Appendix

THE TOXIC SUBSTANCES CONTROL ACT: HISTORY AND IMPLEMENTATION

A.1 Introduction

The Toxic Substances Control Act (TSCA 1976) was the result of six years of negotiating and compromising among the House and Senate, the President's Council on Environmental Quality (CEQ), the Environmental Protection Agency (EPA), the chemical industry, the Commerce Department, and other interested parties. TSCA expanded existing federal authority to regulate the chemical industry by giving EPA the authority to require testing, as well as to regulate the production, use, and disposal of new and existing chemicals. Because it was one of the most important pieces of legislation ever passed to regulate the chemical industry, its provisions were hotly debated by all parties. The following is a brief history of the events that led to the enactment of TSCA.

The CEQ was established by the 1969 National Environmental Policy Act as an agency within the Executive Office of the President. This occurred shortly before the establishment of the EPA in December, 1970. Soon after its inception, CEQ began a study of the potential for metals and synthetic organic chemicals to endanger human health and the environment. At that time, the government had no power to require that chemicals, with the exception of those used as pesticides, drugs, and food additives, be tested before they were put into commerce.

By late 1970, the CEQ had produced a draft report of its study. The publication of this report was delayed until April, 1971, however, so that the CEQ staff could draft the Toxic Substances Control Act of 1971, the first version of the present TSCA. The CEQ report reached the following major conclusions:

1. Toxic Substances are Entering the Environment

> "U.S. consumption of metals with known toxic effects has increased greatly in the last 20 years. ... Similarly, use of synthetic organic chemicals is growing rapidly. ... Although many of these substances are not toxic, the sheer number of them, their increasing diversity and use, and the environmental problems already encountered from some indicate the existence of a problem." (CEQ 1971)

2. These Substances can have Severe Effects

> "The environmental effects of most of the substances discussed in this report are not well understood. Testing has largely been confined to their acute effects, and knowledge of the chronic, long-term effects, such as genetic mutation, is inadequate. Although far from complete, available data indicate the potential

or actual danger of a number of these substances." (CEQ 1971)

3. Existing Legal Authorities are Inadequate

"Government controls over the introduction of toxic substances into the environment are of two types. The first is control over the initial production of a substance and its distribution. ... Although this control technique can be very effective, current authorities cover only a small portion of the total number of potentially toxic substances and do not deal with all uses of a substance which may produce toxic effects." (CEQ 1971)

"The second type of control is media oriented and thus is directed at air and water pollution from various sources. ... Most toxic substances are not exclusively air or water pollutants but can be found in varying quantities in air, water, soil, food, and industrial and consumer products. The multiplicity of ways by which man can be exposed to these substances makes it difficult for the media-oriented authorities to consider the *total* exposure of an individual to a given substance, a consideration necessary for the establishment of adequate environmental standards. Also, in the past no agency has considered itself completely responsible for all such substances in all media." (CEQ 1971)

4. New Legal Authority is Required

"The Council's study indicates the high-priority need for a program of testing and control of toxic substances. ... We should no longer be limited to repairing damage after it has been done; nor should we continue to allow the entire population or the entire environment to be used as a laboratory." (CEQ 1971)

The CEQ report concluded that there were essentially no laws regulating the manufacture, importation, or use of toxic chemical substances in the United States and, therefore, that regulation was critical. Hence, the findings in this report became the basis for TSCA. By early December of 1970, the CEQ was ready to circulate a draft bill to other government agencies for comment. Among its provisions, this bill required manufacturers to notify the EPA at least 90 days before manufacture and distribution of a new chemical substance, gave EPA authority to require testing of the new chemical before manufacture could begin, and gave EPA the power to ban or restrict chemicals that posed substantial risks to human health or the environment.

The issues of premanufacture notification and testing were of concern to the Department of Commerce and the Office of Management and Budget, and were raised to President Nixon for a decision in early February, 1971. The President decided that the premanufacture testing provision should be removed from the bill. Finally, the bill was sent to Congress on February 11, 1971, by EPA Administrator William Ruckelshaus.

The U.S. House of Representatives and Senate passed separate versions of the bill during 1972. Among other differences, the Senate version had considerably more stringent premanufacture controls over chemical substances than the House version, requiring EPA to expressly approve new chemicals. The chemical industry generally supported the much weaker House version.

Early versions of the bill died in the Senate-House Conference Committee during the 92nd and 93rd Congresses. During this time, President Ford's administration first supported and later opposed the premarket provisions of TSCA. In the end, it was the Congressional and chemical companies' Washington staffs who hammered out the compromise bill that was finally passed.

In 1976, Congress was still agonizing over the bill. As fate would have it, Kepone, an insecticide for home use that was manufactured in a dusty refurbished gas station in Hopewell, Virginia, caused an outbreak of severe neurological disorders in dozens of workers. Virginia's Governor closed the nearby James River to commercial and sport fishing. CBS's "60 Minutes" segment on Kepone gave the chemical national media exposure and increased public pressure for the passage of TSCA. There was also considerable public pressure over the risks from polychlorinated biphenyls (PCBs), fluorocarbons, and vinyl chloride.

Finally, the Senate-House Conference Committee reached agreement on the provisions of TSCA in the fall of 1976, just before the Presidential election. The lobbying efforts on all sides had been intense. Chemical industry representatives expressed afterwards that they had agreed to premanufacture notification (which remained in the final bill) in exchange for reduced reporting provisions.

During September, 1976, both the Senate and the House of Representatives finally approved the bill, and sent it to President Ford for his signature. The President's support for the bill was in doubt, because Ford had stated his opposition to major new federal spending programs, especially those that would impose new regulations on industry. The wide-ranging support for the bill, however, effectively precluded his veto. President Ford signed TSCA into law just hours before the bill would have died from a pocket veto. The next day, the President released a statement in support of the bill.

TSCA, as finally passed, covers all organic and inorganic chemical substances and mixtures, both synthetic and naturally-occurring, with the exception of food, food additives, drugs, cosmetics, nuclear materials, tobacco, and pesticides, which are all covered by other legislation. TSCA provides the Agency with authority to:

- require that manufacturers and importers submit information on all new chemical substances prior to manufacture for commercial purposes;

- require that manufacturers and processors collect, maintain, and possibly submit information on chemical substances; and

- regulate chemical substances (both new and existing) that are expected to present or are presenting unreasonable risks to health and the environment.

The provisions for premanufacture review of new chemical substances[20] are contained in section 5 of TSCA. Congress intended section 5 "to provide the administrator with an opportunity to review and evaluate information with respect to the substance to determine if manufacture, processing, distribution in commerce, use or disposal should be limited, delayed or prohibited because data is [sic] insufficient to evaluate the health and environmental effects or because the substance or the new use presents or will present an unreasonable risk of injury to health or the environment." Congress also realized that "the most desirable time to determine the health and environmental effects of the substance, and to take action to protect against any potential adverse effects, occurs before commercial production begins. Not only is human and environmental harm avoided or alleviated, but the cost of any regulatory action in terms of loss of jobs and capital investment is minimized." (U.S. Congress 1976)

Congress charged EPA with the responsibility of preventing chemicals from presenting unreasonable risks to health and the environment: the Act specifies that the risks of using a substance must be compared with the benefits derived from its use. Further, the Agency was directed to implement TSCA in such a manner as not to "unduly impede technological innovation." The objective of creating a balance between preventing unreasonable risk and not hampering innovation has been at the heart of the Agency's premanufacture review program since its beginning.

A.2 The Premanufacture Provisions of TSCA

The Toxic Substances Control Act provides EPA with the authority to identify and control the use of new and existing chemical substances in order to protect human health and the environment. Under section 5 of TSCA, titled Manufacturing and Processing Notices, the EPA is given the authority to regulate new chemical substances prior to their manufacture or import[21] for commercial purposes. The text below discusses the provisions of TSCA that are relevant to the premanufacture authority. First, the terms "chemical substance" and "new" are defined, then section 5 is summarized. Finally, other sections of TSCA that are tangentially relevant to premanufacture review are briefly mentioned.

To date, Congress has not modified the basic provisions of TSCA as presented

20. The term "new chemical substance" is defined in section 3 of TSCA as any chemical substance not included in the Chemical Substance Inventory that is compiled and published under section 8(b).

21. TSCA applies both to substances that are manufactured within the U.S. and to substances imported into the U.S. In the following discussion, the words manufacture or manufacturer are meant to include import or importer.

below. The Agency, in its implementation of TSCA, has promulgated a variety of regulations. Summaries of EPA's regulations are found in Section 1.5, below.

A.2.1 Definition of "Chemical Substance" Under TSCA

The term "chemical substance" is defined in section 3 of TSCA as:

> "any organic or inorganic substance of a particular molecular identity, including (*i*) any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and (*ii*) any element or uncombined radical."

This definition does *not* include:

> "(*i*) any mixture, (*ii*) any pesticide (as defined by the Federal Insecticide, Fungicide, and Rodenticide Act) when manufactured, processed, or distributed in commerce for use as a pesticide, (*iii*) tobacco or any tobacco product, (*iv*) any source material, special nuclear material, or byproduct material (as...defined in the Atomic Energy Act...), (*v*) any article[22]..., and (*vi*) any food, food additive, drug, cosmetic, or device (as...defined in section 201 of the Federal Food, Drug, and Cosmetic Act) when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device."

A.2.2 Definition of "New" Chemical Substance

Section 8(b) of TSCA requires the EPA to identify, compile, keep current, and publish the TSCA Inventory, a list of chemical substances manufactured, imported, or processed for commercial purposes in the United States. The Inventory defines what chemical substances are "existing" in U.S. commerce for TSCA purposes. The Inventory includes not only chemical substances that have been manufactured or imported since January 1, 1975 for "distribution in commerce" but also substances manufactured as intermediates for use by the manufacturer. Substances that are subject to TSCA but are not on the Inventory are considered "new" and are subject to premanufacture notification under section 5 of TSCA. Further discussion of the Inventory and EPA's Inventory reporting regulations is found in the final section of this chapter (A.3.9).

A.2.3 Section 5: Manufacturing and Processing Notices

One of the primary provisions of TSCA is the requirement in section 5 that

22. The Agency has clarified its interpretation of "article" in USEPA 1977c.

manufacturers or importers of new chemicals notify the Agency 90 days before manufacturing a new chemical substance. EPA uses this time to determine if an unreasonable risk may or will be presented by any aspect of the new chemical's lifecycle: its manufacture, processing, distribution in commerce, use, or disposal. If the chemical may or will present an unreasonable risk, EPA has the authority to limit or ban it, thereby reducing the potential for adverse effects to human health and the environment.

Unlike the Federal Food, Drug and Cosmetic Act (FFDCA 1982) administered by the Food and Drug Administration (FDA), which requires drug manufacturers to submit a plethora of test data for a new substance, section 5 of TSCA does not require PMN submitters to test their chemical substances before PMN submission. In short, the FFDCA is a registration statute, whereas TSCA is a weaker notification statute. Frequently, little or no data on health or environmental effects are available for PMN substances, yet EPA must decide within 90 days if such chemical substances are likely to present hazards to human health or the environment. Because EPA is usually operating in the absence of data, section 5(e) of TSCA gives EPA the authority to regulate a new chemical substance if EPA concludes that a chemical substance *may* present an unreasonable risk. If there is sufficient information to make the determination that the substance *will* present an unreasonable risk, EPA has the authority to regulate a new chemical substance under section 5(f).

The nine subsections of section 5 are as follows:

Subsection 5(a). In general. Manufacturers must submit a PMN to the Agency at least 90 days before manufacturing a chemical substance that is not either listed on the TSCA Chemical Substance Inventory or being used for a significant new use. This section also gives EPA authority to promulgate rules establishing significant new uses for certain chemicals if the new uses would increase exposure.

Subsection 5(b). Submission of Test Data. This section relates the section 4 requirements for test data to the requirements for PMN notices and Significant New Use Notices (SNUNs). Any test data required by a section 4 rule must be submitted along with a PMN or SNUN. If a section 4(c) exemption has been granted pending submission of test data, the submitter of a PMN or SNUN substance may not commence manufacture until at least 90 days following submission of the section 4 test data to EPA. In section 5(b)(4), the EPA is given authority to promulgate rules listing chemicals and their respective uses (or other activities) that present or may present an unreasonable risk. If a PMN or SNUN is required for a chemical on this 5(b)(4) list, the PMN or SNUN must contain data to show that the proposed uses will not present an unreasonable risk to health or the environment. Data submitted to EPA under section 5(b) must be made available to the public, subject to the limitations of section 14 (Disclosure of Data, under which EPA must protect certain confidential business information).

Subsection 5(c). Extension of Notice Period. The Administrator may extend the review period for a PMN, a SNUN, or test data by up to 90 additional days if the Administrator has good cause to do so. The extension and the reasoning behind it must be published in the Federal Register (subject to section 14 constraints).

Subsection 5(d). Content of Notice; Publications in the Federal Register. This subsection lists the information to be included in a PMN: (1) information listed in TSCA section 8(a)(2)[23] that is known to or reasonably ascertainable by the submitter; (2) any test data in the possession or control of the submitter that are related to effects on health or the environment; and (3) a description of any other reasonably ascertainable data concerning health or environmental effects. Under section 5(d)(2), EPA is required to publish periodic notices in the Federal Register (FR) subject to the limitations of section 14. Within five working days following receipt of a new PMN, SNUN, or test data, EPA must publish the following information: chemical identity (or generic name), use, and a description of test data received. Monthly, EPA must publish in the FR a list of chemical notices received since the last FR notice, and a list of notices for which the review period has expired since the last notice.

Subsection 5(e). Regulation Pending Development of Information. Under section 5(e), if the Agency determines (1) that the information submitted for a chemical substance is insufficient for assessment of health or environmental effects and that the chemical substance *may* present an unreasonable risk or (2) that the chemical substance *may* result in substantial human or environmental exposure, it may issue an order that limits or bans manufacture, processing, distribution in commerce, use, or disposal of the substance. The order cannot take effect if the Agency does not provide affected parties with 45 days notice prior to the PMN or SNUN expiration date, or if the affected parties object to the order. If objections are filed and the Agency has made the required determination, the Agency is required to file for an injunction in the U.S. District Court. The injunction is given if the court determines that the information provided with the notice is insufficient and that continuing to allow the manufacture or processing of the chemical would present unreasonable risks to human health and the environment. The court has the right to extend the notification period if it will expire before the injunction proceedings are

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23. The items required by TSCA are: the common or trade name, chemical identity, and molecular structure of each chemical substance; the categories or proposed categories of use for such substance; estimates of the total amount of the substance that is manufactured and used, and estimates of the amount that will be manufactured and used, broken out by category of use; a description of the byproducts associated with the substance; the number of individuals exposed, the number that is estimated to be exposed, and the exposure duration; and the manner by which the substance will be disposed. Note that subparagraph 8(a)(2)(e) requires health and safety data, but these data are not under the "reasonably ascertainable" standard.

concluded. The injunction is dissolved once the needed data have been submitted to and evaluated by the Agency.

Subsection 5(f). Protection Against Unreasonable Risks. Section 5(f) gives EPA the authority to limit or ban a PMN or SNUN chemical substance if the use of the substance will present an unreasonable risk before the time that the Agency could promulgate a standard rule under section 6 to protect against such risk. The Agency may issue a proposed rule under section 6(a) that is effective immediately upon its publication in the Federal Register to limit manufacture or use. Alternatively, the Agency may issue a proposed section 5(f) order to prohibit manufacture or use, or may seek a court injunction to prohibit manufacture or use.

Subsection 5(g). Statement of Reasons for Not Taking Action. If EPA does not take regulatory action under sections 5, 6, or 7 against a chemical for which SNUN or section 4 test data are submitted, it then must publish in the Federal Register the reasons explaining why it did not do so.

Subsection 5(h). Exemptions. The Agency may grant exemptions from some or all of the requirements for PMN, SNUN, and test data submissions. Exemptions may be granted from: (1) a PMN or SNUN for a chemical used only for test marketing purposes if there will be no unreasonable risk; (2) test data requirements for a substance that is identical to the one on which data have been submitted under section 5(b)(2); (3) all or part of section 5 requirements for a substance that will not present an unreasonable risk to human health or the environment; and (4) PMN, SNUN, or test data requirements for a substance that is produced temporarily as the result of a chemical reaction used to produce another chemical and to which there will be no human or environmental exposure.

Further, a substance used for scientific experimentation, research, and analysis is exempt from PMN, SNUN, and test data requirements, provided that all parties involved are informed of the risks associated with the particular chemical.

Subsection 5(i). Definition. The terms "manufacturing" and "processing" are defined as manufacturing and processing for commercial purposes.

A.2.4 Other Sections of TSCA Related to Section 5

A.2.4.1 Section 4. Testing of Chemical Substances and Mixtures. The EPA, under TSCA section 4, has the authority to promulgate rules to require manufacturers and processors to test certain new or existing substances for their effects on human health and the environment. This section also establishes the Interagency Testing Committee to assist EPA in prioritizing the chemicals to be tested.

A.2.4.2 Section 6. Regulation of Hazardous Chemical Substances and Mixtures. The EPA has the authority under TSCA section 6, to promulgate rules that regulate the manufacture, processing, distribution, use, or disposal of an existing chemical substance, if it determines that these activities pose an unreasonable risk to human health or the environment. Section 6(e) requires that PCBs be regulated

immediately, and that their manufacture and use be phased out over time.

A.2.4.3 Section 7. Imminent Hazards. EPA may commence a civil action in a U.S. District Court to seize an imminently hazardous chemical substance or mixture, or for relief against its manufacturer or user. An imminently hazardous chemical substance or mixture is one that will present an unreasonable risk of serious or widespread injury to health and the environment before a final section 6 rule could protect against the risk.

A.2.4.4 Section 8. Reporting and Retention of Information. Section 8(a) gives EPA the authority to promulgate rules to require manufacturers and processors to collect, maintain, and submit data about the manufacture and processing of chemical substances in response to Agency requests. These rules do not apply to small manufacturers or processors, or to substances produced only in small quantities for research and development purposes.

Under section 8(b), EPA is required to compile, keep current and publish the Chemical Substance Inventory. Either individual chemical substances or categories of chemical substances may be listed on the Inventory. New substances are added to the Inventory following PMN review and actual manufacture for commercial purposes.

Section 8(c) requires manufacturers, processors, and distributors to maintain records of significant adverse reactions to health or the environment alleged to have been caused by chemical substances.

Section 8(d) allows EPA to promulgate rules under which manufacturers, processors, and distributors are required to submit health and safety data known to or reasonably ascertainable by them.

Under section 8(e), manufacturers, processors, or distributors must immediately submit to EPA any information supporting the conclusion that a chemical substance presents a substantial risk of injury to health and the environment.

A.2.4.5 Section 12. Exports. In general, chemical substances manufactured or processed solely for export are exempt from regulation under TSCA. However, if a substance produced for export presents an unreasonable risk to health or the environment of the United States, EPA may regulate the substance. The Agency may also require section 4 testing of an exported substance to determine whether the substance presents such a risk. A person who intends to export a substance for which information is required under sections 4 or 5(b), or that is subject to a regulatory order or action under Section 5, 6, or 7, must notify EPA, which will, in turn, notify the government of the recipient country.

A.2.4.6 Section 13. Entry into Customs Territory of the United States. No chemical substance, mixture, or article containing a chemical substance or mixture will be allowed into the customs territory of the United States if it fails to comply with any rule or is otherwise in violation of the Act.

A.2.4.7 Section 14. Disclosure of Data. EPA is required to protect confidential business information submitted to the Agency under TSCA from disclosure to the public. Such confidential business information may be disclosed if EPA determines that disclosure is necessary to protect against an unreasonable risk; thus, all data from health and safety studies submitted under TSCA are subject to disclosure.

A.3 Implementation of TSCA

Since TSCA was signed into law in 1976, the EPA has promulgated rules, issued orders, and developed interpretations to implement the provisions of TSCA. This section highlights those rules, orders, and policies that are the most relevant to premanufacture review.

A.3.1 The TSCA Inventory

The TSCA Chemical Substance Inventory, compiled under section 8(b) of TSCA, defines which chemical substances are "existing" in U.S. commerce for purposes of implementing TSCA. The Inventory is not a list of toxic chemicals; toxicity was not a criterion used in determining the eligibility of chemical substances for inclusion on the Inventory.

In 1977, EPA issued its Inventory Reporting Regulations (USEPA 1977a). These regulations and their associated instruction manual (USEPA 1977b) provided guidance for manufacturers to report their existing substances for the Inventory, and, more importantly, established the rules under which all reported substances would be listed on the Inventory. During 1977 and 1978 (USEPA 1979a), manufacturers reported their substances for the Inventory, which was first published in 1979 (USEPA 1979b). Shortly thereafter, there was a reporting period during which processors reported substances they processed that were not already listed on the Inventory (USEPA 1979c). Since that time, new substances have been added following premanufacture review[24] and through corrections of initial Inventory reports and PMNs, incorrectly-reported substances have been removed (for example, see USEPA 1985a). Currently, the Inventory lists over 70,000 chemical substances whose manufacture or processing for commercial purposes in the U.S. has taken place since January 1, 1975. Section 710.4 of the Inventory Reporting Regulations contains the detailed rules for determining which chemical substances were subject to initial Inventory reporting and describes the circumstances under which the manufacture of a substance would be excluded from reporting. These rule provisions were largely carried over into

24. Following PMN review, if EPA has not banned a PMN substance under section 5(f) of TSCA, the manufacturer is free to begin production within any restrictions the Agency may have placed on the substance. The manufacturer must submit a Notice of Commencement (NOC) to the Agency within 30 days following the start of manufacture. Submitters must use EPA Form 7710-56 (USEPA 1995a) for NOCs. Upon receipt of the NOC form, EPA places the PMN substance on the TSCA Inventory. For more information, see 40 CFR Part 720. Premanufacture Notification. Subpart F. Commencement of Manufacture or Import.

section 720.30 of the PMN rule, and are used to determine which substances are subject to PMN notification requirements; because they are so central to the PMN program, they are included in section A.3.9 at the end of this chapter. In addition, the Agency has published two clarifications of the definition of articles, which are excluded from TSCA reporting (USEPA 1985c).

Manufacturers are responsible for determining whether a substance is a new chemical substance under TSCA. The TSCA Chemical Substance Inventory: 1985 Edition (USEPA 1986a) and the 1990 Supplement to the 1985 Edition of the TSCA Inventory (USEPA 1990a) are the most recent hard-copy publications of the non-confidential chemical substance identities. They are available at some public libraries and all federal depository libraries, or may be purchased from the Government Printing Office and National Technical Information Service (NTIS). The NTIS also has computer tape, diskette, and CD-ROM versions of the Inventory that are updated twice a year. In addition, several commercial or government databases including CAS On-line and Dialog Information Services contain up-to-date versions of the non-confidential Inventory. Table A-1 (located at the end of this chapter) lists some of the sources for inventory and other OPPT information.

No publicly available printed or electronic version of the Inventory can be completely up-to-date, because the Inventory is continually changing. Furthermore, detailed information regarding chemical identities claimed as confidential is not included in the published version of the Inventory. The Agency, however, maintains and continually updates a Master Inventory File, which includes all eligible substances that have been reported.

The Agency provides a service to assist those who wish to query the Inventory. A person who intends to manufacture a chemical substance that does not appear on the published Inventory may ask EPA to determine whether the substance in question is included in the Master Inventory File. The Agency will provide an answer only if the person who submits the inquiry is able to demonstrate a "bona fide intent" to manufacture the substance for a commercial purpose.

To demonstrate this intent, in a notice of bona fide intent to manufacture, a manufacturer must submit certain information to EPA. This information includes: the specific chemical identity of the substance (using the currently correct Chemical Abstracts Service name); a signed statement of intent to manufacture for a commercial purpose; a description of the research and development activities conducted to date and the year they were started or, for importers unable to provide this information, substitute information concerning foreign use of the substance; a description of the major intended application or use; an infrared (IR) spectrum or other spectrum if an IR spectrum is not suitable; the estimated date of PMN submission (if the substance is not found on the Inventory); the address of the facility for that is most likely to be used for manufacture or processing; and a description of the most probable manufacturing process. The exact procedures for establishing and submitting a notice of bona fide intent are discussed in detail in the Agency's recent Revision of

Premanufacture Notification Regulations (USEPA 1995a; this supersedes the Agency's former guidance, found in USEPA 1983a). When a bona fide intent has been established with a formal submission, the Agency will perform a comprehensive search of the Master Inventory File to determine conclusively whether the substance in question is already included. The Agency has made a commitment to respond to a bona fide inquiry within 30 days.

A.3.2 Inventory Update Rule

In 1986, the EPA promulgated a rule that requires manufacturers to submit data on production volumes and manufacturing sites for certain chemicals every four years (USEPA 1986b). This rule does not affect the status of any chemicals as being on or not on the TSCA Inventory.

A.3.3 Premanufacture Notification Rule and Form

Any person who plans to manufacture a new chemical substance must submit a PMN, SNUN, or an exemption application[25] to EPA at least 90 days prior to the intended date of the activity. The EPA promulgated regulations governing the PMN process and established the mandatory PMN form in 1983 (USEPA 1983b, USEPA 1983c); the rule and form were revised in 1986 (USEPA 1986c). The form was revised in 1991 (USEPA 1991a), and again in May 1995 (USEPA 1995e). The rule was revised again in 1995 (USEPA 1995a; see also USEPA 1993a). Copies of the current rule, form, and the Instructions Manual for Premanufacture Notification[26] (USEPA 1991b) for PMN submissions are available from the TSCA Assistance Information Service at (202) 554-1404.

As part of the New Chemical Program, the Office of Pollution Prevention and Toxics (OPPT) reviews PMN submissions and determines whether the proposed activities will or may present unreasonable risks. In recent years, an average of nearly 2,300 new chemical substances have been reviewed annually within the New Chemical Program.

The PMN form, as revised in 1995, is used for routine PMNs as well as PMN exemptions and SNUNs; it includes three main sections with additional pages for optional pollution prevention information and a physicochemical properties worksheet. Part I, general information, includes submitter and chemical identity as well as production, import, and use information. Part II contains human exposure and environmental release information for industrial sites controlled by the submitter and for sites controlled by others. Part III is a list of attachments for information requested in Parts I and II and for test data or other information related to the chemical. The submitter is required to provide all information requested in the form to the

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25. Certain classes of chemicals are eligible for exemptions under rules promulgated under section 5(h)(4) of TSCA. An exemption application may replace a PMN in these cases, and may allow manufacture sooner than 90 days.

26. A new instructions manual is under development.

extent that it is known or reasonably ascertainable. If a requested item is not applicable or truly unavailable, the submitter should explain that on the form. Any item that is left blank may cause EPA to declare the PMN incomplete. The 90-day review period for the PMN (or less for exemptions) cannot begin until the submitter provides the missing information.

In 1988, the EPA promulgated a rule requiring PMN submitters to pay user fees (USEPA 1988a). Submitters must remit a user fee of $2,500. This fee is reduced under the certain circumstances: if the submitter is a small business, the user fee is $100; if a PMN for an intermediate substance is submitted simultaneously with a final product PMN, the fee for the intermediate product is $1,000; and if a PMN is filed (with prior Agency consent) for multiple chemicals that are related, the total fee is $2,500.

A.3.4 Biotechnology

TSCA applies to all chemical applications not specifically exempted in the Act. Microorganisms intended for general commercial and environmental applications (e.g., metal leaching, pollutant degradation, enhanced nitrogen fixation) are subject to TSCA. In 1986, the federal agencies involved with the review of biotechnology products announced a policy requiring, among other things, PMN reporting for commercial uses of certain genetically modified microorganisms (OSTP 1986). The notice also requested voluntary reporting for research and development (R&D) uses of these microorganisms involving introductions into the environment. EPA has published a proposed rule under TSCA section 5 that would deal specifically with microorganisms (USEPA 1994). Until this rule is promulgated, submitters should use EPA's Points to Consider (USEPA 1990b) as guidance in the preparation of PMNs for microorganisms. Submitters are also strongly encouraged to have a prenotice consultation with EPA before submitting a PMN for a microorganism. Submitters interested in determining whether a microorganism is already on the TSCA Inventory may submit bona fide inquiries following the Agency's guidance, given in USEPA 1990b.

A.3.5 Exemptions

A.3.5.1 Test Market Exemptions

TSCA section 5(h)(1) authorizes an exemption from PMN requirements for new chemical substances manufactured for test marketing purposes, as long as this activity does not present an unreasonable risk to human health or the environment. These exemptions are granted or denied by EPA following review of a test market exemption application (TMEA). The Agency's regulations for TMEAs are found in the PMN rule and instruction manual, referenced above, and are also addressed in a New Chemical Information Bulletin (USEPA 1986d). The exemption permits a company to assess the commercial viability of a new chemical and to receive customer feedback on product performance before proceeding with a PMN. TMEAs also are advantageous to submitters because the Agency must grant or deny them within 45 days and they require no user fee. EPA reviews a TMEA in essentially the same

manner as a PMN[27] and thus needs similar information from submitters.

A.3.5.2 5(h)(3) Exemption for Research and Development

Section 5(h)(3) of TSCA exempts chemical substances from PMN provisions if they are manufactured only in small quantities solely for purposes of scientific experimentation, analysis, or research and development. The Agency's interpretation of this exemption is given in two Federal Register notices (USEPA 1984b; USEPA 1986c) and a New Chemical Information Bulletin (USEPA 1986d).

A.3.5.3 5(h)(4) Exemptions

To date, EPA has promulgated three 5(h)(4) exemption rules to limit reporting requirements for new chemical substances (see USEPA 1991c and other references given with the specific exemptions):

- substances used in or for instant or "peel-apart" film articles;
- substances manufactured or imported in small quantities and substances with low release and exposure; and,
- polymers that meet certain specified criteria.

More detail about these exemptions is provided below.

A.3.5.4 Instant Film Exemption

Under the terms of this rarely-used exemption, manufacturers may commence manufacture of new chemical substances for incorporation into instant photographic articles immediately after submitting an exemption notice to EPA. The manufacturer must file a PMN and wait until the review period has expired, however, before distributing the new chemical in commerce. Special procedures to contain exposure must also be used until PMN review is completed (USEPA 1982).

A.3.5.5 Low Volume Exemption

In 1985, EPA published a TSCA section 5(h)(4) rule granting a partial exemption from TSCA section 5 reporting requirements for persons who manufacture chemical substances produced in quantities less than 1,000 kilograms per 12 month period (USEPA 1985b). This rule was developed in response to petitions by the Chemical Manufacturers Association (CMA) and other industry groups[28]. The Agency published proposed revisions to this

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27. Because the review period for TMEAs is only 45 days, the Agency uses its usual PMN review process only until the Focus Meeting. During this meeting, Agency staff decide whether to grant or deny any TMEA still in the review process at this point. Refer to Chapter 1 for a discussion of the PMN review process.

28. Section 21 of TSCA allows citizens to petition the Agency for changes in the Agency's implementation of TSCA.

rule in 1993 (USEPA 1993d) and a final revised rule in 1995 (USEPA 1995c).

Under the revised rule, chemical substances may qualify for exemption if their annual production volume is less than 10,000 kg. Manufacturers must submit exemption notices 30 days prior to commencement of manufacture. Exemptions granted previously under the superseded rule will remain effective (and binding).

A.3.5.6 Low Release and Exposure Exemption

Along with the revised low volume exemption, the Agency proposed (USEPA 1993d) and later made final a new exemption, the low release and exposure exemption (LoREX; USEPA 1995c). Substances may qualify for the LoREX exemption, regardless of their production volume, if they meet the release and exposure criteria stated in the rule. To apply for an exemption, manufacturers must submit an exemption notification at least 30 days before beginning production. The Agency is preparing an instruction manual for this new rule; a draft manual is available for comment through the TSCA Assistance Information Service (USEPA 1995f).

A.3.5.7 Polymer Exemption

In 1984, EPA published a TSCA section 5(h)(4) rule granting an exemption for persons who manufacture or import certain polymers (USEPA 1984a). This rule was developed in response to petitions by industry groups. In February 1993, the Agency proposed revisions to this exemption rule (USEPA 1993b) and in March 1995, the Agency published the final rule (USEPA 1995b). A technical guidance manual to assist submitters in complying with the revised exemption is in preparation; a draft manual is available through the TSCA Assistance Information Service (USEPA 1995g).

In general, to be manufactured under this exemption a polymer must meet the polymer definition given in the rule and one or more of three criteria:

- polymers with number-average molecular weight (MW) greater than or equal to 1,000 and less than 10,000 daltons (and oligomer content less than 10 percent below MW 500 and less than 25 percent below MW 1,000);
- polymers with number-average MW greater than or equal to 10,000 daltons (and oligomer content less than 2 percent below MW 500 and less than 5 percent below MW 1,000); and
- polyester polymers manufactured solely from one or more reactants listed in the exemption rule.

In addition, certain classes of polymers cannot be manufactured under this exemption. These polymers include:

- certain cationic polymers;
- polymers that do not meet certain elemental limitations;
- polymers that degrade, decompose, or depolymerize;

- polymers manufactured or imported from monomers and reactants not on the TSCA Chemical Substance Inventory; and

- water-absorbing polymers with number-average MW 10,000 and greater.

Submitters using this exemption are required to keep certain records to verify their eligibility for and compliance with the exemption. They are not required to submit an exemption notification or a Notice of Commencement, but are to report annually the number of polymers being manufactured for the first time during the preceding calendar year under the exemption. In part because submitters do not report the chemical identities of their polymers to EPA, the Agency does not list these polymers on the Inventory.

Manufacturers who submitted polymers to EPA under the previous polymer exemption rule (prior to the effective date of the new rule, May 30, 1995) may either continue to comply with the requirements of the previous exemption rule (USEPA 1984a) or may follow all of the requirements of the new, revised exemption rule (USEPA 1995b).

A.3.6 TSCA Section 5(e) Consent Orders and Significant New Use Rules

Under certain circumstances, EPA uses a section 5(e) order to place restrictions on the manufacture of a new chemical pending development of test data. The order allows manufacture of the new chemical to commence subject to restrictions on processing methods, production volume, and/or use that reduce or limit risks to human health or the environment. Under TSCA, EPA has authority to impose a section 5(e) order by unilateral action, but in practice, EPA usually negotiates section 5(e) consent orders with the affected PMN submitter.

An order restricts the PMN submitter to the aforementioned conditions, but it is not binding on other companies wishing to produce or use the same chemical once the chemical is listed on the TSCA Inventory. Hence, the Agency often promulgates a Significant New Use Rule (SNUR) to restrict the exposure and use of the substance to those identified as acceptable under the section 5(e) order. SNURs apply to all manufacturers. Anyone who desires to use a substance that is subject to a SNUR for a use defined as a significant new use in the SNUR must submit a SNUN at least 90 days before starting to manufacture the substance for the new use. The Agency uses the standard PMN review process to review SNUNs and make an appropriate regulatory determination.

The SNUR procedures (USEPA 1988b; USEPA 1993c; USEPA 1995d) and subsequent SNUN submissions allow EPA to control exposures (and thus, risks) associated with new uses of PMN (or existing) chemicals, changes in processing, and increased production volumes before they become potential problems. Designation of PMN substances for a TSCA section 5(e) order, and subsequently for a SNUR, is based on information received during the initial PMN review. Often, the Agency is forced to base its review of the risks posed by new chemicals on inadequate information received from submitters. In

these instances, the Agency may need to make worst-case (i.e., highest exposure and risk) estimates regarding certain use or exposure factors because submitter data have not been provided. This may lead to more stringent control than necessary. Therefore, if submitters provide comprehensive information, the Agency will be able to make more realistic determinations of the potential for unreasonable risk, such that restrictions may not be necessary.

A.3.7 Polymers: The Two Percent Rule

Originally, identification of new polymers for TSCA Inventory and PMN purposes was based on the amounts of monomers and other reactants used in the reaction, "as charged" to the reaction vessel, and on the dry weight of the polymer (USEPA 1977a). This approach was adopted because it was believed that it would be difficult to identify the exact amounts of monomers or other reactants incorporated in the final polymers. More recently, the Agency revised its two percent rule (USEPA 1995a) so that the two percent could either be interpreted as "as charged" or "as incorporated." For a discussion of the practical application of the revised two percent rule, refer to the Agency's polymer technical guidance manual.

All constituents of a polymer must be listed in a PMN, but a submitter may choose which constituents present at two percent or less will be used in the Inventory description of the polymer. Since July 28, 1989 (USEPA 1989), free radical initiators charged to the reaction vessel at over two percent have also been required to be part of the chemical identity[29]. At present, if free radical initiators are incorporated at less than or equal to two percent, they do not have to be part of the chemical name (USEPA 1995a).

Any constituent listed in the Inventory description must always be present in the PMN substance. The use of additional monomers or reactants will not result in a "new" chemical substance if each of the additional monomers or reactants, as charged or incorporated, amounts to two percent or less of the weight of the polymer.

A.3.8 Importing Chemical Substances

The U.S. Department of the Treasury has amended its customs regulations to fully support the implementation of TSCA (TREAS 1983a; TREAS 1983b; TREAS 1983c). The EPA published companion requirements at about the same time (USEPA 1983d). Importers are required to certify that their shipments are on the TSCA Inventory and are not in violation of TSCA. The EPA has published a two-volume Guide for Chemical Importers/Exporters (USEPA 1991d) that is available from the TSCA Assistance Information Service. Also available are copies of the Agency's database, Chemicals on Reporting Rules Database (CORR) (USEPA 1991e).

A.3.9 Addendum to Appendix: Inventory Reporting Regulations

The following text is copied from the

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29. Initiators used at > 2% have only had to be included in the chemical identity of polymers added to the Inventory since July 28, 1989, the effective date of the Agency's clarification in the Federal Register (USEPA 1989).

Agency's Inventory Reporting Regulations, 40 CFR 710.4. Its purpose here is to clarify the definition of chemical substances for TSCA purposes.

Section 710.4 Scope of the Inventory

(a) *Chemical substances subject to these regulations*. Only chemical substances which are manufactured, imported, or processed "for a commercial purpose," as defined in section 710.2, are subject to these regulations.

(b) *Naturally occurring chemical substances automatically included*. Any chemical substance which is naturally occurring and

(1) which is (I) unprocessed or (ii) processed only by manual, mechanical, or gravitational means; by dissolution in water; by flotation; or by heating solely to remove water; or

(2) which is extracted from air by any means, shall automatically be included in the inventory under the category "Naturally Occurring Chemical Substances." Examples of such substances are: raw agricultural commodities; water, air, natural gas, and crude oil; and rocks, ores, and minerals.

(c) *Substances excluded by definition or section 8(b) of TSCA*. The following substances are excluded from the Inventory:

(1) Any substance which is not considered a "chemical substance" as provided in subsection 3(2)(B) of the Act and in the definition of "chemical substance" in section 710.2(h);

(2) Any mixture as defined in section 710.2(q);

NOTE. -- A chemical substance that is manufactured as part of a mixture is subject to these reporting regulations. This exclusion applies only to the mixture and not to the chemical substances of which the mixture is comprised. The term "mixture" includes alloys, inorganic glasses, ceramics, frits, and cements, including Portland cement.

(3) Any chemical substance which is manufactured, imported, or processed solely in small quantities for research and development, as defined in section 710.2(y); and

(4) Any chemical substance not manufactured, processed or imported for a commercial purpose since January 1, 1975.

(d) *Chemical substances excluded from the inventory*. The following chemical substances are excluded from the inventory. Although they are considered to be manufactured or processed for a commercial purpose for the purpose of section 8 of the Act, they are not manufactured or processed for distribution in commerce as chemical substances *per se* and have no commercial purpose separate from the substance, mixture, or article of which they may be a part. NOTE: In addition, chemical substances excluded here will not be subject to premanufacture notification under section 5 of the Act.

(1) Any impurity.

(2) Any byproduct which has no commercial purpose.

NOTE: A byproduct which has commercial value only to municipal or private organizations who (I) burn it as a fuel, (ii) dispose of it as a waste, including in a landfill or for enriching soil, or (iii) extract component chemical substances which have

commercial value, may be reported for the inventory, but will not be subject to premanufacturing notification under section 5 of the Act if not included.

(3) Any chemical substance which results from a chemical reaction that occurs incidental to exposure of another chemical substance, mixture, or article to environmental factors such as air, moisture, microbial organisms, or sunlight.

(4) Any chemical substance which results from a chemical reaction that occurs incidental to storage of another chemical substance, mixture or article.

(5) Any chemical substance which results from a chemical reaction that occurs upon end use of other chemical substances, mixtures, or articles such as adhesives, paints, miscellaneous cleansers or other household products, fuels and fuel additives, water softening and treatment agents, photographic, (sic) films, batteries, matches, and safety flares, and which is not itself manufactured for distribution in commerce or for use as an intermediate.

(6) Any chemical substance which results from a chemical reaction that occurs upon use of curable plastic or rubber molding compounds, inks, drying oils, metal finishing compounds adhesives, or paints; or other chemical substances formed during manufacture of an article destined for the marketplace without further chemical change of the chemical substance except for those chemical changes that may occur as described elsewhere in this section 710.4(d).

(7) Any chemical substance which results from a chemical reaction that occurs when (I) a stabilizer, colorant, odorant, antioxidant, filler, solvent, carrier, surfactant, plasticizer, corrosion inhibitor, antifoamer or de-foamer, dispersant, precipitation inhibitor, binder, emulsifier, de-emulsifier, dewatering agent, or quality control reagent functions as intended or (ii) a chemical substance, solely intended to impart a specific physicochemical characteristic, functions as intended.

(8) Chemical substances which are not intentionally removed from the equipment in which they were manufactured.

NOTE. -- See note to definition of "intermediate" at section 710.2(n) for explanation of "equipment in which it was manufactured."

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TRI Representative
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Bethesda, MD 20894
(301) 496-6531

National Technical Information Service
5285 Port Royal Road
Springfield, VA 22161
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OPPT Document Control Office
U.S. EPA
401 M Street, S.W. (TS-790)
Washington, DC 20460
(202) 260-1532

OPPT Public Docket Office
U.S. EPA
401 M Street, S.W. (TS-793)
Room G-004, Northeast Mall
Washington, DC 20460
(202) 260-7099

Toxic Release Inventory User Support (TRI/US)
U.S. EPA
401 M Street, S.W. (TS-793)
Room B-0011, Northeast Mall
Washington, DC 20460
(202) 260-1531

TSCA Assistance Information Service (TSCA hotline)
U.S. EPA
401 M Street, S.W. (TS-799)
Washington, DC 20460
(202) 554-1404
Fax: (202) 554-5603
TDD: (202) 554-0551

OPPT Chemical Library
U.S. EPA
401 M Street, S.W. (TS-793)
Room B-002, Northeast Mall
Washington, DC 20460
(202) 260-3944

CAS Inventory Expert Service
2540 Olentangy River Road
P.O. Box 3012
Columbus OH 43210-0012
(800) 848-6538, ext. 2308
or (614) 447-3600
Fax: (614) 447-3747

Dialog Information Services
TSCA Inventory search requests:
(800) ALERT91 (253-7891)
Online access to inventory:
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(301) 321-8440
(800) CIS-USER (247-8737)

Biotechnology Program Information
David Giamporcaro, Chief
Section II
(202) 260-6362

Pollution Prevention Information Clearinghouse (PPIC)
(202) 260-1023 (24-hour answering machine)