has not yet found it necessary to enforce compliance with the Act by means of section 7. When faced with a limit or ban under a section 5(e) or a section 5(f) unilateral or consent order from the EPA, companies withdraw because of the expense involved in challenging such an EPA decision.

Compilation of the Inventory

Because notification rules apply primarily to new chemical substances, EPA needs a list of pre-existing substances. Section 8(b) requires EPA to compile an Inventory of chemicals manufactured or processed in the United States. The Agency did not attempt to include every chemical ever produced, but rather statutorily limited initial reporting

18. See Miller, supra note 8, at 311.
19. Id. at 292.
requirements to those substances produced since January 1, 1975. The Inventory is a massive compilation of more than 63,000 chemicals which provides EPA with an important tool for identifying, prioritizing, and evaluating toxic chemicals, and for developing a profile of the chemical industry in the United States.

EPA continuously adds to the Inventory new chemicals which have cleared the section 5 Premanufacture Review process. Any substance that was not reported for the Inventory by August 30, 1980, or subsequently not added through the PMN process, must undergo the PMN process before it may be manufactured or imported for a chemical purpose. This requirement applies even if the chemical was produced before August 1980. Such a safety mechanism insures that the list will be complete. This aspect of the PMN, however, is one-sided in that it provides for additions to the Inventory but the converse of this overly inclusive process is not always true. Occasionally EPA has removed from the list certain substances that it claims were registered improperly as commercial products and hence "grandfathered" when in fact the substances were only in research and development at the time. These so-called "orphan" chemicals are delisted from the Inventory because the Agency determines them to be chemicals which are not currently being manufactured or imported for chemical use.

Initially EPA indicated that a particular production process would affect the definition of a substance on the Inventory list. This policy meant that identical chemicals with identical properties might not both be on the list for PMN purposes if the production method for one chemical

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20. The Agency gathered data for the initial inventory from 1975 through 1979 pursuant to 40 C.F.R. section 710.3. The year 1975 was chosen to limit coverage to substances produced within a three year period preceding the promulgation of applicable regulations. Final inventory reporting regulations were issued in 42 Fed. Reg. 64,572 (1977).


22. Miller, supra note 8, at 295.

23. Id.
was substantially different from that of the other chemical. EPA has revised its position, and today the production process is irrelevant. EPA has revised its position, and today the production process is irrelevant. Once a chemical is on the list the production method and the particular raw materials used in the production process will not be determinative and require a new submission.

The final Inventory update under section 8(b) was issued in 1986 and required manufacturers and importers of certain chemical substances to report current data on the production, volume, plant site, and site-limited status of the chemical. The initial report was compiled by EPA in 1986, and updating is required every four years. Exemptions apply for certain categories of substances and for small-quantity manufacturers. Updates are required for companies that manufacture or import, for commercial purposes, 10,000 pounds or more of a reportable substance at any time during the most recent fiscal year immediately preceding the reporting period. The Agency provides detailed instructions.

The Update rule also requires each manufacturer or importer subject to the rule to maintain specific records documenting the information submitted to the EPA. In particular, for those substances manufactured at less than 10,000 pounds, known as small quantity exemptions, a manufacturer must maintain production volume records to justify a decision not to report.

Understanding how to use the Inventory is vital to determining if one must prepare a PMN. The EPA has provided a means by which companies which make errors in reporting substances for inclusion on the Inventory may rectify their mistakes, even if the mistakes are not

24. Id.


26. 40 C.F.R. § 710.28 (1991). Small manufacturers are exempt from reporting pursuant to 40 C.F.R. § 710.29; however, production volume records must be maintained to justify a decision not to report.

discovered until years later. EPA has published useful guidance for making Inventory corrections.

THE PREMANUFACTURE NOTIFICATION PROCESS

The PMN regulations supplement the Inventory by providing a process by which chemicals that make it through review without being deemed too risky may be added to the Inventory once introduced into commerce. The PMN regulations are set forth in section 5 of TSCA and apply to anyone who intends to import or manufacture a new chemical substance. Under these regulations an importer, broker, or even a company that purchases directly from foreign suppliers may be subject to PMN requirements. Section 5(d) explains what must be contained within a PMN. For instance, certain information described in section 8(a)(2), such as chemical identification, categories of use, amounts manufactured, percentage of employees who will be exposed, and the manner and method of disposal must be contained in the PMN to the extent the information is known or reasonably ascertainable at the premanufacture stage. Section 5 contains no authorization for EPA to require specific tests. Instead the Agency must use section 4 for this authority once a PMN is filed and the EPA’s review of the PMN has begun.

Within five days of receiving the PMN, EPA must publish in the Federal Register a notice which identifies the chemical substance, lists its intended uses, and describes the toxicological tests required to demonstrate that there will be no "unreasonable risk" of injury. EPA has only forty-five days before the expiration of the notification period to impose a limit

28. Corrections must fall into one of three categories: (1) corrections of the chemical identity of previously reported materials, or (2) corrections to identify previously unrecognized isolated intermediates, or (3) corrections made in response to communications from EPA which identify reporting errors. 45 Fed. Reg. 50,544 (1980).


or prohibition. After this period the manufacturer must file any objections within thirty days. If the Agency fails to take any regulatory action during the ninety day period, the manufacturer or importer is free to commence activities. A Notice of Commencement ("NOC") must be filed once the PMN review period is over and within thirty days of commencement of manufacture. A submitter must maintain records of the material within a PMN for five years after the filing of Notice of Commencement and must maintain data with regard to production volume for three years after the NOC filing date.

**Significant New Use Rules**

In addition to new chemical introductions, significant new uses of an existing chemical trigger PMN requirements. When the Agency determines, pursuant to section 5(e), that a use of an existing chemical is a new use, or that an appreciable increase in a chemical's utilization for an existing purpose has occurred, EPA may issue a Significant New Use Rule (SNUR). Persons submitting a response to a SNUR must comply with the same regulations as those submitting a PMN.

In the past EPA to has promulgated chemical specific regulations indicating that a PMN will be required in a specific instance on an ad hoc basis. This method has proved unwieldy, and the first final SNUR, which dealt with two potassium phosphate chemicals, was not issued until 1984. To expedite the process, a Generic Significant New Use Rule

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31. Section 5(a)(2) states that the Administrator shall make a determination that a use of a chemical is a significant new use after a consideration of all relevant factors, including: (1) the projected volume, (2) the extent to which the new use changes the type or form of exposure of human beings or the environment to the chemical, (3) the extent to which a use increases the magnitude or duration of exposure to human beings or the environment, and (4) the reasonably anticipated manner and methods of manufacturing, processing, distribution, and disposal. 15 U.S.C. § 2604 (1988).

32. Most often a section 5(e) order has been the trigger for the promulgation of a Significant New Use Rule (section 5(e) concerning a limit or ban because of insufficient information to permit a reasoned evaluation).

was promulgated in 1989.\textsuperscript{34}

The Generic Significant New Use Rule establishes standard language for use in designating certain recordkeeping requirements for SNURs. Subpart C establishes recordkeeping requirements which apply to manufacturers, importers and processors of chemical substances. The specific records which are required depend upon the activities designated as significant new uses. EPA specifies the appropriate recordkeeping requirements in Subpart E at the time it issues the SNUR for a particular substance. Such records must be maintained for 5 years from the date of their creation.

\textit{Exemptions from the Premanufacture Notification and Significant New Use Rule Requirements}

The PMN requirements apply to a "new chemical substance" and, once an applicable rule is promulgated, to a "significant new use" of an existing chemical substance. The statutory definition of a "chemical substance" excludes any mixture, pesticide,\textsuperscript{35} food, food additive, drug, cosmetic device,\textsuperscript{36} various nuclear materials,\textsuperscript{37} and any tobacco or tobacco product. In addition to these statutorily enumerated exemptions, section 5(h)(4) provides that the Administrator can exempt a manufacturer of a new substance from all or part of the PMN if the Administrator finds that its production, distribution, use and disposal "will not present an unreasonable risk of injury to health or to the environment."\textsuperscript{38}

\begin{itemize}
  \item 34. 54 Fed. Reg. 31,298 (1989).
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Possible exemptions include the "Polymer Exemption,"\textsuperscript{39} the "Low-Volume Exemption or 'LVE',"\textsuperscript{40} the "Research and Development or "R&D" Exemption,"\textsuperscript{41} and the "Test Marketing Exemption or 'TME'."\textsuperscript{42} An exemption from the PMN requirement, such as a research and development ("R & D") exemption, does not alleviate all recordkeeping requirements. For example, recordkeeping requirements for R & D exemptions are contained in 40 C.F.R. section 720.36 (b)(1)(i). A manufacturer or importer must maintain certain records of its R&D activity, its risk evaluations of new chemicals undergoing R&D, the nature and method of its notification of potential risks, and if distributed, the identity, amount, and recipient of the R&D chemical.

**ADDITIONAL ROUTINE REPORTING REQUIREMENTS**

The PMN process is a routine requirement which any new chemical must undergo. In addition, other information-gathering sections of TSCA remain significant to the Agency's effort to collect and maintain

\textsuperscript{39} Id. Pursuant to section 5(h)(4), the Agency has provided expedited (twenty-one day) review for polymers that are made of a specified list of reactants or have a number-average molecular weight greater than 1000. EPA issued the Polymer exemption after determining that the class of polymers eligible under the polymer exemption rule "would significantly limit the risks to human health and the environment that exempt polymers may present." 49 Fed. Reg. 46,084 (1984).

\textsuperscript{40} EPA has provided for an expedited 21 day review for certain low volume chemicals. The exemption applies if the substance is produced in quantities of 1,000 kilograms or less per year. The LVE is available for each new chemical only once and only to one manufacturer, and a second manufacturer must submit a PMN.

\textsuperscript{41} TSCA section 5(h)(3) exempts from PMN and SNUR requirements small quantities of new chemicals used solely for R&D if the manufacturer or importer notifies persons engaged in R&D of any health risks associated with the substance. Unlike the other exemptions under section 5(h), the manufacturer or importer does not apply for a R&D exemption. Rather, 40 C.F.R. section 720.36 lists the qualifications which must be met for the exemption to apply. No exemption is given for any substance distributed in commerce. 40 C.F.R. § 720.36(d) (1991).

\textsuperscript{42} Under TSCA section 5(h)(1) the Agency may, at its discretion, grant approval of individual TMEs. Such exemptions are subject to revocation or modification at the will of the Administrator if he receives new data which casts significant doubt on former findings.
information about the existing status of all chemical substances and about new developments of these regulated chemicals.

TSCA Section 8(a) provides EPA with the authority to promulgate rules requiring manufacturers to maintain records and make reports concerning the substances they produce, categories of uses, byproducts, environmental and health effects, and numbers of workers exposed. Section 8(d) requires manufacturers to submit to EPA lists of health and safety studies and to provide copies of such studies upon request. The Agency uses its authority under section 8 to investigate specific chemicals and stops the reporting requirement when the need for information ceases.\(^43\) EPA's Office of Toxic Substances coordinates its information-gathering activities with those of other agencies.\(^44\) In addition, the Agency uses "model" rules (formulated pursuant to section 8(a)) and standardized forms to help reduce the cost of compliance to the regulated community and to minimize possible reporting errors.\(^45\)

Section 8(a): "The General Recordkeeping and Reporting Provision of the Act"

Section 8(a) enables EPA to mandate those reporting and recordkeeping requirements the Administrator "may reasonably require." The rule applies to all manufacturers, present and prospective. The Agency's authority is somewhat more limited with regard to recordkeeping of R&D chemicals. The Act grants authority relating to such substances only to the extent that it "is necessary for effective enforcement" of the Act. Small manufacturers are generally exempt from section 8(a). The Administrator, however, can require reports from small manufacturers and processors when chemicals are subject to test rules under section 4, appear on the "risk list" under section 5(b)(4), or are limited under sections 5(e),

\(^{43}\) McKENNA, CONNOR & CUNEO, supra note 4, at 235.

\(^{44}\) Id.

\(^{45}\) Id.
5(f), or 6. Section 8(a) allows the EPA to gather information on certain chemicals about which the Agency is concerned but which do not warrant immediate regulation or restriction.\textsuperscript{46} Data collected under section 8(a) is used to determine how much information exists on a chemical substance or mixture, to set priorities for testing rules under section 4, and to determine regulatory action to be taken under section 6.

The initial list of chemicals subject to the first model reporting rule (the Preliminary Assessment Information Rule) included nearly 2,300 chemicals, but was later reduced to 245 chemicals.\textsuperscript{47} For these, manufacturers must report production, release, and exposure data; the EPA then uses this data to determine which chemicals warrant further testing.\textsuperscript{48} In 1982, 50 chemicals were added to the list. Additionally, the EPA began to require processors to report on listed chemicals whenever manufacturers' reports failed to account for 80 percent of the substance.\textsuperscript{49} Since the promulgation of the PAIR, EPA has issued a model recordkeeping and reporting rule entitled the "Comprehensive Assessment Information Rule" (CAIR)\textsuperscript{50} which will eventually replace PAIR. CAIR is used to gather information for use in risk assessments and in the development of regulatory strategies for 47 substances.\textsuperscript{51} CAIR requires a 100-page standardized report. Periodically, the EPA may amend CAIR, but only to add chemicals. Processors as well as manufacturers and

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\textsuperscript{46} Miller, \textit{supra} note 8, at 296.
\textsuperscript{50} 51 Fed. Reg. 35,762 (1986).
\textsuperscript{51} Initially, EPA promulgated the Preliminary Assessment Information Rule (PAIR). 40 C.F.R. §§ 712.20-30 (1991) (47 Fed. Reg. 26,998 (1982)). CAIR differs from PAIR in several respects. First, in addition to manufacturers and importers, processors are potentially required to report. Second, respondents are no longer required to answer every question on the form, but instead will list specific questions from the entire form which must be answered. Finally, where the PAIR only required general information on production, use and exposure, CAIR will require detailed information in these areas. McKENNA, CONNOR & CUNEO, \textit{supra} note 4, at 240.
importers are subject to reporting requirements under CAIR. 52

Section 8(d): "Health and Safety Studies"

Section 8(d), a broad provision, directs EPA to issue rules requiring any person manufacturing, processing, or distributing a chemical to provide the agency with copies of health and safety studies conducted by, known to, or ascertainable by that person. The intent is to use information from these studies in making regulatory decisions under sections 4, 5, and 6. The rule is necessarily broad; a company must not only submit reports within its possession, but must also submit copies of any other reports of which they know or reasonably should know, regardless of who performed the studies. Section 8(d) applies retroactively. Anyone who has manufactured, imported, or processed a listed chemical anytime in the preceding ten years must submit copies of studies within his possession.

In 1982, EPA issued a final Model Health and Safety Data Reporting Rule requiring certain companies to provide the Agency with unpublished studies. 53 Chemicals which are subject to this Rule include all those which have been subject to a section 4(e) testing rule by the Interagency Testing Committee, asbestos, and any other chemical added to the list by notice and comment rulemaking. The Agency continually adds chemicals and removes them from the list subject to this rule. 40 C.F.R. section 716.11 provides exemptions from this requirement. 54

52. EPA has defined "processor for commercial purposes" to include those who prepare the listed substance for distribution as part of a mixture, an article, or any product containing the listed substances. In addition, the term includes one who uses the listed substance as a reactant or intermediate to produce another substance. Thus, repackagers, chemical producers, mixture producers, and article producers are processors for commercial purposes. See McKenna, Connor & Cuneo, supra note 4, at 182.


54. Companies are required to search for records developed after December 31, 1979, when the revised 8(d) rule was proposed. The rule applies to companies who have manufactured subject chemicals within the last ten years, even if they are not currently doing so. Distributors are exempt, and certain types of studies that the Agency had not found useful in assessing risks and which were burdensome to compile were exempted.
Recordkeeping Rules for Export of Chemicals

TSCA section 12(a) generally exempts from most provisions of the Act any chemical substance, mixture, or article manufactured, processed or distributed solely for export from the United States. However, the recordkeeping and reporting requirements of section 8 continue to apply. Consequently, the EPA may make a finding that the chemical will present an unreasonable risk of injury to health within the United States under 12(b) and deny an export exemption. To make such a determination, the administrator may require additional testing pursuant to section 4.

Section 12 also provides for collection of information about the export of chemicals subject to certain proposed or final testing or regulatory requirements. The Agency provides this information to the government of an importing country to allow that country to initiate its own risk assessment procedures. Section 12(b) requires persons who export chemicals which are subject to final and proposed rules under sections 4, 5, 6, and 7 to notify EPA of the country of destination the first time a chemical is shipped to that country during a calendar year. Notice must be given within seven days of when a country reaches a firm intent to export (in other words, when a binding contractual obligation is reached). EPA has published a list of chemicals subject to 12(b)(2) notification requirements in the Agency's publication "A Guide for Chemical Importer/Exporters Volume 2: List of Import/Export Chemicals."

New chemicals are not subject to the export notification requirements under 12(b) unless they are subject to a section 4 test rule, included on the section 5(b)(4) "risk" list; subject to an order under 5(e) because of insufficient information or under 5(f) because of an unreasonable risk finding, or subject to a proposed or final SNUR.

as well. MCKENNA, CONNOR & CUNEO, supra note 4, at 257.

55. Id. at 288.

Recordkeeping Rules for the Import of Chemicals

Section 13 describes procedures for certifying that imported chemical substances subject to TSCA are in compliance with TSCA. Primarily the U.S. Customs Service, in conjunction with EPA, implements this section of the Act. The Act directs the Secretary of the Treasury to refuse entry of any chemical substance if it fails to comply with any provisions of TSCA. U.S. Customs has published a rule which activates the provisions of section 13 by requiring that importers certify as to the TSCA status of every chemical substance imported. This information permits the Agency to determine if importers of chemicals are complying with applicable TSCA regulations. EPA has issued a policy statement clarifying how the Agency will interpret and implement these regulations.57

Importers may make positive or negative certifications as to the TSCA status of the shipment at the port of entry. The shipment may then be approved or detained at port of entry or port of arrival, according to Customs rules. An importer whose shipment has been detained can submit a written explanation petitioning the EPA to certify that the shipment is in compliance with TSCA and to release the shipment to the importer. EPA may grant or deny the request after an investigation.58

HAZARD REPORTING REQUIREMENTS

Reporting requirements of sections 8(c) and 8(e) place a burden on manufacturers, processors, and distributors to notify the agency of potential adverse health effects as soon as they are discovered. Compliance with section 8(c) concerns reporting of significant adverse reactions, and is similar to section 8(e), which requires broader notification of any situation which may present a "substantial risk of injury."

58. See McKenna, Connor & Cuneo, supra note 4, at 372.
Section 8(c): "Reporting of Significant Adverse Reactions"

Under the language in 8(c), any person who manufactures, processes, or distributes any chemical substance or mixture shall maintain records of "significant adverse reactions" alleged to have been caused by the chemical. The submitter must maintain records relating to possible health reactions of employees for thirty years, and all other recorded allegations for five years. The term "significant" has been interpreted quite narrowly to include only reactions which may indicate a tendency of a chemical substance or mixture to cause long-lasting or irreversible damage to health or environment. Moreover, only previously "unknown" effects need be recorded.

The provision which initially required recordation of oral allegations has been dropped, diminishing the effectiveness of section 8(c) somewhat because worker complaints usually take the form of oral allegations. In addition, only processors in certain very narrow SIC code industries (namely SIC categories 28 and 2911, chemical and allied products, and petroleum refining, respectively) are covered, while manufacturers of "naturally occurring" substances, sole distributors, and retailers are exempted entirely.

EPA opted for record inspection over record submission as a compliance measure; thus no automatic reporting requirement exists for this section. Only those allegations which meet the criteria of 40 C.F.R. section 717.10(b)(2) must be reported, and the firm may chose the form

59. Miller, supra at note 8, at 304.
60. Id.
61. Id.
62. Sole distributors are defined by EPA as persons "solely engaged in the distribution of chemical substances." McKenna, Connor & Cuneo, supra note 4, at 250.
63. In order to constitute an allegation which is recordable under section 8(c), the statement must clearly state the alleged cause of the adverse reaction by identifying one or more of the following: (1) a specific substance; (2) a mixture or article that contains a specific substance; (3) a company process or operation in which substances are involved; and (4) an effluent, emission, or other discharge from a site of manufacturing,
in which to report so long as the form includes the information proscribed in the statute. These changes to the initial interpretation of the section reduced the number of affected firms by over ninety-eight percent, and reflected the Reagan administration's desire for less burdensome regulation.64

Section 8(e)

Section 8(e) functions as the EPA's catchall hazard reporting provision. The other provisions of TSCA have mired EPA in a huge amount of data which takes much time for the Agency to absorb.65 Section 8(e) provides a safety net wherein voluntary reporting is required when the manufacturer, processor, or distributor obtains information about any adverse effects which entail a substantial risk. The language of section 8(e) provides that a manufacturer, producer, or distributor who obtains information which "reasonably" supports the conclusion that a substance presents a "substantial" risk of injury to human health or to the environment shall inform the EPA immediately. The statutory language is full of vagaries, and because this section is the only section of TSCA which is self-enforcing, section 8(e) may be considered the most confusing section of TSCA. Manufacturers must make their own subjective judgments as to whether a specific instance reaches a level of risk such that section 8(e) requires them to report.

EPA has not issued any regulations implementing section 8(e). The Agency has, however, issued guidance on section 8(e) in the "Statement of Interpretation and Enforcement Policy."66 The guidance provides little in the way of specifics, however, and neither TSCA or the legislative processing, or distribution of a substance. 40 C.F.R. § 717.10(b)(2) (1991). Under this definition, no proof or evidence, such as a doctor's report, is required for an allegation to be recordable. McKENNA, CONNOR & CUNEO, supra note 4, at 253.

64. Miller, supra note 8, at 304.

65. Id. at 301.

history contains a clear definition as to what constitutes a "substantial risk". The published guidance merely indicates that the party must examine the seriousness of the effect and the probability of its occurrence. The policy states that an organization may relieve individual officers and employees of liability under section 8(e) if the organization establishes, internally publicizes, and affirmatively implements procedures for employee submission and corporate processing of pertinent information.67

A potential reporter should determine whether the information involves a substantial risk of human health effects, environmental effects, or an emergency incident of environmental contamination. If any of these situations exist, the information must be reported. EPA considers information from both designed, controlled studies and reports concerning and studies of, undesigned, uncontrolled circumstances to "reasonably support" a finding of substantial risk.68 The potential reporter may determine whether the information is exempt from reporting (for example, if the information has already been reported under some mandatory provision of TSCA or other authority administered by the EPA such as CERCLA69 or RCRA70).

The potential reporter must detail as human health effects possible if cancer, birth defects, mutagenicity, or serious or prolonged incapacitation will result from exposure. The guidance policy indicates that for human effects the actual exposure level is not relevant, and potential risk is sufficient. Generally, EPA does not consider acute human toxicity tests such as LD 50 tests reportable under section 8(e).71

The potential submitter must report under section 8(e) because of environmental effects if significant exposure results in any of the following: widespread and previously unsuspected distribution in the

67. Id. at § II.
68. See McKENNA, CONNOR & CUNEO, supra note 4, at 256-259, 264.
71. McKENNA, CONNOR & CUNEO, supra note 4, at 267.
environment; pronounced bioaccumulation; any non-trivial effect not previously known to EPA; ecologically significant changes in population; or significant interference with critical biogeochemical cycles such as the nitrogen cycle.

An emergency incident must be reported if the pattern, extent and amount of the contamination seriously threatens humans with cancer, birth defects, mutation, death, or serious or prolonged incapacitation, or seriously threatens non-human organisms with large-scale or ecologically significant population destruction.

Within the regulations concerning the section 8(e) Compliance Audit Program\(^7\) (discussed in detail in the section regarding penalties, infra), EPA stated that any decision-making process for determining section 8(e) reportability should focus primarily on whether new toxicologic or exposure data offer reasonable support for a conclusion of substantial risk and should not focus to any great extent, if at all, on whether the information is conclusive regarding the risk.\(^7\) Therefore, a decision to report under section 8(e) should involve neither exhaustive health or environmental assessments nor an evaluation of the economic or social benefits of the use(s) of the subject chemical(s). The Agency stressed that companies who received information on certain serious health effects should report immediately and not apply a "weight-of-the-evidence" risk assessment. The only further guidance available on section 8(e) reporting since the 1978 policy statement is the Agency’s public section 8(e) files and the newly issued TSCA section 8(e) reporting guide.\(^7\)

When section 8(e) reports are submitted the TSCA Assistance Office publishes compendiums of chronologically issued status reports indexed by chemical name. These may be obtained from the National Technical Information Service (NTIS). Such files would allow a potential submitter to make comparisons with specific examples of section 8(e) reports that

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73. Id.
have been submitted in the past and examine the Agency's response to these instances.

The Reporting guide includes two major indices. The first section references status reports by toxicological study type with subheadings related to section 8(e) criteria. The second index is cumulative and is arranged by type of study for all initial submissions received under section 8(e) from January 1, 1977 to October 1, 1990. Most of the guide is presented in a question and answer format reflecting primarily the most common questions asked about section 8(e).

Section 8(e) recently has become the focal point of the EPA's enforcement of TSCA. As enforcement standards have tightened, section 8(e) has begun to swallow sections 8(c) and 8(d). The trend is increasingly toward characterization of section 8(c) scenarios as section 8(e) cases. The preponderance of section 8(e) reportings have been scientific studies instead of expected hazardous accidents and releases.

**SPECIFIC REGULATED SUBSTANCES**

_Asbestos_

In addition to the provisions for the regulation of new and existing chemicals under TSCA created in 1976, certain other instances have arisen in which Congress has spoken on specific substances of great concern. Title II of TSCA was added in October 1986, entitled the Asbestos Hazard Emergency Response Control Act ("AHERA"). The Act requires school systems to identify and abate asbestos hazards in school buildings. EPA's Final Regulations implementing AHERA were issued on October 30, 1987, outlining the "responsibility of each local education agency to conduct specified inspections for asbestos-containing material ("ACM") and, if found, to conduct sampling and analysis procedures the results of which should comprise a written assessment as defined in section 763.88 of the

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75. Miller, *supra* note 8, at 304.
76. *Id.* at 305.
regulations." Pursuant to these guidelines, the local education agencies must keep records of the following: (1) response actions and preventive measures employed; (2) fiber release episodes; (3) surveillance activities; and (4) various operations and maintenance activities. In addition, for state and local government workers involved in abatement and disposal, if exposure levels exceed 0.1 fibers/cm, a variety of worker protection requirements, including additional recordkeeping requirements, take effect.

The Act provides methods by which hazards may be removed, but nowhere does the Act require the removal of ACM. Nevertheless, political pressures within the school systems have tended to make removal the preferred option. Asbestos removal is a controversial option because many experts believe that the attempted removal is more risky than leaving the material in place and implementing a monitoring system. Removal is also more expensive.

Previously, the abatement provisions affected only schools; however, the Asbestos School Hazard Abatement Reauthorization Act ("ASHARA") of 1990 became effective November 28, 1991, and represents an attempt by EPA to expand the scope of AHERA. AHERA currently extends authorizations for appropriations for the Asbestos School Hazard Abatement Act ("ASHAA") through 1995. Additionally, section 15 of TSCA extends the requirements for accreditation of companies performing asbestos control to work in public and commercial buildings. Not later than one year from the date of the enactment of ASHARA, the EPA must revise the model contractor accreditation plan promulgated under TSCA section 206(b)(1) "to increase the minimum number of hours of training . . . required for asbestos abatement workers."

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78. Miller, supra note 8, at 320.
80. Id. §§ 763.91, 763.120 (1989).
81. Miller, supra note 8, at 321.
The EPA's ability to use section 6 to place a comprehensive ban on asbestos has been undermined recently. In *Corrosion Proof Fittings v. EPA*, the court undermined EPA's ability to use section 6 to place a comprehensive ban on asbestos. In *Corrosion Fittings*, the Fifth Circuit held, *inter alia*, that EPA's final rule, under section 6 of TSCA, prohibiting the manufacture, importation, processing and distribution of asbestos in almost all products, could not stand, partially because pursuant to the "unreasonable risk" determination, the Agency had failed to give adequate weight to the harm the regulation imposed on the manufacturers and consumers. The court advocated a cost-benefit analysis, and emphasized EPA's duty to consider the economic effect of its decisions. When it stated that "Congress did not enact TSCA as a zero-risk statute," the court squarely addressed EPA's obvious intent to apply TSCA in a broad-brush manner. Clearly the Fifth Circuit's strong language and its emphasis on the requirement, under TSCA, that EPA consider economic impact in its determination of whether a substance creates an "unreasonable" risk will have a major impact on EPA's strategy for TSCA asbestos regulation in the future.

**PCBs**

Section 6(e) of TSCA provides explicit directives to the EPA to promulgate regulations prescribing the disposal and labeling of PCB's, as well as to prohibit the manufacturing, processing, distribution in commerce, and use of PCB's in other than a totally enclosed manner unless specifically authorized or exempted by the EPA. "Scientific research (primarily animal studies) and tragic ecosystem impacts from PCB pollution of the Hudson River and the Great Lakes resulted in recognition by the early 1970's that PCBs were both persistent in the environment and

83. 947 F.2d 1201 (5th Cir. 1991).
84. Id. at 1215.
harmful to human health, even at low levels.\textsuperscript{85} By singling out PCBs for mandated regulation in an otherwise broad and general statute, section 6(e) amounts to a decision by Congress that PCBs do present an "unreasonable risk" to human health and the environment. All manufacture of PCBs was prohibited after January 1, 1979 and all processing and distribution banned after July 1, 1979. However, exemptions may be granted by the EPA allowing use in a non-totally enclosed manner if the EPA determines that no unreasonable risk applies. Categorical exceptions are set forth under 40 CFR section 761.30, and these exceptions are subject to numerous listed use, service, duration, documentation, and notice requirements.

\section*{Penalties for Noncompliance}

TSCA is a strict liability statute and the failure or refusal by any person to comply with the TSCA requirements or rules is unlawful and may subject that person to penalties under section 16, or specified enforcement under section 17. Section 16 authorizes the imposition of both civil and criminal penalties for violations. Under 16(a), EPA can assess a civil penalty in the amount of $25,000 for each violation of section 15, with each day constituting a separate violation. Under section 16(b) any person who "knowingly or willfully" violates any provision of section 15 commits a misdemeanor punishable by up to one year's imprisonment and up to $25,000 for each day of violation. Section 15 establishes the applicable violations under TSCA.\textsuperscript{86}

\textit{EPA's Penalty Policy}

The EPA issued its penalty policy in 1987. The Agency must determine the amount of a civil penalty in two stages. First, the Agency must assess a gravity-based penalty, a figure which may be adjusted on the basis of factors listed in 16(a)(2)(B). EPA may increase the penalty

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upward when any history of prior similar TSCA violations exists. Even if the prior violation involves a different TSCA section or regulation from the one at issue, EPA will adjust upward by twenty-five percent for the first repetition and fifty percent for the second. If, however, the prior violation involves the same or a similar TSCA section or regulation, EPA adjusts the penalty upward by fifty percent for the first repetition and 100 percent for the second.\(^7\)

The EPA has developed a "self-confessor" policy to encourage voluntary reporting of violations of section 5. A firm which voluntarily reports a section 5 violation automatically receives a twenty-five percent reduction in the amount of its civil penalty. A reported disclosure may be one which is not required under section 8(e) or may be one that is made after EPA has received notice of the violation from another source. The EPA may make an additional twenty-five percent reduction if the firm reports within thirty days of its discovery of the violation. The Agency may reduce the penalty further, by an additional thirty percent if the firm has made all reasonable efforts and expended resources above and beyond the requirements of TSCA to further environmentally beneficial measures. Finally, EPA may reduce the penalty by an additional fifteen percent based on the good faith cooperation of the violator. The total reductions may not exceed eighty percent of the assessed penalty.\(^8\)

On May 15th, 1987, EPA issued a revised penalty policy to provide a cap on the number of days a "per day" TSCA penalty can be levied for reporting and recordkeeping violations. There are no caps, however, within this revision for violations of the substantial risk reporting provisions of section 8(e).

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88. McKENNA, CONNOR & CUNEO, supra note 4, at 241.
A One-time Opportunity to Correct Errors:
The Compliance Audit Program

Recently the EPA devised a Compliance Audit Program (CAP)\(^89\) to compensate for the fact that the voluntary reporting provisions applicable to other sections of TSCA did not mitigate harsh penalties for violations of Section 8(e). The stated reason for the development of this one-time voluntary compliance program was to achieve the Agency’s goal of obtaining any outstanding section 8(e) data.\(^90\) On February 1, 1991 EPA announced that firms could register for the CAP program and set forth the text of the agreement provisions within the regulation. On April 26, 1991 the Agency amended the proposed agreement in minor respects and extended the deadline for application to June 18, 1991. Subsequently, on June 20, 1991 the EPA again extended the deadline for two weeks, until July 1, 1991.

The CAP encouraged companies to voluntarily audit their files for studies reportable under section 8(e). The Program set forth guidelines and identified EPA’s enforcement response so that companies could assess liability before deciding whether to participate. The firms who agreed to submit CAP agreed to stipulated civil penalties, $15,000 per study as a penalty for a report involving effects on humans, and $6,000 per study as a penalty for any other report. EPA also agreed to a $1,000,000 ceiling on the total civil penalty for the regulatee. Once the audit ends, the regulatee has 30 days to pay the fines. If the Agency determines that the CAP program is effective it may institute a similar program in the future.

The criminal provisions under TSCA are not as stringent as some of the other environmental statutes, in that the criminal provisions result in misdemeanor and not felony convictions.\(^91\) A violation must be


\(^{90}\) Id. at 4129.

\(^{91}\) However, it is extremely important to note that while the provisions of TSCA do not mandate felonies, failure to report may result in convictions under other generic criminal statutes, such as 18 U.S.C. § 1001 which provides for penalties for making false statements, violation of which may result in a substantial fine, five years imprisonment,
"knowing or willful," and penalties may be assessed for violations of sections 4, 5, 6, or of Title II (AHERA). Failure or refusal to establish or maintain records, submit reports, notices, or other information, or permit access to or copying of records as required by the Act constitutes a misdemeanor under TSCA. Additionally, a misdemeanor may be warranted because of refusal or failure to permit entry or inspection as required by the Act. Finally, the use for commercial purposes of a chemical substance or mixture which a person knew or had reason to know was manufactured, processed or distributed in commerce in violation of section 4 or 6 of TSCA is a misdemeanor. Conviction under section 16(b) may result in a fine of up to $25,000 per day per violation and/or imprisonment for as long as one year. Criminal sanctions under TSCA have been rare, and the enormous civil fines have been by far the most utilized punishment. In fiscal year 1988, civil complaints under TSCA comprised 41.6 percent of all the cases which the EPA brought, and resulted in over $5,000,000 in fines.92

The Environmental Crimes Act of 198993 would have imposed more serious criminal sanctions on those who committed an environmental crime and knowingly or recklessly caused the risk of: (1) imminent death of a human being; (2) serious bodily injury to a human being; or (3) an environmental catastrophe.94 The proposal would have broadened the "knowing endangerment" provision of RCRA to include crimes under other statutes. Such legislation also would have imposed severe penalties on those criminals engaging in two or more environmental crimes which posed a risk to humans or to the environment. The proposed sentences range from 15 years and $25,000 in fines for first violations, up to 30 years in prison and $500,000 in fines for second violations. This bill was

or both. Other such provisions include 18 U.S.C. § 2 (Aiding or Abetting); 18 U.S.C. § 371 (Conspiracy); and 18 U.S.C. § 1505 (Obstruction of Agency Proceedings).


94. Id.
introduced in 1989 and died in the House, but similar legislation may well be reintroduced soon.

CONCLUSION

A clear understanding of the way the provisions of the Toxic Substances Control Act have been formulated to require companies to monitor and track chemicals for the government is critical to any program developed to maintain compliance with this somewhat convoluted Act. The reporting and recordkeeping requirements of the Toxic Substances Control Act are especially important because they enable the government to collect information about chemicals on a general basis, as well as on a "potentially-dangerous situation" basis. Without these requirements, collecting this information would paralyze the government. Anyone involved in the production, manufacture, or import of chemicals should establish a compliance system within the firm to provide a method of avoiding recordkeeping and reporting errors or omissions. The high risks attendant to noncompliance undoubtedly would justify the costs of such a system.