United States
Environmental Protection
Agency

Office of Compliance Monitoring
Washington, DC 20460

November 1992

EPA

Toxic Substances Control Act

§§ 5/8 Inspection Guidance

ACKNOWLEDGMENTS

This manual, intended to provide guidance to Regional inspectors responsible for conducting inspections under Sections 5 and 8 of the Toxic Substances Control Act (TSCA), was prepared by Science Applications International Corporation (SAIC) in partial fulfillment of the U.S. Environmental Protection Agency (EPA) Contract No. 68-C8-0066, Work Assignment C-4-84. The development of the manual was managed by Pamela Saunders, the EPA Work Assignment Manager, Maureen Lydon, Chief of the Compliance Branch, and Philip Milton, Chemical Engineer, of the Office of Compliance Monitoring (OCM).

The manual has been reviewed by EPA Headquarters and several Regional Offices and their comments have been incorporated as appropriate.

George Clark and Carol Winston of SAIC were the Work Assignment and Task Managers, respectively. Principal authors at SAIC include: Timothy Brown, Mark Ernstmann, René Eyerly, Jennifer Gale, Thomas Lavelle, Jody Lehrer, and Travis Wagner.

DISCLAIMER

Neither the United States Government nor its employees makes any warranty, express or implied, or assumes any legal liability for any third party's use of or the results of such use of any information, product, or process discussed in this document. Mention or illustration of company or trade names, or of commercial products, does not constitute endorsement by the U.S. Environmental Protection Agency. It should also be noted that the tables found throughout the manual provide summaries of the regulations as a quick reference for the inspector. However, the inspector should note that these summaries are not intended to substitute for the regulations published in the *Code of Federal Regulations* and *Federal Register*, and thus the appropriate citations are included in these tables for the inspector's use.

TABLE OF CONTENTS

CHAPTER 1 INTRODUCTION

1.0 INTRODUCTION 1-1
1.1 WHAT IS TSCA? 1-1
1.2 PURPOSE OF THIS INSPECTION MANUAL 1-8
1.3 NATIONAL ENFORCEMENT PROGRAM PRIORITIES 1-9

CHAPTER 2 TARGETING OF TSCA SECTION 5 AND 8 INSPECTIONS

2.0 TARGETING OF TSCA SECTION 5 AND 8 INSPECTIONS 2-1
2.1 INTRODUCTION AND PURPOSE 2-1
2.2 OVERVIEW OF TSCA INSPECTION TARGETING PROCESS 2-2
2.3. DESCRIPTION OF TARGETING MECHANISMS 2-6
2.4 INFORMATION SOURCES 2-23
2.5 SETTING PRIORITIES AND SELECTING SPECIFIC TARGETS 2-30

CHAPTER 3 PRE-INSPECTION ACTIVITIES: PREPARATION AND PLANNING

3.0 PRE-INSPECTION ACTIVITIES: PREPARATION AND PLANNING 3-1
3.1 INTRODUCTION 3-1
3.2 REVIEWING EPA RECORDS 3-5
3.3 PROVIDING ADVANCE NOTIFICATION 3-17
3.4 A WRITTEN INSPECTION PLAN 3-25
3.5 GATHERING INSPECTION DOCUMENTS AND EQUIPMENT 3-30

CHAPTER 4 INSPECTION MANAGEMENT

4.0 INSPECTION MANAGEMENT 4-1
4.1 INTRODUCTION 4-1
4.2 AUTHORITY 4-1
4.3 PRELIMINARY STEPS FOR CONDUCTING A TSCA INSPECTION 4-5
4.4 CONSENT TO ENTER AND INSPECT 4-6
4.5 DENIAL OF CONSENT TO ENTER AND INSPECT 4-11
4.6 ADMINISTRATIVE WARRANTS 4-12
4.7 THE OPENING CONFERENCE 4-19
4.8 INSPECTION PLAN REVISIONS 4-25
4.9 THE CLOSING CONFERENCE 4-26

CHAPTER 5 TSCA SECTION 4 INSPECTIONS

5.0 TSCA SECTION 4 INSPECTIONS 5-1
5.1 INTRODUCTION 5-1
5.2 INSPECTION OBJECTIVES 5-5

CHAPTER 6 TSCA SECTION 5 INSPECTIONS 6-1

6.1 INTRODUCTION 6-1
6.2 PREMANUFACTURE NOTICE REQUIREMENTS 6-8
6.3 TSCA SECTION 5(e)/5(f) ORDER 6-23
6.4 SIGNIFICANT NEW USE RULE 6-29
6.5 LOW VOLUME EXEMPTION 6-36
6.6 RESEARCH & DEVELOPMENT EXEMPTION 6-41
6.7 TEST MARKETING EXEMPTION 6-45
6.8 POLYMER EXEMPTION 6-52
6.9 INSTANT FILM CHEMICAL EXEMPTION (IFCE) 6-57
6.10 ZERO EXPOSURE 6-64

CHAPTER 7 TSCA SECTION 8 INSPECTIONS

7.0 TSCA SECTION 8 INSPECTIONS 7-1
7.1 INTRODUCTION 7-1
7.2 SECTION 8(a) 7-4
7.3 SECTION 8(a): INVENTORY UPDATE RULE 7-21
7.4 SECTION 8(c): ALLEGATIONS OF SIGNIFICANT ADVERSE HUMAN HEALTH OR ENVIRONMENTAL EFFECTS 7-26
7.5 SECTION 8(d): HEALTH AND SAFETY STUDIES 7-32
7.6 SECTION 8(e): NOTIFICATION OF SUBSTANTIAL RISKS 7-35

CHAPTER 8 TSCA SECTIONS 12 AND 13

8.0 TSCA SECTIONS 12 AND 13 8-1
8.1 INTRODUCTION 8-1
8.2 TSCA SECTION 12 EXPORT NOTIFICATION RULE 8-1
8.3 TSCA SECTION 13 IMPORT RULE 8-3

CHAPTER 9 BIOTECHNOLOGY REGULATION

9.0 BIOTECHNOLOGY REGULATION 9-1
9.1 INTRODUCTION 9-1
9.2 BACKGROUND 9-1
9.3 CURRENT POLICY 9-2
9.4 OTHER ISSUES 9-4
9.5 SUMMARY 9-5

CHAPTER 10 POST-INSPECTION ACTIVITIES

10.0 POST-INSPECTION ACTIVITIES 10-1
10.1 INTRODUCTION 10-1
10.2 FOLLOWUP 10-1
10.3 THE INSPECTION REPORT 10-2
10.4 WHAT TO DO WITH COMPLETED INSPECTION REPORT 10-9

APPENDICES

APPENDIX 1 OCM MEMORANDUM TO IMD REQUESTING TARGETING PRINTOUTS
APPENDIX 2 GUIDANCE FOR REQUESTING TSCA SECTION 5 AND 8 ENFORCEMENT REQUESTS
APPENDIX 3 LIST OF INDUSTRIAL PROCESS REFERENCES
APPENDIX 4 RECOMMENDED PROCEDURES FOR ENFORCEMENT PERSONNEL RESPONSIBLE FOR HANDLING SECTION 5 CONFIDENTIAL BUSINESS INFORMATION
APPENDIX 5 SAMPLING PROCEDURES
APPENDIX 6 REGIONAL POLLUTION PREVENTION CONTACTS
APPENDIX 7 CHEMICALS ON REPORTING RULES (CORR) DATABASE
APPENDIX 8 PREMANUFACTURE NOTICE
APPENDIX 9 GLOVE TESTING GUIDELINE
APPENDIX 10 PAIR FORM
APPENDIX 11 EPA POLICY: STATEMENT OF INTERPRETATION AND ENFORCEMENT POLICY; NOTIFICATION OF SUBSTANTIAL RISK (43 *FR* 11110)
APPENDIX 12 REPORTING GUIDANCE: TSCA SECTION 8(E) COMPLIANCE AUDIT PROGRAM
APPENDIX 13 FINAL RULE: CHEMICAL IMPORTS AND EXPORTS; GENERAL IMPORT REQUIREMENTS AND RESTRICTIONS POLICY FOR IMPORT OF CHEMICAL SUBSTANCES (48 *FR* 55462)
APPENDIX 14 ANNOUNCEMENT OF POLICY AND NOTICE FOR PUBLIC COMMENT: COORDINATED FRAMEWORK FOR REGULATION OF BIOTECHNOLOGY (51 *FR* 23302)
APPENDIX 15 INSPECTION CHECKLIST

BLANK PAGE

Chapter One

Introduction

Page

1.0 INTRODUCTION 1-1

1.1 WHAT IS TSCA? 1-1

1.1.1 SUMMARY: TSCA SECTION 4 1-3
1.1.2 SUMMARY: TSCA SECTION 5 1-3
1.1.3 SUMMARY: TSCA SECTION 8 1-5
1.1.4 SUMMARY: TSCA SECTION 12 1-6
1.1.5 SUMMARY: TSCA SECTION 13 1-7

1.2 PURPOSE OF THIS INSPECTION MANUAL 1-8

1.3 NATIONAL ENFORCEMENT PROGRAM PRIORITIES 1-9

1.3.1 HEADQUARTERS-REGIONAL MEMORANDUM OF AGREEMENT (MOA) PROCESS 1-9
1.3.2 FY 1993 NATIONAL PROGRAM PRIORITIES 1-9
1.3.3 HQ-REGIONAL MEMORANDUM OF AGREEMENT 1-10

BLANK PAGE

1.0 INTRODUCTION

1.1 WHAT IS TSCA?

In 1976, Congress enacted the Toxic Substances Control Act (TSCA) to "... regulate commerce and protect human health and the environment by requiring testing and necessary use restriction on certain chemical substances, and for other purposes." In the years following its enactment, TSCA was amended to add two new titles governing asbestos and radon. These titles, mentioned only for informational purposes, are not the subject of this manual.[1] Throughout the remainder of this manual, the use of the term "TSCA" refers to Title I only.

TSCA contains several congressional findings that form the basis for regulating toxic substances. Two of these findings are that humans and the environment are exposed yearly to many chemical substances and mixtures and that the manufacturing, processing, distribution in commerce, use, and disposal of some of these chemicals and mixtures may pose an unreasonable risk of injury to health or the environment.

TSCA is composed of 31 sections, requiring that specific actions pertaining to chemical substances or mixtures be taken by either the affected community or by the U.S. Environmental Protection Agency (EPA) to protect human health and the environment. TSCA, and the rules promulgated pursuant to TSCA, regulate the manufacturing, processing, distribution in commerce, use, and disposal of chemical substances and mixtures. The term "chemical substance," as defined by TSCA, lists numerous exclusions, including pesticides, tobacco and tobacco products, nuclear materials and byproducts, food, food additives, drugs, cosmetics, and devices.[2]

TSCA is different from other environmental laws administered by EPA in two major ways: TSCA regulates the manufacturing and use aspects of chemical substances, while other environmental laws regulate the waste streams of chemical manufacturing and/or use operations; and TSCA regulates chemicals that have not yet been manufactured and introduced into commerce whereas other

---

[1] TSCA was amended in 1986 and in 1988, each time by creating a new title: Title II (the Asbestos Hazard Emergency Response Act (AHERA) of 1986), which concerns asbestos-containing materials in public and private elementary and secondary schools, and Title III (the Indoor Radon Abatement Act of 1988), which pertains to indoor radon gas pollution. These titles are not addressed in this inspection manual.

[2] For specific definitions of each exemption from the term "chemical substance" under TSCA, see Section 3 of TSCA ("definitions").

environmental laws pertain to chemicals already in the stream of commerce. TSCA's regulation of chemical substances prior to their introduction into commerce (i.e., new chemicals) allows EPA to obtain data necessary to assess the potential risks of such chemicals early on and to take any regulatory action that may be necessary to protect human health and the environment before the substance reaches the environment or the consumer. In addition, EPA regulates chemical substances and mixtures already being manufactured and introduced into commerce (i.e., existing chemicals). TSCA's regulations for existing chemicals allow EPA to obtain data necessary to assess the potential risks of these chemicals in commerce and to regulate their manufacture, processing, distribution in commerce, use, and disposal if they pose an unreasonable risk to human health or the environment. Therefore, for TSCA regulatory purposes, chemicals are divided into two categories: new chemicals and existing chemicals. The different sections of TSCA pertain to one or both of these categories. For example, Section 5 of TSCA governs new chemicals by requiring the submission to EPA of a Premanufacture Notice (PMN) by manufacturers, while Section 6 can be used to regulate existing chemicals.

Under TSCA Section 6, EPA is authorized to regulate chemical substances and mixtures only where the Agency has made an initial finding that such substances or mixtures pose, or will pose, an unreasonable risk of injury to human health or the environment. In addition, in making a regulatory determination under the law, Section 2 of TSCA requires EPA to consider the "environmental, economic, and social impact" of each regulatory action taken or proposed.

The major sections of TSCA that are the subject of this manual are Sections 4, 5, 8, 12, and 13. These sections pertain to the following topics: testing of chemical substances (Section 4); PMNs and PMN exemptions (Section 5); reporting and retention of information (Section 8); exports of chemical substances (Section 12); and imports of chemical substances (Section 13). Section 4 inspections pertaining to Good Laboratory Practices (GLPs) are not covered in this manual because they are conducted separately in accordance with other EPA guidance. EPA is responsible for conducting compliance monitoring inspections under these sections of TSCA to ensure that the regulated community (manufacturers, importers, and processors) comply with TSCA. In the manual, Section 4 is addressed in Chapter 5, Section 5 in Chapter 6, Section 8 in Chapter 7, and Sections 12 and 13 in Chapter 8. In addition, the manual discusses EPA's policy on biotechnology in Chapter 9. The following paragraphs summarize the sections of TSCA that are addressed in the manual. Detailed discussions of the requirements under each section are found in the appropriate chapters.

1.1.1 SUMMARY: TSCA SECTION 4

Section 4(a) provides the authority for EPA to require by rule that testing be conducted by manufacturers, importers, or processors to determine the effects of a chemical substance or mixture when the Administrator determines that the manufacture, distribution, processing, use, or disposal of the chemical substance or mixture may present an unreasonable risk to health or the environment. When EPA promulgates a test rule under Section 4(a), the rule must include identification of the substance for which testing is required, the standards for the development of the test data, and specification of the period of time for which the data must be submitted.

A company manufacturing, importing, or processing a chemical subject to a Section 4 test rule must submit a letter of intent to conduct the testing or apply for and receive an exemption. An exemption is granted if the chemical substance or mixture is equivalent to another substance for which test data have been submitted under another rule and submission of such data would be duplicative of test data that have been submitted or will be developed. If the exemption is granted on the basis of previously submitted data and is granted within the reimbursement period for such test data, then the company granted the exemption must provide fair and equitable reimbursement to the person who previously submitted the test data.

Companies conducting testing under Section 4 test rules and consent orders must follow the GLP Standards that are contained in 40 CFR Part 792 and the applicable test standard required by the rule or consent order.

1.1.2 SUMMARY: TSCA SECTION 5

Section 5(a) of TSCA prohibits any person from manufacturing or importing a new chemical substance [i.e., one that does not appear on the chemical substance list (or Inventory)] established under Section 8(b) without notifying EPA at least 90 days prior to that activity. Notification is done through the submittal of a PMN. This PMN requirement enables EPA to screen a new chemical before its commercial production or importation begins. The review period is intended to provide EPA with an opportunity to review and evaluate information pertaining to the substance to determine whether manufacture, processing, distribution in commerce, use, or disposal should be limited or prohibited because of insufficient data with which to determine health and environmental effects of the substance or because the substance will present an unreasonable risk of injury to health and the environment. After

making the required findings, EPA may take any of a number of actions to regulate the chemical substance as discussed below.

If EPA takes no action to limit use or delay the review period, the submitter may begin production, but must submit a Notice of Commencement (NOC) within 30 days. The submitter may withdraw its PMN at any time during the review process without giving a reason.

If the Administrator determines that the information available is insufficient to permit a reasonable evaluation of the health and environmental effects of a chemical substance with respect to which notice is required and that the manufacture, processing, distribution in commerce, use, and disposal of such a substance may present an unreasonable risk to health or the environment, (or the substance will be produced in substantial amounts that may either enter the environment or cause substantial or significant human exposure to the substance), then s/he may issue a proposed order [i.e., Section 5(e) order], to take effect on the expiration of the notification period, prohibiting or limiting the manufacture, processing, distribution in commerce, use, or disposal, of such a substance.

If the Administrator determines that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance presents or will present an unreasonable risk of injury to health or environment, s/he may either issue a rule under Section 6, limiting the amount of such substance that may be manufactured, processed, or distributed (or take other actions under Section 6) or issue an order under Section 5(f). Under a Section 5(f) order, the Administrator may prohibit the manufacture, processing, or distribution of a chemical substance or may seek an injunction to prohibit manufacture, processing, or distribution. A proposed rule issued under Section 5(f) will take effect immediately upon publication in the *Federal Register*. A Section 5(f) order becomes effective on the expiration of the notification period.

Under Section 5(a)(2), the Administrator, by rule and after the consideration of specific factors, may determine that the use of a chemical substance constitutes "a significant new use," and thus requires a significant new use rule (SNUR). Any person who intends to manufacture or process such a substance for a "significant new use" (i.e., a non-ongoing use) must submit to the Administrator, at least 90 days before beginning manufacture or processing, notification of the intent to do so. This significant new use notice (SNUN) is functionally equivalent to a PMN except that its scope is limited to the particular significant new use. Thus, a SNUR turns an "existing chemical" into a "new chemical" for purposes

of TSCA Section 5 by requiring submission of a SNUN on the existing substance before it is manufactured or processed for the significant new use. Also, a SNUR can apply to processors as well as manufacturers and importers, unlike PMNs, which apply to manufactures and importers only.

TSCA Section 5(h) establishes exemptions from the PMN requirement. Some of the exemptions are chemical substances intended for test marketing or research and development and chemicals specifically exempted by a rule promulgated by EPA (such as the exemption for low-volume chemicals, polymers, and instant photographic films). Some of these exemptions require prior application to EPA and EPA approval. Others, such as the research and development exemption, are automatic if the company meets the criteria specified in the pertinent regulations.

1.1.3 SUMMARY: TSCA SECTION 8

TSCA Section 8 consists of five subsections that establish reporting and record keeping requirements. Chemical manufacturers, importers, and processors and in certain cases distributors may be required (unless exempt) to submit certain reports and/or maintain records.

Under Section 8(a), EPA has the authority to establish, by rule, record keeping and reporting requirements for manufacturers, importers, and processors of chemical substances. The Preliminary Assessment Information Rule (PAIR) requires manufacturers and importers to submit a two-page form with information about any chemical listed by EPA in 40 CFR §712.30. EPA has also promulgated the Comprehensive Assessment Information Rule (CAIR), which requires manufacturers, importers, and processors to submit information in response to certain questions selected from a 140-page form on chemicals identified by the EPA and listed in 40 CFR §704.225.

TSCA Section 8(b) requires EPA to maintain and update the TSCA Chemical Substances Inventory Database, which lists each chemical substance that is manufactured or processed in the United States for commercial purposes. The Inventory not only provides the basis for distinguishing between new and existing chemicals under TSCA, but also provides information on the extent and volumes of manufacturing and/or use of chemicals in commerce. Under TSCA Section 8(a), EPA promulgated the Inventory Update Rule to keep the Inventory current by requiring manufacturers and importers to periodically report on chemicals on the Inventory.

Under TSCA Section 8(c), companies are required to record "allegations of significant adverse reactions" to any substance/mixture they manufacture, import, process, or distribute. EPA has issued an interpretive rule under Section 8(c) (40 CFR Part 717) that requires manufacturers, importers, and certain processors of chemical substances and mixtures to keep records concerning the allegations, and report to EPA those records upon notice in the *Federal Register* or upon notice by letter.

The TSCA Section 8(c) rule provides a mechanism to identify previously unknown chemical hazards. It may reveal (to EPA or an individual record keeper) patterns of adverse effects which otherwise may not be noticed or detected.

TSCA Section 8(d) provides EPA with the authority to promulgate rules to require manufacturers, importers, or processors (or prospective manufacturers, importers, or processors) to submit to the Administrator of EPA lists and/or copies of ongoing and completed health and safety studies. Under this authority, EPA has promulgated a model health and safety data reporting rule (40 CFR Part 716), which was developed to gather a broad range of data on specifically listed chemical substances and mixtures for which EPA requires information in fulfilling the goals of TSCA (e.g., to support the testing program and risk assessment).

Section 8(e) of TSCA requires that "...any person who manufactures, processes, or distributes in commerce a chemical substance or mixture and who obtains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to human health or the environment shall immediately inform the Administrator of such information unless such person has actual knowledge that the Administrator has been adequately informed of such information."

1.1.4 SUMMARY: TSCA SECTION 12

Section 12(a)(1) of TSCA exempts any chemical substance, mixture, or article containing a chemical substance or mixture from the Act (except for the purposes of Section 8 of TSCA) if:

- The chemical substance, mixture, or article is being manufactured, processed, or distributed in commerce for export only; and
- Such substance, mixture, or article, or any container in which it is enclosed, bears a stamp or label stating that the substance, mixture, or article is intended for export.

Section 12(b) of TSCA requires any person who exports, or intends to export, a chemical substance or mixture to notify EPA of such export to a foreign country if any of the following actions have been taken under TSCA with respect to that chemical substance or mixture:

- Data are required under Sections 4 or 5(b).
- An order has been issued under Section 5.
- A rule has been proposed or promulgated under Section 5 or 6.
- An action is pending, or relief has been granted under Section 5 or 7.

EPA issued a final export reporting rule on December 16, 1980 (45 FR 82844; 40 CFR Part 707). Under this rule, an exporter must submit to EPA by letter, a notice of the first export, within the calendar year, for the substance or mixture. Notice is required for the first export or intended export to each foreign country in a calendar year. The notice must be postmarked within 7 days after acceptance of a definite contractual obligation to export or an equivalent intracompany agreement to export. Where the actual export occurs less than 7 days after the export obligation or agreement has been executed, the notice must be submitted to EPA no later than the same day as the export.

After EPA has received the first annual notification from the exporter, EPA must then notify the importing country's government of the exportation of the chemical, of any existing or proposed EPA regulatory action against the chemical, and of the availability of test data on the chemical submitted to EPA.

1.1.5 SUMMARY: TSCA SECTION 13

TSCA Section 13 requires the Secretary of the Treasury (U.S. Customs Service) to refuse entry into the customs territory of the United States of any chemical substance or mixture if it fails to comply with any rule in effect under TSCA, or if it is offered for entry in violation of Sections 5 or 6, a Section 5 or 6 rule/order, or a Section 7 order. In addition, because TSCA defines importers as manufacturers, importers may be subject to testing requirements under Section 4 and reporting requirements under Section 8.

The U.S. Customs Service (Customs) published a rule concerning Section 13 on August 1, 1983, in 48 FR 34734 (19 CFR §12.118). The Customs rule sets forth general certification requirements and detention procedures. However, it does not address how a chemical shipment and its import would

comply with TSCA. EPA issued a policy statement December 13, 1983, in 48 FR 55462 (40 CFR Part 707). It explains how EPA interprets and executes its responsibilities outlined in the Customs' Chemical Substances Import Rule. The main purpose of the EPA policy statement is to describe what compliance with TSCA means.

Under the Customs rule, the importer of a chemical shipment must certify at the port of entry for shipments entering commerce in the U.S. that either the shipment is subject to TSCA and complies with all applicable rules and orders or the shipment is not subject to TSCA. An importer can accomplish the certification and discharge his obligations related to the import by signing a brief typed or reprinted statement on an entry document, invoice, or attachment.

Certification of compliance with TSCA is required for chemical substances imported in bulk or as part of mixtures. Because some chemicals (e.g., tobacco and tobacco products) are not chemical substances subject to TSCA, the Customs rule requires importers to certify that such chemicals are not subject to TSCA. The rule does not require certification for chemical substances imported as part of articles, unless EPA requires reporting under a specific TSCA rule.

1.2 PURPOSE OF THIS INSPECTION MANUAL

Congress delegated responsibility for enforcing, and for promulgating rules pursuant to TSCA to the EPA. EPA is responsible for ensuring compliance with and enforcement of TSCA. A comprehensive compliance and enforcement program is necessary to ensure that EPA meets its congressional mandate to protect human health and the environment.

An integral part of EPA's compliance program is the compliance monitoring inspection, conducted to ascertain whether regulated facilities are complying with TSCA and the regulations promulgated pursuant to it. This manual is intended to provide guidance to EPA inspectors who conduct compliance inspections under TSCA Sections 4 (non-GLP), 5, 8, 12, and 13. While there are other EPA guidance materials pertaining to TSCA inspections, and to environmental compliance inspections generally, this manual is intended to only supplement them. Therefore, inspectors may and should refer to other documents as necessary when performing inspections to determine compliance with TSCA Sections 4 (non-GLP), 5, 8, 12, and 13.

1.3 NATIONAL ENFORCEMENT PROGRAM PRIORITIES

The purpose of this section is to provide to the inspector a discussion of the program priority-setting process and the current program priorities. The Office of Compliance Monitoring, in consultation with the Office of Pollution Prevention and Toxics and the Regions, sets enforcement and compliance priorities to achieve National program objectives.

1.3.1 HEADQUARTERS-REGIONAL MEMORANDUM OF AGREEMENT (MOA) PROCESS

Based on the FY 1992 National OPPTS meeting, the Assistant Administrator, Linda Fisher, decided that OPPTS should proceed to develop a process whereby Headquarters and Regional Offices would prepare and enter into joint Memoranda of Agreement. All Regions are expected to participate.

The intended purpose of the OPPTS HQ-Regional MOAs is to implement the pesticide and toxic programs so as to achieve national program objectives in a way that recognizes the relevant circumstances or conditions in the different regions. What this means is that both Regional and Headquarters management will reach agreement on program goals, flexibility, and discretion. The goal of the MOA process is to fully utilize available resources to address regional and national priorities for prevention, pesticides, and toxics. The process is being implemented in the spirit of improving HQ-Regional teamwork and partnerships for OPPTS programs. HQ and Regions recognize that the growing demand on resources to meet an ever increasing array of priorities requires that agreements be reached on Regional and National priorities.

1.3.2 FY 1993 NATIONAL PROGRAM PRIORITIES

The FY 1993 National priorities for the TSCA Section 5 and 8 Inspection Program are for areas with potential for high risk. This area has been identified as new chemicals inspection. New chemical resources are to be used for priority inspections targeting: non-submitters of PMNs (including importers); parties to risk-based Section 5(e) Consent Orders; companies subject to SNURs; and holders of low-volume exemptions. After priority inspections have been addressed, remaining compliance and enforcement resources may be used for the purposes of grant oversight and evaluation, conducting multimedia or other special enforcement initiatives, or to meet compliance/enforcement needs in other toxics areas. Any inspections Regions wish to conduct over and above the number established between Headquarters and the Regional Office in the MOA process, for the new chemicals inspection category may be used in assessing compliance with new chemical R&D and test marketing exemptions.

1.3.3 HQ-REGIONAL MEMORANDUM OF AGREEMENT

Each Region should insert its current operating HQ-Regional Memorandum of Agreement for the TSCA Section 5 and 8 program here.

Chapter Two

Targeting TSCA Section 5 and 8 Inspections

Page

2.0 TARGETING OF TSCA SECTION 5 AND 8 INSPECTIONS 2-1

2.1 INTRODUCTION AND PURPOSE 2-1

2.2 OVERVIEW OF TSCA INSPECTION TARGETING PROCESS 2-2

2.2.1 OVERVIEW 2-2
2.2.2 PAST EXPERIENCE 2-4

2.3. DESCRIPTION OF TARGETING MECHANISMS 2-6

2.3.1 NON-SUBMITTERS 2-9

2.3.1.1 BACKGROUND 2-9
2.3.1.2 EXPERIENCE 2-9
2.3.1.3 POTENTIAL SERIOUSNESS OF VIOLATION 2-10
2.3.1.4 STRATEGY 2-10

2.3.2 TSCA SECTION 5(e)/(f) ORDERS 2-11

2.3.2.1 BACKGROUND 2-11
2.3.2.2 EXPERIENCE 2-12
2.3.2.3 TYPES AND POTENTIAL SERIOUSNESS OF VIOLATIONS 2-12

2.3.3 SIGNIFICANT NEW USE RULES 2-13

2.3.3.1 BACKGROUND 2-13
2.3.3.2 EXPERIENCE 2-13
2.3.3.3 TYPES AND POTENTIAL SERIOUSNESS OF VIOLATIONS 2-14

2.3.4 PMN EXEMPTION APPLICATIONS 2-15

2.3.4.1 BACKGROUND 2-15
2.3.4.2 EXPERIENCE 2-15
2.3.4.3 TYPES AND POTENTIAL SERIOUSNESS OF VIOLATIONS 2-16

2.3.5 PREMANUFACTURE NOTIFICATION (PMN) 2-16

2.3.5.1 BACKGROUND 2-16
2.3.5.2 EXPERIENCE 2-17
2.3.5.3 TYPES AND POTENTIAL SERIOUSNESS OF VIOLATIONS 2-17

2.3.6 TSCA SECTION 8 2-18

2.3.6.1 BACKGROUND 2-18
2.3.6.2 EXPERIENCE 2-19
2.3.6.3 TYPES AND POTENTIAL SERIOUSNESS OF VIOLATIONS 2-19

2.3.7 OTHER POTENTIAL TARGETING MECHANISMS 2-20

2.3.7.1 TIPS AND COMPLAINTS 2-21
2.3.7.2 MULTI-MEDIA TARGETS 2-22
2.3.7.3 HIGH-RISK CHEMICALS 2-23
2.3.7.4 GEOGRAPHIC-BASED TARGETING 2-23

2.4 INFORMATION SOURCES 2-23

2.4.1 TSCA SECTION 5(e)/(f) 2-24
2.4.2 SNURs 2-24
2.4.3 PMN EXEMPTIONS 2-26
2.4.4 PMNs WITHDRAWN 2-26
2.4.5 TSCA SECTION 8 TARGETING 2-27
2.4.6 MULTI-MEDIA 2-28
2.4.7 NON-SUBMITTERS 2-29

2.5 SETTING PRIORITIES AND SELECTING SPECIFIC TARGETS 2-30

2.5.1 DEVELOPING A MASTER LIST 2-30
2.5.2 SETTING PRIORITIES AMONG TARGETING AREAS 2-30
2.5.3 SELECTING SPECIFIC FACILITIES WITHIN TARGETING AREAS 2-32

LIST OF FIGURES

FIGURE 2-1	FLOW CHART OF TARGETING AND INSPECTION	2-3
FIGURE 2-2	SETTING PRIORITIES (WEIGHTS) AMONG PROGRAM AREAS	2-33
FIGURE 2-3	TARGETING WORKSHEET 1	2-34
FIGURE 2-4	SELECTING FACILITIES WITHIN PROGRAM AREAS	2-36
FIGURE 2-5	TARGETING WORKSHEET 2	2-37

LIST OF TABLES

TABLE 2-1A	SUMMARY OF INSPECTIONS BY TYPE AND YEAR	2-5
TABLE 2-1B	SUMMARY OF ACTIONS BY TYPE AND YEAR	2-5
TABLE 2-2A	SUMMARY OF INSPECTIONS BY TYPE AND REGION	2-7
TABLE 2-2B	SUMMARY OF ACTIONS BY TYPE AND REGION	2-7
TABLE 2-3	SUMMARY OF STATISTICS ON SUBMISSIONS AND EPA ACTIONS	2-8
TABLE 2-4	INFORMATION AVAILABLE IN TARGETING PRINTOUTS FROM IMD THROUGH OCM	2-25

BLANK PAGE

2.0 TARGETING OF TSCA SECTION 5 AND 8 INSPECTIONS

2.1 INTRODUCTION AND PURPOSE

The purpose of the Toxic Substances Control Act (TSCA) Sections 5 and 8 inspection program is not only to monitor compliance and identify violators, but also to establish an enforcement presence and to provide a deterrent effect for potential violations. To this end, it is important to focus limited resources on significant, enforceable, and nationally important cases that can serve as examples. At the same time, however, it is important to maintain a neutral approach to identifying potential facilities to be inspected, based on clearly stated, previously established priorities.

This chapter has several purposes. First, it provides an explanation and background on mechanisms currently being applied in Regional inspection programs for identifying potential violators. Second, it can serve as a reference to educate new inspectors in targeting issues and activities. Third, it introduces schemes for ranking and prioritizing identified inspection targets to meet specific Regional concerns and resource constraints.

The remainder of this chapter is organized into four sections. Section 2.2 provides an overview of the inspection targeting process and some historical information on the TSCA Sections 5 and 8 inspection program. Section 2.3 provides a detailed description of various targeting mechanisms that have been used or proposed by National Enforcement Investigations Center (NEIC) and Regional inspectors and past guidance from Headquarters, including a discussion of the relevant statutory language. Section 2.4 discusses the types of data and databases that are available to help Regional inspectors find the information they need to identify potential violators. Section 2.5 discusses specific implementation approaches and how to select specific facilities based on established priorities and ranking schemes.

2.2 OVERVIEW OF TSCA INSPECTION TARGETING PROCESS

2.2.1 OVERVIEW

Targeting identifies facilities for inspection based on their potential for violation of TSCA requirements. Various mechanisms or criteria can be used to identify potential violators. In addition, priorities among different targeting mechanisms can be set in several ways, with the intent that limited resources be allocated in a way that maximizes the potential to mitigate hazards to health or the environment.

Because there are so many options for targeting, national guidance on inspection strategies and priorities is needed to ensure consistency, while allowing for necessary flexibility among Regions and program areas. In addition, uniform guidance is important to satisfy the requirements of a Neutral Administrative Inspection Scheme (NAIS). The objective of an NAIS is to identify and select inspection targets for the purpose of increasing compliance by facilities subject to the law and to meet the standard established in *Marshall v. Barlow's, Inc.* (436 U.S. 307, 1978) that a NAIS be used for facility selection. An NAIS provides a rationale for selection of specific facilities, so that a court reviewing an inspection scheme will see how decisions were made and how the final scheme was justified.

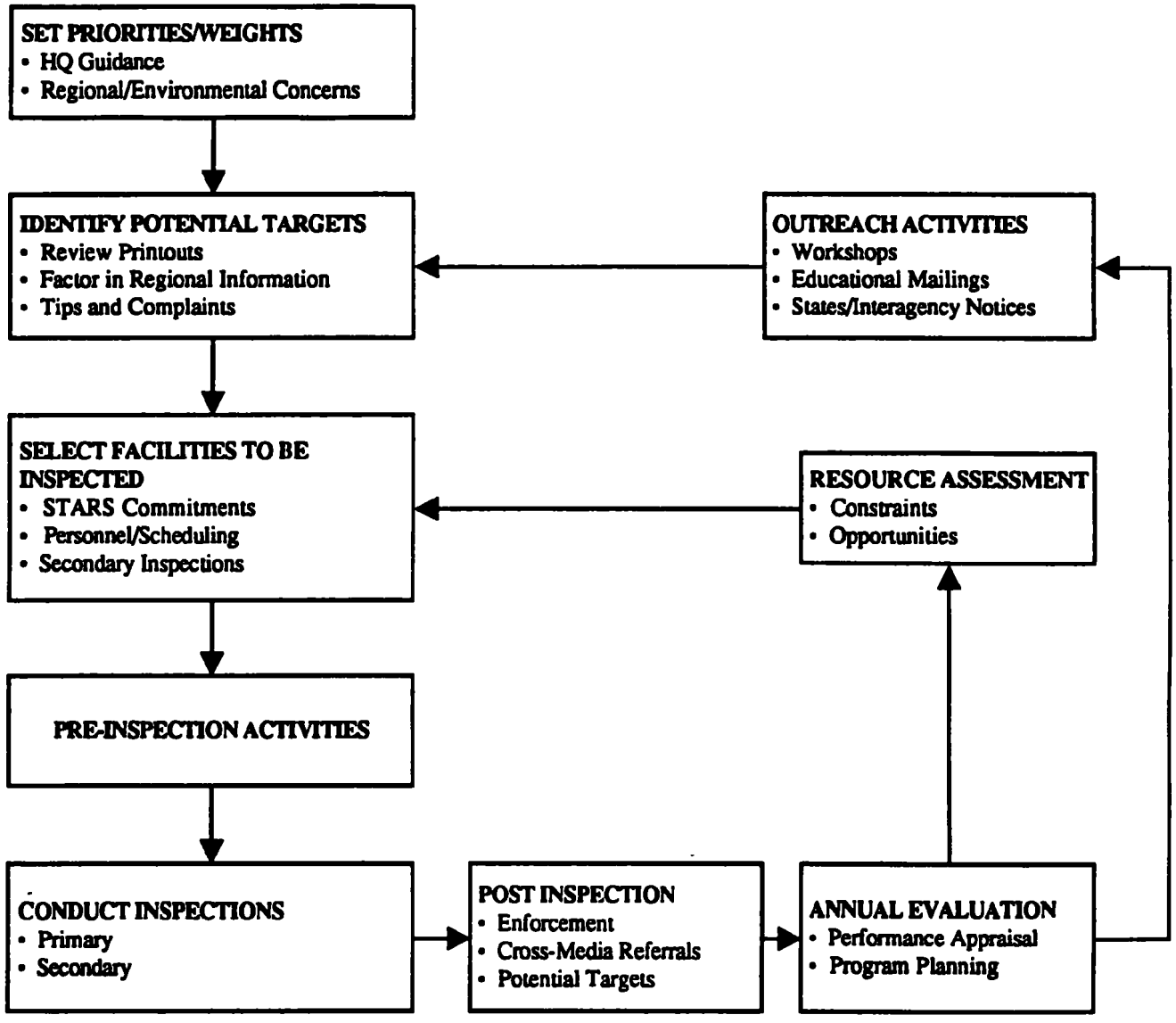
In response to the need to achieve better communication and exchange between the Regions and Headquarters, OCM held a conference on the TSCA Section 5 and 8 program in June of 1991. Among other things, participants at the conference identified targeting and inspection strategies as an important area for discussion. Regions specifically asked for more detailed targeting guidance and practical priorities. This targeting guide is a response to the issues and ideas raised at the conference.

Figure 2-1 is a flow chart of the targeting and inspection process. This flow chart helps to provide a conceptual perspective for this entire guidance manual. This chapter deals with identifying potential violators and setting priorities to select individual inspection targets. Chapter 3 deals with pre-inspection preparation activities, while Chapter 4 deals with inspection management (i.e., conducting inspections). Activities associated with specific types of inspections (e.g., Section 5 inspections, PAIR inspections) are discussed in Chapters 5 through 8. Finally, Chapter 10 discusses post-inspection activities, such as writing the inspection report.

The flow chart presented in Figure 2-1 not only serves to link the activities discussed in each chapter, but also helps to identify important functions that are not discussed in detail in this document.

FIGURE 2-1

FLOW CHART OF TARGETING AND INSPECTION



Performance evaluation, assessment of resource levels, and outreach activities are important to the success of the overall TSCA inspection program, even though they are not discussed in detail in this manual. For example, each Region must evaluate resources available for inspections and then develop specific inspection priorities, targets, and commitments for the year.[1] The flow chart helps to show that this annual resource assessment and prioritization are parts of a continuing process that can build on lessons learned from the past year of activity. Similarly, outreach activities can be viewed as part of the inspection program and as one of the links between individual inspections and the next year's targeting process. Outreach activities may result in improved compliance or revision of priorities and resource allocations.

2.2.2 PAST EXPERIENCE

As a basis for understanding targeting strategies, it is useful to have some historical information on the results and effectiveness of past efforts. Traditionally, facilities have been identified and inspections have been conducted based on the types of violations under the various sections of TSCA. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and TSCA Tracking System (FTTS) records data on the types of inspections conducted, types of violations found, and actions taken. This information is extracted by the Office of Compliance Monitoring (OCM) into the National Compliance Database (NCDB), which was available for analysis. Such background information can also provide a context for evaluating proposed changes in priorities.

Table 2-1A summarizes information on past inspections and their distribution across different types of inspections for the years 1986 to 1991. Table 2-1B summarizes actions that resulted from these inspections for the same period. The categories of inspections listed appear in the database and correspond roughly to the types of inspections conducted by Regions. It is important to note that the categories of inspections are not mutually exclusive. That is, a given facility that is the site of a Section 5 and a Section 8 inspection will be counted as two inspections. In addition, some of the categories do not provide a fine level of resolution. For example, the category titled simply "inspection" may represent a comprehensive inspection of all areas, but the individual areas may also be recorded. Furthermore, actions in a given year do not necessarily result from inspections in the same year. For these reasons, these data must be interpreted with caution. Further information on each of the categories can be obtained from the *FIFRA/TSCA Tracking System (FTTS) FTTS Database Information* (September 1991).

[1] These decisions must be documented to satisfy the requirements of a NAIS to show how Regional priorities were derived from a neutral scheme and resource constraints.

TABLE 2-1A SUMMARY OF INSPECTIONS BY TYPE AND YEAR

Inspection Type	Year								Total	% Of All Inspections
	U[1]	1986	1987	1988	1989	1990	1991	1992		
Chemical Substance Exemption	0	1	1	22	24	5	8	0	61	2.9
Inspection	72	29	17	101	83	91	118	2	513	24.0
Sec. 5(e)/(f) Order	1	0	4	13	6	4	9	0	37	1.7
Failure to Notify	1	3	4	6	20	3	3	0	40	1.9
Premanufacture Notice	23	28	38	76	79	27	53	1	325	15.2
SNUR	0	0	0	0	0	0	1	0	1	0.0
Test Marketing Exemption	0	0	5	2	1	2	3	0	13	0.6
Section 5 Total	**97**	**61**	**69**	**220**	**213**	**132**	**195**	**3**	**990**	**46.3**
Comprehensive Inspection	7	0	1	8	13	57	98	1	185	8.7
Sec. 8(c) Records Rule	51	29	35	85	59	31	23	1	314	14.7
8(d) Health/Safety Studies	0	6	12	22	13	7	13	0	73	3.4
8(a) Level a Rule	37	14	26	23	32	18	23	0	173	8.1
Inventory Update Rule	57	16	20	113	65	20	51	0	342	16.0
Sec. 8(e) Substantial Risk	3	4	9	15	15	12	3	0	61	2.9
Section 8 Total	**155**	**69**	**103**	**266**	**197**	**145**	**211**	**2**	**1,148**	**53.7**
Total Inspections	**252**	**130**	**172**	**486**	**410**	**277**	**406**	**5**	**2,138**	

[1] The numbers in this column represent inspections that were not identified by date.

TABLE 2-1B SUMMARY OF ACTIONS BY TYPE AND YEAR

Type	Year								Total	% of All Actions
	U[1]	1986	1987	1988	1989	1990	1991	1992		
Chemical Substance Exemption	2	0	0	0	0	0	0	1	3	1.4
Inspection	5	0	0	2	2	12	14	4	39	17.7
Section 5(e)/(f) Order	0	0	0	1	0	1	1	1	4	1.8
Failure to Notify	0	0	0	0	0	3	3	2	8	3.6
Premanufacture Notice	20	1	1	7	8	18	16	11	82	37.3
SNUR	0	0	0	0	0	0	0	0	0	0.0
Test Marketing Exemption	0	0	0	0	0	0	0	0	0	0.0
Section 5 Total	**27**	**1**	**1**	**10**	**10**	**34**	**34**	**19**	**136**	**61.8**
Comprehensive Inspection	1	0	0	0	0	4	3	6	14	6.4
Sec. 8(c) Records Rule	0	0	0	0	1	1	1	0	3	1 4
Sec. 8(d) Health/Safety Rule	0	0	0	0	0	0	0	0	0	0 0
Sec. 8(a) Level a Rule	5	1	1	1	2	3	6	3	22	10 0
Inventory Update Rule	14	0	0	5	3	11	5	5	43	19 5
Sec. 8(e) Substantial Risk	0	0	0	0	0	2	0	0	2	0.9
Section 8 Total	**20**	**1**	**1**	**6**	**6**	**21**	**15**	**14**	**84**	**38.2**
Total Actions	**47**	**2**	**2**	**16**	**16**	**55**	**49**	**33**	**220**	

[1] The totals in this column represent inspections that were not identified by date.

However, comparisons between the two tables provide some interesting observations. For example, premanufacture notice (PMN) inspections accounted for about a third of the total Section 5 inspections, but over half of the actions taken as a result of Section 5 violations. Although this comparison clearly shows that PMNs are a plentiful source of violations, this disparity could result for several reasons: PMN violations are commonly found as a result of other types of inspections, PMN violations are easier to document than other types of inspections, or inspectors routinely spend more time searching for PMN violations than other types. Inventory Update Rule (IUR) inspections show a similar pattern: the proportion of IUR violations compared to Section 8 violations exceeds the proportion of IUR compared to total Section 8 inspections conducted.

Some categories of inspection activity show the opposite trend. For example, Section 8(c) inspections represent 27 percent of the total Section 8 inspections but only about 3.6 percent of Section 8 enforcement actions. This could mean that firms are generally in compliance or that violations are difficult to document. Depending on the actual reasons, OCM or a particular Region could evaluate priorities for the distribution of future inspections based on a review of these types of data. In addition, a more detailed analysis of this type of historical information on inspected firms (or submitters), by industrial category or location, could be useful in designing approaches to improve coverage of unknown, non-submitting facilities (see Section 2.3.1 of this chapter).

Tables 2-2A and 2-2B present the same information on inspections and actions broken down by Region, rather than by year. These tables show the relative differences among Regions in types of inspections conducted, which may reflect differences in resource levels and priority placed on various types of inspections. Also, the table reflects the fact that some Regions have been conducting inspections longer than others.

To provide background on the size of the program, Table 2-3 shows overall statistics on the numbers of various types of submissions from industry and actions by EPA under TSCA Section 5. The table provides some perspective on the volume of new chemical submissions, EPA actions, and the size of the inspection workload.

2.3. DESCRIPTION OF TARGETING MECHANISMS

The following section describes the various types of mechanisms that can be used to target TSCA Section 5 and 8 inspections. The numbers in parentheses indicate the subsections of this chapter in which they

TABLE 2-2A SUMMARY OF INSPECTIONS BY TYPE AND REGION

Inspection Type	Region											Total	% Of All Inspections
	I	II	III	IV	V	VI	VII	VIII	IX	X	HQ/ NEIC		
Chemical Substance Exemption	0	29	17	0	15	0	0	0	0	0	0	61	2.9
Inspection	20	110	106	18	156	17	22	17	32	5	10	513	24.0
Sec. 5(e)/(f) Order	1	18	9	0	8	0	0	0	0	0	1	37	1.7
Failure to Notify	0	13	11	0	0	0	0	0	0	0	16	40	1.9
Premanufacture Notice	0	150	94	4	54	0	1	0	0	0	22	325	15.2
SNUR	0	1	0	0	0	0	0	0	0	0	0	1	0.0
Test Marketing Exemption	0	7	4	0	2	0	0	0	0	0	0	13	0.6
Section 5 Total	21	328	241	22	235	17	23	17	32	5	49	990	46.3
Comprehensive Inspection	18	16	6	18	45	17	16	12	32	5	0	185	8.7
Sec. 8(c) Records Rule	0	38	162	1	108	0	1	4	0	0	0	314	14.7
8(d) Health/Safety Studies	0	23	13	0	37	0	0	0	0	0	0	73	3.4
8(a) Level a Rule	0	63	82	0	19	0	2	0	0	0	7	173	8.1
Inventory Update Rule	1	127	143	0	65	0	2	0	0	0	4	342	16.0
Sec. 8(e) Substantial Risk	0	9	7	3	38	0	1	1	0	0	2	61	2.9
Section 8 Total	19	276	413	22	312	17	22	17	32	5	13	1,148	53.7
Total Inspections	40	604	654	44	547	34	45	34	64	10	62	2,138	

TABLE 2-2B SUMMARY OF ACTIONS BY TYPE AND REGION

Type	Region											Total	% Of All Actions
	I	II	III	IV	V	VI	VII	VIII	IX	X	HQ/ NEIC		
Chemical Substance Exemption	0	1	2	0	0	0	0	0	0	0	0	3	1.4
Inspection	2	3	4	4	13	0	3	2	2	0	6	39	17.7
Sec. 5(e)/(f) Order	0	1	2	0	0	0	0	0	0	0	1	4	1.8
Failure to Notify	0	4	0	0	0	0	0	0	0	0	4	8	3.6
Premanufacture Notice	0	30	26	3	11	0	0	0	1	0	11	82	37.3
SNUR	0	0	0	0	0	0	0	0	0	0	0	0	0.0
Test Marketing Exemption	0	0	0	0	0	0	0	0	0	0	0	0	0.0
Section 5 Total	2	39	34	7	24	0	3	2	3	0	22	136	61.8
Comprehensive Inspection	1	4	1	1	3	0	2	2	0	0	0	14	6.4
Sec. 8(c) Records Rule	0	0	0	0	1	0	0	2	0	0	0	3	1.4
8(d) Health/Safety Studies	0	0	0	0	0	0	0	0	0	0	0	0	0.0
8(a) Level a Rule	0	9	6	0	4	0	0	0	0	0	3	22	10.0
Inventory Update Rule	0	17	15	0	9	0	0	0	0	0	2	43	19.5
Sec. 8(e) Substantial Risk	0	0	0	0	0	0	0	0	0	0	2	2	0.9
Section 8 Total	1	30	22	1	17	0	2	4	0	0	7	84	38.2
Total Actions	3	69	56	8	41	0	5	6	3	0	29	220	

TABLE 2-3 SUMMARY OF STATISTICS ON SUBMISSIONS AND EPA ACTIONS

TYPE OF SUBMISSION	YEAR								TOTAL
	1979-1984	1985	1986	1987	1988	1989	1990	1991	
Premanufacture Notifications	4,201	1,462	1,691	1,775	2,421	1,037	1,934	1,385	15,906
Test Market Exemption Application	310	61	57	30	18	28	18	25	547
Polymer Exemption Applications	0	154	238	248	318	174	239	178	1,549
Low Volume Exemptions	0	94	237	276	237	265	553	279	1,941
Total New Chemical Submissions	4,511	1,771	2,223	2,329	2,994	1,504	2,744	1,867	19,943
Notices of Commencement	2,585	780	793	825	929	540	856	259	7,567
EPA Actions									
Section 5(e) Orders Issued	68	47	67	61	34	54	86	87	504
Section 5(f) Actions Issued	4	0	0	0	0	0	0	0	4
PMNs Withdrawn in Face of Action	95	78	92	100	133	122	73	86	779
Upfront (Voluntary) Testing Actions									351
Average Prenotice Consultations Per Year									1,200

Source: Data are taken from the OTS New Chemicals Program Annual Report.

are discussed.

- Non-submitters (2.3.1)
- TSCA Section 5(e)/5(f) orders (2.3.2)
- Significant new use rules (2.3.3)
- PMN exemption applications (2.3.4)
- Premanufacture Notification (PMN) (2.3.5)
- TSCA Section 8 (2.3.6).

Four additional targeting mechanisms include the following:

- Tips and complaints
- Multi-media targets
- High-risk chemicals
- Geographic targets.

These four potential targeting mechanisms are not widely or systematically used, so they are discussed only in general terms (in Section 2.3.7) to give inspectors some practical ideas for applying these new

approaches. This guide discusses each of the targeting mechanisms listed. As other mechanisms or priorities are identified, they can be documented and inserted to ensure that the guide is a comprehensive reference.

2.3.1 NON-SUBMITTERS

2.3.1.1 BACKGROUND

In accordance with Section 5(a) of TSCA, no person may manufacture or process a new chemical substance for a non-exempt commercial purpose without notifying EPA at least 90 days prior to that activity. Notification is accomplished through the submittal of a PMN. The purpose of this requirement is to provide EPA with the opportunity to determine whether the uncontrolled manufacture, importation, processing, use, distribution in commerce, or disposal will present an unreasonable risk of injury to health and the environment. A non-submitter is a person who fails to submit a premanufacture notification to EPA prior to manufacturing or importing a new chemical substance.

One of the most serious violators of TSCA is the non-submitter, that is, a person failing to submit a PMN for a chemical substance when one is required. Two apparent reasons for non-notification are ignorance of the requirements and misidentification of the chemical substance.

- Ignorance of the requirements. A number of violations occur as a result of ignorance of the requirements. The older the TSCA program gets, the less likely that such violations will occur. However, importing new chemical substances remains a serious issue. That is, American manufacturers or processors who may not normally deal with TSCA may import a new chemical substance without the knowledge of the PMN program. Or a foreign entity may wish to begin exporting to the United States and find a distributor or other handler. Both parties may be unaware of PMN requirements under TSCA.

- Misidentification of the chemical substance. To determine whether a chemical substance is new and therefore requires a PMN, it must be determined whether the chemical is listed in the TSCA chemical substance inventory. The chemical substances are listed by the Chemical Abstract Services (CAS) chemical name or a generic chemical name. It is possible that a potential manufacturer or importer incorrectly identifies the name of a chemical substance, which could result in an incorrect determination that the chemical is contained in the inventory.

2.3.1.2 EXPERIENCE

Enforcement statistics characterizing the potential non-submitter community are very limited. This is partly due to the limited number of inspections, reliance on self-confessions, limited tracking effort, and the absence of many non-submitters from the TSCA tracking system (and, thus, these non-submitters may

not be inspected for other purposes). Although the potential risk to health and the environment from non-submitters is high, it is difficult and resource-intensive to target non-submitters given the nature of the violation. It is important to note that non-submitters under Section 5(a) may also violate other TSCA requirements, including Section 13 import certification. Although it is unclear how they were identified, Table 2-2 shows that 40 inspections were conducted for "failure to notify," resulting in eight enforcement actions taken by EPA. In addition, EPA's Enforcement Accomplishments Report for FY 1990 highlights some enforcement cases involving non-submitters:

- Region II issued an administrative complaint to DSM Resins, Inc. (a subsidiary of a large Dutch-based chemical conglomerate), citing a failure to file a PMN and failure to certify under Section 13. The Region is proposing a penalty of $2.3 million. The company self-confessed the violations.

- The EPA filed an administrative complaint and gravity-based penalty of $1,909,000 against the P.D. George Company for failing to file PMNs for nine subject chemical substances and Notices of Commencement (NOCs). The company subsequently filed the PMNs and NOCs. The Chief Judicial Officer ratified a consent agreement for a $527,850 fine; recovery and incineration of buried drums of paint waste; and a Sections 5 and 8 audit to identify and report additional violations.

- The EPA filed a civil complaint and proposed a $285,000 fine against Union Camp Corporation for failing to submit a PMN. A consent agreement was reached where a $106,000 penalty was assessed in addition to the submission of a revised company policy and procedures for PMN compliance and a 5-year program of annual, day-long new chemical compliance meetings for responsible employees.

2.3.1.3 POTENTIAL SERIOUSNESS OF VIOLATION

Failing to submit a PMN is a serious violation, because the particular chemical has the potential to cause an unreasonable risk to health and the environment and because EPA and the public are unaware of the risk. The actual threat is difficult to assess because EPA has not had the opportunity to assess the potential risk that the chemical substance may present. That is the purpose of the PMN process -- to provide EPA with the opportunity to review the potential risk to health and the environment of the chemical substance.

2.3.1.4 STRATEGY

Identifying non-submitters presents a unique challenge to EPA because non-submitters have never made previous submissions under TSCA. To encourage compliance by both submitters and non-submitters, outreach should be used to inform the regulated community of their obligations under TSCA. One tool used in Region I to meet this goal is outreach through direct mailings, press releases, and workshops.

- Direct mail. Based on the information sources discussed in Section 2.4 of this chapter, a Regional list of chemical manufacturers, importers, processors, and suppliers could be developed. The mailing may include press releases on previous non-submitters as well as an announcement for the EPA's self-confessor program. Such a mailing also may generate tips and complaints from competitors or workers.

- Press releases. Some Regions have a policy to issue press releases related to administrative and civil penalties. For any non-submitter penalized, the Region should aggressively distribute press releases with special focus on the monetary penalty. Press releases could be sent to all appropriate news media including television. However, non-submitter press releases also could be sent to appropriate trade associations, foreign consulates, customs brokers, etc.

- Workshops. Periodically, the Regions conduct workshops or conferences focusing on TSCA compliance or education. During these gatherings, an effort should be made to either inform participants of the ramifications of non-submittal or to provide literature (such as a press release) with a similar message.

The critical factor in effectively targeting non-submitters is possessing information that characterizes the population. However, only limited information currently exists at EPA to assist in targeting non-submitters. Historical information on non-submitters (previous violations), such as the ratio of importers to domestic manufacturers, typical sizes of the companies, the types of chemicals, regions, countries of origin, points of entry into the U.S., and primary SIC Codes, could be used to increase the effectiveness of the targeting effort by characterizing the non-submitter population. An effort to develop and maintain such statistics could improve Regions' abilities to target non-submitters.

2.3.2 TSCA SECTION 5(e)/(f) ORDERS

2.3.2.1 BACKGROUND

Any company intending to manufacture or import a new chemical substance must give EPA 90 days prior notice under TSCA Section 5. This PMN requirement enables EPA to screen a new chemical before its commercial production or importation begins. TSCA Section 5(e) allows EPA to issue an administrative order regulating or limiting the manufacture of a new chemical substance if the Agency finds (1) that there is insufficient information to evaluate the risk of a chemical substance and (2) that the chemical may present an unreasonable risk to health or the environment, or that substantial amounts will enter the environment or there will be substantial human exposure. A Section 5(e) order can restrict or ban the manufacture, distribution, use, or disposal of a chemical pending development of data sufficient to allow EPA to reasonably evaluate any risks posed by the chemical in question.

Prior to issuing a Section 5(e) order, EPA will often negotiate a "consent order" with the PMN submitter. Typically, in a Section 5(e) consent order, the manufacturer will be permitted to proceed with commercial manufacture in return for adhering to any restrictions on production, distribution, use, or disposal that EPA deems necessary. Thus, in the face of a Section 5(e) order, a PMN submitter has three choices: negotiate a consent order, fight a unilateral order, or withdraw the PMN (which the submitter may do without explanation).

Section 5(f) orders are similar but less common because they may prohibit manufacture totally, limit the amount, or specify the conditions of manufacture. Also, the risk standard of Section 5(f) is more exacting than that of Section 5(e).

2.3.2.2 EXPERIENCE

As noted in the previous section, Section 5(e) orders are much more common than Section 5(f) orders. As shown in Table 2-3, from FY 1986 through FY 1991, 504 Section 5(e) orders and only 4 Section 5(f) orders have been issued. Table 2-2A indicates that in all Regions, 37 inspections have taken place under Sections 5(e) and (f) (1.7 percent of total inspections).

2.3.2.3 TYPES AND POTENTIAL SERIOUSNESS OF VIOLATIONS

Generally, Section 5(e)/5(f) orders are issued in response to a Section 5(a) PMN when EPA has serious concerns about a chemical. Accordingly, potential Section 5(e)/5(f) violations warrant high priority. Companies subject to a Section 5(e) order should be inspected to determine whether the chemical has been produced for commercial purposes and whether an NOC was submitted. They should also be checked for compliance with terms of the Section 5(e) order, including all personal protective and hazard communication provisions. The circumstances of the Section 5(e)/(f) order must also be considered when looking at Section 5(e)/(f) orders as an inspection targeting mechanism. Section 5(e) orders can be grouped into two categories in descending order of priority:

- Orders with an NOC. If manufacture has commenced, more risk to human and environmental health will be present than when manufacture has not commenced. Section 5(e) and 5(f) orders regulate high-risk chemicals and often will have provisions requiring the use of personal protective clothing and respiratory protection, and/or particular hazard communication requirements. This type of Section 5(e) order thus merits the highest priority. An inspector can tell if manufacture has commenced by looking up, by PMN number, the date of commencement on the NOC printout. The facility should then be targeted for an inspection in which the inspector looks at, among other things, compliance with worker protection, hazard communication and restrictions on manufacturing, use, and disposal, as well as production

volume to see whether the testing trigger has been exceeded. It is also possible to search the Management Information Tracking System (MITS), Document and Personnel Security System (DAPSS), and the Confidential Business Information Tracking System (CBITS) to obtain this type of data. MITS is available on-line through the Information Management Division's (IMD) Public Data Branch. If possible, the Project Manager in Office of Pollution Prevention and Toxics (OPPT) for that particular PMN should be consulted prior to the inspection (see Chapter Three).

- Orders without an NOC. If an NOC has not been received in the first year after the Section 5(e) Consent Order was signed, the inspector will want to ascertain why an NOC was not filed. Has manufacture begun without notifying EPA? Depending on the chemical, this could be a very serious situation. Conversely, if manufacturing has not yet commenced, why not? The inspector may consider obtaining this information through less labor- and resource-intensive means (such as a telephone call) prior to committing to a full on-site inspection.

2.3.3 SIGNIFICANT NEW USE RULES

2.3.3.1 BACKGROUND

Section 5(a)(2) of TSCA authorizes EPA to determine that a use of a chemical substance is a "significant new use." EPA must make this determination by rule after considering all relevant factors, including those listed in Section 5(a)(2). Section 5(a)(2) factors generally relate to the extent to which a use changes the volume of a chemical's production or the type, form, magnitude, or duration of exposure to it. Once EPA determines that a use of a chemical substance is a significant new use, Section 5(a)(1)(B) of TSCA requires persons to submit a significant new use notice (SNUN) to EPA at least 90 days before they manufacture, import, or process the chemical substance for that use.

Persons subject to a SNUR are required to comply with the same notice requirements and EPA regulatory procedures as submitters of PMNs under Section 5(a)(1)(A) of TSCA. In particular, these requirements include the information submission requirements of Section 5(b) and (d)(1), the exemptions authorized by Section 5(h)(1), (2), (3), and (5), and the regulations at 40 CFR Part 720. EPA may take regulatory action under Section 5(e), 5(f), 6, or 7 to control the activities for which it has received a SNUR notice. If EPA does not take action, Section 5(g) of TSCA requires EPA to explain in the *Federal Register* its reasons for not taking action. It should be noted that a SNUR potentially has a broader application than the PMN regulations because it applies to processors, as well as manufacturers and importers.

2.3.3.2 EXPERIENCE

There has been very little experience with SNUR inspections. Only one inspection has taken place to date (in FY 1991); it did not result in any enforcement action as yet.

2.3.3.3 TYPES AND POTENTIAL SERIOUSNESS OF VIOLATIONS

Violations involving SNURs would be very similar to PMN violations, especially for non-reporting. SNURs can be divided into three general categories:

- Section 5(e) SNURs. A SNUR can be used to effectively extend the terms of a Section 5(e) consent order to all other manufacturers, processors, and importers based on the finding that any "use" other than those allowed in the Section 5(e) consent order could significantly increase exposure.

- Non-section 5(e) SNUR. EPA will promulgate a SNUR only if the substance meets one or more of the concern criteria listed in 40 CFR §721.170(b). Essentially, these criteria call for a SNUR if exposures likely to result from new uses not in the PMN would have called for a Section 5(e) order if they had been in the PMN.

- Existing chemical SNUR. A substance is already in commerce when EPA becomes aware of a use or uses that could significantly increase human exposure to the substance. The SNUR applies to all manufacturers, importers, and processors, even those who may already be using the substance.

SNUR violations may also occur within areas that overlap regulatory programs. The "Generic SNUR" promulgated at 40 CFR Part 721, establishes five categories of standard significant new uses, two of which cross over into areas that have traditionally been within the purview of the Occupational Safety and Health Administration (OSHA) (Protection in the Workplace, Section 721.63, and Hazard Communication, Section 721.72). Section 721.63 designates as a standard significant new use any manner of manufacturing, importing, or processing associated with any use of the chemical substance if the manufacturer, importer, or processor has not established a program whereby each person who is reasonably likely to be exposed to the chemical is provided with and required to wear appropriate personal protective equipment. Section 721.72 designates as a standardized significant new use any manner or method of manufacture, import, or processing associated with any use without establishing a hazard communication program. Most provisions of this section parallel those of OSHA's Hazard Communication Standard (HCS) except that EPA's rule differs in five respects: (1) EPA makes the hazard determination, rather than the employer; (2) EPA provides language for labels and material safety data sheets, whereas OSHA allows employers to develop language; (3) EPA does not provide trade secret protection as does OSHA's HCS; (4) EPA requires listing of environmental hazards on labels and Material Safety Data Sheets (MSDSs), whereas OSHA does not; and (5) under the SNUR hazard communication program, EPA can require labeling, etc., based on a finding that a substance may present a risk, whereas OSHA's hazard communication restrictions generally apply to chemicals that are known to present certain hazards.

Inspection targeting for SNURs will focus on two primary areas: (1) failure of manufacturers, importers, or processors to submit a SNUN (either for new or existing substances and in relation to a Section 5(e) order); and (2) "generic SNUR" inspections (targeting and/or inspections could be done in cooperation with OSHA). For example, when inspecting a company for compliance with Section 5(e) orders that have been followed up with SNURs, an inspector can make note of the company's customers while reviewing their records for the order. If a processor/customer is found, that processor/customer is subject to required recordkeeping under 40 CFR §721.125 and to any use restrictions of the SNUR itself.

2.3.4 PMN EXEMPTION APPLICATIONS

2.3.4.1 BACKGROUND

The previous Section described the PMN (Section 5) process. TSCA Section 5 also provides several exemptions from the requirement to submit a full PMN. Exemptions exist for low volume production (LVE), test marketing (TME), research and development (R&D), polymers (PE), and chemicals used in instant photographic films (Instant Film Chemical Exemption or IFCE). In most cases, an application and EPA review are required to obtain an exemption, but these are less onerous than those for a full PMN. In practice, discussions of exemptions generally deal with LVEs, PEs, and TMEs, because R&D exemptions require no application (although the company must comply with recordkeeping requirements), and because the photographic film exemption applies to only a few firms.

2.3.4.2 EXPERIENCE

The historical data in Table 2-3 provide some perspective on the size of the exemption program. From 1985 to 1991, the regulated public submitted 237 TME applications (or about 34 per year), 1,549 PE applications (or about 221 per year), and 1,941 LVE applications (or about 277 per year). For all years combined, exemption applications make up nearly 20 percent of new chemical submissions to EPA. No information is available on R&D exemptions because applications are not required.

Table 2-1A shows the numbers of inspections undertaken by EPA by type of inspection for each year since 1986. Inspections initiated to evaluate compliance with PMN exemptions account for only about 3.5 percent of EPA's inspection activity. Furthermore, these were concentrated in 1988 and 1989 and in Regions II, III, and V. Of 74 exemption inspections conducted, only 3 resulted in actions (see Table 2-1B). In terms of past inspection activity, exemptions have not been a large or important part of the inspection and enforcement program.

2.3.4.3 TYPES AND POTENTIAL SERIOUSNESS OF VIOLATIONS

There are several types of exemptions and several mechanisms by which EPA can identify potential violations. Regions may consider exemption applications as a lower priority than other categories of potential violations because exemptions are offered for categories of chemicals or activities that present lower risk of environmental harm than other categories. For example, LVEs deal only with low volumes of chemicals, PEs apply only to chemicals of certain specifications that are expected to pose low risk, and TMEs apply to chemicals to be test marketed for some limited time period. In the case of TMEs, one may expect either that the test period will be followed by market failure and hence no use, or market success and expanded use triggering a full PMN.

However, it is important to verify compliance with restrictions on the testing period and maximum production quantity, to maintain an enforcement presence, and to ensure that the exemption process is not being abused. Abuse may be most likely in the low volume and research and development areas. There are several mechanisms by which EPA can identify potential violations.

- Denied or invalid exemption applications without PMN following. This may be a useful category to target because the firm was apparently poised to manufacture, but was denied the venue of an exemption. After denial, the firm could go through the PMN route, could terminate plans to manufacture, or could manufacture illegally.

- Withdrawn exemption applications. As with withdrawn PMNs, facilities that have withdrawn exemption applications have not necessarily done anything wrong. However, if there is some reason to inspect "for cause" (e.g., because the facility may have manufactured without an approved exemption or PMN), then it would be more serious. Inspectors should always check to see whether a PMN was submitted after the exemption application was withdrawn.

- Multiple exemption applications. Multiple exemption applications may indicate some of the same problems as multiple PMNs. The submitter may have recently become aware of TSCA rules and is trying to come into compliance for past violations. On the other hand, multiple applications may indicate that a lot of activity is occurring at the facility and that it should be investigated.

- Active/granted exemptions. For granted applications, submitters are bound by the conditions in the exemption document. The inspector may want to target facilities that have exemptions with restrictions. These restrictions, or conditions, should be verified when the inspector is on site.

2.3.5 PREMANUFACTURE NOTIFICATION (PMN)

2.3.5.1 BACKGROUND

TSCA Section 5(a) requires all chemical manufacturers and importers to notify EPA 90 days before manufacturing or importing a new chemical substance. During the 90-day period (or 180 days if EPA

requests an extension), EPA reviews the information in a PMN to determine whether the substance presents or may present an unreasonable risk to public health or the environment. Based on this review, EPA has the authority to take action to control use or handling of the substance and prevent large-scale distribution. If EPA takes no action to limit use or delay the review period, the submitter may begin production, but must submit an NOC within 30 days of commencement of manufacture or import for a non-exempt commercial purpose. If EPA chooses to regulate use or production of the substance, a Section 5(e) order will be issued (as discussed in Section 2.3.2). The submitter may withdraw its PMN at any time during the review process without giving a reason. In addition, there are several mechanisms by which a manufacturer or importer can be exempted from the full PMN reporting requirements. These are discussed in Section 2.3.5.

2.3.5.2 EXPERIENCE

A brief review of historical data will provide some perspective on the size of the PMN program and EPA's inspection program. Table 2-3 shows that as of 1991, on average, 1,707 PMNs have been submitted to EPA each year since 1986, with a total of 15,906 since 1979. Of these 15,906, 7,567 (or almost 50 percent) have been followed by NOCs, 504 have been followed by Section 5(e) orders, and 779 have been withdrawn in the face of regulatory action.

Table 2-1A shows the numbers of inspections undertaken by EPA by type of inspection for each year since 1986. Inspections initiated to evaluate compliance with PMN requirements account for a large part of EPA's TSCA inspection activity. They accounted for about a third of the 990 inspections conducted under TSCA Section 5 in the period from 1986 to 1991. Table 2-1B shows 82 cases where PMN violations resulted in some type of action, such as an administrative order, to correct a violation. Although PMN inspections represent only a third of the total Section 5 inspections, PMN violations account for over half of the violations found in all Section 5 inspections.

2.3.5.3 TYPES AND POTENTIAL SERIOUSNESS OF VIOLATIONS

There are several mechanisms by which EPA can identify potential violations. These are described in order of relative importance.

- PMNs withdrawn in the face of regulatory action. If EPA requests information or data that indicates an intention to regulate use or production of the substance, the submitter is permitted to withdraw the PMN. This may indicate that the firm is trying to avoid regulatory or informational burdens and may manufacture without approval. Manufacturing without approval would be a

potentially serious violation because EPA was in the process of deciding that the substance represented a sufficient environmental or health risk to warrant control.

- Multiple PMNs in a short time period. Several PMNs may be submitted at the same time if the submitter was not aware of the notification requirement or "discovered" substances in use that were not on the inventory. This situation may indicate that production was already occurring before the PMN was submitted and that someone was trying to cover up past violations. This would be a potentially serious violation because EPA would have had no opportunity to review the characteristics of these substances, which could represent an environmental or health risk.

- PMNs with early NOC. If an NOC is submitted within a few days of the expiration of the 90-day PMN review period, it may indicate that the firm was not waiting for a response from EPA, but was already manufacturing.

- Withdrawn PMNs (with no anticipated action). There may be several reasons for a manufacturer to withdraw a PMN: there may be no market for the product; existing chemical replacements may have been found; or EPA data requests may be too onerous for the projected profitability of the chemical. This should be a low priority unless there is some other reason to believe that the company is actually manufacturing.

- PMNs with no NOC after review period has passed. As with withdrawn PMNs, the lack of an NOC of manufacturing may simply indicate that the firm found that the product would not be profitable for a variety of reasons, but that the company wants to retain the option to begin production. This situation should be a low priority unless there is reason to believe that the company is actually manufacturing, perhaps because of a tip, complaint, or other information.

2.3.6 TSCA SECTION 8

2.3.6.1 BACKGROUND

TSCA Section 8 consists of five subsections that establish reporting and recordkeeping requirements, as described in Chapter 1. Chemical manufacturers, processors, and/or distributors may be required (unless exempt) to submit reports and/or maintain records under Section 8. While all Section 8 requirements are important, it is difficult to target a facility for some of them because EPA does not maintain any formal records or databases covering each of the subsections of Section 8 [e.g., Section 8(c)]. Because of this, the following targeting section will only address the four Section 8 rules for which EPA databases exist: Preliminary Assessment Information Rule (PAIR) and Comprehensive Assessment Information Rule (CAIR) [Section 8(a), Inventory Update Rule (IUR) [Section 8(b)], and Section 8(d). Based on EPA HQ guidance in the 1993 MOA process, Section 5 inspections are generally considered higher priority than Section 8 inspections.

2.3.6.2 EXPERIENCE

The following section provides an overview of the number of inspections and enforcement actions related to PAIR, CAIR, IUR, or Section 8(d) that EPA has handled in the past six years.

Historical data provide perspective on the size of the PAIR, CAIR, and IUR inspection programs. Between 1986 and 1991, EPA conducted 173 PAIR inspections (see Table 2-1A). The most inspections known to be conducted between 1986 and 1991 in one year (i.e., 32) occurred in 1989, and the fewest known occurred in 1986 (i.e., 14). PAIR inspections constitute 8.1 percent of total TSCA inspections. Table 2-2A shows only four Regions (Regions II, III, V, VII) and OCM and/or NEIC have conducted inspections for compliance with PAIR. Regions II and III are responsible for the majority of these inspections (63 and 82 inspections, respectively). From these inspections, 22 PAIR enforcement actions (10 percent of total enforcement actions) have occurred (see Table 2-1B). No information is available on CAIR inspections.

From 1986 to 1991, EPA performed 342 IUR inspections (Table 2-1A). These inspections evaluating compliance with IUR accounted for 16 percent of the total TSCA inspections, and almost 30 percent of Section 8 inspections. Table 2-2A indicates that Regions II, III, and V conduct the majority of IUR inspections. EPA has pursued 43 IUR enforcement actions since 1986. Over 50 percent of the total Section 8 enforcement actions stem from IUR actions.

Data concerning Section 8(d) will also provide some perspective on the size of its inspection program in relation to the rest of Section 8 and Section 5 inspections. Since 1986, 73 inspections have been conducted and all occurred in Regions II, III, and V (See Table 2-2A). Section 8(d) inspections account for 3.4 percent of the total TSCA inspections.

2.3.6.3 TYPES AND POTENTIAL SERIOUSNESS OF VIOLATIONS

Section 8 inspections tend to occur in conjunction with Section 5 inspections, although the Section 8 inspection is usually secondary. However, noncompliance with Section 8 can result in harm to health or the environment. Mechanisms exist that EPA may use to identify potential violations of PAIR, CAIR, and IUR, including the following:

- Nonreporters. PAIR and CAIR nonreporting is a serious violation because the chemicals subject to these rules are, by definition, of higher concern to EPA than other chemicals on the Inventory. EPA is trying to fill data gaps for these chemicals through information collection. Unfortunately,

identifying nonreporters is a difficult task (see Section 2.3.1). To target potential non-reporters, the inspector should verify that the facility in question reported to the initial Inventory and compare it to the lists of facilities reporting under PAIR, CAIR, or the IUR. Review of the Toxics Release Inventory (TRI) submittals together with IUR submitter information may also generate potential PAIR and CAIR targets for those chemicals subject to such reporting requirements.

- Late reporters. While late reporting is not as serious as nonreporting, it could be an indication of other violations. PAIR, CAIR, and IUR set reporting dates, after which a facility would be in violation of TSCA regulations.

2.3.7 OTHER POTENTIAL TARGETING MECHANISMS

To increase the effectiveness of the TSCA compliance monitoring program, the regulated community needs to be accurately identified and characterized. Because the TSCA program has been in place for more than 15 years, the TSCA regulated community is relatively well known. Unfortunately, the large size of the program and limited EPA resources restrict the ability to do widespread compliance monitoring. Thus, targeting the regulated community to increase the efficient use of resources to conduct compliance monitoring is essential. Section 2.3 addresses each significant TSCA regulatory program and outlines the targeting methods used historically for compliance with existing resources. Recently, other targeting mechanisms have been suggested. Although there is limited experience with these mechanisms in the TSCA program, they could be used with more program development and changes of emphasis to risk. This section, however, outlines other potential targeting mechanisms for the general TSCA program and not necessarily for specific programs.

Descriptions are provided to stimulate discussion and pilot trials at the Regional level. These are not specified as policy, but as potential tools to be used. Some of these tools are beyond the scope of Regional targeting, but some elements could be incorporated into ongoing activities. These general targeting mechanisms include the following:

- Tips and complaints
- Multi-media targets
- High-risk chemicals
- Geographic targets.

2.3.7.1 TIPS AND COMPLAINTS

Tips and complaints continue to be a top priority with Headquarters. Although tips and complaints may be submitted by anyone, the main sources of information include referrals from the Office of Prevention, Pesticides, and Toxic Substances (OPPTS), other Regions, and industry. Headquarters forwards all tips and complaints to the appropriate Region as Investigation Requests. Tips and complaints are expected to be the highest noncompliance rate group and deserve the highest priority.

Tips and complaints from the public are not as common under TSCA as for other EPA programs such as RCRA and Superfund. This is because it is more difficult to "see" a violation under TSCA (e.g., failure to submit a PMN) than violations in other media. There are organizations that potentially could provide tips and complaints under TSCA and thus bring potential violators to the EPA's attention. However, for tips and complaints to be useful and successful, the public and regulated community need to be educated as to what may constitute a TSCA violation. Examples of potentially useful compliance education projects include public service announcements, presentations at conferences and meetings, and public information pamphlets. Such ideas like the ones described here could be implemented as a joint pilot program with Headquarters and Regional participation.

- Industry could be a major source of tips alleging violations under TSCA. Industry could be made aware that those firms that violate the requirements of TSCA are operating at an economic advantage over those companies acting in a responsible manner. An educated industry might be willing to provide tips to the EPA to prevent this economic advantage. Industry has the resources, expertise, connections, and motivation to ensure that other companies act responsibly. By capitalizing on this situation, the EPA could better target its resources toward non-complying companies.

- Labor unions have quickly become a powerful force in promoting compliance within individual companies. Unions should be instructed that those workers simply following orders but violating TSCA are not necessarily excused from potential civil or criminal penalties if there is just cause. In addition, unions could be made aware that their members' health and safety may be threatened when noncompliance with TSCA occurs. Unions need to be trained to fully understand the requirements of Section 8(c), allegations of adverse reactions, and 8(e), notice of substantial risk.

- Public interest groups are less likely to provide tips and complaints than industry and unions because they have less access to information. However, environmental groups tend to be vigilant and knowledgeable about environmental statutory and regulatory compliance. Their existence is an important element in ensuring the success of the Section 8(c) program. Therefore, education efforts could focus on their rights under Section 8(c). Although similar in nature to environmental groups, citizen groups tend to be less sophisticated concerning knowledge of the statutory and regulatory programs. Whereas environmental groups benefit from national organizations, citizen groups tend to be local in nature. Nevertheless, their support could be valuable, and education concerning Section 8(c) should be considered.

2.3.7.2 MULTI-MEDIA TARGETS

The purpose of multi-media compliance inspections is to assess compliance with a number of applicable Federal environmental statutes in single visits. A multi-media inspection can involve dual or multiple program compliance inspections. This approach can effectively use investigatory personnel to reduce multiple visits to the same facility. Thus, a multi-media compliance inspection may audit a facility's chemical manufacturing process, wastewater discharges, hazardous waste management program, and air emissions with a team of specifically trained inspectors. Multi-media inspections are not necessarily meant to be all-inclusive. In fact, some inspectors may not be specifically assigned or trained under a program (e.g., TSCA). In this situation, such an inspector would be in a position to refer potential violations to the appropriate program.

EPA's National Enforcement Training Institute, NEIC, has developed training programs for multi-media inspections. The inspector training consists of four levels. Level 1 is for single program inspections; Level 2 is training to screen for and report on the more obvious or key indicators of noncompliance in all environmental programs areas relevant to a particular facility; Level 3 training is for multi-program inspections to train lead inspectors for two or more compliance programs; and Level 4 training is for an inspector to lead a team or conduct either a multi-media or multi-program inspections for a facility or site. By training compliance inspectors in this manner, referrals resulting from other activities and programs could significantly increase the success of the targeting program.

In addition, the TSCA program can use information available through other EPA regulatory programs to identify potential violators. Firms that are permitted, regulated, or inspected under other EPA programs provide information regularly to EPA under the reporting provisions of the several environmental statutes. In addition, EPA regularly collects information on these firms through investigative efforts and enforcement actions. Some of this information may help the TSCA program to identify facilities for inspection. In return, the TSCA program may be able to provide useful information to other program areas from the non-confidential business information (CBI) it maintains. At the Regional level, inspectors could provide summaries of inspection results to other programs routinely, or provide more specific information when potential violations in other program areas are discovered in individual inspections.

One excellent source of information kept by various EPA offices is the Integrated Data for Enforcement Analysis (IDEA) System. This system is described in detail in Section 2.4.6.

2.3.7.3 HIGH-RISK CHEMICALS

Some Regions have suggested that high-risk chemicals need to be targeted because they present the greatest threat to health and the environment. The PAIR and CAIR are designed to gather information on high-risk chemicals, so the targeting procedure described in Section 2.3.6 will address this issue to some extent. In addition, there are a number of sources that publish lists of high-risk chemicals. Based on these lists, Regions could determine whether these chemicals are produced and at what quantities to determine targeting effort. Sources for identifying high-risk chemicals include the following:

- Interagency Testing Committee (ITC). Established by Section 4(e) of TSCA, the ITC makes recommendations to EPA concerning which chemicals should be given priority by EPA for the development of test rules. The ITC revises the Priority List, which consists of no more than 50 priority chemicals, every 6 months and publishes it in the *Federal Register*. These chemicals will then become subject to PAIR and Section 8(d).

- EPCRA Section 313. Section 313 of EPCRA, the Emergency Planning and Community Right-to-Know Act, requires regulated facilities to report releases of designated toxic chemicals to EPA. The information must include the amount and destination of the release of the toxic chemical. Regions could access the TRI database to determine which toxic chemicals are being released and where. This could also assist in geographic-based targeting inspections.

- Clean Air Act Amendments. These amendments included a statutory list of 189 air toxics that require regulation. They have been identified as potentially causing a significant risk to human health and the environment.

- Clean Water Act. The Clean Water Act list of priority pollutants and the RCRA program listed wastes provide potential chemicals of concern that could be investigated in the TSCA program.

2.3.7.4 GEOGRAPHIC-BASED TARGETING

Region III and Region V, in their FY 1991 Core TSCA Inspection Schemes, identified geographic targeting as a method to be used to focus inspection activity. For example, the Chesapeake Bay and the Kanawha Valley areas have been identified through the Toxic Release Inventory database as areas threatened by toxic chemicals. However, other geographic identifications, such as priority waterbodies or non-attainment areas in the air program, could be used as the basis for similar targeting schemes. Targeting a percentage of inspections on non-submitters in geographic areas of concern would be a simple criterion to impose, after identifying potential facilities to be inspected by other means.

2.4 INFORMATION SOURCES

This section introduces a variety of information sources that are available for identifying facilities potentially subject to TSCA requirements. Several databases maintained by EPA/IMD form the core of

the TSCA targeting effort and the information sources discussed here. The Office of Compliance Monitoring is expected to provide targeting data to Regional inspectors on a semiannual basis. This targeting information is prepared by IMD at the request of OCM, as described in the example memorandum found in Appendix 1. Table 2-4 summarizes the information contained in these printouts. The following section discusses information sources for targeting facilities for the specific TSCA sections or regulations. Information sources for non-submitters are discussed at the end of Section 2.4. Although a variety of sources are available to assist in identifying potential non-submitters, it is not possible to rely solely on one mechanism at this time.

2.4.1 TSCA SECTION 5(e)/(f)

The information relevant to potential Section 5(e)/(f) violations appears in CBI Printouts A and D and Non-CBI Printout I described in Table 2-4. CBI Printout A contains information on all submitters of information under Section 5 by plant site address, including contact name, telephone, site address, and submission number. CBI Printout D contains information on withdrawn PMNs and those that were followed by a Section 5(e)/(f) order, listed by address. Information presented includes company name and address, contact information, date and disposition of the PMN, and the chemical name. Potential inspection targets should be readily identifiable from this printout. A more detailed summary of the information to be provided regularly and examples of targeting printouts appear in Section 2.4 of this chapter.

Non-CBI Printout I contains information on the dates of PMNs and NOCs, including case number, end-date of PMN review period, date of NOC (if any), number of elapsed days since the end of the PMN review period, and plant address and company name. This information can be sorted by Region or by PMN case number.

The Compliance Division of OCM is expected to forward all Section 5(e) and (f) orders and their underlying PMNs to the Regions where the plant sites are located so that Regional inspectors can target these facilities. In practice, most CBI data are not yet available for Regional use, but can be obtained through an enforcement request (see Section 2.4 and Appendix 2).

2.4.2 SNURs

The means of obtaining information on which facilities are manufacturing SNUR chemicals has not yet been resolved. One information source is the customer list of current manufacturers, as discussed above under Section 5(e), or the inspector may ask, during an inspection, if the company has ever submitted

TABLE 2-4 INFORMATION AVAILABLE IN TARGETING PRINTOUTS FROM IMD THROUGH OCM

TITLE OF PRINTOUT	DESCRIPTION OF INFORMATION AVAILABLE
CBI Printouts	**Contain Confidential Business Information**
A. TSCA Section 5 Submitter Information	Includes Region, Company Name, Technical Contact, Telephone Number, Plant Site Address, and Submission Number; Sorted by Plant Site Address, Region, and Zip Code.
B. PAIR Submitter Information	Includes Company Name, Technical Contact, Telephone Number, Plant Site Address, Submission Number, CAS Number, and Chemical Number; Sorted by Plant Site Address, Region, and Zip Code.
C. IUR Submitter Information	Includes Company Name, Plant Site Address, DUNS Number, UPD-From Number, Postmark, Identifying Number, Chemical Name, Production Volume, and Manufacturer/Importer Status; Sorted by Plant Site Address, Region, and Zip Code.
D. Withdrawn PMNs or PMNs Followed by §5(e)/(f) Order	Includes Region, PMN Number, Company Name, Technical Contact, Telephone Number, Plant Site Address, Date Received, NOC Date, Disposition Date and Code, and Chemical Name; Sorted by Plant Site Address, Region, and Zip Code.
E. Withdrawn, Denied, Invalid TMEAs Information	Includes Region, PMN Number, Company Name, Technical Contact, Telephone Number, Plant Site Address, Date Received, NOC Date, Disposition Date and Code, and Chemical Name; Sorted by Plant Site Address, Region, and Zip Code.
F. Withdrawn, Denied, Invalid LVEAs Information	Includes Region, PMN Number, Company Name, Technical Contact, Telephone Number, Plant Site Address, Date Received, NOC Date, Disposition Date and Code, and Chemical Name; Sorted by Plant Site Address, Region, and Zip Code.
G. Withdrawn, Denied, Invalid PEAs Information	Includes Region, PMN Number, Company Name, Technical Contact, Telephone Number, Plant Site Address, Date Received, NOC Date, Disposition Date and Code, and Chemical Name; Sorted by Plant Site Address, Region, and Zip Code.
H. CAIR Submitter Information	Includes Company Name, Technical Contact, Telephone Number, Plant Site Address, Submission Number, CAS Number, and Chemical Number; Sorted by Plant Site Address, Region, and Zip Code.
Non-CBI Printouts	**Contain Non-Confidential Business Information**
I. PMN/NOC Information	Includes Case No., End-date of PMN Review Period, NOC Date, No. of Elapsed Days Between these Two Dates, Plant Site State and City, and Company Name; Sorted by Region and PMN Number.
J. TSCATS Information	Includes Region, Dunn & Bradstreet Number, CAS Number, Chemical Name, TSCA Section, Title of Study, Date Received, Submitter Name, and Plant Site Address.

any SNUNs. A check of the Chemicals on Reporting Rules (CORR) list will also reveal whether any of a company's products are the subject of SNURs. It should be noted that the CORR list is prepared by chemical identity, not by manufacturer, so it will be less useful for targeting than for checking information about specific products of specific companies.

2.4.3 PMN EXEMPTIONS

Referring again to Table 2.4, the information relevant to exemption applications appears in CBI Printouts A, E, F, and G. CBI Printout A contains information on all submitters of information under Section 5 (that is, PMNs and all exemption applicants) by plant site address, including contact name, phone, site address, and submission number. This printout would be useful for identifying firms with multiple submissions and for finding the submission number to cross-reference to other printouts.

CBI Printout E contains information on withdrawn, denied, or invalid TME applications. CBI Printout F contains information on withdrawn, denied, or invalid LVE applications. CBI Printout G contains information on withdrawn, denied, or invalid PE applications. Each of these printouts contains information on company name and address, contact information, date and disposition of the application, and the chemical name, sorted by address. Firms identified on printout E, F, or G can be cross-checked to printout A to see whether a PMN followed denial of the exemption application.

2.4.4 PMNs WITHDRAWN

The information relevant to potential PMN violations appears in CBI Printouts A and D and in Non-CBI Printout I. CBI Printout A contains information on all submitters of information under Section 5 by plant site address, including contact name, phone, site address, and submission number. This printout would be useful for identifying firms with multiple submissions and for finding the PMN submission number to cross-reference to other printouts.

CBI Printout D contains information on withdrawn PMNs and those that were followed by a Section 5(e)/(f) order, sorted by address. The information presented includes company name and address, contact information, date and disposition of the PMN, and the chemical name.

Non-CBI Printout I contains information on the dates of PMNs and NOCs, including case number, date of end of PMN review period, date of NOC (if any), and number of elapsed days from the end of the review period to the receipt of the NOC, as well as plant address and company name. The same

information is presented in two forms, sorted by Region and sorted by PMN case number, to facilitate searching from either starting point. This printout would be useful for identifying PMNs with early NOCs (or with no NOCs).

Another information source relevant to PMNs is the PENTA (Section 5) System, maintained by the Information Management Division of OPPT. The PENTA System contains information and analyses considered during EPA's review of PMN submissions. The database can be searched by facility (e.g., by address, by DUNS number), rather than just by chemical. Most of the data are CBI, and this database is not yet available for Regional use. However, information from this database can be obtained through an Enforcement Request (ER). The procedures for making an ER are outlined in Section 3.2.4.

2.4.5 TSCA SECTION 8 TARGETING

As discussed previously, there is no single automated data system for tracking Section 8 submissions and targeting potential violations. However, IMD maintains several automated databases that may help in gathering information on potential targets.

- CUS. The Chemical Update System (CUS) contains all of the Inventory update information. EPA is currently updating CUS since the last IUR reporting period ended February 21, 1991 (extended from December 23, 1990). Inspectors can search this database, by facility, for IUR submitter information, such as the chemical names and CAS Registry Numbers reported. Searches should also reveal companies that submitted a late IUR form. Regions were provided information on submitters under the 1986 and 1990 IUR on diskette in April 1992.

- PAIR. The PAIR 8(a) Level A database houses all the data collected on PAIR-regulated chemicals. Inspectors can search this database for PAIR submitter information such as manufacturing location, company name, chemical name, and CAS Registry Number reported.

- CAIR. The CAIR database includes detailed production, raw materials, processing, use, environmental fate, worker exposure, environmental release, physical and chemical properties, and waste generation and handling data on listed chemicals.

- TSCATS. The TSCA Test Submissions (TSCATS) database lists all persons who have supplied EPA with copies of Section 8(d) studies. This database also includes a listing of all Section 8(e) reports to EPA.

Information in these data systems for specific facilities can be accessed through an Enforcement Request.

2.4.6 MULTI-MEDIA

The TSCA program can use information available through other EPA regulatory programs to identify potential violators. In addition, each EPA media program regularly collects information on these firms through investigative efforts and enforcement actions. EPA's Office of Enforcement has developed the Integrated Data Enforcement Analysis (IDEA system) for integrating and analyzing cross-program information from the many databases maintained by EPA for enforcement targeting, screening, and multi-media initiatives. The *User's Guide to the IDEA System*, dated August 2, 1991, from the Office of Enforcement, provides instruction on how to access the system through the EPA National Computer Center (NCC) IBM mainframe. Since the system allows the user to obtain enforcement-sensitive information, access is limited and special authorization is required. Even without this access, however, the *Guide* is valuable because it provides a list of the data elements available in the following databases:

- Aerometric Information Retrieval System (AIRS) Facility Subsystem (AFS)
- Comprehensive Environmental Response, Compensation, and Liability Information System (CERCLIS)
- Civil docket
- Facility Index System (FINDS)
- Federal Facility Index System (FFIS)
- Hazardous Waste Data Management System (HWDMS)
- Permit Compliance System (PCS)
- Resource Conservation and Recovery Information System (RCRIS)
- Toxic Release Inventory (TRI)
- National Compliance Database (NCDB).

Even without access to NCC, these databases may be accessed directly and locally in most cases by Regional personnel in the appropriate program office. The information in these media databases could be used directly for targeting or indirectly for ranking facilities within targeting categories. This process is discussed in more detail in Section 2.5.

2.4.7 NON-SUBMITTERS

Finding non-submitters is perhaps the most difficult task in targeting TSCA violations. This is because there are thousands of chemicals, manufacturers, processors, and importers of chemical substances. Many of the non-submitters are discovered through voluntary disclosure on the part of the company. However, most non-submitters probably go undetected. A variety of information sources are available that can assist in identifying potential non-submitters. The tools that can provide assistance include the following three computerized information sources:

- FACTS (Facility and Company Tracking System)
- FINDS (Facility Index System
- TRIS (Toxic Release Inventory System).

In addition, EPA's IDEA System provides access to FINDS and TRIS. These systems are described in detail in Section 3.2.3.1.

Directories and trade associations also can identify companies engaged in TSCA-related chemical manufacturing and/or importing. Sources include:

- Directory of Chemical Producers
- Chemical Week
- Chemical Marketing Reporter
- Chemical Week's Buyer's Guide
- American Importers Association Directory
- Registry of American Importers and Exporters.

These documents are available in many libraries. Information from other agencies includes the OSHA Industry List and U.S. Customs brokers licensed by geographic region of principal operation. Internally generated information may include tips and complaints from other offices within EPA and customer and supplier lists from previously-inspected TSCA facilities.

The following section describes how information developed from these various sources can be used to develop a master list of potential facilities to be inspected and how individual facilities can be selected (targeted) from the master list.

2.5 SETTING PRIORITIES AND SELECTING SPECIFIC TARGETS

This section revisits the main targeting steps outlined in the flowchart (Figure 2-1) and provides more detail on how to proceed from identification of facilities with potential violations to selection of specific facilities for investigation. A two-step framework is developed to serve as a model for prioritization and selection.

2.5.1 DEVELOPING A MASTER LIST

The procedures and criteria in Section 2.3 and the information sources in Section 2.4 should be used to identify all facilities that may warrant inspection. This may result in many dozens of potential inspectees, which form the master list. Because it is unlikely that thorough inspections can be conducted at each of these facilities in one fiscal year, it is necessary to select a subset of individual facilities, based on Regional priorities and resource constraints.

2.5.2 SETTING PRIORITIES AMONG TARGETING AREAS

Resources are a primary issue in determining which facilities to inspect. Staff availability, travel budgets, competing assignments, and reporting schedules have to be factored into the decision of how many facilities can be selected from the master list. Many of these decisions are normally made at the time that STARS commitments are made in late summer. However, it is useful to re-evaluate resources and staff availability at several points throughout the fiscal year.

The next step is to allocate the inspections across the areas of potential violation, discussed in Section 2.3. Priorities among program areas will be decided at the Regional level with guidance from Headquarters, based on the Memoranda of Agreement (MOA) process, and will vary over time and from Region to Region. Several issues should be considered when priorities are being set. One issue is the distinction between two types of priority-setting mechanisms, "targets" and "triggers." "Targets" are criteria or weights assigned to guide selection of facilities to achieve a balance of inspections among different types of potential violations. An example of a target in the form of a weighted allocation is "20 percent of inspections should be selected from non-submitters." In contrast, "triggers" are events or circumstances of sufficient concern that they warrant inspection, without regard to balance among other categories of activity. For example, a Region may decide to conduct inspections at all facilities for which a tip is received from Headquarters or all facilities subject to 5(e) orders. Targets can be used to set relative priorities among inspection categories. Triggers, on the other hand, force a response to particular events.

Each Region must consider the appropriate balance between targeting and triggering mechanisms, based on Regional concerns and resources.

Because inspections are the basis of enforcement and case development, the process used for selection of facilities necessarily influences the types and seriousness of violations found. Most Regions find two conflicting objectives in conducting inspections and issuing cases. On the one hand, there is the need to get as many cases issued as possible, to establish an enforcement presence, and to justify the program internally and externally. This creates an incentive to seek out simple, fast inspection targets (and cases) and do a lot of them. On the other hand, there is a need for big cases, with large penalties, national publicity, and deterrent effects. These are typically complex, resource-intensive efforts. This creates an incentive to seek out inspections (and cases) at large, complex facilities, perhaps with multiple plant sites nationwide. Each Region will have to consider these conflicting incentive structures and strike an appropriate balance when establishing a Regional targeting scheme.

Based on past experience and targeting documents, many Regions assign priority weights to different sections of TSCA or areas of violation. For example, in its FY 1991 NAIS, Region III decided to allocate 10 to 20 percent of inspections to follow up tips and complaints, 10 to 20 percent to previous year's leftovers, 5 to 10 percent to Section 5(e)/(f) orders and SNURs, and so on. In a similar scheme, Region V allocated 20 percent of inspections in FY 1991 to particular geographic areas of concern. Other Regions have experience with weighting based on coverage of past inspection activity. For example, 20 percent of inspections may be allocated to facilities that have not been inspected in the last 2 years. Similarly, to increase coverage, a Region may want to allocate some proportion of inspections to plants that were identified, but not inspected, in previous years.

These allocations will reflect Regional decisions and priorities. They may result in part from past experience, Headquarters guidance, and efforts to coordinate with other Regions or programs. The discussions of individual targeting mechanisms in Section 2.3 address the potential seriousness of violations in each category. This may provide some perspective that will assist the Regions in developing relative rankings for directing inspection efforts. Headquarters guidance in the "OPPTS Regional Priorities and Guidance for FY 1993 Memoranda of Agreement (MOAs)," dated June 24, 1992, states:

> ...resources are to be used for priority inspection targeting non-submitters of PMNs (including importers); parties to 5(e) risk-based orders; parties to SNURs; and holders of low-volume exemptions.

These objectives should be factored into Regional targeting decisions. HQ will provide the Regions with the 1993 MOA targeting priorities.

To assist Regional inspectors in targeting facilities, Figures 2-2 and 2-3 provide a framework for consolidating and tabulating the results of a targeting scheme. It is provided as an optional tool that may assist Regional personnel in evaluating alternative priorities or weighting systems. The worksheet is completed for fictional Region A to clarify its use.

At the top of the form is a space for recording the total number of inspections planned by the Region. This number results from internal resource decisions and commitments. This is the number of inspections that can be allocated across the various inspection categories and target areas.

The left column includes all the targeting criteria discussed in Section 2.3. Column A, "Number of Facilities Identified," can be completed by Regional personnel after reviewing the targeting printouts, working files, databases, and other information developed during identification of potential targets. This is a summary of the "master list" developed at the start of the targeting process (see Sections 2.3 and 2.5.1). Column B is used to record the weight assigned to each targeting criterion. For example, a Region may want to allocate 40 percent of inspections to non-submitters. Column C is the product of the number of planned inspections and the weight (percentage) assigned in Column B. Column C is the number of inspections to be conducted in each targeting area; it is the number of facilities to be selected randomly from the master list in each targeting area. This activity is discussed in the next section.

2.5.3 SELECTING SPECIFIC FACILITIES WITHIN TARGETING AREAS

Once priorities and budgets are set and the categories of inspections are determined, individual facilities must be selected from within each targeting area on the master list. This can be done randomly or on a prioritized basis. The objective of a NAIS is to ensure that there is a rational method of choosing individual plants, so there is a justification and so that the same facilities are not inspected every year. For random selection, one assigns a number to each facility in the category and uses a random number generator (available on most calculators or in tables at the back of statistics books) to select facilities until the Regional goal for inspections in that group is met.

For selection on a prioritized basis, Figures 2-4 and 2-5 provide another framework for selecting facilities from within groups. The approach is based on a simple scoring system. It is intended to offer a quick

FIGURE 2-2

SETTING PRIORITIES (WEIGHTS) AMONG PROGRAM AREAS

Example Worksheet 1

TOTAL NUMBER OF PLANNED INSPECTIONS ____

	A	B	C
Targeting Criterion	**# Facilities Identified on Master List**	**Targeting Weight Assigned**	**# Facilities to be Selected**
Non-Submitters			
5(e)/(f)			
SNUR			
PMN Withdrawn			
PMN Exemption			
PMN/*Bona Fide*			
IUR			
CAIR/PAIR			
Other Section 8			
Other			
Tips/Complaints			
Geographic			
Multimedia			
Chemical Risk			

Instructions:

1. *The number of planned inspections is based on Regional resources, decisions, and commitments.*
2. *Column A can be completed from the targeting printouts and working files used to identify potential facilities to be inspected.*
3. *Column B must be completed based on Regional priorities and concerns. It should include the weight (percentage) assigned to each targeting criterion.*
4. *Column C is completed by multiplying the weight (percentage) in Column B by the number of planned inspections found at the top of the page. Fractions should be rounded.*
5. *Column C is for the number of inspections to be selected randomly from each targeting criterion.*

FIGURE 2-3

TARGETING WORKSHEET 1

Example Worksheet 1

TOTAL NUMBER OF PLANNED INSPECTIONS	10

	A	B	C
Targeting Criterion	**# Facilities Identified on Master List**	**Targeting Weight Assigned**	**# Facilities to be Selected**
Non-Submitters	6	40%	4
5(e)/(f)	3	20%	2
SNUR	-		
PMN Withdrawn	3	10%	1
PMN Exemption	3	20%	2
PMN/*Bona Fide*	2	0%	
IUR	2	0%	
CAIR/PAIR	2	0%	
Other Section 8			
Other			
Tips/Complaints	1	10%	1
Geographic			
Multimedia			
Chemical Risk			

Instructions:

1. *The number of planned inspections is based on Regional resources, decisions, and commitments.*
2. *Column A can be completed from the targeting printouts and working files used to identify potential facilities to be inspected.*
3. *Column B must be completed based on Regional priorities and concerns. It should include the weight (percentage) assigned to each targeting criterion.*
4. *Column C is completed by multiplying the weight (percentage) in Column B by the number of planned inspections found at the top of the page. Fractions should be rounded.*
5. *Column C is for the number of inspections to be selected randomly from each targeting criterion.*

assessment of each facility based on different areas of concern that may apply. It is not intended to serve as a formal assessment of facilities' actions or violation potential. As in the previous worksheet, the first column includes all the targeting criteria discussed in Section 2.3. Using the master list, the facilities identified as potential targets are listed in the second column. Using information from printouts and files, the inspector can complete the shaded portion of the worksheet, based on which concerns are found, by checking each box that applies for a given facility. Although not comprehensive, the worksheet includes several categories of risk or concern that may indicate a higher priority for inspection. In the risk category, spaces are provided as follows:

- Geographic. Is the facility located in a geographic area of special concern?

- Toxicity/exposure/volume. Does the facility manufacture a chemical with a high degree of toxicity, potential for exposure, or large volume?

- Multi-media. Are there multi-media impacts or concerns about the facility from other program offices?

The area of concern about "coverage" is designed to address previous inspection activities or multiple submissions from a facility. Spaces are provided for recording the following issues:

- Never inspected. Was an inspection at the facility never conducted or conducted more than 2 years ago?

- Multiple submissions. Did the facility submit information under several provisions of TSCA, or was it identified under several targeting criteria?

- Previous target. Was the facility identified as a target in past years but not inspected because of resource constraints?

Space is also provided to record whether the facility was the subject of a tip or complaint from Headquarters or another Region. Finally, space is left for other issues identified by the Region, such as past violations, pending actions, etc. These could be identified from the IDEA system, as previously discussed.

The final column reflects the "score" assigned to the facility based on adding the checks from each of the areas of concern in the shaded section. The intent is that facilities with higher "scores" would be selected for inspection ahead of those with lower scores, until the Regional goal for inspections is achieved. Of course, more complex scoring systems could be applied to produce a finer level of assessment.

FIGURE 2-4

SELECTING FACILITIES WITHIN PROGRAM AREAS

Example Worksheet 2

Targeting Criterion	Facilities	Risk Concerns			Coverage Concerns			Reg/HQ Tip	Other Issues	Total "Score"
		Geog.	Tox/Exp/ Volume	Multi-Media	Never Insp.	Multi-Submit.	Previous Target			
Non-Submitters	1)									
	2)									
	3)									
	4)									
	5)									
	6)									
5(e)/(f)	1)									
	2)									
	3)									
SNUR	1)									
	2)									
	3)									
PMN Withdrawn	1)									
	2)									
	3)									
Bona Fide	1)									
	2)									
	3)									
IUR	1)									
	2)									
	3)									
CAIR and PAIR	1)									
	2)									
	3)									
Other	1)									
	2)									
	3)									

Instructions:

1. *Complete the first column using names or code numbers of facilities from targeting printouts and working files.*
2. *For each facility (potential target), review available information and check all applicable "concerns" listed in the shaded columns, or develop a score for each concern.*
3. *Total the checks (or scores) in the final column.*
4. *Choose high scoring facilities in each group for inspection until Regional goals/resources are met.*

FIGURE 2-5

TARGETING WORKSHEET 2

Example Worksheet 2

Targeting Criterion	Facilities	Risk Concerns			Coverage Concerns			Reg/HQ Tip	Other Issues	Total "Score"
		Geog.	Tox/Exp/ Volume	Multi-Media	Never Insp.	Multi-Submit.	Previous Target			
Non-Submitters	1) ABC Inc.				✓					1
	2) XXX Chemicals				✓					1
	3) Joe's Imports				✓					1
	4) Sam's Imports	✓			✓					2
	5) Mom's Chemicals	✓		✓	✓			✓		4
	6) GAC Inc.				✓					1
5(e)/(f)	1) Big Chemical		✓			✓		✓		3
	2) DEF Co.						✓			1
	3) GHI Imports									0
SNUR	1) N/A									
	2)									
	3)									
PMN Withdrawn	1) Shady Co.	✓	✓			✓				3
	2) XYZ Inc.		✓			✓				2
	3) Many Products		✓			✓				2
Bona Fide	1) XM Ports									0
	2) Shady Co.					See above				N/A
	3)									
IUR	1) JKL Inc.							✓		1
	2) MNO Inc.									0
	3)									
CAIR and PAIR	1) XYZ Inc.		✓			See above				N/A
	2) KEM Inc.		✓							1
	3)									
Other	1) PLAST Inc.	✓		✓				✓		3
	2)									
	3)									

Instructions:

1. *Complete the first column using names or code numbers of facilities from targeting printouts and working files.*
2. *For each facility (potential target), review available information and check all applicable "concerns" listed in the shaded columns, or develop a score for each concern.*
3. *Total the checks (or scores) in the final column.*
4. *Choose high scoring facilities in each group for inspection until Regional goals/resources are met.*

A partially completed model of Worksheet 2 is provided for review. The framework in Worksheet 2 can be applied independently or in conjunction with the framework developed in Worksheet 1 (which provides the number to pick in each category). Combinations of approaches can be used also.

After individual facilities are selected, the pre-inspection activities in the next chapter may commence. Also, secondary facility targets may be selected, based on proximity or other criteria.

Chapter Three

Pre-Inspection Activities: Preparation and Planning

Page

3.0 PRE-INSPECTION ACTIVITIES: PREPARATION AND PLANNING 3-1

3.1 INTRODUCTION 3-1

3.1.1 TARGET SHEET 3-2

3.2 REVIEWING EPA RECORDS 3-5

3.2.1 PURPOSE 3-5
3.2.2 TYPES OF INFORMATION TO REVIEW 3-6
3.2.3 INFORMATION SOURCES 3-9

3.2.3.1 EPA FILES AND DATABASES 3-9
3.2.3.2 EPA INFORMATION MANAGEMENT DIVISION DATABASES 3-10
3.2.3.3 COMMERCIAL DATABASES 3-13

3.2.4 INFORMATION REQUESTS FOR EPA HEADQUARTERS 3-13
3.2.5 CONFIDENTIAL BUSINESS INFORMATION CONSIDERATIONS 3-15

3.3 PROVIDING ADVANCE NOTIFICATION 3-17

3.3.1 IDENTIFICATION OF CONTACT PERSON TO NOTIFY 3-18
3.3.2 ITEMS ADDRESSED IN ADVANCE NOTIFICATION 3-19
3.3.3 FOLLOWUP LETTER 3-25

3.4 A WRITTEN INSPECTION PLAN 3-25

3.4.1 PURPOSE 3-25
3.4.2 ELEMENTS OF THE INSPECTION PLAN 3-28

3.5 GATHERING INSPECTION DOCUMENTS AND EQUIPMENT 3-30

3.5.1 TYPES OF DOCUMENTS 3-30
3.5.2 INSPECTION EQUIPMENT 3-32

LIST OF FIGURES

Page
FIGURE 3-1 SAMPLE TARGET SHEET 3-3
FIGURE 3-2 FACTS SAMPLE D&B DISPLAY 3-11
FIGURE 3-3 SAMPLE D&B REPORT 3-14
FIGURE 3-4 SAMPLE TSCA INVENTORY SEARCH FORM 3-16
FIGURE 3-5 SAMPLE LETTER OF NOTIFICATION 3-26
FIGURE 3-5 SAMPLE LETTER OF NOTIFICATION (Continued) 3-27
FIGURE 3-6 SAMPLE TRACKING SHEET 3-31

LIST OF TABLES

TABLE 3-1 TYPES OF EQUIPMENT 3-34

3.0 PRE-INSPECTION ACTIVITIES: PREPARATION AND PLANNING

3.1 INTRODUCTION

This chapter contains guidance on conducting pre-inspection activities pertaining to the Toxic Substances Control Act (TSCA). A good inspection begins with planning, which should commence well before the inspector visits the subject facility. Planning is the means by which the inspector identifies all the required activities to be completed during the inspection, from obtaining records before the inspection through writing reports and following up.

Planning includes conducting a thorough review, prior to the inspection, of the U.S. Environmental Protection Agency (EPA) records and data pertaining to the facility to be inspected (including data that may be obtained from the subject facility itself). This saves time in the long run because familiarity with the operations, history, and compliance status of the subject facility decreases the need for covering these areas during the limited time typically spent onsite. In addition, planning promotes a better relationship with the regulated community because the EPA inspector should be better able to answer questions concerning the application of TSCA requirements to a particular facility. It also enhances the facility's confidence in the EPA inspector and aids in establishing good relationships with facility representatives.

Another important benefit of planning is to enhance the inspector's ability to identify and document potential violations and thus provide more time to collect necessary data to assist Case Development Officers (CDOs) in their subsequent compliance and enforcement activities. Ultimately, planning an inspection may actually take more time than the inspection itself but will result in a more efficient and productive inspection overall.

The objectives of inspection planning are to:

- Understand the objectives of the inspection
- Understand TSCA and applicable regulations
- Be familiar with the compliance history and physical site layout of the particular facility to be inspected
- Be well-versed in the policies and procedures governing TSCA inspections

- Have the proper equipment and material for conducting the inspection ready to take to the inspection site (see Section 3.5.2)
- Be prepared to collect and record documents and samples taken from the facility
- Be familiar with the safety plan for protection from potential hazards on the facility site.

Once a facility has been selected for inspection (discussed in detail in Chapter 2) proper planning should ensure the following:

- A properly focused inspection
- A systematic framework for comparing a facility's operating practices against applicable TSCA regulations
- Use of the most efficient and effective approach for conducting the inspection, considering the available personnel and funding
- Clearly established task assignments in the field when more than one inspector will be onsite.

This chapter describes the planning process that should take place prior to any routine (e.g., nonemergency) TSCA inspection. (In an emergency situation, little or no time is available for planning. In such instances, the inspector should consult with her/his supervisor and/or the Region Counsel.) The basic elements of inspection planning are: reviewing EPA and other records and data concerning the subject facility (Section 3.2); providing advance notification of the inspection to the facility (Section 3.3); preparing a written inspection plan to be followed during the actual inspection (Section 3.4); and gathering inspection documents and equipment (Section 3.5).

3.1.1 TARGET SHEET

The target sheet is a one-page summary of EPA information on a particular Premanufacture Notification (PMN) or PMN exemption. If applicable, the inspector should use the target sheet to organize and summarize the available information on the PMN or PMN exemption. A sample target sheet is shown in Figure 3-1. Generally, one chemical substance is described on each target sheet. In some cases, however, a group of related chemicals can be included on the same sheet. There may be more than one target sheet for a given facility to be inspected if the inspection is to include an investigation into more than one PMN or PMN exemption. A target sheet should be prepared if a chemical substance manufactured by the subject facility is subject to a Significant New Use Rule (SNUR).

FIGURE 3-1

SAMPLE TARGET SHEET

Place all CBI information in brackets.		
Region(s)	TME #	PMN #
Parent Company: Address: Technical Contact:		Phone:
Industrial Site(s):		
Chemical Name: Generic: Specific: Trade:		
Use:		
Restrictions (if TMEs)/Special Concerns:		
Supplementary Information:		
Notice Manager:		
Indicates company location which submitted PMN or applied for PMN exemption.		

The target sheet should include the following information:

- PMN or PMN exemption number.

- Disposition of the PMN or PMN exemption and the relevant date.

  - The reason for the inspection is stated on the disposition line of the form. For example, PMN is withdrawn, suspended, or denied; Test Marketing Exemption (TME) is denied or granted with restrictions; Low Volume Exemption (LVE) is denied or granted with restrictions; facility to be inspected is the subject of a Section 5(e)/5(f) order, rule, or injunction; or chemicals manufactured by the facility are candidates for a SNUR.

  - To date, facilities have not been targeted for inspection solely on the basis of chemicals being SNUR candidates. However, if a facility is targeted for inspection for another reason (e.g, PMN withdrawn), the inspector should examine records kept by the facility on chemicals subject to SNURs to determine if the company is manufacturing the subject chemicals in the manner described in the PMN or Section 5(e)/5(f) order. Generally, a chemical substance becomes a SNUR candidate if EPA believes that a new use, a different manufacturing process, or increased production will increase worker exposure or environmental release to the extent that there will be concern. Therefore, EPA wants to be informed if the substance is being manufactured in volumes much greater than that outlined in the PMN or PMN exemption.

- Information on the parent company, including name, address, technical contact and telephone number, and the industrial site(s).

  - The parent company and the industrial site(s) can be found on the facility's PMN or PMN exemption submittal. If the facility is small, there will generally be only one business address. Sometimes, the facility specifically identifies one manufacturing plant at which they will make a chemical substance (or substances); at other times, the facility will list several possible manufacturing sites.

  - The technical contact is the facility representative who will be contacted concerning the inspection process and the appropriate site for the inspection. The technical contact often can help the Region determine the proper location of the inspection, which is generally based on the reason for the inspection. For example, in situations involving TMEs granted with restrictions, or Section 5(e) or (f) orders, rules, or injunctions, where manufacturing is permitted but limited, the inspection should be conducted at the plant site where the manufacturing takes place. For cases concerning withdrawn or incomplete PMNs, withdrawn or denied TMEs, or Section 5(e) or 5(f) orders where manufacturing is completely banned, the preferable inspection site may be the site where the commercial development and marketing files are located. This is because manufacturing for commercial purposes is not allowed under any circumstances, so inspecting the manufacturing site may only be advisable after a review of these files to ascertain whether the prohibited activity is occurring. In some cases, it may be appropriate or necessary to inspect both facility locations (e.g., facility headquarters where the research or marketing

files may be located and the manufacturing site). Section 6.1.2 of this manual describes the various sites that the inspector should consider when scheduling the inspection.

- Chemical name: generic, specific, and trade.
- Use (of the chemical substance).
- Restrictions or special concerns [for TMEs, LVEs, Polymer Exemption (PEs), etc.]
- Supplementary information, including a listing of information in the package other than the target sheet.
- Office of Pollution Prevention and Toxics (OPPT) Notice Manager and phone number, which can be found in MITS. The OPPT Notice Manager is the EPA Headquarters person most knowledgeable about the PMN or PMN exemption at issue. The Notice Manager should be contacted if the inspector has questions about the facility or the chemical substance that is the subject of the target sheet.

3.2 REVIEWING EPA RECORDS

A thorough review of EPA records for the facility to be inspected is a critical component of pre-inspection preparation. This section focuses on the review of EPA written records and databases, which together will supply the inspector with crucial background information pertaining to the facility to be inspected. However, the inspector should also supplement record review activities by interviewing appropriate EPA personnel who may have additional information or knowledge of the subject facility. The appropriate persons to interview will be based on the inspector's need for clarifying issues or data discovered during the record review process and on the need for additional information. When reviewing the available information on a facility, the inspector should identify and focus on the information most relevant to the purpose of the inspection.

Section 3.2 discusses the purpose of pre-inspection records review; types of information to be reviewed; sources of information; procedures for requesting information from EPA Headquarters; and CBI considerations for the records review process.

3.2.1 PURPOSE

Proper review of EPA records prior to the inspection of a subject facility is essential to the overall success of compliance inspection efforts. By taking this important preparatory step, the inspector can

obtain crucial information on the facility to be inspected, including data on the specific regulatory requirements that apply to the facility as well as site-specific background information on compliance history and facility operations. The information obtained from such reviews (and supplemented by interviews with knowledgeable EPA personnel) help the inspector to develop the written inspection plan (Section 3.4) and gather inspection documents and equipment (Section 3.5). In addition, facility representatives may be more responsive to an inspector who has a thorough understanding of the facility operations and structure.

In general, the objectives of the records review include the following:

- Become familiar with facility size, operations, physical layout
- Learn about facility compliance history
- Discover inadequacies and inconsistencies in the information on the subject facility that the inspector may want to clarify during the inspection
- Minimize inconvenience to facility personnel by not having to ask for basic facility-specific information that may already be in EPA records and avoid having to spend on site time doing so
- Clarify technical and legal issues before conducting the inspection
- Develop a useful and comprehensive written inspection plan that focuses on the issues for the facility
- Make more efficient use of EPA personnel and funding by saving time once at the inspection site.

3.2.2 TYPES OF INFORMATION TO REVIEW

There are several types of information, described below as separate information categories, that may be obtained by reviewing EPA records (i.e., databases and written files). The specific databases that should be searched to obtain this information and the procedures for requesting the search(es) to be done by EPA Headquarters are described in Sections 3.2.3 and 3.2.4.

Several examples of the types of information the inspector should search for during the record review process are described in the following list. Obtaining all this information may not be possible; however,

because of its value to the inspection process, the inspector should expend significant efforts to obtain these and other types of information on the facility.

- General facility information. Some of the general information on a facility that the inspector should look for during the records review process includes:

  - Maps and/or aerial photographs the showing location of the facility and its relationship to the surrounding area
  - Names, titles, and telephone numbers of facility officials and/or representatives
  - Organizational structure
  - Special facility entry requirements (see Section 4.4.1 on entry of facilities)
  - Past and present (and possibly future) operations and production levels
  - Safety equipment and health and safety training requirements
  - Water, air, and waste treatment and pollution control equipment
  - Descriptions of the facility's (and/or the company's or parent company's) recordkeeping and filing systems
  - Physical layout of facility
  - Size of facility.

  These types of information are particularly useful in assisting the inspector to plan the details of the inspection and allocate time and resources, as well as prepare necessary documents and equipment. For example, information on personnel and organizational structure can help the inspector determine who should be interviewed during the inspection or at the start of the inspection. Data on facility-specific entry requirements may help the inspector determine whether it is necessary to obtain a warrant. Information not available from EPA Headquarters or from Region TSCA files may be available from other program offices in the Region. Water, air, and waste permit applications and inspection reports, for example, could have any or all of this information on a facility.

- Previous inspection and enforcement information. By reviewing EPA inspection records from previous inspections conducted at the particular facility, the inspector may obtain the following:

  - Compliance history, including reports, followup studies, findings, and remedial action
  - Specific details on past or present noncompliance
  - Previous enforcement actions
  - Pending enforcement actions and compliance schedules.

The inspector should be especially attentive to repeated compliance problems and pending enforcement actions and compliance schedules. When these have occurred, verification of current compliance in those particular areas will probably become the major objective of the inspection.

TSCA inspectors should also review inspection records, compliance histories, and enforcement actions under other programs, including the water, air, and hazardous waste programs. This information can also be critical in planning an inspection and understanding the facility.

- Special exemptions from TSCA requirements. The inspector should ascertain whether EPA has granted any PMN exemptions to the particular facility to be inspected (e.g., test marketing exemption). The inspector must also determine whether any additional requirements may have been placed on the facility as a condition of granting the exemption.

- Reports prepared by the facility that were obtained during previous inspections. The inspector should review any reports prepared by the facility (e.g., self-monitoring reports) that may be found in EPA files. The inspector may review these reports to determine whether there are any discrepancies between the self-monitoring records and the EPA records. The inspector may want to further investigate any discrepancies, either by requesting clarification from the facility during the advance notification (see Section 3.3) or during the inspection. Therefore, the inspector should make note of these discrepancies, as well as the proposed method for addressing them, in the written inspection plan (see Section 3.4).

- Permits and permit applications. The inspector should review any facility operating permits or permit applications. Such documents may provide information on limitations and requirements applicable to discharges, emissions, and operations; compliance schedules; and monitoring, analytical, and reporting requirements. While the inspector is concerned only with documenting potential TSCA violations, EPA is interested in encouraging comprehensive environmental compliance inspections focusing on compliance with more than one EPA-administered law [e.g., a combined TSCA and Emergency Planning and Community Right to Know (EPCRA) inspection] would make it beneficial to review such permits for indications of potential violations of other EPA statutes.

  As noted above, all programs, permits, and applications can also be useful for providing background information. In addition, monitoring and spill data could alert an inspector to the presence of an unexpected chemical of concern, while EPA staff in other programs who are knowledgeable about the facility may be able to provide insight into facility operations.

- Correspondence. Correspondence between the facility and EPA (or the State) may provide important information to the inspector concerning manufacturing, processing, importation, or other activities that are regulated under TSCA, as well as information on compliance issues. In addition, EPA's response to correspondence from the facility can affect the requirements that are applicable to the facility. Once again, the inspector should review TSCA-related correspondence but may review EPA correspondence related to other program areas, such as air, water, and the Resource Conservation and Recovery Act (RCRA).

- Laws and regulations. Although it seems obvious, its importance bears emphasis: the inspector should review and identify the TSCA regulations that apply to the facility to be inspected. Therefore, the inspector should undertake a general review of TSCA regulations prior to the inspection, giving special attention to the specific regulatory provisions that apply to the facility. For example, as the inspector obtains information on the subject facility suggesting that a TME exists, the inspector should review the TME provisions of the regulation. The inspector also should always take copies of the act and the appropriate *Code of Federal Regulations* to the inspection site for reference purposes.

- Technical reports. The inspector should review and, if necessary, take to the inspection site copies of EPA or other publications that provide generic information on industrial process operations. As noted elsewhere, the inspector's knowledge of the processes and associated control equipment at a facility can be instrumental in ensuring the success of an inspection. A list of technical references is provided in Appendix 3.

The inspector must keep in mind when reviewing documents that some of the information may be misleading or nonapplicable. For example, PMNs are generally submitted by corporate headquarters, but chemicals are manufactured at a different site (i.e., production site). Thus, the corporate headquarters site may not be the appropriate site to inspect.

3.2.3 INFORMATION SOURCES

The potential sources of information pertaining to a facility to be inspected will be the same from inspection to inspection (i.e., EPA databases and written EPA files). Actual sources of useful information, on the other hand, will vary from site to site. This makes the inspector's search of EPA files for appropriate data, both hardcopy as well as information contained in EPA databases, of particular importance. The database search(es) often serve as the major source of TSCA-specific information for an inspector. In some cases, however, other sources (e.g., other program offices, files, and staff) can be of equal or greater importance and nearly always can provide valuable supplemental information. Major databases are described below, as well as the types of data that may be found in each database.

3.2.3.1 EPA FILES AND DATABASES

The inspector should search the Regional files for any information relating to the facility to be inspected. Some Regions may have a filing system or database from which the inspector can get information on the subject facility obtained through compliance monitoring activities of other Regional programs [e.g., National Pollutant Discharge Elimination System (NPDES) permitting, RCRA]. In addition, the Federal

Insecticide and Fungicide and Rodenticide Act (FIFRA) and TSCA Tracking System (FTTS) should be searched to determine if the company has been inspected previously.

The inspector should also check other EPA databases for information on the facility to be inspected. The following list highlights available EPA databases that can contain information relevant to the inspection:

- IDEA (Integrated Data for Enforcement Analysis) System. This is a new database developed by the Office of Enforcement to integrate information from various databases maintained by different program offices for enforcement targeting, case screening, and multi-media initiatives. A *User's Guide to the IDEA System*, dated August 2, 1991, provides instructions on how to access the system through the EPA National Computer Center IBM mainframe.

- FACTS (Facility and Company Tracking System). This database provides detailed information on names, addresses, employment, sales, and Standard Industrial Classification (SIC) codes. Facilities with SIC Codes 28xx and 2911 or that are within a particular geographic area can be specified. The database is available through on-line connection to the EPA National Computer Center. A sample FACTS display is shown in Figure 3-2.

- FINDS (Facility Index System). This database is designed to track facilities subject to various Federal environmental laws, including the Resource Conservation and Recovery Act (RCRA), the National Pollutant Discharge Elimination System (NPDES), and Clean Air Act (CAA). The purpose of this database is to cross-check for cross-media analysis. It is available through on-line access to the EPA National Computer Center.

- TRIS (Toxic Release Inventory System). This database contains information on facilities subject to Emergency Planning and Community Right-to-Know Act (EPCRA), Section 313 reporting. Facilities subject to reporting meet the following criteria: (1) they manufactured, imported, or processed more than 25,000 pounds of any of the listed chemical substances for required Toxic Release Inventory (TRI) reporting or they used in any other way 10,000 pounds or more of a TRI chemical, (2) they conducted general manufacturing activities (classified within SIC Codes 20-39, and (3) they employed the equivalent of 10 or more full-time employees. The TRIS database contains information on the facility, identification of the toxic chemical, the amount of chemical released, and the media to which it was released. Information on accessing this database can be obtained from the EPCRA Section 313 Regional contact or by contacting TRI User Support at 202-260-9419.

3.2.3.2 EPA INFORMATION MANAGEMENT DIVISION DATABASES

The following list contains a summary of the Confidential Business Information (CBI) computer databases with TSCA information. The Information Management Division (IMD) maintains these databases. As part of inspection targeting, OCM will request summaries of selected information from these databases which will then be supplied to the Regions (discussed in Section 2.4). EPA Regions will have the ability

FIGURE 3-2

FACTS SAMPLE D&B DISPLAY

```
 NATP              U.S. ENVIRONMENTAL PROTECTION AGENCY              06/12/92
 FACTS             FACILITY AND COMPANY TRACKING SYSTEM              05:52:47
 FAQD04P3               DUN & BRADSTREET DISPLAY                     FAQD04M3
--------------------------------------------------------------------------------
FACILITY NAME:      ICI AMERICAS INC                    DUNS-NO:      054718580
SECOND NAME:        STUART PHARMACEUTICALS DIV
FACILITY ADDRESS:   NEW MRPHY RD/CONCORD PIKE           PHONE:     302-886-3000
                    WILMINGTON              DE  19897
MAILING ADDRESS:

COUNTY NAME:        NEW CASTLE                          MSA:              9160
PARENT/SUBS:        P/S NO OF SUBS:  3    HQ/BR:    H   NO OF BR:          110
PARENT/HQ COMP:     ICI AMERICNA HOLDINGS                               057146011
ULTIMATE  COMP:     ICI AMERICNA HOLDINGS                               057146011
LINE OF BZNESS:     MFG PESTICIDES       YEAR STARTED:  1971  MANUFACTURING:   N
SIC CODES:          2879   2861    2834    3672
CEO NAME/TITLE:     B LOCHTENBERG/CHAIRMAN OF THE BOARD
EMPLOYEES HERE:     3000 ACTUAL              TOTAL EMP:  12000 ACTUAL
TOTAL SALES:        3264037000 ACTUAL
          LIST SUBS/BRANCHES (Y):            LIST PARENT/HQ (Y):
--------------------------------------------------------------------------------
   PF1/13 = HELP            PF3/15 = PREV              PF4/16 = MAIN
Esc for ATtention, Home to SWitch    |      Capture Off        |  Application
```

to get information directly from some of the IMD databases (e.g., CICIS, CCID, and CUS) as they get on-line access.

- Chemical Directory (ChemD). Using Molecular Access System (MACCS) software, the Confidential Data Branch maintains structural data on Section 5 Inventory chemicals. This system is linked to the various CBI systems.

- Chemicals in Commerce Information System (CICIS). This system is the TSCA Section 5 Inventory, comprising data on the chemicals being produced when TSCA was enacted and reported initially in 1978 and 1979, plus those chemicals added by Notice of Commencement after EPA review of PMNs. The CBI version adds those CBI chemicals for which CAS Registry Numbers have been assigned. In addition, the CBI version contains all submitter and production data received in the Initial Inventory reporting period, as well as via the PMN process. The CICIS report allows quick accounting for many of a company's chemicals when checking their general production inventory.

- Confidential Chemicals Identification (CCID). This database contains nomenclature and related information for Inventory chemicals reported in the beginning and added via Notice of Commencement, where chemical identity was claimed confidential. Many of the entries are not CAS-registered.

- Chemical Update System (CUS). This system includes data submitted to EPA under the Inventory Update Rule every 4 years. These data relate to organic chemicals on the Inventory, excluding polymers, and include producer/importer and production volume data. This system, used with CBI CICIS, provides current information on chemical production.

- Comprehensive Assessment Information Rule (CAIR) System. This includes detailed production, raw materials, processing, use, environmental fate, worker exposure, environmental release, physical/chemical properties, and waste generation and handling data on Section 8(a) listed chemicals (see Chapter 7). Companies required to report also submit considerable economic and financial data, which are housed in the system.

- Document and Personnel Security System (DAPSS). This system serves two purposes: it catalogues documents submitted to and developed by EPA that contain CBI, and it lists EPA staff cleared for access to TSCA CBI and the dates on which their clearances expire.

- Confidential Business Information Tracking System (CBITS). This local area network based personnel security and document tracking system contains data similar to that contained in DAPSS and tracks documents received since October 15, 1990.

- PENTA (Section 5). This system contains only CBI pertaining to PMNs and Exemption Applications, together with review analyses of the data. Certain common fields are loaded from Management Information Tracking System (MITS); most other data are available only in the PENTA.

- MITS. This system tracks new chemicals and contains non-CBI versions of information from PENTA.

- 8(a) Level A Preliminary Assessment Information Rule (PAIR) System. This system contains data collected under Section 8(a) of TSCA on chemicals identified periodically by the Interagency Testing Committee (also see Chapter 7).

3.2.3.3 COMMERCIAL DATABASES

In addition to reviewing information contained in the above databases for information pertaining to a particular facility or chemical manufactured by a facility, the inspector should search the Dun & Bradstreet (D&B) Report or other commercial data systems to obtain additional information, such as the type of business and the size. (A sample D&B report is shown in Figure 3-3).

This report exists in several versions, including the Site Report. This report is usually adequate for most TSCA inspection purposes and is generally current. Therefore, an available printout is a good indication that the company is in business and that the plant site is active. The report will include the name and telephone number of a manager or other senior level official. The inspector may obtain information from D&B by contacting the Information Services Branch of the National Enforcement Investigations Center (NEIC).

3.2.4 INFORMATION REQUESTS FOR EPA HEADQUARTERS[1]

The inspector will need to request information pertaining to TSCA Sections 5 and 8 (and to a particular facility's compliance status under these sections) from EPA Headquarters prior to (and possibly after) a TSCA inspection. The inspector requests such data by submitting a TSCA Enforcement Request (ER) to OCM. Regions may request the following types of information, among others, by submitting an ER to OCM:

- TSCA Inventory status
- PMN and PMN exemptions
- Section 8 reports
- Technical assistance and opinions
- Company specific information/pre-inspection data.

[1] The procedures described in this section reflect current policy. However, the policy is being reconsidered in light of OPPT reorganization. Therefore, the inspector should first contact the OCM ER coordinator regarding the ER policy.

FIGURE 3-3

SAMPLE D&B REPORT

DUNS: 08-212-4637 DFA of California (Inc.)	Date Printed:	Rating: Branch
Box 86 Fresno, CA 93707 1855 S Van Ness Fresno, CA 93721	Agricultural Laboratory SIC No. 73 99 Telephone: (209) 233-7249	Employs 10

Branch Manager: H. Riedle

Amounts may be rounded to nearest figure in prescribed ranges.

Payments Reported	Paying Record	High Credit	Now Owes	Past Due	Selling Terms	Last With
10/87	(001)	2,500	2,500			1 mo.
06/87	Ppt-Slow 15	2,500	2,500	1,000	N30	1 mo.
10/86	Disc	50	-0-	-0-		2-3 mo.

This is a branch: headquarters are located at 303 Brokaw Road, Santa Clara, CA. Headquarters D-U-N-S 07-631-5126. The manager has authority to make purchases of supplies. Bills are paid generally from headquarters. This branch operates as the Fresno district of and laboratory for dried fruit and tree nuts.

Facilities:

Rents 6,000 sq. ft. in one story brick building, normal condition. Premises neat.

Location:

Industrial section on well traveled street.
11-06 (9A0 /158) 052 160

Full Display Complete

The inspector should note that requests for certified statements or documents involving Sections 4, 6, or 12 should be sent to OCM. Inspectors are advised that multiple requests should not be made. (A sample ER form for requesting a search of the TSCA Inventory is shown in Figure 3-4.) A policy memo entitled Guidance for Requesting TSCA Section 5 and 8 Enforcement Requests, dated March 12, 1992, is contained in Appendix 2. This package contains the procedures for submitting requests for information from IMD as well as sample forms that should be used. All enforcement requests are generally processed in approximately four weeks. Therefore, there may be situations where documents that should be reviewed prior to the inspection cannot be delivered to Regions prior to the scheduled inspection time. In such instances, the inspector should ensure that copies of such documents are made available by the facility for review onsite. In an emergency situation, the turn-around time can be expedited, but the Region submitting the request should provide a detailed explanation of the emergency situation.

In addition, the inspector may request IMD to provide a certified statement, certifying any number of TSCA-related facts. Examples of such certifications include the following:

- A particular chemical was added on a specified date to the TSCA Inventory.
- A chemical was submitted for review and reviewed under the premanufacture notification (PMN) provisions of TSCA.
- A chemical was not submitted for PMN review and was not added to the Inventory.
- A chemical has completed EPA's Low Volume Exemption Application review process.
- The date of submission of TSCA §8(a) required (e.g., PAIR Form) report.

3.2.5 CONFIDENTIAL BUSINESS INFORMATION CONSIDERATIONS

Section 14 of TSCA and EPA regulations (40 CFR Part 2) protect CBI from disclosure. CBI includes trade secrets (including process, formulation, or production data), the uncontrolled disclosure of which could cause damage to a facility's competitive position. In general, disclosure of CBI is prohibited; however, there are certain specific and limited exceptions (see 40 CFR Part 2).

The inspector should keep in mind that information obtained from a facility during a TSCA inspection can, for the most part, be disclosed in response to a request from the general public, or other requesting

FIGURE 3-4

SAMPLE TSCA INVENTORY SEARCH FORM

SEARCH OF COMPLETE TSCA INVENTORY
EPA - REGION ____

OCM Received __/__/__
ER No.

Priority _____ Date _____

Inspector _____

Phone Number _____

Certified Statement ☐YES ☐NO CAS No _____

SPECIAL NOTE FOR DYES: At a minimum, you must provide a valid chemical name (not trade name) and/or chemical structure.

☐ **Substance is not a Color Index name**

☐ **Substance is not hydrate**

CHEMICAL NAME

_____
_____
_____

STRUCTURE

MOLECULAR FORMULA

USE

COMPANY NAME

INVENTORY REFERENCE
(Inventory Form No.)

IMD RESPONSE SECTION

Search completed on _____
Date placed on inventory _____
PMN # (If applicable) _____

☐**Not on inventory**
☐**Invalid CAS number**
☐**Valid CAS number is not equivalent to submitted chemical name**

party, under the Freedom of Information Act (FOIA). However, if the data have been properly claimed as CBI, they may not generally be disclosed under FOIA.

An inspector must present notice to facility representatives of their right to claim data at the facility as CBI (see Section 4.7.4) and such claims are frequently made. Because the inspector is very likely to require access to CBI before (i.e., while preparing for an inspection), during, and after an inspection, the inspector must be knowledgeable of EPA procedures governing access to, handling of, and disclosure of CBI. The inspector and others who may use the information must have TSCA-CBI access authorization, since only authorized individuals may have access to CBI. An inspector may need access to CBI data that a subject facility submitted to EPA or provides during the inspection as well as information that was collected during a prior inspection. (See Appendix 4, for information on handling CBI under TSCA.)

A CBI-cleared inspector may obtain access to CBI documents at EPA by requesting access to the information from the TSCA Document Control Officer (DCO). The TSCA DCO is responsible for the following:

- Verifying that the requesting inspector is on the authorized CBI access list
- Providing a copy of the CBI document to the inspector
- Determining whether the inspector has secure storage approved by EPA, if the CBI is to be kept by the inspector for more than a day.

It is very likely that most data obtained from EPA Headquarters is CBI. In order to facilitate the transfer of CBI information to the Regions for use in conducting inspections under TSCA, EPA established a policy authorizing telephone discussion of CBI information obtained by EPA under Section 5 including the provisions on PMNs and TMEs. Basically, communication by telephone can include CBI when the contact is from Region to Region, Region to specified Headquarters offices, Headquarters to Region, or Headquarters/Region to subject facility. (See Appendix 4 for specific details on the handling of CBI.)

3.3 PROVIDING ADVANCE NOTIFICATION

EPA is not required by law to provide advance notice of inspection. However, an inspector may opt to provide such notification, based on the circumstances of the particular inspection and facility. In such

instances, a facility may be notified in writing and/or by telephone that an inspection under TSCA will take place. It is up to the discretion of the inspector and the Regional office to decide whether or not to provide advance notification.

Because of the highly technical nature of these inspections, the sensitivity of the information involved, and the need to ensure that appropriate personnel and records are available for inspection, the company, in most cases, is notified in advance that an inspection is planned. (For inspections involving certain well-documented complaints or tips, prior notification to the company may not be desirable. Headquarters will notify the Region if this is the case.)

The potential advantages and disadvantages associated with providing advance notification are as follows:

- Potential advantages
  - The facility will have the necessary documents, records, or personnel accessible to the inspector, saving valuable time on site and requiring less time during followup stages of the inspection.
  - The subject facility appreciates being provided advance notification so that its regular operations are not interrupted, thereby fostering a cooperative relationship between EPA and the regulated industry.
- Potential disadvantages
  - The inspector may not have the opportunity to view the subject facility under normal operating conditions, because the facility, with advance notification, could tailor its operations to fit preconceived notions of what the inspector may want to see.
  - At a facility suspected of violating TSCA requirement(s), the company officials might be encouraged to alter or destroy evidence confirming the violation(s).

3.3.1 IDENTIFICATION OF CONTACT PERSON TO NOTIFY

If the decision is made to provide advance notification, the inspector must determine which individual at a particular facility is the appropriate one to arrange the inspection. This determination can be difficult. The technical contact identified on the target sheet may be the initial contact. However, another senior-level person, such as Plant Manager, Regulatory Affairs Manager, Environmental Affairs Officer, Laboratory Director or other official of equivalent rank, may serve as the contact for arranging

and coordinating the inspection. The inspector may want to review the PMN, TME, PAIR submittal, or other available documents submitted to EPA to obtain names of contact persons. The D&B report can also be used, which usually provides the name and telephone number of the senior person in charge of a listed facility. If the inspector is unable to obtain names through these methods, s/he should call the company's general number and ask to speak to the person in charge of environmental or regulatory affairs, or if there is no such person, possibly the health or safety officer or laboratory director.

3.3.2 ITEMS ADDRESSED IN ADVANCE NOTIFICATION

If advance notification is provided, the inspector should make note of this in the inspection report (discussed in Chapter 10). Specific objectives of advance notification include the following:

- Scheduling the inspection.
- Determining the appropriate site(s) for the inspection, including identification of where the necessary records, as specified in the inspection plan, are located. Records the inspector needs to review should be described as specifically as possible.
- Ensuring that personnel are available to accompany EPA inspectors during the inspection.
- Ensuring that someone onsite will be able to make claims of TSCA CBI.
- Encouraging the facility to transfer all records to the plant site before the inspection.

If the facility representative contacted does not cooperate, the inspector's supervisor and the Compliance Branch Coordinator at EPA Headquarters should be consulted for instructions on how to proceed.

When providing advance notification by telephone to the appropriate contact person at the facility (i.e., the technical contact or other individual), the inspector should discuss the following items:

- Introduction. The inspector should begin the telephone contact by introducing herself/himself as an EPA inspector or other person with the authority to conduct TSCA Section 5 and 8 inspections. The inspector should discuss the nature and purpose of the inspection. If the inspection is routine, as opposed to "for cause" (i.e., based on a tip or complaint), this fact should be conveyed. If the inspection is being conducted "for cause," the inspector should obtain guidance from her/his supervisor and/or Regional Counsel as to the nature and amount of information that should be conveyed during the initial telephone conversation.

- Administrative details of the inspection. The inspector should discuss several administrative matters pertaining to the inspection. Specifically, the inspector should establish the following:

  - The location of and directions to the inspection site
  - The date and time of the intended inspection
  - The name and title of the facility employee or official who will serve as the designated contact person for the inspection, if such person will be different from the one contacted during this advance telephone notification
  - The fact that the facility should have certain records and other data available for review during the inspection and that certain facility personnel should be available during the inspection for interviews
  - The need to tour the manufacturing and other operational areas of the facility
  - The types of safety equipment that may be needed to tour the facility
  - The company's right to claim TSCA CBI for any information collected at the facility (see Section 4.7.4, for discussion of CBI)
  - A followup letter that will be sent which includes: the purpose and scope of the inspection, the records that the facility should make available for review by the inspector during the inspection (discussed below), information on the right of the facility to claim data as CBI under TSCA, and the name of an EPA contact.

- Specific records to be made available. The inspector should inquire as to whether the company has submitted to EPA any of the following records (in addition to those of which the inspector is already aware):

  - Premanufacture notifications, bona fide inquiries, or any PMN exemption applications
  - Section 8(a) Level A PAIR or CAIR reports, Section 8(c) allegation records, Section 8(d) reports or lists, or Section 8(e) substantial risk reports (see Chapter 7)
  - Section 12(b) notifications
  - Clarifying information that the inspector may want to discuss based on any discrepancies or uncertainties discovered during the review of EPA records on the facility.

In addition, the inspector should establish if any Section 5(e)/5(f) orders, consent decrees, injunctions or SNURs are in effect and their status (i.e., whether the subject chemicals are in production or not). The inspector should also determine whether the facility has an active Section 8(c) file of health and environmental allegations and whether the facility has Section 8(c) and/or 8(e) policy and procedures on

file at the site or elsewhere. The inspector should inquire as to whether the facility has any other TSCA-related policies, procedures, and/or submittals on file that may be reviewed during the inspection. The inspector also should obtain information concerning the status of the facility's current research and development activities at the site and whether the development of new chemicals is involved.

If the answer is "yes" to any of the above inquiries, or the inspector already has information indicating that the answer is "yes," the inspector should request that the facility contact make any or all of the records and/or reports detailed below available for examination during the inspection (even if the inspector already has some of the copies, since s/he should verify EPA's records). Since the following records and other data are so numerous, the inspector may want to simply inform the facility contact of the general topic headings of the records/data listed below and send the details in the followup letter prior to the inspection. The inspector should request the facility contact to make available the following records and data, among others, during the inspection:

- General information on facility
  - Facility's current annual report.
  - Facility's organizational chart.
  - Facility's recordkeeping procedures and policies for keeping production, sales, and inventory records/reports.
  - Facility's written policy on classification of R&D, test marketing, and commercial chemicals/products.
- General inventory
  - A listing of all manufactured or imported chemicals produced during the most recent 12 months, as well as raw materials and isolated intermediates should be requested. The listing should give CAS number, chemical name, and trade name for each chemical. (This list can be requested by the inspector only to assist in completion of the inspection in a timely manner. There is no regulatory requirement that it be prepared or maintained by the company. The inspector should indicate to the facility the reason for the request and advise that it is voluntary.)
- PMN
  - Copy of complete PMN submittal(s), including all attachments.
  - EPA's acknowledgment of receipt.

- Copies of all correspondence relating to PMN(s).
- Copies of all bona fide inquiries related to PMNs.
- Copies of Notices of Commencement, if submitted.
- Import and shipping records.
- Invoices and sales records.
- Inventory records.

- Research and Development (R&D) Exemption
  - Records of production, notification, and disposition for any R&D exempt batches of the PMN substance(s) that were produced or imported.

- TME
  - Copy of TME application(s), a copy of the *Federal Register* notice (if not already available), and copies of any correspondence with EPA regarding review and/or approval of the application.
  - All records of production, import, or distribution of the TME chemical.
  - Copies of any *bona fide* inquiries related to the subject TME.
  - Records of production, import, notification, and disposition for any claimed R&D exempt batches of the TME substance that were produced or imported.

- LVE
  - Copy of the LVE application.
  - Copy of the LVE *Federal Register* notice (if not already available).
  - Copies of correspondence with EPA regarding the exemption, including a copy of the bona fide inquiry, if applicable.
  - All production and other records for the LVE material, including records related to customer notification.
  - All batch, customer, sales, and disposition records for any of the LVE chemical produced or imported.
  - Internal corporate correspondence regarding the development and production (or importation) of the LVE chemical.

- Instant Film Chemical Exemption (IFCE)
  - Copy of the IFCE application.
  - Copy of the IFCE *Federal Register* notice (if not already available).
  - Copies of correspondence with the EPA regarding the exemption.
  - Internal corporate correspondence and memos regarding the development and production or importation of the IFCE chemical.
  - All production, importation, training, and treatment records for the IFCE chemical.
  - All batch, customer, sales, inventory, and other disposition records for all of the IFCE material.
- PE
  - Copy of the PE application.
  - Copy of the PE *Federal Register* notice (if not already available).
  - Copies of any correspondence with EPA regarding the exemption.
  - Copies of any internal corporate correspondence regarding the development, production, or import of the PE material.
  - Information regarding sources and/or raw materials (monomers, catalysts, and linking agents) necessary for the production of the PE substance.
  - Production and other records required by 40 CFR §723.250(r), including documentation that the requirements of 40 CFR §723.250(e)(1)(2) are met.
  - All batch, sales, inventory, and other disposition records for any PE material made or imported by the company or facility.
- Section 8(a) Level A Preliminary Assessment Information Rule (PAIR) reports
  - Copies of production, batch, or other records used to calculate the reported values, including onsite and offsite use. If the firm is a suspected nonreporter of a PAIR report for a particular chemical, the production and batch records for the appropriate time period should be requested to be made available for the inspection.
  - Copies of typical timesheets, production schedules, costing records, or other documentation used to determine worker exposure.
  - Copies of any correspondence with EPA or within the facility regarding reporting, interpretation, accuracy, or other aspects of the PAIR submittal.

- Section 8(b) chemical inventory update reporting

  - Chemical Inventory Reporting forms and exemptions with supporting data for the reporting periods in 1986 and 1990 and 4 year intervals thereafter.

- Section 8(c) records and reports of significant adverse reactions

  - Recordkeeping system for allegations.

- Section 8(d) health and data reporting rule

  - Copies of Section 8(d) submitted studies and/or a list of ongoing unpublished health and safety effects studies.

  - Copies of any internal correspondence or correspondence with the Agency regarding any actual or potential Section 8(d) submittals.

  - Any existing testing data or data files relating to a TSCA Section 8(d) listed chemical, including monitoring and/or epidemiological study data or reports.

- Section 5(e)/5(f) consent order, injunction or rule

  - Copies of the final Section 5(e)/5(f) order, injunction or rule, and associated PMN(s).

  - Copies of any internal memoranda or external correspondence (particularly with EPA) regarding the Section 5(e)/5(f) order, injunction, or rule.

  - Original records or copies of all records required to be kept according to the terms of the Section 5(e)/5(f) order, injunction, or rule, particularly with respect to production, training, protective equipment testing, and product disposition.

- SNUR

  - Copy of the specific SNUR and associated PMN (if a new chemical).

  - Copies of any internal memoranda or external correspondence (particularly with EPA) regarding the SNUR.

  - Original records or authentic copies of all records required to be kept according to the terms of the SNUR, particularly with respect to production, training, protective equipment testing, and product disposition.

3.3.3 FOLLOWUP LETTER

Once the inspection has been arranged by telephone and the appropriate topics have been discussed, the inspector should send a detailed followup letter to the facility contact person. Basically, the letter will confirm in writing the items discussed by phone, including the agreed-upon date and time of the inspection, the right of authorized persons at the facility to claim data as CBI, and the specific records that should be made available for review. The letter should stress that EPA reserves the right to review all records pertaining to activities subject to TSCA and that the list is not necessarily comprehensive (i.e., that records and data other than those specified in the letter may be inspected and copied). Figure 3-5 provides a sample letter.

This letter should not be designated as CBI, and therefore should not include any CBI information. A copy of the letter should be sent to the appropriate EPA Regional Counsel.

3.4 A WRITTEN INSPECTION PLAN

After reviewing EPA records and giving advance notification of the inspection (if the inspector decides to provide such advance notification), the next step is to develop a comprehensive, well-organized, written inspection plan. The inspector should ensure that key aspects of the inspection are not overlooked when developing this plan. Also, the inspector should use the plan to brief facility officials during the opening conference on the general approach to the inspection (see Section 4.7.3). However, the inspector should not provide facility officials with a copy of this plan, because the inspector may want to deviate from the plan during the course of the inspection.

3.4.1 PURPOSE

The main purpose of the written inspection plan is to serve as a guide or blueprint to the entire inspection process at the subject facility. The inspector should keep in mind that one of the most important objectives of the inspection is to collect enough documentation of potential violations of TSCA to assist the CDO in her/his efforts to determine compliance and take appropriate enforcement actions against subject facilities. Therefore, the plan should, among other things, identify which records and areas of the particular facility (e.g., R&D records and R&D laboratory) should be inspected. Section 3.4.2 outlines the elements of a basic inspection plan.

Some Regions may have developed standard inspection checklists to guide the inspector during the inspection process and also to help save time at the site. The inspector and his/her supervisor may want

FIGURE 3-5

SAMPLE LETTER OF NOTIFICATION

Dear _____:

In confirmation of our telephone conversation on _____, EPA plans to conduct an inspection at your company's facility located at _____, under the authority of Section 11 of the Toxic Substances Control Act (TSCA) 15 U.S.C. 2610, on _____, 19___, at approximately _____. The purpose of this inspection is to determine compliance with the requirements of Sections 5, 8, 12, and 13 of TSCA that are applicable to the chemical manufactured, imported, processed, or used at your facility. During the inspection, the inspector may (1) review and (if necessary) copy reports, files, data and correspondence that are either required to be maintained by TSCA or are applicable to the chemicals manufactured, imported, processed, or used; (2) observe process operations; (3) evaluate monitoring practices, equipment, and sites, if appropriate; (4) interview personnel; and (5) collect official samples, if necessary. In addition, the inspector may take photographs of selected subjects.

Among the specific areas to be addressed are:

- Premanufacturing notices (PMNs) submitted by your facility, or requests for exemption from the PMN review process, including low volume, test marketing, and polymer exemptions.

- Research and development activities and procedures in effect at the facility, specifically as related to compliance with the recordkeeping requirements of the TSCA research and development exemption.

- Recordkeeping and reporting under TSCA Section 8 rules, including Preliminary Assessment Information Rule (PAIR), Comprehensive Assessment Information Rule (CAIR), Inventory Update Rule (IUR), and Sections 8(c), 8(d), and 8(e).

- Facility or corporate policies developed to ensure compliance with Sections 5, 8, 12, and 13 of TSCA.

In order to expedite the above reviews, please have available at the time of the inspection all records and documents relating to any specific submissions that you have made to the Agency, including PMNs, requests for exemptions, Section 8 reports, and Section 12(b) notifications. Also please have available a list of all chemical substances manufactured, imported, processed, or used by your facility during each of the past 5 years. This list will greatly assist in completion of the inspection in a timely manner. This list should include an accepted chemical name, Chemical Abstracts Service (CAS) Registry Numbers, and any synonyms or trade names

FIGURE 3-5

SAMPLE LETTER OF NOTIFICATION (Continued)

for each chemical that is manufactured (including isolated intermediates), imported, or used as raw material in manufacturing processes. For chemicals purchased for other uses, please provide as much information as possible. To expedite the inspection, you are encouraged to consolidate at the inspection site all the records specified. You should note that this list is not necessarily comprehensive, and the inspector may want to inspect other records or information not included on the list.

Pursuant to regulations appearing at 40 CFR Part 2, Subpart B and, specifically, Section 2.306, you are entitled to claim any or all the information provided to EPA or collected by EPA during the inspection as confidential business information. Such information can be disclosed by EPA only in accordance with the procedures set forth in the regulations (cited above). Any such claim for confidentiality must conform with the requirements set forth in 40 CFR Section 2.203(b). If you do not assert a confidentiality claim for information provided to EPA, it may be released to the public without further notice.

If you have any questions, please contact me at _(phone number)_. Thank you for your assistance in this matter.

Sincerely,

(Inspector, TSCA Sections 5 and 8)

cc: TSCA Sections 5 and 8 Coordinator (*if different from inspector*)
EPA Regional Counsel, Region __
Others as appropriate (including facility technical contact if another person is the primary contact for this inspection)

to use the checklist in preparing the plan and/or append or adapt any such checklist to the written inspection plan.

The investment of time required to produce a quality inspection plan can save time for the inspector once at the inspection site. Also, the inspector can make better use of facility officials' time if a well-prepared plan guides the inspection.

3.4.2 ELEMENTS OF THE INSPECTION PLAN

Written inspection plans may vary in length and subject matter, but should include at least the following components:

- Objective of the background data search and review and the inspection
- Scope and assessment topics of interest/concern
- Anticipated inspection activities and field techniques
- Safety (or contingency) procedures.

The following guidelines should assist the inspector in developing these components:

- Objective of inspection and background data. This introductory section should provide a brief history of factors relevant to the particular facility (e.g., previous inspection dates and types of inspections, whether any potential compliance issues were identified and what they were). This section should also identify the objective or reason for the inspection. This will vary from inspection to inspection (e.g., "for cause," random, case development, or followup). More specific objectives may also be identified in addition to the overall objective.

- Scope and assessment topics. The inspection plan should clearly establish the scope of the inspection and the assessment topics. The scope of the inspection is a function of the overall objective of the inspection. For example, if the inspection is "for cause," then the scope of the inspection should include whatever records, operations, and areas of the facility that will need to be inspected to determine compliance with the provisions of TSCA suspected of being violated; if the inspection is comprehensive and will entail determining compliance with many provisions of TSCA (e.g., Sections 5, 8, 12, and 13) then the scope of the inspection should be all records and processes relevant to determining such compliance. Some discussion of the boundaries of the inspection should be included (i.e., if the inspection will include a tour of the facility, as well as records review and interviews with personnel, or will only focus on a records review).

Once the scope has been identified, the inspection plan should designate the assessment topics. Assessment topics can be roughly defined as the major regulatory areas to be covered during the inspection [e.g., TSCA Section 5 or Section 8(b)]. The assessment topics should be further broken down into specific questions to be asked of facility officials concerning the particular assessment topic and specific associated tasks. For example, if the main assessment topic is R&D exemption pursuant to Section 5, an important question would be how the subject facility defines research and development. In addition, the inspector will want to examine the R&D records and interview the R&D Director. The related tasks would be the review of any written research and development documentation. Detailed information on assessing compliance with the regulatory requirements of Sections 4, 5, 8 and 12/13 are presented in Chapters 5, 6, 7, and 8 respectively.

- Inspection activities. Once the assessment topics have been established, the inspector must determine the most appropriate inspection activity or method of assessing compliance and gathering evidence of potential violations (e.g., observation, records review, interviews, collect samples) for each task.

  Compliance and assessment and evidence collecting techniques can be organized in an inspection plan as follows:

  - Observation. List what activities, operations, and/or equipment will be observed (e.g., manufacturing processes and equipment).

  - Records review. List facility records that will be reviewed to determine statutory and regulatory compliance, along with the regulatory citation(s) applicable to each record that must be maintained, as well as a description of the required content of each record.

  - Conduct of interviews. List the titles, and names if known, of key personnel with whom meetings should be held to determine compliance with specific regulatory provisions (e.g, to determine compliance with R&D provisions, interview the R&D Director about standard operating procedures for R&D at the facility).

  - Sample collection. Develop a sampling plan according to EPA policy and guidance. Sampling inspections also require detailed advance quality assurance and logistical planning. Sampling, discussed in Appendix 5, is done only in very specific situations.

- Safety (or contingency) Procedures. Develop appropriate safety procedures for the type of inspection activity being conducted. Safety procedures for a TSCA inspection should identify the expected hazards and types of exposures to be encountered, and necessary safety equipment, and should include an emergency evacuation plan. For example, if the inspection involves taking a tour of the facility, safety glasses, shoe covers, and a hard hat may be required. The inspector should identify the facility's safety requirements when calling to schedule the inspection. In the case of handling and collecting samples, toxic chemical substances always pose a certain degree of hazard and must be handled accordingly. The inspector should ensure that the written inspection plan contains at least the applicable safety guidelines if samples are to be collected. In general, the inspector should try to identify any safety concerns that may arise during the inspection and plan accordingly.

For each of the tasks and its associated inspection activity, the inspection plan should list the activities that are the highest priority first, and then list additional activities that may be accomplished depending on the availability of time and resources.

3.5 GATHERING INSPECTION DOCUMENTS AND EQUIPMENT

In addition to preparing the written inspection plan and reviewing EPA records prior to conducting the inspection, the inspector should also gather and prepare the necessary documents and equipment to be used during the inspection.

To accomplish this task, a tracking sheet should be filled out through Part A (see Figure 3-6.) This is then returned to the Inspection/Official File. The tracking sheet should be completed after the inspection. The completed tracking sheet can be used for inspection monitoring purposes. (Any additional company sites for possible future Sections 5 and 8 inspections should also be recorded on the tracking sheet once the subject inspection has been completed.)

3.5.1 TYPES OF DOCUMENTS

No single list of documents and equipment can be appropriate for all inspections. The list provided below is intended for guidance purposes only. The inspector's experience in the field and information obtained during pre-inspection planning should assist in preparing lists tailored to specific inspection sites and needs.

Specific needs will be determined by the requirements of the inspection, the availability of equipment, conditions at the facility, EPA policies, and whether or not advance notification of an inspection will be given. Documents necessary for the inspection should be prepared in advance of the inspection, whenever possible. The inspector must have the following documents for any inspection under TSCA.

- Notice of Inspection (discussed in Section 4.2.4). This is required under TSCA Section 11 and must be presented upon arrival at the inspection site.
- Inspection Confidentiality Notice (discussed in Sections 4.7.3 and 4.7.4.1). This document is used to inform facility officials of their right to claim inspection data as CBI under TSCA.

FIGURE 3-6

SAMPLE TRACKING SHEET

INSTRUCTIONS:

1. Complete Part A
2. When the inspection is completed, fill out Part B.
3. Use as documentation to help in preparing the inspection report.

PART A

INSPECTOR:_____

COMPANY:_____ PHONE: _____

ADDRESS:_____

_____

☐ Headquarters ☐ Manufacturing ☐ Processing ☐ Importing ☐ R & D

Date of Contact:_____

Date of Letter Mailed:_____

Date(s) of Inspection:_____

Inspection Materials and Equipment Needed:

Inspection Notebooks: 1 2 3 4 5 6 _____ ☐ Camera ☐ TSCA Stamp

Inspection Form Sets: 1 2 3 4 5 6 _____ ☐ Sampling Equipment

PART B

Tip and Complaints:	☐ Yes	☐ No	8(c):	☐ Yes	☐ No
5e/5f:	1 2 3	_____	8(e):	☐ Yes	☐ No
TME:	1 2 3	_____	8(a) Level A:	1 2 3	_____
Bonafides:	1 2 3	_____	8(b):	☐ Yes	☐ No
Specific PMN:	1 2 3	_____	8(d):	☐ Yes	☐ No
Generic PMN:	1 2 3	_____	13:	☐ Yes	☐ No
LVE:	1 2 3	_____			
PE:	1 2 3	_____			

Company Submitting Additional Information by: _____

Record Forms Used For This Inspection:

_____ Inspection Notebook
_____ TSCA Inspection Confidentiality Notice
_____ Notice of Inspection
_____ Receipt for Samples and Documents
_____ Declaration of CBI
_____

- Declaration of Confidential Business Information (discussed in Sections 4.7.4 and 4.9.2). This is the form on which information and/or documents claimed by facility officials as CBI are described.

- Receipt for Samples and Documents (discussed in Section 4.9.2). This document must list all samples and documents taken during an inspection by the inspector.

In addition, the inspector should be certain to take these documents and materials on an inspection:

- Copies of TSCA and regulations. Inspectors should have copies of TSCA and the regulations (found in two volumes of the CFR: 40 CFR Parts 700-789 and Parts 790-end) promulgated pursuant to the act available upon request. Having such data available can help improve the relationship between EPA and the regulated community, which can foster better facility compliance with TSCA.

- Chemicals on Reporting Rules (CORR) list (contained in Appendix 7)

- EPA outreach materials. Inspectors should provide current, relevant educational, and/or guidance information to facility officials upon request or as deemed appropriate by the inspector. The inspector may also inform the facility of the information available and how companies can obtain such information by calling the EPA TSCA Assistance Information Service (Hotline) at (202) 554-1404. The inspectors should discuss information available through the EPA Pollution Prevention Information Clearinghouse (PPIC) and ways companies can obtain such information by calling PPIC Technical Support at (703) 821-4800. Also, the inspector can provide the name of the Regional pollution prevention contact to the company. A list of current Regional pollution prevention contacts is provided in Appendix 6.

- Administrative information. Travel authorizations and telephone numbers of travel and procurement personnel who may need to be contacted should be taken by the inspector when on travel.

3.5.2 INSPECTION EQUIPMENT

The types of equipment that an inspector takes to an inspection site will vary from inspection to inspection, depending upon the nature and extent of the inspection and the type of the facility to be inspected. The inspector should use her/his best judgment, based on training and inspection experience and on knowledge gained preparing for the inspection, in determining what equipment is necessary for a particular inspection. The equipment should be well-maintained and in good condition at the time of the inspection. Therefore, prior to each inspection, the inspector should check the equipment to make sure that it is in good working condition.

Since each inspection is unique, no single list of equipment or forms can be devised that will fit every inspection situation. The types of equipment most likely to be needed during a TSCA inspection are summarized in Table 3-1.

TABLE 3-1 TYPES OF EQUIPMENT

General	Safety[2]	Emergency	Sampling[3]
• Camera • Film and flash equipment • Pocket calculator • Tape measure • Clipboard • Waterproof pens, pencils, and markers • Locking briefcase • "Confidential Business Information" stamp • Stamp pad • Pre-addressed envelopes (e.g., to Document Control Officer) • Plastic covers • Plain envelopes • Polyethylene bags • Disposable towels or rags • Portable typewriter (or personal computer) • Portable copying machine • Flashlight and batteries • Pocket knife • Merck index	• Safety glasses or goggles • Face shield • Ear plugs • Rubber-soled, metal-toed, non-skid shoes • Liquid-proof gloves (disposable, if possible) • Coveralls, long-sleeved • Long rubber apron • Hard hat • Plastic shoe covers, disposable • Respirators and cartridges • Self-contained breathing apparatus	• Substance-specific first aid information • Emergency telephone numbers • First-aid kit with eyewash • Fire extinguisher • Soap, waterless hand cleaner, and towels • Supply of clean water for washing	• Crescent wrench, bung opener • Siphoning equipment • Weighted bottle sampler • Bottom sediment sampler • Liquid waste samplers (e.g., glass samplers) • Auger, trowel, or core sampler • Scoop sampler • Sample bottles/containers (certified clean bottles with teflon-lined lids) • Labeling tags, tape • Storage and shipping containers with lids • Ice chest • Container for contaminated material • Hazard labels for shipping samples • Ambient air monitor • Field document records • Department of Transportation (DOT) special 12B cartons • Vermiculite or equivalent packing • Thermometer • Colorimetric gas detection tubes • pH equipment • Explosimeter

[2]In accordance with EPA policy, a TSCA inspector may not do field work without first completing an approved health and safety training program. Personnel who use respiratory protection equipment must also complete specialized training, which includes training on protective equipment selection criteria. Program-specific safety training has been developed for field personnel facing particular risks.

[3]Detailed information on collecting samples is given in Appendix 5.

Chapter Four

Inspection Management

Page

4.0 INSPECTION MANAGEMENT 4-1

4.1 INTRODUCTION 4-1

4.2 AUTHORITY 4-1

4.2.1 INSPECTIONS 4-1
4.2.2 SUBPOENAS 4-2
4.2.3 CREDENTIALS 4-2
4.2.4 WRITTEN NOTICE OF INSPECTION 4-3

4.3 PRELIMINARY STEPS FOR CONDUCTING A TSCA INSPECTION 4-5

4.4 CONSENT TO ENTER AND INSPECT 4-6

4.4.1 ENTRY BY CONSENT 4-6
4.4.2 RELUCTANCE TO GIVE CONSENT 4-7
4.4.3 CONDITIONAL CONSENT 4-8
4.4.4 WITHDRAWAL OF CONSENT 4-10
4.4.5 INSPECTOR JUDGMENT 4-10

4.5 DENIAL OF CONSENT TO ENTER AND INSPECT 4-11
4.6 ADMINISTRATIVE WARRANTS 4-12

4.6.1 PROCEDURES FOR SECURING AND EXECUTING A WARRANT 4-15
4.6.2 SEEKING A PRE-INSPECTION WARRANT 4-18

4.7 THE OPENING CONFERENCE 4-19

4.7.1 PURPOSE 4-19
4.7.2 PROCEDURES 4-20
4.7.3 TSCA CONFIDENTIAL BUSINESS INFORMATION 4-23

4.7.3.1 TSCA INSPECTION CONFIDENTIALITY NOTICE 4-23
4.7.3.2 DECLASSIFICATION OF CBI 4-25
4.7.3.3 CONFIDENTIALITY CLAIMS 4-25

4.8 INSPECTION PLAN REVISIONS 4-25

TABLE OF CONTENTS (Continued)

4.9 THE CLOSING CONFERENCE 4-26

4.9.1 PURPOSE 4-26
4.9.2 PROCEDURES 4-26
4.9.3 COMPLIANCE OUTREACH 4-30

LIST OF FIGURES

FIGURE 4-1 NOTICE OF INSPECTION 4-4
FIGURE 4-2 TSCA INSPECTION CONFIDENTIALITY NOTICE 4-21
FIGURE 4-3 DECLARATION OF CONFIDENTIAL BUSINESS INFORMATION 4-24
FIGURE 4-4 RECEIPT FOR SAMPLES AND DOCUMENTS 4-28

LIST OF TABLES

TABLE 4-1 LONG-EXISTING EXCEPTIONS TO REQUIREMENT TO OBTAIN A WARRANT 4-14

4.0 INSPECTION MANAGEMENT

4.1 INTRODUCTION

This chapter discusses the required procedures for entering a facility subject to the Toxic Substances Control Act (TSCA) to conduct an inspection under the statute. This chapter also presents the statutory requirements, as well as the U.S. Environmental Protection Agency (EPA) policies. Guidance is provided to the TSCA inspector on the preliminary aspects of a TSCA inspection, ranging from a discussion of the importance of facility owner/operator consent to a listing of procedures for conducting the opening and closing conferences. Procedures for conducting the inspection to assess compliance with various sections of TSCA are covered in succeeding chapters.

4.2 AUTHORITY

4.2.1 INSPECTIONS

In order to enter a facility to conduct a compliance inspection pursuant to TSCA, the inspector must ensure that s/he has statutory authority to inspect such a facility. Statutory authority stems from Section 11 of TSCA, which specifies:

- Who may conduct an inspection ("...the Administrator, and any duly designated representative of the Administrator...").
- Which facilities may be inspected ("...any establishment, facility, or other premises in which chemical substances or mixtures are manufactured, processed, stored, or held before or after their distribution in commerce..."). The inspector may also inspect "...any conveyance being used to transport chemical substances, mixtures, or such articles in connection with distribution in commerce." (This implies authority to inspect importers' premises where no chemicals are stored on site.)

An inspection under TSCA may be conducted only after the inspector has presented the following items to the owner, operator, or agent in charge:

- Appropriate credentials (discussed in Section 4.2.3)
- Written Notice of Inspection (i.e., of the "premises or conveyances" to be inspected) (discussed in Section 4.2.4).

In accordance with Section 11 of TSCA, an inspection must be conducted in the following manner:

- Commenced and completed with reasonable promptness
- Conducted at reasonable times, within reasonable limits, and in a reasonable manner.

The scope of a TSCA inspection may include inspection of "...records, files, papers, processes, controls, and facilities...." However, Section 11 of TSCA prohibits, unless described with reasonable specificity in the required written Notice of Inspection, the inspection of the following data:

- Financial data
- Sales data (other than shipment data)
- Pricing data
- Personnel data
- Research data (other than data required under TSCA or a rule promulgated under TSCA).

4.2.2 SUBPOENAS

Section 11 of TSCA grants subpoena authority to EPA. The EPA Administrator may "...require the attendance and testimony of witnesses and the production of reports, papers, documents, answers to questions, and other information...." by subpoena. Regional Counsel may want to examine the rules of the court for that jurisdiction to determine whether EPA is responsible for the transportation costs of a witness required to testify.

U.S. district courts have the authority to order compliance with such subpoenas. In addition, any failure to obey a court order concerning a subpoena is punishable as contempt.

4.2.3 CREDENTIALS

Section 11 of TSCA requires the EPA Administrator or any "...duly designated representative of the Administrator..." who conducts an inspection of a facility subject to TSCA to present the owner, operator, or agent in charge with "appropriate credentials" and with a written Notice of Inspection (discussed in Section 4.2.4). The inspection may be made only upon presentation of such credentials. The credentials are identifying papers that state the holder of the papers (i.e., the inspector) is authorized to conduct inspections pursuant to TSCA. Therefore, prior to conducting the inspection, and after

introducing herself/himself, the inspector must present the appropriate credentials. The credentials are issued by the EPA Administrator or her/his designee.

Inspectors must present credentials whether or not facility officials request identification. Appropriate credentials indicate that the holder is a lawful representative of the Administrator and is authorized to conduct inspections under TSCA. Credentials should be accessible at all times. Once facility officials have viewed the credentials, they may wish to telephone the EPA Regional office for verification of the inspector's identification, which is permissible. However, credentials may not be photocopied. The inspector should make a note in her/his field log that credentials were presented.

4.2.4 WRITTEN NOTICE OF INSPECTION

As soon as the inspector has identified herself/himself and presented the required credentials, s/he must present to the owner, operator, or agent in charge of the subject facility a written notice of "...the premises or conveyances to be inspected." This Notice of Inspection (see Figure 4-1) informs the owner, operator, or agent in charge of the reason for an inspection under Section 11 of TSCA (i.e., for inspecting a facility or conveyance to determine compliance with TSCA, or for inspecting financial, sales, or other normally excluded data) and contains the inspector's address and signature. Although the time of the intended inspection is not required, the scheduled time (and date) of the inspection should be included in the Notice of Inspection to establish that the inspection was requested at a reasonable time, as required by Section 11 of TSCA.

The inspector presents the Notice of Inspection after arrival at the subject facility. TSCA does not require the inspector to provide advance notification of the inspection to the facility, but some inspectors may choose to provide such notice (discussed in detail in Chapter 3). A separate inspection notice must be presented for each inspection, but a separate notice is not required for each entry made during the period covered by the inspection (e.g., for each separate day of a multi-day inspection).

Data that are ordinarily exempt from an inspection under TSCA may be inspected if they are specifically listed in the Notice of Inspection. Facility officials should also be informed verbally of the intent to inspect such data, which may include financial, sales, pricing, personnel, and research data. Since these five categories of exempt data sometimes appear on documents that the inspector routinely examines, such as import invoices, the inspector may choose to check the boxes on the NOI that delineate these categories of data. The inspector should acknowledge that financial, sales, pricing, personnel, and

FIGURE 4-1
NOTICE OF INSPECTION

EPA

United States Environmental Protection Agency
Washington, D.C. 20460
Toxic Substances Control Act

Form Approved
OMB No. 2070-0007
Approval Expires 10-31-92

NOTICE OF INSPECTION

The public reporting burden for this collection of information is estimated to average 8 minutes per response. This estimate includes time for reviewing instructions, searching existing data sources, gathering and maintaining the needed data, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information to the Chief, Information Policy Branch (PM-223), US Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460, and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503, marked ATTENTION: Desk Officer for EPA.

1. Investigation Identification			2. Time	3. Firm Name
Date	Inspector No.	Daily Seq. No.		
4. Inspector Address				5. Firm Address

REASON FOR INSPECTION

Under the authority of Section 11 of the Toxic Substances Control Act:

☐ For the purpose of inspecting (including taking samples, photographs, statements, and other inspection activities) an establishment, facility, or other premises in which chemical substances or mixtures or articles containing same are manufactured, processed or stored, or held before or after their distribution in commerce (including records, files, papers, processes, controls, and facilities) and any conveyance being used to transport chemical substances, mixtures, or articles containing same in connection with their distribution in commerce (including records, files, papers, processes, controls, and facilities) bearing on whether the requirements of the Act applicable to the chemical substances, mixtures, or articles within or associated with such premises or conveyance have been complied with.

☐ In addition, this inspection extends to *(Check appropriate blocks)*:

- ☐ A. Financial data
- ☐ B. Sales data
- ☐ C. Pricing data
- ☐ D. Personnel data
- ☐ E. Research data

The nature and extent of inspection of such data specified in A through E above is as follows:

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Inspector Signature		Recipient Signature	
Name		Name	
Title	Date Signed	Title	Date Signed

EPA 7740-8 Rev (8-91) Inspection File

research data might appear on documents that s/he inspects for non-exempt reasons.

Research data should not be treated like sales and pricing information. If a facility claims an R&D exemption, the inspector should ascertain whether the facility is eligible for the exemption by requesting all records that the facility is required to keep according to 40 CFR §720.78. If the facility cannot supply the inspector with the required records, the facility may have violated Section 5 of TSCA. Therefore, the inspector should demonstrate her/his interest in looking at the R&D data by checking the appropriate box on the NOI.

The inspector should make a note in the inspection notebook that the Notice of Inspection was presented and should keep a copy of the notice for the records.

4.3 PRELIMINARY STEPS FOR CONDUCTING A TSCA INSPECTION

The following procedures should be used by the TSCA inspector to ensure compliance with statutory requirements and EPA policy covering TSCA inspections:

- In order to comply with the statutory requirement that the inspection of a facility subject to TSCA be conducted at a reasonable time, the inspector should inspect the facility only during normal working hours, unless mitigating circumstances, such as an emergency, require that an inspection be conducted during non-business hours.

- The inspector should arrive at the facility at the time designated (if it has been included) in the Notice of Inspection. As previously discussed, TSCA does not require advance notice of inspection or that the written Notice of Inspection include the time of the inspection, but the inspector may want to include the time on the Notice of Inspection as documentation.

- The inspector should enter the facility through the main entrance. If the inspector sent an advance letter (or notice) of inspection to the facility, and in response the facility designated a different entrance, the inspector should use the designated entrance.

- Upon arrival at the facility, the inspector should present his/her credentials to the guard, if the facility has one. TSCA requires only that credentials be presented to "owner, operator, or agent in charge," but the inspector may present them to others as a courtesy. Inspector credentials should be kept accessible throughout the inspection. EPA policy does <u>not</u> allow for credentials to be photocopied. Business cards <u>do not</u> constitute credentials but may be used for introductory purposes as appropriate.

- The inspector should ask the guard (or the secretary or receptionist, if there is no guard) to see the facility owner, operator, or agent in charge.

- The inspector may sign a visitor's log or register if requested to do so. However, the inspector may not sign any such sheet or other document if it contains restrictive language limiting the scope of the inspection, the manner in which the inspection may be conducted, or the manner in which information may be used (e.g., a waiver, release of liability, restriction on the use of photographic or other recording devices). Attempts to restrict the inspection are discussed in detail in Section 4.4.3.

- Once the owner, operator, or agent in charge has been located, the inspector must present such a facility official with proper inspector credentials and the Notice of Inspection.

- Although TSCA does not require that a TSCA inspector obtain consent from the facility owner, operator, or agent in charge to enter a facility to conduct an inspection, it is EPA policy that the inspector obtain such consent. Therefore, if an inspector is denied entry to a facility to conduct an inspection under TSCA, or if the facility owner, operator, or agent in charge attempts to impose conditions upon the entry (i.e., conditional entry), the inspector should take action as described in Section 4.4.3.

4.4 CONSENT TO ENTER AND INSPECT

4.4.1 ENTRY BY CONSENT

Although EPA has statutory authority to enter a facility subject to TSCA for the purposes of conducting an inspection under the statute, and may do so without obtaining consent, facility officials sometimes withhold consent or attempt to impose restrictions or conditions upon entry. However, EPA policy requires the inspector to obtain such consent for the inspection. Therefore, the inspector should not conduct an inspection until s/he has accomplished one of the following tasks:

- Obtained consent prior to conducting the inspection

- Or, if unable to obtain consent, followed proper procedures governing what must be done when entry to a facility is denied or when conditions or restrictions are imposed by facility officials upon authorized TSCA inspectors (discussed in Sections 4.5 and 4.4.3, respectively).

Consent to enter must be given knowingly and freely. The inspector must not coerce or lie to facility officials in order to induce consent. For example, the inspector must not suggest that failure to permit entry may result in the imposition of civil or criminal penalties, since the entry may then be considered non-consensual (i.e., because of the "threat" of negative consequences).

Express consent is not necessary (i.e., the absence of express denial constitutes consent). Entry remains voluntary and consensual unless there is a withdrawal of consent (discussed in Section 4.4.4). Consent must be given by the person in possession (i.e., the possessor) of the premises, or by some other person

with authority to give consent at the time of the inspection. An owner does not always have possession, and so may not be authorized to give consent; for example, the owner may have rented the property to a tenant who is on the property. If someone in possession of the facility cannot be located, the inspector must make a good faith effort to determine who may otherwise consent to the entry (such as the agent in charge). The inspector should present her/his credentials to that individual and record the name and title of that person in the inspection record book.

The TSCA inspector must obtain express consent to enter the premises for each uncredentialed person who intends to accompany the inspector on an inspection. If consent is not given, these persons may not enter the premises to be inspected. No uncredentialed person may have access to confidential business information (CBI) unless s/he has been authorized for CBI access by the Information Management Division (IMD) of the Office of Pollution Prevention and Toxics (OPPT). IMD circulates monthly a list of persons with CBI clearance to the Regional and program Document Control Officers (DCOs).

In most instances, if the inspector follows proper procedures upon arrival at the facility (i.e., presentation of credentials and Notice of Inspection), it will be simple to obtain consent to enter. However, special situations may arise, as follows:

- Owner/operator reluctance to give consent
- Conditional consent
- Withdrawal of consent.

These situations and the inspector's responsibilities in each situation are discussed below.

4.4.2 RELUCTANCE TO GIVE CONSENT

The receptiveness of facility officials toward an inspector may vary from facility to facility. If consent to enter a facility is denied outright, the inspector should follow the procedures governing denial of entry (discussed in Section 4.5). However, in some instances, facility representatives express reluctance rather than actually refuse to allow an inspector to conduct an inspection. Often this reluctance is due to a misunderstanding by facility representatives of EPA or facility responsibilities under TSCA, or to concerns over perceived inconveniences to the facility operations as a result of the inspection. Such concerns are usually resolved through diplomacy and discussion.

In such instances, an inspector should tactfully ascertain the reasons for facility officials' reluctance and try to resolve the problems. The inspector should also explain in detail the purpose of the inspection. However, it is crucial during any negotiations or discussions that an inspector does not agree to any restrictions on the scope of an inspection authorized under TSCA. In addition, the inspector should avoid issuing threats of any kind or making inflammatory statements.

If there is still difficulty in obtaining consent after the discussion, the inspector may inform facility representatives diplomatically that the issuance of a subpoena is one of EPA's options, under Section 11 of TSCA for obtaining access to records and other data. In addition, the inspector may suggest to facility representatives that they speak with their attorney concerning EPA inspection and subpoena authority. If entry is still denied, the inspector should withdraw from the facility and contact her/his supervisor for further instructions. Under no circumstances should the inspector attempt to gain entry or consent to enter by coercive actions or by making statements that suggest that the facility representatives could be fined or otherwise "punished" unless entry is allowed.

4.4.3 CONDITIONAL CONSENT

Conditional consent refers to any attempt by facility officials to restrict the inspection after entry or to condition entry upon the adherence to restrictions imposed by the officials. Some of the more common types of conditions that facility officials try to impose on the inspector are the following:

- Waivers, indemnity agreements, or releases
- Confidentiality or secrecy conditions or agreements
- Photographic or tape recording restrictions
- Requirements concerning health and safety gear or training
- Duplication of the inspector's notes or credentials for facility review
- Denial of access to certain areas of facility.

Generally, any attempt by facility officials to cause inspectors to deviate from standard inspection procedures should be interpreted as an effort to impose conditions on consent. EPA policy is that inspectors should never agree to restrictions or conditions on the scope or nature of the inspection. The inspector must never sign any document that could compromise EPA's right to conduct an inspection. Any effort by facility officials to impose one or more conditions should be considered denial of consent. In such circumstances, the inspector should follow the procedures governing denials of consent (see

discussion in Section 4.5). However, reasonable requests (such as requesting the inspector to wear a visitor's badge, hard hat, or safety eyeglasses) should not generally be considered "conditions," and the inspector may comply with such requests.

Even if the inspector is permitted to enter the facility without being asked to comply with conditions or restrictions, the inspector should be constantly aware of any attempt by facility representatives after entry to impose such conditions. If this should occur, the inspector must regard this attempt as a denial of consent and follow appropriate procedures (discussed in Section 4.5).

Some areas in which facility officials may attempt to impose restrictions are discussed below.

- Waivers and other restrictive agreements. EPA inspectors have the right and the responsibility to refuse to sign any agreement or waiver that promises that records or other data obtained from the facility will not be released to any third party. Any attempt by a facility to restrict inspection activities by requiring inspectors to sign such restrictive agreements should be viewed as a denial of consent to inspect the facility and treated accordingly. (However, during the opening conference, inspectors must advise the facility owner, operator, or agent in charge of her/his right to claim such data as CBI and of the procedures for making such claims.)

- Restrictions on use of photographic or other recording equipment. TSCA inspectors may document evidence of potential violations at the facility by means of tape recordings, photography, or recording by electronic devices with a visual taped readout or by other methods. Inspectors have the authority to use these recording devices, which include aerial overflights, LIDAR (a type of radar used to detect and measure distant air emissions of particulate matter), and other aerial or ground surveillance sense-enhancement devices. Facility officials often attempt to restrict the use of any or all of such devices by EPA inspectors. Any attempt by a facility to restrict the use of such devices is considered a denial of consent and appropriate procedures governing such denials should be followed. Facility officials should be advised that photographs and other information/data gathered by recording equipment may be claimed as CBI (see Section 4.7.4).

- Health and safety restrictions. The inspector should ascertain the facility safety and applicable Occupational Safety and Health Administration (OSHA) requirements before the inspection, if possible. The inspector should be aware that s/he is subject to the applicable safety requirements of the facility. For example, if safety boots and glasses are required to walk through the manufacturing area, then the inspector must wear them. However, EPA inspectors cannot be required to participate in the facility's safety training program as a condition of conducting a TSCA inspection. If facility officials make such a demand, the inspector should refuse and should treat the situation as a denial of consent.

- Refusal to allow access to certain areas of facility. If during the course of the inspection access is denied or restricted to certain areas of the facility, the inspector should make a notation describing such denial or restriction in the field notebook and identify which portion of the inspection could not be completed due to the denied or restricted access. However, despite the

access restriction, the inspector should proceed with the remainder of the inspection. After leaving the facility, the inspector should contact her/his supervisor to determine whether a warrant should be obtained to complete the inspection.

4.4.4 WITHDRAWAL OF CONSENT

Occasionally, facility officials may initially consent to an inspection and later withdraw the consent during the inspection. Consent to the inspection may be withdrawn at any time after entry has been made. EPA policy concerning withdrawal of consent is to view it as an outright denial of consent. In such cases, appropriate procedures should be followed (discussed in Section 4.5). All activities and evidence obtained prior to the withdrawal of consent are valid. Therefore, evidence obtained by the inspector before consent was withdrawn would be usable in any subsequent enforcement actions and should be retained by the inspector. The inspector should not give any evidence that has been collected before the withdrawal of consent back to the facility if asked by the facility official.

4.4.5 INSPECTOR JUDGMENT

Whenever it appears that facility officials, through statements or actions (such as physically blocking entry), are denying or restricting consent to conduct the inspection authorized by TSCA, the inspector must use independent judgment to determine the actual effect the limitation will have on the inspection.

Sometimes inspectors are able to reach an agreement with facility representatives concerning a condition apparently imposed upon the inspection or to find a way around the difficulty. Inspectors should keep in mind that attempts to negotiate with facility officials are based on the independent judgment of the inspectors and, as such, there are risks involved (e.g., having a court declare later that consent was obtained coercively and, therefore, was not consent). If the inspector is in doubt, s/he should consult Regional Counsel.

The inspector always has the option of departing the facility premises and following the procedures for securing and executing a warrant (discussed in Section 4.6.1). The inspector can choose to discontinue the inspection at any time after the inspection has begun. The following examples illustrate how inspectors have actually handled situations that might have been considered denials of entry:

- Restrictive language in sign-in book or form. The inspector should draw a line through objectionable language before signing, obtain a photocopy, and make a note in her/his field log

about it. The inspector should also inform the facility officials of the modification s/he made and request that a facility official initial it.

- Photographs. When facility officials state they do not want photographs taken of the facility, the inspector can proceed with the inspection, raising the issue of photographs again only when a particular photograph is essential to the inspection. If photography is still not permitted, the inspector can follow the procedures for securing and executing a warrant (discussed in Section 4.6.1).

- Safety training. Inspectors cannot be required to participate in a facility's safety training course prior to entry. However, if the facility has a relatively short safety briefing that will not interfere with the inspector's ability to complete the planned inspection in a timely manner, the inspector may want to attend the briefing. Inspectors are sometimes able to learn valuable information about the facility's layout and operations at such orientations.

4.5 DENIAL OF CONSENT TO ENTER AND INSPECT

The first thing that an inspector must keep in mind when facility officials deny consent to conduct a TSCA inspection is to refrain from making any inflammatory remarks or statements that could jeopardize subsequent enforcement actions brought against the facility by EPA at a later date. For example, the inspector must not discuss any potential penalties that are authorized under Section 15 of TSCA for refusal to permit entry or inspection. If such potential penalties were discussed and consequently facility officials permitted the inspection to be conducted, officials could later claim such statement was a form of coercion. A court could rule at a subsequent proceeding challenging the inspection that some or all of the evidence collected during the inspection is inadmissable. For example, if the TSCA NOI fails to mention that financial, sales, pricing, personnel, or research data will be examined by the inspector, and s/he does in fact examine these records this action might be challenged. As another example, the inspector should not threaten facility officials with the fact that s/he will "get a warrant," even though EPA may later try to secure a warrant to conduct the inspection. This is because a court of law, which later may review the search procedures used by EPA, may interpret the statement as coercive, invalidating the search.

In practice, refusal by facility officials to permit entry for inspection purposes is not likely to lead to civil or criminal penalties if it is based upon facility officials' desire to see a warrant before entry is permitted, even though Section 15 of TSCA states that it is unlawful for anyone to refuse entry or inspection as required by Section 11.

In the event that entry is denied, the inspector should write the following information (which will be helpful should EPA decide to obtain a warrant at a later date) in her/his field notebook:

- Facility name and address
- Name, title, and telephone number of person who refused entry
- Name, address, and telephone number of the facility's attorney
- Date and time of refusal
- 'Reason for facility's refusal to allow EPA inspector to enter and/or to inspect facility
- Description of facility appearance, including number of buildings and general observations, such as housekeeping practices
- Any reasonable suspicion that refusal stemmed from desire to prevent discovery of regulatory/statutory violations.

After making the above notations in her/his field notebook, the inspector should immediately leave the premises and contact her/his supervisor, who will confer with Regional Counsel concerning the desirability of obtaining a warrant. The inspector should ensure that the facility officials have been given a copy of the written Notice of Inspection to show that proper procedures were followed.

Generally, after Regional Counsel is contacted, s/he will discuss the matter of the inspection by telephone with facility officials in order to resolve the issues surrounding the inspection. If the matter can be resolved in this manner, the inspection should proceed without further delay. However, if Regional Counsel is unable to solve the problem, the inspector should discuss with her/his supervisor the possibility of obtaining a warrant.

4.6 ADMINISTRATIVE WARRANTS

A warrant is a judicial authorization for an appropriate official (e.g., EPA inspector, U.S. Marshal, or other Federal officer) to enter a specifically described location and perform specifically described functions. An administrative warrant, in a TSCA inspection proceeding, is issued by a magistrate at EPA. The warrant may be obtained (i) when facility officials have denied entry to an inspector, (ii) when consent to inspect has been withdrawn during an inspection, or (iii) in advance of inspection. EPA must first have a substantive right to enter the premises before the use or the issuance of an administrative

warrant is proper. EPA's authority to conduct inspections under Section 11 of TSCA serves as the basis for an administrative warrant being issued by a magistrate.

While almost every EPA statute, including TSCA, contains a provision expressly authorizing the Administrator and/or authorized representatives to enter a subject facility to conduct an inspection pursuant to the particular law, EPA policy is that where facility officials deny or withdraw consent, a warrant must be obtained. The idea behind this policy is that it is less time consuming (and less costly in the long run, given the possibility of a legal challenge) to take the precautionary action of obtaining a warrant rather than forcibly entering the facility against the wishes of facility representatives. EPA obtains a warrant in order to validate its statutory authority to enter. The warrant serves as judicial confirmation of EPA entry authority.

The decision of whether to secure a warrant will be made by Regional Counsel in consultation with the Compliance Division, Office of Compliance Monitoring (OCM), and the Toxics Litigation Division, Office of Enforcement (OE). Once the Regions and EPA Headquarters have decided that a warrant should be secured, precise procedures must be followed for obtaining and executing the warrant (discussed in Section 4.6.1).

Warrants are applied for and obtained ex parte; that is, without the knowledge of the other side. Therefore, it is inappropriate to give facility officials advance notification of an inspection that will occur under a warrant. It may be a criminal offense for anyone to disclose the existence of a warrant prior to its execution.

The ability to secure a warrant is important to government officials, especially to inspectors. In addition to serving as judicial confirmation of EPA's statutory right to enter and inspect a facility, a warrant affords substantial legal protection to an inspector from private suits for damages. A valid warrant gives an official absolute immunity from liability for activity conducted in conformity with the warrant.

The inspector should be aware that there are several long-existing exceptions to the requirement to obtain a warrant. They are summarized in Table 4-1.

TABLE 4-1
LONG-EXISTING EXCEPTIONS TO REQUIREMENT TO OBTAIN A WARRANT

Exception	Description
Exigent (Emergency) Circumstances	• Includes potentially hazardous circumstances, as well as situations in which evidence relating to a suspected violation may have been destroyed • In an emergency, with insufficient time to obtain a warrant, a warrantless inspection is permissible • Regions must exercise judgement
Plain View	• Legal construction of the courts consisting of three required elements: 1. Lawful presence: The inspectors must have lawful and justified presence, gained through statutory authority, valid search warrant, consent, or "open fields" 2. Inadvertent discovery: Evidence is discovered accidentally. The plain view doctrine will not apply if the inspector is searching for particular evidence 3. Apparently Incriminating Nature: Inspector must have reasonable grounds to believe immediately that the item in plain view constitutes evidence of a violation of the law
Open Fields	• Areas where land owner normally has no reasonable expectation of privacy • Valid consent is preferred procedure • Inspectors may be trespassers, but will not prevent lawful use of evidence • Authority does not extend to residences or areas immediately surrounding residences

4.6.1 PROCEDURES FOR SECURING AND EXECUTING A WARRANT

The process of securing and executing the warrant involves numerous steps and people. The inspector plays a critical role in the process of seeking a warrant. The inspector's knowledge and experience pertaining to the circumstances of the particular case are crucial to the drafting of warrant documents. Attorneys and inspectors work together to draft all necessary warrant documents. Inspectors have the following responsibilities in the warrant procurement process:

- Gather enough information so that a very specific description of the premises to be inspected can be obtained.
- Specify in detail the items to be searched and/or seized
- Describe in as much detail as possible the statutes and/or regulations (and the exact provisions of each, if known) that have or may have been violated.

The steps involved in securing and executing a warrant are as follows:

1. Contact the Regional Office. The inspector should discuss with her/his supervisor the facts regarding the denial or withdrawal of consent to enter or to conduct the inspection, or the need (if any) for a pre-inspection warrant (discussed in Section 4.6.2). The determination will then be made whether to seek a warrant. If the decision is that a warrant should be secured, the Region will consult with Headquarters and someone will be designated to contact the U.S. Attorney.

2. Contact EPA Headquarters Compliance Monitoring Office. The Regional office should notify OCM and OE prior to obtaining a warrant.

3. Contact the U.S. Attorney. If a decision is made that a warrant should be obtained to conduct an inspection of a particular facility, the appropriate Regional official will contact the U.S. Attorney of the U.S. District in which the facility is located. EPA will assist the U.S. Attorney in the preparation of the warrant and affidavits.

4. Apply for the Warrant. The application for a warrant identifies the statutes and regulations under which EPA is seeking the warrant. The name and location of the premises to be inspected should be clearly identified and, if possible, the owner and/or operator of the premises should be named.

   Generally, EPA must draft three documents to obtain a warrant: an application for a warrant; an accompanying affidavit; and the warrant itself. Each document contains the caption of the U.S. District Court of jurisdiction in which the facility is located, the title of the action, and the title of the particular document. Occasionally, a Memorandum of Points and Authorities in Support of Warrant Application also will be filed. This legal brief explains why the magistrate should issue the warrant.

The application may be 1 or 2 pages, if the factual background for seeking the warrant is stated in the affidavit. The application is prepared and signed by the U.S. Attorney or by the Assistant U.S. Attorney. The inspector should apply for a warrant as soon as possible after the denial or withdrawal of consent to enter and inspect and after discussions with the inspector's supervisor.

5. Prepare the Affidavits. The affidavits are critical documents that support a warrant application. An affidavit consists of consecutively numbered paragraphs that describe all facts that support the issuance of a warrant.

   The inspector's assistance is essential in the preparation of the affidavit. The inspector must help prepare a detailed description of the premises and the items to be inspected and/or seized. Details of the premises include the following: address (lot and range number or longitude and latitude, if appropriate); description of surrounding area; position on the block; number of buildings and relation of each to one another; description of each building (including color, height, construction material); and signs and other unique identifying characteristics.

   The affidavit is signed by a person with first-hand knowledge of all the facts (typically, the inspector). However, "hearsay" or "second-hand" knowledge can be used. In cases where entry has been denied, the inspector who was denied entry usually signs the affidavit. An affidavit is a sworn statement that must be notarized or sworn to before a magistrate.

6. Prepare the Warrant for Signature. A warrant authorizes an appropriate official (e.g., U.S. Marshal or EPA inspector) to enter a specifically described location and perform specifically described functions. The warrant also includes a "return of service," an inventory of the items seized, and the warrant itself (see Step 9). Since the inspection is limited by the terms of the warrant, it is important to specify to the greatest extent possible the areas to be searched (i.e, inspected), identifying any records or other documents to be inspected and/or seized, samples to be taken, etc. While a broad warrant may be permissible in civil administrative inspections, an overly broad or vague warrant will probably not be signed by the magistrate.

   The draft warrant should be prepared in advance for signature by the magistrate. Once signed, the warrant can be executed (i.e., the search authorized by the warrant may be conducted) and is enforceable.

   The inspector should accompany the attorney(s) to the office of the magistrate, if possible. Sometimes questions arise that the inspector may be able to answer, under oath, that may be added to the affidavit in support of the warrant.

7. Serve the Warrant. The warrant is served on the owner or the agent in charge of the facility to be searched prior to the conduct of the search (i.e., inspection). If there is a likelihood that entry will be refused even with a warrant, or that violence might occur, the inspector should be accompanied by a U.S. Marshal. In this instance, the U.S. Marshal is principally charged with executing the warrant, and the inspector should abide by the U.S. Marshal's decisions.

8. Inspect With the Warrant. Warrants are executed by a physical entry onto the premises. Local law or court rules may also require the handing of a copy of the warrant to someone in possession, ownership, or control of the premises to be searched or a display of a copy of the warrant in a prominent place (this is called "service"). The inspector must never relinquish the original warrant;

it must be returned to the magistrate. The inspector (or U.S. Marshal, as the case may be) must certify in the "return of service" portion of the warrant that service (or notice) was accomplished.

The warrant must be executed without undue delay and within the time period stated in the warrant (generally 10 days). Also, the warrant will usually direct that it be executed during daylight hours.

If the facility representative refuses entry to an inspector who has a warrant, but is not accompanied by a U.S. Marshal, the inspector should leave the premises and inform her/his supervisor and the Assistant U.S. Attorney about the incident. Appropriate action will then be taken, such as (1) sending the inspector back to the facility accompanied by a U.S. Marshal, or (2) seeking a citation for contempt.

The inspector should conduct the inspection in strict conformity with the warrant. The inspector is only authorized to inspect, copy, and/or seize items as authorized by the warrant. The inspector must keep a complete list of every item taken or copied, as this list will form the basis of the inventory that must be returned with the warrant to the magistrate at the conclusion of the inspection. In addition, the inspector must give facility officials receipts for all items copied or seized.

There are several points that inspectors should keep in mind when conducting an inspection with a warrant:

- If questions arise in the field about the scope of the warrant, call Regional Counsel. If the inspector discovers items that should have been included in the scope of the warrant, Counsel may be able to convince the magistrate to amend the warrant by telephone. If a few items taken are later found to be beyond the scope of the warrant, they will have to be returned. This will not normally affect the items taken pursuant to the warrant. However, if too many items are taken, this could void the entire warrant or result in suppression of all evidence.

- Keep in mind the "plain view" doctrine. Under this doctrine, the inspector would be able to seize items as long as s/he is lawfully present on the premises to see the items in plain view, without intentionally searching for them, and has reasonable grounds to believe that the items constitute evidence of a violation of the law. (See Table 4-1.)

- Interview as many individuals as possible to assist in accomplishing inspection objectives. There are no restrictions on asking questions, although there is no obligation for facility representatives or employees to respond.

- If an inspector reasonably fears that destruction of records may occur during the time s/he is attempting to copy records on site, then seizure and sequestration (restricting access to the records by anyone) would probably be authorized. In such a case, it may be better to risk a court ruling that the documents must be returned to the possessor than to suffer their certain loss.

- Any records to be taken by the inspector can be claimed as CBI and the appropriate procedures for declaring CBI should be followed (see Section 4.9.2).

9. Return the Warrant. After the inspection has been completed, the person who executed the warrant (i.e., the U.S. Marshal or whoever performs the inspection) must sign the "return of service" form, indicating the name of the person served with the warrant, the address of the facility searched (i.e., inspected), and the date of execution of the warrant. The person who executed the warrant must next submit the return of service form, an inventory of property seized (if any) from the facility, and the warrant itself to the U.S. Attorney. The U.S. Attorney will formally return the executed warrant to the issuing magistrate or judge. The inventory not only allows the court to determine whether the inspection was conducted within the scope of the warrant, but also serves as the official record of items seized.

   If anything is physically taken from the premises, such as records or samples, an inventory of such items must be submitted to the court, and the inspector must be present to certify that the inventory is accurate and complete.

   It is essential that the magistrate or judge receive the returned executed warrant within the time limit stated within the warrant. If the activities are not completed during the allowed time period, the warrant can usually be renewed, or a new one is issued based on updated information.

10. Address Challenges to the Warrant. There is always the possibility that facility representatives will challenge a warrant and the evidence obtained as a result of the warrant. The warrant and all evidence gathered pursuant to it could be invalidated by the courts. Some of the typical bases for challenges to a warrant or evidence obtained pursuant to it are listed below:

    - Insufficient cause for issuance of the warrant
    - Insufficient affidavit supporting the warrant
    - Inaccurate information in the supporting affidavit
    - Inadequate description of the premises to be searched or of the items to be seized
    - Searches beyond the scope of the warrant
    - Failure to follow appropriate procedures in executing or returning the warrant.

    In order for a warrant, or evidence obtained pursuant to it, to be successfully challenged, in whole or in part, usually someone must make a prejudicial mistake at some point in the warrant process. If the mistake is sufficiently serious, an entire case could be lost. The procedures for obtaining, executing, and returning a warrant are well defined and established and must be followed as closely as possible.

4.6.2 SEEKING A PRE-INSPECTION WARRANT

A warrant may be obtained prior to the inspector entering the facility to conduct the inspection. The pre-inspection warrant is different from a warrant received after an inspection has begun in that it does not require that a facility official deny entry to an inspector. A pre-inspection warrant may be issued at the

discretion of the Regional office. The inspector may want to consider obtaining a pre-inspection warrant if one of the following situations exists:

- A violation is suspected that could be covered up during the time needed to secure a warrant after the inspector arrives on site.
- Prior correspondence with facility officials (e.g., review of EPA records) or other contact with such officials provides reason to believe that entry will be denied when the inspector arrives
- The facility is unusually remote from the Regional office or a U.S. District Court so that obtaining a warrant at a later stage in the inspection process would be inconvenient to EPA.

4.7 THE OPENING CONFERENCE

4.7.1 PURPOSE

Once the EPA inspector has presented her/his credentials and the required notice for conducting an inspection, it is time for the opening conference. The inspector should ask whether a conference room or office is available where s/he can conduct the opening conference and review facility records and files. The opening conference provides an ideal opportunity for the inspector to strengthen EPA-industry relations. The inspector's role, in addition to that of determining compliance problems at facilities subject to TSCA, can be that of an educator and public relations liaison with industry. The inspector can serve in this role throughout the inspection, but especially during the opening and closing conferences.

The inspector should be prepared to demonstrate her/his thorough understanding of the major sections of TSCA (i.e., those under which EPA compliance inspections are conducted) and the applicable regulations. Industry must also be familiar with the requirements of TSCA and the regulations in order to comply with the law. Therefore, it is crucial for inspectors to be well-versed in TSCA and the regulations promulgated pursuant to it, including any new regulations, as they are published in the *Federal Register*. The inspector should always have copies of such regulations on hand. During the course of an inspection, it may be necessary to refer some industry questions or requests (e.g., for TSCA-related publications) to the TSCA Hotline or to refer other matters to appropriate EPA Region or Headquarters staff.

During the opening conference, the inspector should have the following objectives:

- Establish a rapport with facility officials

- Conduct the meeting on a positive and professional note
- Answer questions concerning TSCA and applicable regulations and have copies of TSCA available upon request plus citations to any applicable regulations
- Do not overstep authority to accommodate facility officials (e.g., do not give opinions about the acceptability of facility practices or whether the facility is in compliance with TSCA and/or applicable regulations)
- Collect and document necessary data to support Case Development Officers (in the Regions and at EPA Headquarters) in their efforts to bring necessary enforcement actions; for example, collect background facility information (i.e., sales revenue) necessary to assess the facility's ability to pay
- Update existing facility records on file at EPA Regions and Headquarters.

4.7.2 PROCEDURES

The inspector should begin the opening conference by outlining inspection objectives in general terms to inform facility officials of the purpose and scope of the inspection. The inspector should then present the facility owner (or her/his designated agent) with the TSCA Inspection Confidentiality Notice (Figure 4-2). This notice informs the facility representative of the right to claim as CBI any information (e.g., documents, records, physical samples, or other material) collected from the facility during the inspection. Facility officials should also be briefed on EPA's CBI procedures and on their right to make CBI claims (see Section 4.7.3).

The inspector should then describe the inspection plan (prepared prior to the opening conference) to facility officials. By providing a description of the inspection plan, the inspector fosters an atmosphere of cooperation between EPA and the facility, which is important for ensuring an understanding by both parties of TSCA compliance issues. By keeping the discussion of the inspection plan general (i.e., by not disclosing all details of all the types of records and other data that will be inspected and perhaps copied), the inspector can avoid providing advance warnings to facility officials.

The inspector should keep in mind throughout the opening conference the need to update existing facility records in EPA Regional and Headquarters files. Information may be available in annual reports, advertising solicitations, or stockholders reports. This information may include the following items: length of time in business; types of products manufactured; plant site locations; estimated number and

FIGURE 4-2
TSCA INSPECTION CONFIDENTIALITY NOTICE

EPA

United States Environmental Protection Agency
Washington, D.C. 20460
Toxic Substances Control Act

Form Approved
OMB No. 2070-0007
Approval Expires 10-31-92

TSCA INSPECTION CONFIDENTIALITY NOTICE

The public reporting burden for this collection of information is estimated to average 5 minutes per response. This estimate includes time for reviewing instructions, searching existing data sources, gathering and maintaining the needed data, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information to the Chief, Information Policy Branch (PM-223), US Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460, and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503, marked ATTENTION: Desk Officer for EPA.

1. Investigation Identification			2. Firm Name
Date	Inspector No.	Daily Seq. No.	
3. Inspector Name			4. Firm Address
5. Inspector Address			6. Chief Executive Officer Name
			7. Title

TO ASSERT A CONFIDENTIAL BUSINESS INFORMATION CLAIM

It is possible that EPA will receive public requests for release of the information obtained during inspection of the facility above. Such requests will be handled by EPA in accordance with provisions of the Freedom of Information Act (FOIA), 5 USC 552; EPA regulations issued thereunder, 40 CFR Part 2; and the Toxic Substances Control Act (TSCA), Section 14. EPA is required to make inspection data available in response to FOIA requests unless the Administrator of the Agency determines that the data contain information entitled to confidential treatment or may be withheld from release under other exceptions of FOIA.

Any or all the information collected by EPA during the inspection may be claimed confidential if it relates to trade secrets or commercial or financial matters that you consider to be confidential business information. If you assert a CBI claim, EPA will disclose the information only to the extent, and by means of the procedures set forth in the regulations (cited above) governing EPA's treatment of confidential business information. Among other things, the regulations require that EPA notify you in advance of publicly disclosing any information you have claimed as confidential business information.

A confidential business information (CBI) claim may be asserted at any time. You may assert a CBI claim prior to, during, or after the information is collected. The declaration form was developed by the Agency to assist you in asserting a CBI claim. If it is more convenient for you to assert a CBI claim on your own stationary or by marking the individual documents or samples "TCSA confidential business information," it is not necessary for you to use this form. The inspector will be glad to answer any questions you may have regarding the Agency's CBI procedures.

While you may claim any collected information or sample as confidential business information, such claims are unlikely to be upheld if they are challenged unless the information meets the following criteria:

1. Your company has taken measures to protect the confidentiality of the information, and it intends to continue to take such measures.
2. The information is not, and has not been, reasonably obtainable without your company's consent by other persons (other than governmental bodies) by use of legitimate means (other than discovery based on showing of special need in a judicial or quasi-judicial proceeding).
3. The information is not publicly available elsewhere.
4. Disclosure of the information would cause substantial harm to your company's competitive position.

At the completion of the inspection, you will be given a receipt for all documents, samples, and other materials collected. At that time, you may make claims that some or all of the information is confidential business information.

If you are not authorized by your company to assert a CBI claim, this notice will be sent by certified mail, along with the receipt for documents, samples, and other materials to the Chief Executive Officer of your firm within 2 days of this date. The Chief Executive Officer must return a statement specifying any information which should receive confidential treatment.

The statement from the Chief Executive Officer should be addressed to [illegible] and mailed by registered, return-receipt requested mail within 7 calendar days of receipt of the Notice. Claims may be made any time after the inspection, but inspection data will not be entered into the special security system for TSCA confidential business information until an official confidentiality claim is made. The data will be handled under the agency's routine security system unless and until a claim is made.

TO BE COMPLETED BY FACILITY OFFICIAL RECEIVING THIS NOTICE:	If there is no one on the premises of the facility who is authorized to make business confidentiality claims for the firm, a copy of this Notice and other inspection materials will be sent to the company's chief executive officer. If there is another company official who should also receive this information, please designate below.
I have received and read the notice.	

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature		Name
Name		Title
Title	Date Signed	Address

EPA 7740-4 Rev (9-91)

Inspection File

types of employees; general description of physical facilities; general financial information; corporate structure (parent company and subsidiary); names of corporate officers; and management structure.

The most important objective of the opening conference is to obtain as much information concerning the particular facility's operations and practices as possible. In addition, the inspector should use the opening conference to question facility officials about such practices, operations, and any other data that may not have been included in EPA records or that require clarification. The inspector should refer to the facility's organizational chart to learn who is in charge of what operations at the facility and whom to contact for additional information.

Important data to gather at the opening conference includes the following:

- Type and extent of operations conducted at the facility. Inquire about the type of operational activities that take place at the facility from an operational perspective, including details on manufacturing, importing, processing, research and development (R&D), etc.

- Types of chemicals. Obtain information on the types of chemicals processed, manufactured, imported, sold, etc. Also obtain information on the nature and extent of any R&D activities at the facility and what chemical substances are the subjects of these activities.

- Types of records retained by facility. Gather information on the types of records maintained by the facility to record manufacture, imports, sales, inventory, R&D, etc.

- TSCA-related policies. Obtain copies of any facility policies related to TSCA Sections 4, 5, 8, 12, and 13. Any differences between these policies and the actual requirements of these sections of TSCA should be brought to the immediate attention of facility officials, without discussing whether there are any potential or actual violations of TSCA.

- Staff/employee information. Obtain information concerning the number of full and part time employees and what percentage of employees work in various areas, including manufacturing, processing, sales, and R&D.

- Corporate fiscal year. Ascertain the corporate fiscal year of the facility for the purposes of reporting under Section 8(a) and inventory updates.

- TSCA applicability to facility operations. Verify that facility operations and programs have not changed in such a way as to affect the applicability of TSCA to facility operations. For instance, the inspector may learn that a facility has recently obtained a new permit to store wastes on site or that it no longer manufactures a particular chemical. Obtaining such information will allow the inspector to revise the inspection plan as necessary.

- Existing facility environmental programs. Ask whether any environmental programs are in place at the facility (e.g., effluent sampling, analysis, reporting, training, inspection,

maintenance of pollution control equipment, emergency response). The name(s) and telephone numbers of any person(s) in charge of these programs the facility should be obtained.

- Key contact persons and accountability. Determine the facility's chain-of-command in cases of emergency and the responsibilities of various staff members in the facility operations.

To save time, the inspector should resolve logistical issues at the opening conference in preparation for the actual inspection. The following factors should be considered:

- Having facility official accompany inspector. Before the inspection is conducted, make arrangements with facility officials for a facility representative to accompany the inspector on the inspection. The representative should be able to describe facility layout and operations and to indicate what data, records, etc., should be claimed as CBI. (Facility claims of confidentiality may only be made by an individual with the authority to make such claims, as discussed in Section 4.7.3.3.)

- Establishing a meeting schedule. Arrange for a schedule of necessary meetings to be developed, based on the inspection plan and the inspector's understanding of the responsibilities of various facility officials. This schedule will allow individuals enough time to prepare for discussions with the inspectors.

- Scheduling closing conference. Set a specific time and place for the closing conference (discussed in Section 4.9). This conference will provide a final opportunity to gather information from facility officials, to answer questions, and to complete administrative duties. The closing conference will also provide a forum for summarizing the inspection.

4.7.3 TSCA CONFIDENTIAL BUSINESS INFORMATION

4.7.3.1 TSCA INSPECTION CONFIDENTIALITY NOTICE

The TSCA inspector must present the facility owner (or her/his designated agent) with the TSCA Inspection Confidentiality Notice (Figure 4-2) at the start of the opening conference. This notice informs the facility representative of the right to claim any information (e.g., documents, records, physical samples, or other material) collected from the facility during the inspection as confidential. All CBI claims must be made by completing the Declaration of Confidential Business Information form (Figure 4-3). This form can protect many items from public disclosure.

The inspector should also have available, if possible certification that s/he is authorized to have access to CBI. A handwritten note from the DCO is sufficient or the facility can call the DCO for such information.

FIGURE 4-3
DECLARATION OF CONFIDENTIAL BUSINESS INFORMATION

United States Environmental Protection Agency
Washington, D.C. 20460
Toxic Substances Control Act

Form Approved
OMB No. 2070-0007
Approval Expires 10-31-92

DECLARATION OF CONFIDENTIAL BUSINESS INFORMATION

The public reporting burden for this collection of information is estimated to average 5 minutes per response. This estimate includes time for reviewing instructions, searching existing data sources, gathering and maintaining the needed data, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information to the Chief, Information Policy Branch (PM-223), US Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460, and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503, marked ATTENTION: Desk Officer for EPA.

1 Investigation Identification			2. Firm Name
Date	Inspector No.	Daily Seq. No.	
3. Inspector Address			4. Firm Address

Information designated as confidential business information

No.	Description

ACKNOWLEDGEMENT BY CLAIMANT

The undersigned acknowledges that the information described above is designated as Confidential Business Information under Section 14(c) of the Toxic Substances Control Act. The undersigned further acknowledges that he/she is authorized to make such claims for his/her firm.

The undersigned understands that challenges to confidentiality claims may be made, and that claims are not likely to be upheld unless the information meets the following guidelines: (1) The company has taken measures to protect the confidentiality of the information and it intends to continue to take such measures; (2) The information is not, and has not been reasonably attainable without the company's consent by other persons (other than governmental bodies) by use of legitimate means (other than discovery based on a showing of special need in a judicial or quasi-judicial proceeding); (3) The information is not publicly available elsewhere; and (4) Disclosure of the information would cause substantial harm to the company's competitive position.

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Inspector Signature		Claimant Signature	
Name		Name	
Title	Date Signed	Title	Date Signed

EPA 7740-2 Rev (8-91)

4.7.3.2 DECLASSIFICATION OF CBI

The facility owner or designated agent should be informed that an authorized facility official may declassify information claimed as CBI in the original submission of the Declaration of Confidential Business Information. However, the inspector must inform the facility official that such declassification cannot be made verbally, but rather must be made through a letter waiving confidentiality sent to the EPA DCO for OPPT. A separate letter must be sent for each item for which confidentiality is to be waived.

4.7.3.3 CONFIDENTIALITY CLAIMS

The inspector must determine whether the facility official to whom the Confidentiality Notice was given is authorized by the facility to make claims of confidentiality. The official's signature must be obtained on the notice certifying that the person does or does not have such authority. The facility owner is assumed to have such authority. In most cases, it is expected that the agent designated by the owner will also have such authority. It is possible that the facility officials will want to consult with their attorneys concerning this issue.

If no one at the site has the authority to make business confidentiality claims, the notice and other inspection materials should be sent to the CEO of the company within 2 days of the inspection. The CEO will then have 7 calendar days in which to make confidentiality claims. During this 7-day period, the inspector should follow routine security measures in the event that records taken during the inspection are subsequently claimed as CBI. For example, the inspector should file the records in a secured area instead of leaving them on her/his desk.

The facility official may also designate a company official, in addition to the CEO, who should also receive a copy of the notice and other inspection materials. Space is provided on the notice form for such a designation.

4.8 INSPECTION PLAN REVISIONS

After the opening conference, the inspector should have sufficient information to decide whether any substantial changes to the inspection plan are necessary. If no changes to the plan are necessary, the inspector should proceed with the inspection. If changes are required, then inspection activities should be altered accordingly and appropriate notes made in the inspector's notebook.

When revising the inspection plan, the inspector should keep in mind time constraints and resource limitations (e.g., funds and manpower) and ensure that the revised inspection can be conducted using the same equipment that has been brought on site.

If the review is being conducted by an inspection team (instead of by a single inspector), revision of the inspection plan should focus on the appropriateness of task assignments in addition to other concerns. Assignments given to inspection team members should be re-evaluated and adjusted as necessary based on information gathered during the opening conference as well as the expertise and responsibilities of the various inspectors.

When the inspection team is actually assembled on site, where first-hand observations of facility size, layout, and complexity are possible, it is important to determine again whether inspection activities can actually be completed in the allotted time and whether each team member's task assignments are reasonable given time and scheduling constraints. The inspection team may excuse themselves and ask to have a few moments alone to discuss possible scheduling modifications.

The various procedures the inspector should follow in determining compliance with Sections 4, 5, 8, 12, and 13 of TSCA are discussed in Chapters 5 through 8.

4.9 THE CLOSING CONFERENCE

4.9.1 PURPOSE

The purpose of the closing conference is to allow the inspector and facility representatives to resolve final administrative matters concerning the inspection. At the conclusion of the TSCA inspection, the inspector holds a closing conference with facility officials to summarize the inspection proceedings, complete and submit to facility representatives certain forms related to the inspection (discussed in Section 4.9.2), and obtain from facility officials any outstanding records or other data needed by the inspector.

4.9.2 PROCEDURES

The inspector should summarize the inspection findings in an objective and factual manner. During the conference, it is critical that the inspector refrain from drawing conclusions regarding any potential violations that may have been discovered during the inspection. For example, an inspector conducting an inspection of a facility operating with an R&D exemption might report the absence or presence of the

following information: 1) copies of or citations to information reviewed to determine risks, and 2) documentation of the nature and method of risk notification. By reporting whether s/he discovered this information, the inspector is presenting her/his inspection findings. If, however, the inspector links her/his findings to the Section of TSCA which the facility has potentially violated, then the inspector has discussed a potential violation. The same objectives that govern the manner in which an inspector should conduct the opening conference (discussed in Section 4.3) apply to the closing conference as well.

The inspector should clarify any final questions and provide the facility officials with the opportunity to ask any final questions. If the inspector wants to obtain additional documents not available at the time of the closing conference, the inspector should request these documents and agree upon a reasonable date by which the facility officials should submit the documents. However, the inspector should make every effort to obtain all necessary records during the inspection, thus keeping the need for follow-up information to a minimum. The inspector should request that any documents that the company may decide to submit to EPA Headquarters or correspondence with EPA resulting from the inspection be copied and sent to her/him.

During the closing conference, the inspector must also require the facility officials to complete 2 forms related to the inspection process. These forms are the Declaration of Confidential Business Information (Figure 4-3) and the Receipt for Samples and Documents (Figure 4-4).

- Receipt for samples and documents. The inspector must provide facility officials with a copy of the TSCA Receipt for Samples and Documents, which lists and describes each document and sample taken by the inspector from the facility. This receipt must be signed and dated by a facility official and the inspector. The receipt should identify the following:

  - A description of all physical samples taken

  - A description of all records, photographs, or other property taken (particularly crucial when inspecting with a warrant)

  - A brief description of information claimed as CBI (which should be listed on the Declaration of Confidential Business Information form).

  The purpose of this detailed receipt is to show that facility officials knew exactly what documents and samples were taken and to allow full review by facility officials of the documents and samples collected so that confidentiality claims can be made.

FIGURE 4-4
RECEIPT FOR SAMPLES AND DOCUMENTS

EPA

United States Environmental Protection Agency
Washington, D.C. 20460
Toxic Substances Control Act

Form Approved
OMB No. 2070-0007
Approval Expires 10-31-92

RECEIPT FOR SAMPLES AND DOCUMENTS

The public reporting burden for this collection of information is estimated to average 6 minutes per response. This estimate includes time for reviewing instructions, searching existing data sources, gathering and maintaining the needed data, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information to the Chief, Information Policy Branch (PM-223), US Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460, and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503, marked ATTENTION: Desk Officer for EPA.

1. Investigation Identification			2. Firm Name
Date	Inspector No.	Daily Seq. No.	
3. Inspector Address			4. Firm Address

The documents and samples of chemical substances and/or mixtures described below were collected in connection with the administration and enforcement of the Toxic Substances Control Act.

Receipt of the document(s) and/or sample(s) described is hereby acknowledged:

No.	Description

Optional:
Duplicate or split samples: Requested and Provided ☐ Not Requested ☐

Certification
I certify that the statements I have made on this form and all attachments thereto are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Inspector Signature		Recipient Signature	
Name		Name	
Title	Date Signed	Title	Date Signed

EPA 7740-1 Rev (8-91)

Inspection File

- Declaration of CBI. The inspector must also provide facility officials with a copy of the TSCA Declaration of Confidential Business Information. This form must include a list of each document, photograph, or other data claimed by an authorized facility representative as CBI. Both the inspector and the claimant (i.e., the facility official) must sign and date the completed document.

  The inspector should not suggest or advise that any document or other item be claimed as confidential. The decision must be left entirely to the facility official. However, the inspector may and should answer questions concerning claims of confidentiality (e.g., when a claim is considered appropriate). The inspector should note that CBI claims on occasion are unfounded. CBI claims should be considered for review and challenge in a manner consistent with the requirements of 40 CFR §2.203. IMD personnel can provide assistance to the inspector in reviewing CBI claims to determine if they are valid. The inspector should inform facility officials that each declared item should meet all four criteria listed on the claim form and that those that do not meet all four criteria, should not be listed as CBI. (For additional information on CBI, see Chapter 3.)

  The inspector should keep in mind that some data may have been declared CBI during the inspection. These items should be confirmed with facility officials and added to the CBI declaration form.

- No authorized claimant. If no on site facility official is authorized to make CBI claims at the time of the closing conference, the inspector should:

  - Make a copy of the completed and signed Receipt for Samples and Documents.

  - Make a copy of the completed and signed TSCA Inspection Confidentiality Notice (discussed in Section 4.7.4.1).

  - Complete the top portion only (i.e., investigation identification information, firm name, inspector address, firm address) of the Declaration of Confidential Business Information form.

  - Mail the three forms (above) certified, return-receipt-requested to the CEO of the facility within 2 days of the inspection. (The CEO will have 7 calendar days to make CBI claims on the declaration form.)

  - If another company official has also been designated to make CBI claims, the three forms should be sent to that official in addition to the CEO.

  The inspector need not take any measures during the 7-day period mentioned above beyond following the routine security procedures normal for inspection data collected from the facility. However, immediately upon notification of the Regional DCO by the appropriate facility officials (i.e., those authorized to claim CBI) that data is being claimed CBI, EPA will commence TSCA-CBI procedures with respect to such data. If a CBI claim is made, it is the responsibility of the DCO to notify all parties (i.e., inspector, laboratory, case preparation staff, and any others who may be handling the information) of the fact that the data is CBI and to log the material as required.

4.9.3 COMPLIANCE OUTREACH

Since the inspector is often the only contact between EPA and the regulated industries, s/he should be aware of opportunities to promote compliance with EPA regulations. The closing conference provides an ideal opportunity to offer various kinds of help to facility officials. The inspector will have just completed an inspection and will have first-hand knowledge of questions, problems, and possible solutions.

However, in this role, the inspector should be careful to answer only those questions that are within her/his ability or authority. The inspector should never recommend that a particular step be taken to address a problem. Such advice may be wrong, and if the facility is later found to be in noncompliance, EPA's ability to pursue an enforcement action would be jeopardized. However, the inspector can offer or suggest resources that are available to facility officials to help solve problems (e.g., technical publications, special services). Inspectors should refer questions and problems to other EPA personnel as needed, and follow up with those personnel when practical to see that facility officials receive a response.

Since the purpose of the inspection process is to promote compliance, as well as to identify violations, it is important for the inspector to help raise the level of a facility's awareness of TSCA requirements. The closing conference is an ideal opportunity for the inspector to promote compliance by disseminating EPA literature to the facility. The following publications may be recommended or given to the facility to increase their awareness of TSCA requirements.

Toxic Substances Control Act

- Public Law 94-469. October 11, 1976. *Toxic Substances Control Act.*

  An act to regulate commerce and protect human health and the environment by requiring testing and necessary use restrictions on certain chemical substances, and for other purposes.

- Public Law 97-129. December 29, 1981. *Amendment to the Toxic Substances Control Act.*

  An act to amend the Toxic Substances Control Act to authorize appropriations for fiscal years 1982 and 1983.

- U.S. EPA. July 1990. "Subchapter R: Regulations; Toxic Substances Control Act." In *Federal Register*, vol. 40, parts 700-789 and 790-end. Washington, DC.

  Regulations developed by EPA to guide the implementation and enforcement of TSCA.

General Information

- U.S. EPA. June 1987. *The Layman's Guide to the Toxic Substances Control Act.* Office of Toxic Substances. Washington, DC.

  A discussion of the major provisions of TSCA intended to familiarize the public with the law.

- U.S. EPA. 1985. TSCA Chemical Substances Inventory. Washington, DC.

  The 1985 edition updates the printed Inventory and supersedes previous versions. The new Inventory is not a list of toxic substances but a register of the more than 63,000 chemical substances in the United States regulated by TSCA.

Section 5 Information

- U.S. EPA. November 1991. *New Chemicals Program (EPA-560/1-91-005).* Office of Toxic Substances. Washington, DC.

  A Q&A fact paper about EPA's New Chemicals Program, which is part of the Office of Toxic Substances and which reviews PMN submissions to identify substances requiring regulatory action.

- U.S. EPA. September 1983. "Supplementary Premanufacture Questions and Answers." Washington, DC.

  A compilation of PMN-related questions and answers, including coverage of what must be reported, data on the new chemical, confidentiality, and who must report.

- U.S. EPA. No date. "Background on PMNs, Section 5(e) Orders, and Significant New Use Rules and Summary of Direct Final Rule." Washington, DC.

  A one-page fact sheet.

- U.S. EPA. No date. "Toxic Substances Control Act Section 5(a)(2) Significant New Use Rule." Washington, DC.

  Fact sheet.

Section 8 Information

- U.S. EPA. June 1991. *TSCA Section 8(e) Reporting Guide.* Office of Toxic Substances, Office of Pesticides and Toxic Substances. Washington, DC.

  A guide for the regulated community complying with Section 8(e) of TSCA intended to make certain information more accessible and to provide both general and specific examples of submitted information, plus EPA's comments on such submissions.

- U.S. EPA. June 1989. *Comprehensive Assessment Information Rule: Question and Answer Document.*. Washington, DC. (Also March 1989 and December 1988 versions)

  A section-by-section listing of common questions, and their answers, asked by those in the regulated community.

- U.S. EPA. September 1988. "TSCA Section 8(c) Allegations of Significant Adverse actions." Existing Chemical Assessment Division, Office of Toxic Substances. Washington,DC.

  A Q&A fact sheet about Section 8(c) of TSCA.

- U.S. EPA. August 1990. *Instructions for Reporting for the Partial Updating of the TSCA Chemical Inventory Data Base (EPA 560/7-90-006).* Office of Toxic Substances. Washington DC.

- U.S. EPA. No date. "Toxic Substances Control Act (TSCA): TSCA Section 8(a)."

  Q&A fact sheet.

- U.S. EPA. No date. "Toxic Substances Control Act (TSCA): TSCA Section 8(c)."

  Q&A fact sheet.

- U.S. EPA. No date. "Toxic Substances Control Act (TSCA): TSCA Section 8(d)."

  Q&A fact sheet.

Sections 12 and 13 Information

- U.S. Department of the Treasury. August 1, 1983. "Customs Regulations Amendments Relating to Special Classes of Merchandise. Final Rule." In *Federal Register*, vol. 48, p. 34734. Customs Service. Washington, DC.

  This rule amends the Customs Regulations to regulate the entry of any chemical substance imported in bulk or as part of a mixture into the customs territory of the United States.

- U.S. EPA. April 1991. *Toxic Substances Control Act: A Guide for Chemical Importers/Exporters: An Overview (EPA 560/1-91-001).* Office of Toxic Substances. Washington, DC.

  This publication summarizes the requirements of sections 12(b), Exports, and 13, Imports, of TSCA, and the rules and policies issued under these sections.

- U.S. EPA. December 16, 1980. "Chemical Imports and Exports; Notification of Export. Final Rule." In *Federal Register*, vol. 45, p. 82845. Washington, DC.

This rule outlines procedures for exporters to submit notifications to EPA under section 12(b) of TSCA.

Existing Chemicals

- U.S. EPA. No date. TSCA Section 5(a)(2) Significant New Use Rules for Existing Chemicals, Frank Kover, Chief, Chemical Screening Branch, (202) 382-3436.

- U.S. EPA. No date. For Your Information (FYI) Submissions: An Overview, Jacqueline Favilla, FYI Coordinator, OTS, (202) 475-8823.

- U.S. EPA. No date. TSCA Section 4 -- Test Rules, Chief, Test Rules Development Branch, (202) 475-8130.

- U.S. EPA. No date. TSCA Section 8(c) Allegations of Significant Adverse Reactions, TSCA Assistance Office, (202) 554-1404.

- U.S. EPA. No date. Comprehensive Assessment Information Rule (CAIR), Joan Kuchkuda, Chemical Screening Branch, (202) 382-3832.

- U.S. EPA. No date. Chemical Advisories, Dr. Laurence S. Rosenstein, Chief, Risk Assessment Branch, (202) 382-3832.

- U.S. EPA. No date. Section 8(e) of the Toxic Substances Control Act: An Overview, David R. Williams TSCA Section 8(e) Coordinator, OPPT, (202) 382-3468.

  A collection of fact sheets and designated EPA contacts from the Existing Chemicals Assessment Division of OPPT.

Chapter Five

TSCA Section 4 Inspections

Page

5.0 TSCA SECTION 4 INSPECTIONS 5-1

5.1 INTRODUCTION 5-1

5.1.1 CONSENT AGREEMENTS 5-1
5.1.2 SELECTION OF A CHEMICAL SUBSTANCE FOR A TEST RULE . . . 5-2
5.1.3 APPLICABILITY OF TEST RULES 5-2

5.2 INSPECTION OBJECTIVES 5-5

5.2.1 PHASE 1 INSPECTION 5-5
5.2.2 PHASE 2 INSPECTION 5-7

LIST OF TABLES

TABLE 5-1 40 CFR PART 799 SUBPART C CHEMICALS SUBJECT TO TESTING CONSENT ORDERS 5-3
TABLE 5-2 40 CFR PART 799 SUBPART B SPECIFIC CHEMICAL TEST RULES 5-8
TABLE 5-3 40 CFR PART 799 SUBPART D MULTICHEMICAL TEST RULES 5-9

BLANK PAGE

5.0 TSCA SECTION 4 INSPECTIONS

This chapter addresses inspections under Toxic Substances Control Act (TSCA) Section 4, which provides the U.S. Environmental Protection Agency (EPA) with the authority to establish test rules applicable to companies manufacturing, importing, or processing chemical substances that EPA determines are subject to testing requirements. Another objective of TSCA Section 4 inspections is to ensure that facilities that perform the required tests comply with prescribed Good Laboratory Practice (GLP) Standards which represent the procedural and quality control aspects of a TSCA Section 4 test rule. This chapter does not address the GLP inspections. However, they are being performed by the Office of Compliance Monitoring (OCM) Laboratory Data Integrity Assurance Division, the National Enforcement Investigations Center (NEIC), or by Regions 2, 3, and 5, in conjunction with OCM.

5.1 INTRODUCTION

TSCA Section 4 authorizes EPA to require manufacturers, importers, and processors of chemical substances and mixtures to test select chemicals to determine whether they have adverse health or environmental effects. In addition, EPA has implied authority to enter into enforceable consent agreements requiring testing in which they provide procedural safeguards equivalent to those that apply when testing is conducted by rule.

5.1.1 CONSENT AGREEMENTS

Consent agreements adopted pursuant to TSCA Section 4 are "orders" for the purposes of TSCA Section 15, and EPA regards failure to comply with any aspect of a consent agreement as a "prohibited act" under TSCA Section 15. EPA and industry can conserve resources by reaching consent agreements instead of using the formal rulemaking procedures, but consent agreements have limitations. While enforceable against its signatories, a consent agreement is not enforceable against a non-participatory party, and it does not set in motion the reimbursement procedures.

EPA uses enforceable consent agreements to accomplish testing when a consensus exists among EPA, affected manufacturers, importers, and/or processors, and interested members of the public concerning the need for and scope of testing. If such a consensus does not exist and EPA believes that it can make the findings specified in TSCA Section 4(a) (and listed below), EPA will initiate proceedings to

promulgate test rules. Chemicals subject to testing consent orders (as of March 4, 1992) are listed in Table 5-1.

The inspector should note that the responsibility of enforcing compliance with consent agreements belongs to OCM's Laboratory Data Integrity Assurance Division. The inspector should be aware of the contents of a consent agreement. For example, a consent agreement may also require that if EPA promulgates a SNUR applicable to the test chemical under TSCA Section 5(a)(2), the consent agreement will have the status of a test rule for purposes of TSCA Section 5(b)(1)(A), and manufacturers, importers, and/or processors signing the agreement must comply with the data submission requirements imposed by that provision.

5.1.2 SELECTION OF A CHEMICAL SUBSTANCE FOR A TEST RULE

EPA exercises its authority under Section 4 when it can make certain statutory findings about the substances of concern and when industry fails to develop data on its own. The required findings are that a chemical may present a substantial risk, there are insufficient data already available to perform a reasoned risk assessment, and that testing is required to develop such data. Test rules can be found at 40 CFR Part 799.

The Interagency Testing Committee (ITC) was established to recommend chemicals to EPA for priority testing. The total number of chemical substances and mixtures on an ITC list may not exceed 50. Within 12 months of EPA's receipt of an ITC recommendation, EPA must either initiate rulemaking requiring testing or must publish its reasons for not doing so.

5.1.3 APPLICABILITY OF TEST RULES

Each test rule will specify for its selected chemical(s) whether the responsibility to conduct the required test results is borne by (1) each person who manufactures or imports or intends to manufacture or import the chemical; (2) each person who processes or intends to process the chemical; or (3) manufacturers, importers, and processors.

Manufacturers, importers, and processors of the chemicals identified in a TSCA Section 4 rule may be required to test these chemicals and bear the costs. To avoid duplication of testing activity and to share costs, two or more companies subject to a test rule may join together to form a "consortium" or "joint

TABLE 5-1 40 CFR PART 799 SUBPART C
CHEMICALS SUBJECT TO TESTING CONSENT ORDERS

Subject Chemical	CAS Number
Aniline	62-53-3
1,1,1-Trichloroethane	71-55-6
Di-n-butyl phthalate	84-74-2
Di-n-hexyl phthalate	84-75-3
2-nitroaniline	88-74-4
2-chloroaniline	95-51-2
3,4-dichloroaniline	95-76-1
2,4-dinitroaniline	97-02-9
2,6-dichloro-4-nitro-aniline	99-30-9
4-nitroaniline	100-01-6
4-chloroaniline	106-47-8
Triethylene glycol monomethyl ether	112-35-6
Triethylene glycol monoethyl ether	112-50-5
Di-2-ethylhexyl phthalate	117-81-7
Ditridecyl phthalate	119-06-2
Dimethyl phthalate	131-11-3
Triethylene glycol monobutyl ether	143-22-6
3,4-Dichlorobenzotrifluoride	328-84-7
Octamethylcyclotetrasiloxane	556-57-2
Methyl tert-butyl ether	1634-04-4
C.I. Disperse Blue 79:1 Acetamide,N-[5-[bis[2-(acetyloxy) ethyl]amino]-2-[(2-bromo-4,6-dinitrophenyl)azo]-4-methoxy-phenyl]-	3618-72-2
Diundecyl phthalate	3648-20-2
Crotonaldehyde	4170-30-3
Diisodecyl phenyl phosphite	25550-98-5
Diisodecyl phthalate	26761-40-0
Ditridecyl phthalate (mixed isomers)	68515-47-9
Diisodecyl phthalate (mixed isomers)	68515-49-1
Dihexyl phthalate (mixed isomers)	68515-50-4
4-Nonylphenol, branched	84852-15-3
Mesityl oxide (56 *FR* 43878)	141-79-7
4-vinylcyclohexane (56 *FR* 47912)	100-40-3
Sodium cyanide (56 *FR* 65442)	143-33-9
Acrylic acid (57 *FR* 7656)	79-10-7

venture" to sponsor a member company or a qualified third party to conduct the required tests and to submit data on behalf of the consortium or joint venture. The law provides for sharing of the testing costs by all manufacturers, importers, or processors subject to a particular test rule. Other companies are typically granted an exemption from the testing regulation if EPA determines that the chemical they manufacture or process is equivalent to a substance for which data have already been submitted, making further testing duplicative.

If a company manufactures, imports, or processes a chemical substance subject to a TSCA Section 4 test rule, then the company must either submit a letter of intent to conduct testing or apply for an exemption from the requirements of the applicable test rule. Processors are typically granted a conditional exemption on the assumption that manufacturers will submit the letter of intent. EPA considers letters of intent to test as commitments to sponsor the tests for which they are submitted, unless EPA agrees to an exemption application when more than one person indicates an intent to sponsor equivalent tests.

TSCA Section 4 requires companies that receive an exemption before the end of the reimbursement period to provide "fair and equitable reimbursement" to those manufacturers or processors who had to bear the full cost of testing the subject chemical. The reimbursement period for any test data for a chemical substance or mixture is a period beginning on the date the test data are submitted and ending 5 years later or at the expiration of a period that EPA determines was necessary to develop the data, whichever is later. If the parties cannot agree on the amount and method of reimbursement, TSCA Section 4 authorizes EPA to promulgate rules for the determination of fair and equitable reimbursement for costs incurred with respect to a chemical substance or mixture. EPA has promulgated a Data Reimbursement Rule at 40 CFR Part 791. For any questions relating to the reimbursement process, the inspector should contact the program office.

Rigorous enforcement and compliance with TSCA Section 4 test rules are vital to the overall effectiveness of TSCA since data submitted pursuant to TSCA Section 4 test rules allow EPA to determine which chemicals should be further scrutinized through substantive control regulations under TSCA Sections 6 and 7. TSCA Section 4 data, in conjunction with information received under TSCA Section 5, may also serve as the basis for a decision to limit or prohibit the manufacturing or processing of a new chemical under TSCA Sections 5(e) or 5(f).

5.2 INSPECTION OBJECTIVES

The inspection objectives to determine compliance with TSCA Section 4 are:

- To verify that those companies subject to a TSCA Section 4 test rule submitted a letter of intent to conduct the required testing, and that the information submitted in the letter of intent is truthful, complete, and timely (Phase 1).
- To verify that those companies subject to a TSCA Section 4 test rule that did not submit a letter of intent during a Phase 1 inspection applied for and received an exemption, and that the information submitted in the exemption application is truthful, complete, and timely (Phase 1).
- To identify companies that are manufacturing, importing, or processing a chemical subject to a TSCA Section 4 test rule and that have failed to submit a letter of intent to conduct the required testing or applied and received an exemption from testing (Phase 2).

The Phase 2 inspection (i.e., identify failure to submit a letter of intent to test or obtain an exemption) is usually done in conjunction with the TSCA Section 5 general inventory part of the inspection (discussed in Chapter 6). During the Phase 2 inspection, the inspector will verify that those firms eligible for an exemption from the testing requirements of a TSCA Section 4 rule applied for and received an exemption.

5.2.1 PHASE 1 INSPECTION

The inspector should review an official copy of the company's letter of intent to conduct testing or application for an exemption before the inspection, if possible. These documents can be obtained from the Information Management Division (IMD) through an Enforcement Request (discussed in Chapter 3). The following guidelines should assist the inspector in determining compliance with this aspect of a TSCA Section 4 test rule and its implementation.

The inspector should review company documentation (i.e., correspondence) to verify that the company notified EPA by letter no later than 30 days after the effective date of the test rule of its intent to conduct testing. The effective date of each test rule is stated in one of the last paragraphs of the applicable test rule.

The inspector should verify that the letter of intent is accurate and complete by checking that the letter includes the following information:

- Identification of the test rule
- Name, address, and telephone number of the firm(s) sponsoring the tests
- Name, address, and telephone number of the appropriate individual to contact for further information
- For sponsors participating in a testing consortium, a list of all members of the consortium
- A list of the testing requirements (e.g., health or environmental effects or other characteristics)
- If EPA is requiring testing of more than one representative substance, identification of the test substance the sponsor(s) intends to use in each test.

A company that is not manufacturing, importing, or processing the subject chemical as of the effective date of the test rule, or by 30 days after the effective date of the rule, but that begins manufacturing, importing, or processing the test chemical before the end of the reimbursement period, must submit the letter of intent to test or application for an exemption by the date the manufacture, import, or processing begins. The inspector should check the date on which the company commenced manufacture, import, or processing of the chemical and verify that the letter of intent or an application for exemption was submitted on or before that date. If a letter of intent to test has been submitted by the company, the inspector should then ensure that testing protocols were established and submitted in a timely manner.

If the company claims an exemption from a TSCA Section 4 test rule, the inspector should review facility records (i.e., facility correspondence) to verify that an application for an exemption from testing requirements for the test rule has been submitted to EPA no later than 30 days after the effective date of the test rule.

The inspector should verify that the exemption application contains the following:

- Identification of the test rule, the chemical identity, and the Chemical Abstracts Service (CAS) Registry Number of the test substance on which the application is based
- Specific testing requirements(s) from which an exemption is sought and the basis for the exemption requested
- Name, address, and telephone number of the applicant
- Name, address, and telephone number of the appropriate individual to contact for further information

- If required in the test rule to establish equivalence, the chemical identity of the test substance on which the application is based and the equivalence data specified in 40 CFR §790.85.

A company that is not manufacturing, importing, or processing the subject chemical as of the effective date of the test rule, or by 30 days after the effective date of rule, but that begins manufacturing, importing, or processing the test chemical before the end of the reimbursement period and is claiming an exemption must submit an exemption application by the date manufacture, import, or processing begins. The inspector should check the date on which the company commenced manufacture, import, or processing of the chemical and verify that the application was submitted on or before that date.

Companies that submit an application for exemption from testing requirements and have the application approved must then make reimbursement payments to the company that did the original testing on the subject chemical. Such payments are negotiated between the two parties involved; however, if an agreement cannot be reached, EPA has developed procedures (40 CFR Part 791) and a formula for calculating costs (40 CFR §791.40). The inspector should examine the facility records to identify any reimbursement payments made by the company. The reimbursement payment amounts, combined with the inspector's knowledge of the production volume of the test rule chemical, and the national production volume (obtainable from the program office during the followup stage of the inspection) will allow the inspector to determine whether the facility is meeting its exemption and reimbursement requirements. If no reimbursement payments are identified, the company may be in violation of its exemption requirements.

5.2.2 PHASE 2 INSPECTION

The second phase of the inspection identifies companies subject to a TSCA Section 4 test rule that have failed to submit letters of intent to conduct testing. During the inspection, the inspector should compare the company's current list of manufactured, imported, or processed chemicals against the latest Chemicals on Reporting Rules (CORR) list (see Appendix 7). Lists of specific chemicals and multichemical substances for which test rules have been promulgated (as of July 1, 1991) are presented in Tables 5-2 and 5-3, respectively. If the company's current inventory indicates the production of a chemical or multichemical substance subject to a TSCA Section 4 test rule for which a letter of intent to conduct testing or an application for an exemption was not submitted, the inspector should obtain (1) copies of records that indicate the total volume of chemical manufactured, imported, or processed, and (2) copies of batch records and import records to determine the number of times the company may have violated

TABLE 5-2 40 CFR PART 799 SUBPART B
SPECIFIC CHEMICAL TEST RULES

Authority (40 CFR)	Subject Chemical	CAS Number
799.500	Anthraquinone	684-65-1
799.925	Biphenyl	92-52-4
799.940	Bisphenol A	80-05-7
799.1051	Monochlorobenzene	108-90-7
799.1052	Dichlorobenzenes	95-50-1; 106-46-7
799.1053	Trichlorobenzenes	87-61-6; 120-82-1
799.1054	1,2,4,5-Tetrachlorobenzene	95-94-3
799.1250	Cresols	95-48-7; 108-39-4; 106-44-5
799.1285	Cumene	98-82-8
799.1550	1,2-Dichloropropane	78-87-5
799.1560	Diethylene glycol butyl ether and diethylene glycol butyl ether acetate	112-34-5; 124-17-4
799.1575	Diethylenetriamine (DETA)	111-40-0
799.1645	2-Ethylhexanol	104-76-7
799.1650	2-Ethylhexanoic acid	149-57-5
799.1700	Fluoroalkenes	75-02-5; 75-38-7; 116-14-3
799.2155	Commercial hexane	110-54-3; 96-37-7
799.2175	C9 aromatic hydrocarbon fraction	N/A
799.2200	Hydroquinone	123-31-9
799.2325	Isopropanol	67-63-0
799.2475	2-Mercaptobenzothiazole	149-30-4
799.2500	Mesityl oxide (MO)	141-79-7
799.2700	Methyl ethyl ketoxime	96-29-7
799.3175	Oleylamine	112-90-3
799.3300	Unsubstituted phenylenediamines	106-50-3; 1624-57-75
799.3450	Propylene oxide	75-56-9
799.4000	Tetrabromobisphenol A	79-94-7
799.4360	Tributyl phosphate	126-73-8
799.4400	1,1,1-Trichloroethane	71-55-6
799.4440	Triethylene glycol monomethyl ether	112-35-6

TABLE 5-3 40 CFR PART 799 SUBPART D
MULTICHEMICAL TEST RULES

Subject Chemical	CAS Number
Acetamide, 2-fluoro	640-19-7
Bis(2-chloroethoxy)methane	111-91-1
Bis(2-chloroisopropyl)ether	108-60-1
4-Bromobenzyl cyanide	16532-79-9
Bromoform	75-25-2
4-Chlorobenzo-trichloride	5216-25-1
2,4-D	94-75-7
Dibromomethane	74-95-3
1,2-Dichlorobenzene	95-50-1
1,1-Dichloroethane	75-34-3
1,3-Dichloropropanol	96-23-1
Dihydrosafrole	94-58-6
Endrin	72-20-8
Ethyl methacrylate	97-63-2
Maleic hydrazide	123-33-1
Malononitrile	109-77-3
Methanethiol	74-93-1
Methyl chloride	74-87-3
p-Nitrophenol	100-02-7
Pentachlorobenzene	608-93-5
Pentachloroethane	76-01-7
1,2,4,5-Tetrachlorobenzene	95-94-3
Trichloromethanethiol	75-70-7

TSCA since the relevant chemical became subject to a test rule. Manufacturers, importers, and processors subject to a test rule who do not submit to EPA either a letter of their intent to conduct tests or a request for an exemption from testing for each test rule are considered in violation of that rule beginning on the 31st day after the effective date of the test rule or on the date manufacture begins.

Chapter Six

TSCA Section 5 Inspections

Page

6.0 TSCA SECTION 5 INSPECTIONS 6-1

6.1 INTRODUCTION 6-1

6.1.1 PMN EXCLUSIONS AND EXEMPTIONS 6-3
6.1.2 INSPECTION SITES 6-6

6.2 PREMANUFACTURE NOTICE REQUIREMENTS 6-8

6.2.1 INSPECTION OBJECTIVES 6-8
6.2.2 PHASE 1 INSPECTION 6-11
6.2.3 PHASE 2 INSPECTION 6-22

6.3 TSCA SECTION 5(e)/5(f) ORDER 6-23

6.3.1 INSPECTION OBJECTIVES 6-25
6.3.2 INSPECTION GUIDELINES 6-25

6.4 SIGNIFICANT NEW USE RULE 6-29

6.4.1 RULE-MAKING PROCEDURES 6-29
6.4.2 SNUN REQUIREMENTS 6-30
6.4.3 INSPECTION OBJECTIVES 6-31
6.4.4 INSPECTION GUIDELINES 6-31

6.5 LOW VOLUME EXEMPTION 6-36

6.5.1 INSPECTION OBJECTIVES 6-37
6.5.2 INSPECTION GUIDELINES 6-39

6.6 RESEARCH & DEVELOPMENT EXEMPTION 6-41

6.6.1 INSPECTION OBJECTIVES 6-42
6.6.2 INSPECTION GUIDELINES 6-42

6.7 TEST MARKETING EXEMPTION 6-45

6.7.1 INSPECTION OBJECTIVES 6-45
6.7.2 INSPECTION GUIDELINES 6-48

TABLE OF CONTENTS (CONTINUED)

Page

6.8 POLYMER EXEMPTION 6-52

6.8.1 INSPECTION OBJECTIVES 6-55
6.8.2 INSPECTION GUIDELINES 6-55

6.9 INSTANT FILM CHEMICAL EXEMPTION (IFCE) 6-57

6.9.1 INSPECTION OBJECTIVES 6-57
6.9.2 INSPECTION GUIDELINES 6-60

6.10 ZERO EXPOSURE 6-64

LIST OF FIGURES

FIGURE 6-1 MANAGEMENT INFORMATION TRACKING SYSTEM (MITS) DATABASE 6-13
FIGURE 6-2 EXAMPLE – FEDERAL REGISTER STATUS REPORT 6-14
FIGURE 6-3 NOTICE OF COMMENCEMENT LISTING 6-16
FIGURE 6-4 SAMPLE PRODUCT TREE 6-17
FIGURE 6-5 MANUFACTURING OPERATION 6-20
FIGURE 6-6 EXAMPLES OF TEST DATA 6-21
FIGURE 6-7 SAMPLE SECTION 5(f) ORDER 6-24
FIGURE 6-8 SAMPLE *FEDERAL REGISTER* NOTICE GRANTING TEST MARKETING EXEMPTION 6-51

LIST OF TABLES

TABLE 6-1 CHEMICALS NOT SUBJECT TO PREMANUFACTURE NOTIFICATION . . . 6-4
TABLE 6-2 SUBMISSION REQUIREMENTS 6-7
TABLE 6-3 PREMANUFACTURE NOTIFICATION (PMN) 6-9
TABLE 6-4 PERSONS REQUIRED TO SUBMIT A SIGNIFICANT NEW USE NOTICE (SNUN) 6-32
TABLE 6-5 PERSONS EXEMPT FROM THE SNUN REPORTING REQUIREMENTS . . . 6-33
TABLE 6-6 LOW VOLUME EXEMPTION (LVE) 6-38
TABLE 6-7 RESEARCH AND DEVELOPMENT (R&D) EXEMPTION 6-43
TABLE 6-8 NOTIFICATION OF RISKS-R&D EXEMPTION 6-45
TABLE 6-9 RECORDKEEPING-R&D EXEMPTION 6-46
TABLE 6-10 TEST MARKETING EXEMPTION (TME) 6-47
TABLE 6-11 POLYMER EXEMPTION (PE) 6-54
TABLE 6-12 INSTANT FILM CHEMICAL EXEMPTION (IFCE) 6-58

6.0 TSCA SECTION 5 INSPECTIONS

6.1 INTRODUCTION

This chapter contains background information and guidance to assist the inspector in conducting inspections under Toxic Substances Control Act (TSCA) Section 5. Specifically, this chapter covers inspections to determine compliance with the Premanufacture Notice (PMN) rule, Section 5(e)/5(f) orders, and significant new use rules (SNURs), including certain exemptions thereunder. The inspector should keep in mind that throughout this chapter whenever the terms "chemical" or "chemical substance" are used they mean "any organic or inorganic substance of a particular molecular identity, including any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and any element or uncombined radical," as defined in TSCA Section 3(2). Exclusions from this definition can be found in Section 6.1.1 of this Chapter. Section 6.2 of this chapter covers chemicals that are subject to Premanufacture Notice (PMN) requirements and how the inspector can determine if the firm manufacturing (or importing) the new chemical substance is complying with these requirements. The inspector should note that the TSCA definition of "manufacture" includes "import," and wherever this chapter refers to "manufacture," it follows that "import" is included in that reference. The chapter also covers inspections to determine compliance with Section 5(e)/5(f) orders and Significant New Use Rules (SNURs) for chemicals being manufactured or imported that are subject to such orders and/or rules in Sections 6.3 and 6.4, respectively.

If the firm is not complying with the PMN requirements (i.e., has not submitted a PMN) because the chemical is being manufactured or imported under an exemption, then the inspector must determine if that firm is complying with the conditions of or meeting the criteria for the applicable exemption. The guidelines for conducting these exemption inspections are detailed in Sections 6.5 (Low Volume Exemption), 6.6 (Research and Development Exemption), 6.7 (Test Marketing Exemption), 6.8 (Polymer Exemption), 6.9 (Instant Film Chemical Exemption), and 6.10 (Zero Exposure Exemption) of this chapter. The sequence of this chapter reflects the FY 1993 OPPTS inspection priorities which will be included in the Regional Memoranda of Agreement. These priorities are to inspect non-submitters of PMNs, TSCA Section 5(e) orders, SNURs, and holders of Low Volume Exemptions. Throughout the chapter, the inspector will find tips and examples to help explain how the regulations apply and how they are interpreted. In addition, the tables found throughout the chapter provide summaries of the regulations as a quick reference for the inspector. The inspector should note that these summaries are not intended

to substitute for the regulations published in the *Code of Federal Regulations* (CFR) and the *Federal Register*, and the appropriate citations are thus included in the tables for the inspector's use.

When an inspector is doing a TSCA Section 5 inspection, s/he is generally focusing on one or more chemicals. The most appropriate way to approach the inspection is from a chronological perspective. This means the inspector will examine the target chemical(s) by looking first at the research and development (R&D) stage, next at the test marketing stage (if applicable), then at the PMN process, and finally at the production stage under a Section 5(e)/5(f) order (if applicable). The inspector should review the records in this sequence. In conjunction with a chronological study of the subject chemical and as the first activity in the inspection, the inspector should consider requesting the appropriate company official (probably the R&D Director, Director of Manufacturing, Chief Operations Officer) make a chronological, technical presentation on one of the targeted chemicals. The inspector should also note that TSCA Section 8 inspections are often conducted in conjunction with TSCA Section 5 inspections, depending on the amount of time available. For detailed information on conducting TSCA Section 8 inspections, the inspector should refer to Chapter 7.

Finally, when interviewing company employees during the inspection, the inspector may advise both the company management and the individual(s) being interviewed that employee rights are protected under Section 23(a)(3) of TSCA. This section of TSCA states that it is unlawful for a company or employer to discharge or otherwise discriminate against an employee who assists with or participates in any EPA action intended to ascertain compliance with TSCA. If possible, employees should be interviewed in private; however, participation by company officials or their legal representatives is not restricted by the statute or regulations.

Under TSCA Section 5, EPA reviews all "new chemical substances" subject to PMN requirements prior to their being manufactured or imported for a commercial purpose. A new chemical substance, as defined in Section 3(2) of TSCA, is any chemical substance that is not included on the TSCA Section 8(b) Inventory. A new chemical substance is also one that is not specifically excluded from regulation under TSCA (e.g., pesticides, drugs, cosmetics).

The overall objectives of the TSCA Section 5 inspection program are to ensure that:

- Firms manufacturing new TSCA substances have complied with PMN and PMN exemption requirements.

- Firms subject to TSCA Section 5(e) and Section 5(f) orders, rules, or injunctions are complying with specific restrictions.

- Firms manufacturing chemicals in such a manner that they are subject to SNURs are complying with Significant New Use Notification (SNUN) requirements.

These objectives are discussed in detail in the appropriate sections of this Chapter. Because of the interrelationship between TSCA Section 5 and TSCA Section 8(b), several of the firm's Inventory of Existing Chemical Substances submissions should be checked during a TSCA Section 5 inspection to ensure that all chemicals submitted for the Inventory were properly reported.

6.1.1 PMN EXCLUSIONS AND EXEMPTIONS

TSCA Section 3(2)(B) excludes from the definition of "chemical substances" any mixture; any pesticide [as defined in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)] when manufactured, processed, or distributed in commerce for use as a pesticide; tobacco or any tobacco product; any source material, special nuclear material, or byproduct material [as defined in the Atomic Energy Act (AEA) of 1954 and regulations issued under the AEA]; and 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.

Chemical substances falling into any of the above categories are not regulated by TSCA, unless they are designated specifically for a TSCA use. For example, as a chemical moves through the manufacturing process, its status (i.e., intended or not intended for use as a pesticide) can change. TSCA regulates raw materials and inert ingredients until they become components of a pesticide. Then EPA considers them to be subject to FIFRA.

Certain types of chemical substances not subject to PMN requirements are summarized in Table 6-1. Furthermore, there are other chemical substances that do not have to fulfill the PMN requirements because they meet the definition of a PMN exemption.

TSCA Section 5(h) provides the authority to establish exemptions from the PMN requirements for chemical substances subject to TSCA jurisdiction. The following six types of exemptions have been established:

- Low Volume Exemption (LVE)

TABLE 6-1 CHEMICALS NOT SUBJECT TO PREMANUFACTURE NOTIFICATION

Authority (40 CFR)	FR Publication Date	Chemical Identification
720.22(b)(1)	48 FR 21745 May 13, 1983	New chemical substances imported as part of an article.
720.30(b)	48 FR 21745 May 13, 1983	Any mixture as defined in 720.3(u). This exclusion applies only to a mixture as a whole and not to any chemical substances which are part of the mixture.
720.30(e)	48 FR 21746 May 13, 1983 (as amended 51 FR 15101 April 22, 1986)	Any new chemical substance manufactured solely for export if, when the substance is distributed in commerce: • The substance is labeled in accordance with TSCA §12(a)(1)(B). • The manufacturer knows that the person to whom the substance is being distributed intends to export it or process it solely for export as defined in 721.3.
720.30(h)	48 FR 21746 May 13, 1983	The chemical substances described below [720.30(h)], which have no commercial purpose separate from the substance, mixture, or article of which they are a part, are not subject to notification requirements.
720.30(h)(1)	48 FR 21746 May 13, 1983	Any impurity.
720.30(h)(2)	48 FR 21746 May 13, 1983	Any byproduct not used for commercial purposes.
720.30(h)(3)	48 FR 21746 May 13, 1983	Any chemical substance which results from a chemical reaction that occurs incidental to exposure of another chemical substance, mixture, or article to environmental factors.
720.30(h)(4)	48 FR 21746 May 13, 1983	Any chemical substance which results from a chemical reaction that occurs incidental to storage or disposal of another chemical substance, mixture, or article.
720.30(h)(5)	48 FR 21746 May 13, 1983	Any chemical substance which results from a chemical reaction that occurs upon end use of another chemical substance, mixture, or article, and which is not itself manufactured or imported for distribution in commerce or for use as an intermediate.

TABLE 6-1 CHEMICALS NOT SUBJECT TO PREMANUFACTURE NOTIFICATION (Continued)

Authority (40 CFR)	Effective	Chemical Identification
720.30(h)(6)	48 FR 21746 May 13, 1983	Any chemical substance which results from a chemical reaction that occurs upon use of curable plastic or rubber molding compounds, inks, drying oil, metal finishing compounds, adhesives, or paints, or any other chemical substance formed during the manufacture of an article destined for the marketplace without further chemical change of the chemical substance except for those chemical changes that occur as described elsewhere in this paragraph.
720.30(h)(7)	48 FR 21746 May 13, 1983	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 defoamer, dispersant, precipitation inhibitor, binder, emulsifier, deemulsifier, dewatering agent, agglomerating agent, adhesion promoter, flow modifier, pH neutralizer, sequesterant, coagulant, flocculent, fire retardant, lubricant, chelating agent, or quality control reagent functions as intended, or (ii) a chemical substance, which is intended solely to impart a specific physicochemical characteristic, functions as intended.
720.30(h)(8)	48 FR 21746 May 13, 1983	Any non-isolated intermediate.
720.30(i)	51 FR 15102 April 22, 1986	Any chemical substance which is manufactured solely for non-commercial R&D purposes (including scientific experimentation, research, or analysis conducted by academic, government, or independent not-for-profit research organizations), unless the activity is for eventual commercial purposes.

- Research and Development (R&D) Exemption
- Test Marketing Exemption (TME)
- Polymer Exemption (PE)
- Instant Film Chemical Exemption (IFCE)
- Zero Exposure Exemption.

These exemptions are discussed in detail in Sections 6.5 through 6.10 of this chapter. Summaries of the submission requirements for the PMN and the PMN exemptions are contained in Table 6-2.

6.1.2 INSPECTION SITES

Generally, PMN and PMN exemption-related information can be found in four locations that are based on the separate corporate functions. Therefore, TSCA Section 5 inspections may be rather inconvenient to complete, as some inspections will require inspectors to visit or gather information at multiple inspection sites. The four sites where PMN and PMN exemption information can be found are as follows:

- Production and/or import site(s). This is the facility (or facilities) where a PMN chemical is being commercially produced (or imported); therefore, it will normally be the site identified on the PMN form (Part II; Section A; Item 1). This site may also be the location where the test marketing chemical is produced or imported. The PMN, TME, LVE, PE, or IFCE production or import records are usually kept at this site, and it represents the most important site to visit for review of such records. The inspector verifies production amounts and dates here.

- Submitting office. The submitting office represents the point of consolidation of regulatory efforts to develop and market a new chemical. This location is often the corporate or division level headquarters of the company and is normally the location of the personnel identified on the PMN form (Part I; Section A; Items 1a, 1b, and often 2). R&D-related activities often take place at this location. As much information as possible regarding the PMN or applicable exemption should be confirmed at the submitting office, particularly if chemical testing and/or production data can be brought together at this location for compliance review purposes. If any questions about the PMN or exemption-related data or records still remain, a followup inspection may be conducted at the R&D and/or production facilities.

- R&D facility. The R&D facility is usually the site where the new TSCA chemical is being synthesized and identified and where its basic chemical and physical properties are determined. This site may be the same as that of the submitting office. However, the technical contact is often an individual closely associated with R&D (Part I; Section A; Item 2). In general, the inspector should verify the technical information of Parts I and III of the PMN form at the R&D site, particularly the substantiation of the chemical structure of the PMN chemical. This usually requires verification by a chemist. Therefore, non-chemist inspectors should collect spectral and

TABLE 6-2 SUBMISSION REQUIREMENTS

Type of Notification	Authority (40 CFR)	Requirements
Premanufacture Notice	720.40(a) 720.40(b) 720.102(b)	• Notice: Use of standard PMN form (EPA Form No. 7710 - 25) is required • Submit 90 days before commencement of manufacture or import • Submit NOC on, or no later than, 30 days after the first day of commercial manufacture or import
Research and Development Exemption	720.36(a)	• No application or notice required
Test Marketing Exemption	720.38(a) 720.38(d) 720.38(e)	• Application: Use of standard PMN form is not required; a letter containing required information is sufficient • 45-day review period; submitter must await EPA approval before commencing manufacture • NOC not required • EPA may impose restrictions to ensure that the substance will not present a risk to health or the environment.
Low Volume Exemption	723.50(a)(2) 723.50(a)(2)	• Notice (of intent to manufacture): Use of standard PMN form is not required • Submit 21 days before commencement of manufacture
Polymer Exemption	723.250(f)(1) 723.250(f) 723.250(f)	• (Limited Premanufacture) Notice: Use standard PMN form; manufacturer must indicate clearly on the form a claim for the PE and must complete applicable portions of the form • Submit 21 days prior to the date of manufacture • NOC required within 30 days of manufacture
Instant Film Chemical Exemption	723.175(i) 723.175(i)	• Notice: Use of standard PMN form is not required • Submit to EPA when manufacture begins
Significant New Use Notice	721.25(a) 721.25(a) 721.25(d)	• Notice: Use of standard PMN form is required • Submit 90 days before commencement of manufacture, import, or processing • 90-day review period must expire before commencement of manufacture, import, or processing
"Zero Exposure" Exemption	TSCA Section 5(h)(5)	• Application: EPA has never required manufacturers of non-isolated intermediates, to which this exemption primarily applies, to apply for an exemption. Rather, under the PMN regulations, EPA has granted a blanket exemption to all such manufactures.

other data for further review. If possible, the inspector should also compare these analytical data with ongoing production quality control data. Byproducts and impurities, as well as their method(s) of detection, also require substantiation at the R&D site, as well as validation of associated analytical methods and associated detection limits. The inspector should also verify the completeness of test data submitted at the R&D site to the extent possible (Part II; Section B).

- Processing site. This site is where a PMN chemical or chemical subject to an exemption is formulated, made into articles, or otherwise transformed without undergoing further chemical reaction or modification for commercial purposes. A processor may also represent the importer of record for chemicals received from outside the United States. The site may or may not be controlled by the chemical manufacturer, as described in Part II of the PMN form. Except when an importer is being inspected for PMN compliance, this is the lowest priority facility to inspect of the four described sites.

6.2 PREMANUFACTURE NOTICE REQUIREMENTS

The PMN requirements apply to "new chemical substances" and to "significant new uses" of existing chemical substances, as determined by the promulgation of a SNUR under TSCA Section 5(a)(2) (discussed in Section 6.10). Under TSCA Section 5(a)(1) and 40 CFR Part 720, manufacturers or importers of new chemical substances are required to submit 90 days prior to manufacturing or importing a PMN of their intention to conduct such activities, as well as any test data in their possession or control or other data concerning the health and environmental effects of the new chemical substance that are known to or reasonably ascertainable by the submitter, in accordance with 40 CFR §720.50. The requirements for PMN submissions are summarized in Table 6-2. A copy of the PMN form is included in Appendix 8.

TSCA Section 5(d)(1) specifies the information that must be provided in PMNs. The specific regulatory requirements that apply to the PMN are summarized in Table 6-3. The inspector must verify this required information in her/his effort to detect and document possible TSCA violations.

6.2.1 INSPECTION OBJECTIVES

The objectives of an inspection to assess compliance with the PMN requirements are the following:

- To check the accuracy and technical content of a PMN submitted by a manufacturer or importer and that no commercial manufacturing occurred before the end of the review period (Phase 1 Inspection)

TABLE 6-3 PREMANUFACTURE NOTIFICATION

Authority (40 CFR)	FR Publication	Requirements
720.45	48 FR 21747-21748 May 13, 1983	Notice must include:
720.45(a)(1)-(3) 720.45(b) 720.45(c) 720.45(d) 720.45(e) 720.45(f)	48 FR 21748 May 13, 1983	• Chemical identification and structure • Impurities • Known synonyms or trade names • Description of byproducts • Estimated maximum production volume - first year - any 12-month period during first 3 years • Description of intended category of use
720.45(g)(1) 720.45(g)(2) 720.45(g)(3) 720.45(g)(4) 720.45(g)(5)	48 FR 21748 May 13, 1983	For sites controlled by the submitter: • Identity of sites • Process description of each manufacture, processing, and use operation • Worker exposure information • Information on release of substance to the environment
720.45(h)	48 FR 21748 May 13, 1983	For sites not controlled by the submitter: • Description of each type of processing and use operation • Identification of estimated number of processing or use sites • Identification of situations in which worker exposure and/or environmental release will occur • Number of workers exposed • Duration of worker exposure • Controls that limit worker exposure and environmental release
720.50(a)-(b)	48 FR 21748 May 13, 1983	• Health and environmental effects test data in the submitter's possession or control, or known to or reasonably ascertainable by the submitter

TABLE 6-3 PREMANUFACTURE NOTIFICATION (Continued)

Authority (40 CFR)	FR Publication	Requirements
720.50(d) 720.50(d)(1) 720.50(d)(2) 720.50(d)(3)	48 FR 21749 May 13, 1983	Data that need not be submitted: • Data previously submitted to EPA • Efficacy data • Non-U.S. exposure data
720.78 720.78(a)(1) 720.78(b)(2) 720.78(b)(2) 720.78(b)(2)	48 FR 21751 May 13, 1983 As amended by 51 FR 15102-15103 April 22, 1986	Recordkeeping: PMN submitter must retain documentation of: • Other data [720.50(b)] in the submitter's possession or control • Production volume for the first 3 years of production or import • Date of commencement of manufacture or import • Information must be retained for 5 years from the date of commencement of manufacture or import

- To identify firms manufacturing or importing a chemical that is not on the TSCA Section 8(b) Inventory (i.e., the TSCA Inventory) and is not covered by a PMN exemption, but for which the manufacturer or importer has not submitted a PMN (Phase 2 Inspection).

6.2.2 PHASE 1 INSPECTION

When checking for compliance with the PMN, the inspector should review the PMN documents before the inspection and verify the information contained in the PMN form at the inspection site by reviewing company records, interviewing company employees, and touring the facility.

A complete PMN inspection will address the following aspects of the PMN:

- Chemical identification and structure
- PMN 90-day review date
- Notice of Commencement (NOC) date
- Impurities
- Byproducts
- Proposed volume of production
- Proposed categories of use
- Process description
- Worker exposure
- Release and disposal information
- Health and environmental effects testing data
- Pollution prevention and recycling (optional).

In order to conduct the PMN review effectively, the inspector should identify all of the names used by the company for the subject chemical (including R&D designations) and the chemical's end use product(s). These names include chemical names, common names, trade names, synonyms, proprietary designations, in-house jargon, and acronyms. This will ensure that the inspector is fully aware when these references to the subject chemical occur in other records under review. Some of these names may be listed in the PMN (Part 1; Section B; Item 4); other designations may be identified through interviewing and review of company records and research files.

Confirming the accuracy of two dates is the most important element of the PMN inspection from a compliance standpoint. These two dates are the 90-day review date and the NOC date. The following guidelines should assist the inspector in assessing compliance with the PMN requirements:

- Verifying chemical identification and structure. The manufacturer or importer must specify whether the chemical substance is a Class 1 or a Class 2 substance or a polymer. The chemical name, the molecular formula, the Chemical Abstract Service (CAS) Registry Number (if available), and a structural diagram of the chemical substance are required on the PMN and the chemical identification and structure is verified by OPPT. Therefore, the inspector will only check the Material Safety Data Sheet (MSDS) (if available), the chemical composition or formulation data, or the product literature to verify the chemical identity.

- Verifying the PMN 90-day review date. The 90-day review period begins on the date the Office of Pollution Prevention, and Toxics (OPPT) Document Control Officer (DCO) receives the PMN. The inspector must confirm that the submitter has waited until the final day of the 90-day review period before beginning to manufacture or import the new chemical substance. The inspector should note that the 90-day review period can be suspended so that "day 90" may not be 90 days after the submission's receipt. The 90-day review date for a PMN can be found in the Management Information Tracking System (MITS) database (Figure 6-1) and the appropriate *Federal Register* Status Reports, which are issued on a monthly basis (Figure 6-2). MITS tracks the review status of PMNs and any associated correspondence about new chemicals. During the inspection, the inspector should verify production/import status of all batches (or runs) of the PMN chemical under review from the first synthesis (which may be R&D) up through the first commercial production (or import) after the NOC. The inspector will obtain this information through the following methods:

  - Interviews with company officials

  - Review of research, production, batch, and business records.

  The inspector should verify these records, which may be available in a variety of forms, by reviewing routine production, batch, inventory, and sales records for at least one year prior to the official 90-day review date. Company batch records may be kept by product, reactor vessel, and/or chronological sequence and should also be randomly checked for evidence of any early commercial production of the PMN chemical. By reviewing purchasing, import, duty, or inventory records, the inspector should also verify for compliance PMN chemicals that are imported. The inspector should also review and copy sales records to substantiate commercialization of a chemical if s/he suspects the facility has begun commercial manufacture before the end of the review period. The inspector should also verify that batches claimed by company personnel to be manufactured for the purposes of R&D were in fact manufactured for such purposes.

  If a PMN under review has been formally withdrawn, the 90-day review period is terminated, and there will be no 90-day review date. In this case, no commercial manufacture or import should have occurred, and any such commercial manufacture or import will be a violation of TSCA. The inspector should review company correspondence to verify that the PMN has been withdrawn.

FIGURE 6-1

MANAGEMENT INFORMATION TRACKING SYSTEM (MITS) DATABASE

```
 ***********                    PMN MASTER RECORD                    ***********
 * NON-CBI *                  REPORT DATE:  07/10/92                 * NON-CBI *
 ***********                                                         ***********
PMN NUMBER  : P-91-1108                    PROGRAM MANAGER: ASCI
DAY RECEIVED: 6/11/91                     TECH. INTEGRATOR:
END OF NOTICE PERIOD: 9/8/91   FR 5(D)2:VOL:        PG:          DATE:
INTERIM STATUS:                                                AS OF:
DISPOSITION: FOCUS DROP                                        AS OF: 7/1/91
STATUS UPDATE REPORT PAGE:  1655
CHEMICAL NAME: Oligomeric thiodiethylen-bis-(5-dimethoxyl-1,4-dih
               ydropyridien-3-carboxyllate), including oilgomers c
               ontaining some pyridine moieties from the partial
               oxidation of dihydropyridine moieties
GENERIC NAME: NO
SUBMITTER NAME: ** CBI **
SUBMITTER CITY:                                  STATE:
DOMESTIC OR IMPORTED:  DOMESTIC                  DATE 5(C) EXT. SIGNED:
STANDARD REVIEW DATE:                              DATE OF ENFORCEMENT:
SUSPEND DAY IN REVIEW PROCESS: 0
REVIEW DAY: 20
DATE OF NOC:  2/4/92    NUMBER OF DAYS PAST REVIEW PERIOD MANUF. COMM:  149
SUSPENSION:             RESTART:                 DAYS IN SUSPENSION:  0

Esc for ATtention, Home to SWitch   |     Capture Off     |  Application


 ***********                    PMN MASTER RECORD                    ***********
 * NON-CBI *                                                         * NON-CBI *
 ***********                  REPORT DATE:  07/10/92                 ***********
PMN NUMBER  : P-91-1108

DATE VOLUNTARY CONTROLS AGREED TO:

VOLUNTARY TEST TYPE:          DATE VOLUNTARY CONTROLS AGREED TO:
       1)                                  1)
       2)                                  2)
       3)                                  3)
       4)                                  4)
       5)                                  5)
VOL. ACTION COMMENTS   :

5E TEST  TYPE: 1)             5E TEST  DATE: 1)
               2)                            2)
               3)                            3)
               4)                            4)
               5)                            5)
```

FIGURE 6-2

EXAMPLE – FEDERAL REGISTER STATUS REPORT

ENVIRONMENTAL PROTECTION AGENCY

[OPPTS-63147; FRL 4044-4]

Premanufacture Notices; Monthly Status Report for September 1991

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Section 5(d)(3) of the Toxic Substance Control Act (TSCA) requires EPA to issue a list in the Federal Register each month reporting the premanufacture notices (PMNs) and exemption request pending before the Agency and the PMNs and exemption requests for which the review period has expired since publication of the last monthly summary. This is the report for September 1991.

Nonconfidential portions of the PMNs and exemption request may be seen in the TSCA Public Docket Office NE-G004 at the address below between 8 a.m. and noon and 1 p.m. and 4 p.m., Monday through Friday, excluding legal holidays.

ADDRESSES: Written comments, identified with the document control number "[OPPTS-63147]" and the specific PMN and exemption request number should be sent to: Document Processing Center (TS-790), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., rm. L-100, Washington, DC 20460. (202) 382-3532.

FOR FURTHER INFORMATION CONTACT: David Kling, Director, Environmental Assistance Division (TS-799), Office of Pollution Prevention and Toxics, Environmental Protection Agency, rm. EB-44, 401 M St., SW., Washington, DC 20460 (202) 382-3725.

SUPPLEMENTARY INFORMATION: The monthly status report published in the Federal Register as required under section 5(d)(3) of TSCA (90 Stat. 2012 (15 U.S.C. 2504)), will identify: (a) PMNs received during September; (b) PMNs received previously and still under review at the end of September; (c) PMNs for which the notice review period has ended during September; (d) chemical substances for which EPA has received a notice of commencement to manufacture during September; and (e) PMNs for which the review period has been suspended. Therefore, the September 1991 PMN Status Report is being published.

Dated: January 21, 1992.

Ruby N. Boyd,

Acting Director, Information Management Division, Office of Pollution Prevention and Toxics.

Premanufacture Notice Monthly Status Report for SEPTEMBER 1991.

I. 125 Premanufacture notices and exemption requests received during the month:

PMN No.

P 91-1370	P 91-1371	P 91-1372	P 91-1373
P 91-1374	P 91-1375	P 91-1376	P 91-1377
P 91-1378	P 91-1379	P 91-1380	P 91-1381
P 91-1382	P 91-1383	P 91-1384	P 91-1385
P 91-1386	P 91-1387	P 91-1388	P 91-1389
P 91-1390	P 91-1391	P 91-1392	P 91-1393
P 91-1394	P 91-1395	P 91-1396	P 91-1397
P 91-1398	P 91-1399	P 91-1400	P 91-1401
P 91-1402	P 91-1403	P 91-1404	P 91-1405
P 91-1406	P 91-1407	P 91-1408	P 91-1409
P 91-1410	P 91-1411	P 91-1412	P 91-1413
P 91-1414	P 91-1415	P 91-1416	P 91-1417
P 91-1418	P 91-1419	P 91-1420	P 91-1421
P 91-1422	P 91-1423	P 91-1424	P 91-1425
P 91-1426	P 91-1427	P 91-1428	P 91-1429
P 91-1430	P 91-1431	P 91-1432	P 91-1433
P 91-1434	P 91-1435	P 91-1436	P 91-1437
P 91-1438	P 91-1439	P 91-1440	P 91-1441
P 91-1442	P 91-1443	P 91-1444	P 91-1445
P 91-1446	P 91-1447	P 91-1448	P 91-1449
P 91-1450	P 91-1451	P 91-1452	P 91-1453
P 91-1454	P 91-1455	P 91-1456	P 91-1457
P 91-1458	P 91-1459	P 91-1460	P 91-1461
P 91-1462	P 91-1463	P 91-1464	P 91-1465
Y 91-0214	Y 91-0215	Y 91-0216	Y 91-0217
Y 91-0218	Y 91-0219	Y 91-0220	Y 91-0221
Y 91-0222	Y 91-0223	Y 91-0224	Y 91-0225
Y 91-0226	Y 91-0227	Y 91-0228	Y 91-0229
Y 91-0230	Y 91-0231	Y 91-0232	Y 91-0233
Y 91-0234	Y 91-0235	Y 91-0236	Y 91-0237
Y 91-0238	Y 91-0239	Y 91-0240	Y 91-0241
Y 91-0242			

II. 313 Premanufacture notices received previously and still under review at the end of the month:

PMN No.

P 88-0237	P 88-0880	P 88-0438	P 88-0819
P 88-1184	P 88-1488	P 88-1497	P 87-0185
P 87-0323	P 87-0802	P 87-1272	P 88-0881
P 88-0886	P 88-1271	P 88-1273	P 88-1276
P 88-1274	P 88-1882	P 88-1723	P 88-0887
P 88-1889	P 88-1811	P 88-1897	P 88-1898
P 88-1899	P 88-1902	P 88-1904	P 88-1905
P 88-1909	P 88-2000	P 88-2001	P 88-2109
P 88-2198	P 88-2212	P 88-2213	P 88-2228
P 88-2229	P 88-2230	P 88-2236	P 88-2404
P 88-2518	P 88-2529	P 88-0089	P 88-0090
P 88-0091	P 88-0284	P 88-0321	P 88-0365
P 88-0366	P 88-0367	P 88-0368	P 88-0536
P 88-0576	P 88-0697	P 88-0721	P 88-0773
P 88-0836	P 88-0837	P 88-0857	P 88-0857
P 88-0858	P 88-0859	P 88-0863	P 88-1098
P 88-1099	P 90-0002	P 90-0009	P 90-0188
P 90-0189	P 90-0211	P 90-0237	P 90-0268
P 90-0269	P 90-0280	P 90-0291	P 90-0362
P 90-0363	P 90-0372	P 90-0441	P 90-0580
P 90-0584	P 90-0581	P 90-0600	P 90-0628
P 90-0707	P 90-1280	P 90-1311	P 90-1318
P 90-1319	P 90-1320	P 90-1321	P 90-1322
P 90-1358	P 90-1422	P 90-1464	P 90-1511
P 90-1527	P 90-1528	P 90-1529	P 90-1530
P 90-1531	P 90-1564	P 90-1592	P 90-1684
P 90-1687	P 90-1716	P 90-1720	P 90-1722
P 90-1723	P 90-1748	P 90-1797	P 90-1960
P 90-1983	P 90-1987	P 90-1988	P 90-1994
P 90-1995	P 91-0004	P 91-0081	P 91-0101
P 91-0102	P 91-0107	P 91-0109	P 91-0109
P 91-0110	P 91-0111	P 91-0112	P 91-0112
P 91-0118	P 91-0177	P 91-0178	P 91-0179
P 91-0180	P 91-0222	P 91-0228	P 91-0230
P 91-0231	P 91-0232	P 91-0233	P 91-0241
P 91-0243	P 91-0244	P 91-0245	P 91-0246
P 91-0247	P 91-0248	P 91-0288	P 91-0288
P 91-0289	P 91-0291	P 91-0442	P 91-0464
P 91-0465	P 91-0469	P 91-0467	P 91-0468
P 91-0469	P 91-0470	P 91-0471	P 91-0472
P 91-0487	P 91-0490	P 91-0501	P 91-0503
P 91-0514	P 91-0521	P 91-0532	P 91-0540
P 91-0572	P 91-0584	P 91-0600	P 91-0810
P 91-0839	P 91-0885	P 91-0886	P 91-0888
P 91-0889	P 91-0701	P 91-0732	P 91-0783
P 91-0818	P 91-0820	P 91-0827	P 91-0831
P 91-0863	P 91-0892	P 91-0903	P 91-0905
P 91-0912	P 91-0914	P 91-0915	P 91-0934
P 91-0939	P 91-0940	P 91-0941	P 91-0988
P 91-1000	P 91-1009	P 91-1010	P 91-1011
P 91-1012	P 91-1013	P 91-1014	P 91-1015
P 91-1016	P 91-1017	P 91-1018	P 91-1019
P 91-1020	P 91-1021	P 91-1022	P 91-1023
P 91-1024	P 91-1025	P 91-1026	P 91-1027
P 91-1028	P 91-1029	P 91-1030	P 91-1031
P 91-1032	P 91-1033	P 91-1034	P 91-1035
P 91-1036	P 91-1037	P 91-1038	P 91-1039
P 91-1040	P 91-1041	P 91-1042	P 91-1043
P 91-1044	P 91-1045	P 91-1046	P 91-1047
P 91-1048	P 91-1049	P 91-1050	P 91-1051
P 91-1052	P 91-1053	P 91-1054	P 91-1055
P 91-1056	P 91-1057	P 91-1058	P 91-1059
P 91-1060	P 91-1061	P 91-1062	P 91-1063
P 91-1064	P 91-1065	P 91-1066	P 91-1067
P 91-1068	P 91-1069	P 91-1070	P 91-1071
P 91-1072	P 91-1073	P 91-1074	P 91-1075
P 91-1077	P 91-1118	P 91-1117	P 91-1118
P 91-1131	P 91-1153	P 91-1161	P 91-1162
P 91-1163	P 91-1169	P 91-1191	P 91-1209
P 91-1210	P 91-1231	P 91-1232	P 91-1233
P 91-1234	P 91-1238	P 91-1239	P 91-1240
P 91-1243	P 91-1259	P 91-1269	

- Verifying Notice of Commencement (NOC) date. In accordance with 40 CFR §720.102(b), an NOC must be submitted to the EPA on, or within, 30 calendar days of the first day of manufacture or import of a PMN chemical that has passed the 90-day review period.

  PMNs approved prior to the effective date of the PMN rule (i.e., May 13, 1983) should have submitted NOCs by that date (or within 30 days). The inspector can find the NOC date on the Notice of Commencement Listing (Figure 6-3), which is prepared every six months and distributed to the Regions, or from company correspondence with EPA.

  The NOC phase of the PMN inspection will normally constitute an extension of the overall PMN production date review. The date of first commercial production or import of a PMN chemical should be verified by reviewing company production or other records. The information from these records should then be compared with the NOC date.

  A company is in violation if it does not submit an NOC within 30 days of initial commercial manufacture or import of a PMN chemical. The company is also in violation if it has submitted an NOC and no commercial manufacture or import has actually been initiated by that date (i.e., a false NOC).

  If records or dates do not definitely address whether specific batches of a PMN chemical were produced before the 90-day review date or more than 30 days prior to the NOC date, then the inspector should obtain a signed statement or letter from a knowledgeable corporate official stating the exact purpose, details of production, and disposition of any batch(es) in question.

DEFINITIONS
Class 1 chemical substance is a substance whose composition, except for impurities, can be represented by a definite chemical structural diagram. Examples of such substances are 1,3 butadiene, benzene, and sodium chloride.
Class 2 chemical substance is a substance whose composition cannot easily be represented by a definite structural diagram. Such substances are generally derived from natural sources or complex reactions. Their composition may be complex, difficult to characterize, and variable. Examples are chlorinated naphthalene, the glycerol monoester of hydrogenated cottonseed oil acids, or a reaction product of specified reactants.
A polymer is a substance composed of molecules characterized by the regular or irregular repetition of one or more types of identical monomeric units. In most cases, the number of monomeric units is quite large and not precisely known.

- Verifying impurities. The manufacturer or importer must list in the PMN the impurities anticipated in the chemical substance by name, CAS Registry Number, and weight percent of the total substance. The inspector should review facility records to verify the impurities in the chemical substance against the information provided in the PMN. Information on the impurities can generally be found in the quality control analyses or specifications for the product. It may also be possible for the inspector to find out information about the impurities from the reactants and raw materials employed during the manufacturing process. A sample product tree is shown in Figure 6-4. The inspector should note that in this figure, raw materials are coded as 10—

FIGURE 6-3 NOTICE OF COMMENCEMENT LISTING

NOTICE OF COMMENCEMENT INFORMATION 11:16 WEDNESDAY, FEBRUARY 13, 1991 158

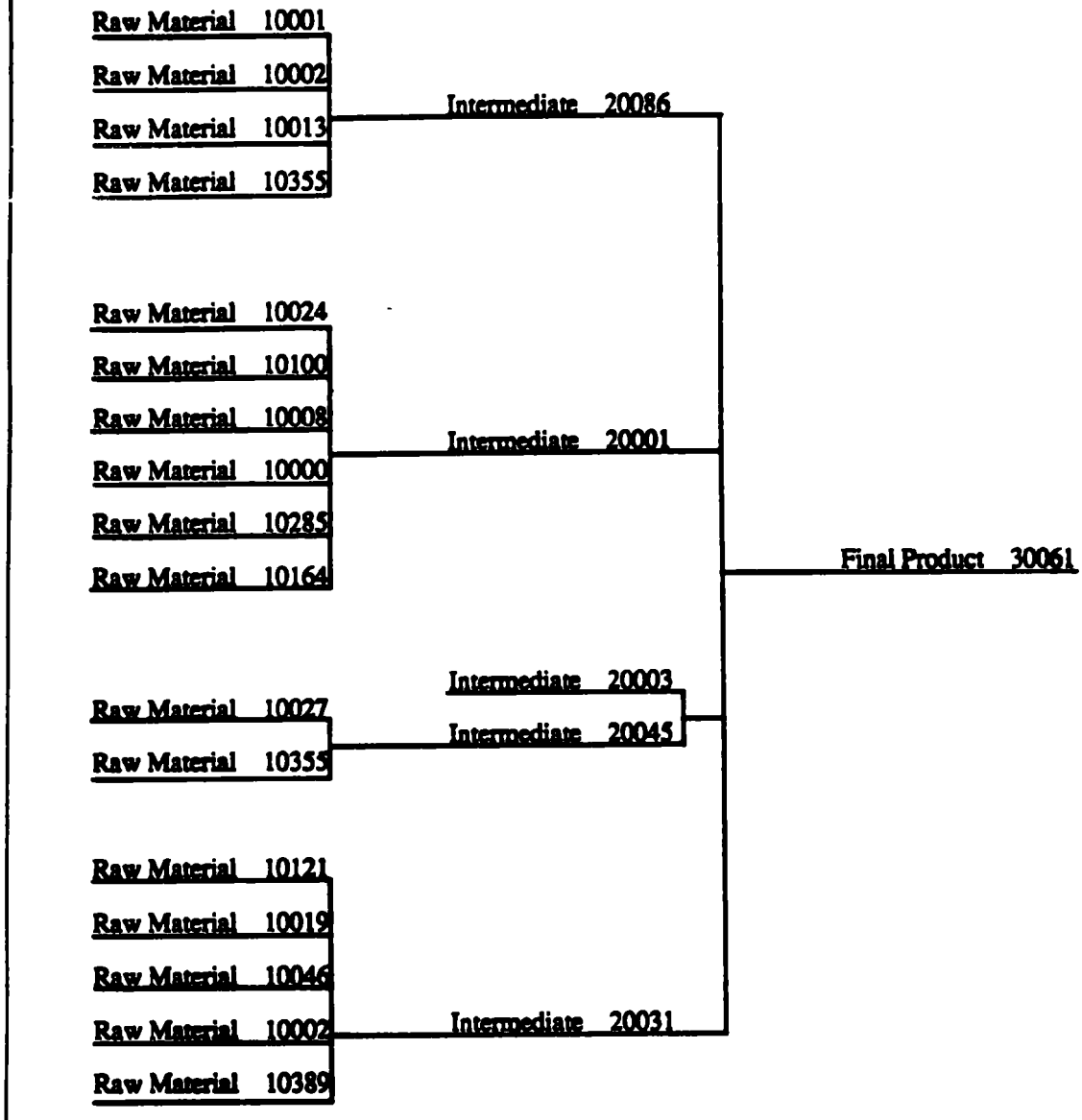
REGION=IX

Case #	End of PRN Review	NOC Date	Elapsed NO. of Days	PLANT SITE State	PLANT SITE City	CO Name
P-88-0810	08/16/88	09/02/88	109	CA	GLENDALE	PRODUCTS RESEARCH & CHEMICAL CORPORATION
P-88-0815	08/16/88	08/01/90	687	CA	GLENDALE	PRODUCTS RESEARCH & CHEMICAL CORPORATION
P-88-0843	08/18/88	07/05/88	48	CA	TORRANCE	SHIN-ETSU SILICONES OF AMERICA, INC.
P-88-0881	08/22/88	07/27/88	64	CA	TORRANCE	SHIN-ETSU SILICONES OF AMERICA, INC
P-88-0946	06/04/88	08/18/88	75	CA	SANTA FE SPRINGS	PILOT CHEMICAL COMPANY
P-88-0947	06/04/88	08/19/88	76	CA	SANTA FE SPRINGS	PILOT CHEMICAL COMPANY
P-88-0995	06/12/88	02/06/89	239	CA	SOUTH SAN FRANCISCO	THE O'BRIEN CORPORATION
P-88-1009	06/14/88	02/15/89	246	CA	TORRANCE	SHIN-ETSU SILICONES OF AMERICA, INC
P-88-1010	06/14/88	08/03/88	50	CA	TORRANCE	SHIN-ETSU SILICONES OF AMERICA, INC
P-88-1011	06/14/88	12/05/89	539	CA	TORRANCE	Shin-Etsu Silicones of America, Inc.
P-88-1012	06/14/88	12/05/89	539	CA	TORRANCE	SHIN-ETSU SILICONES OF AMERICA, INC
P-88-1437	08/21/88	10/13/88	53	CA	GLENDALE	Products Research & Chemical Corp.
P-88-1438	08/21/88	10/11/88	51	CA	GLENDALE	Products Research & Chemical Corp.
P-88-1696	10/11/88	04/28/89	199	CA	LOS ANGELES	Daicel (U.S.A.), Inc.
P-88-1747	10/29/88	12/07/88	39	CA	TUSTIN	Ricoh Electronics Inc.
P-88-1760	10/30/88	02/14/89	107	CA	TORRANCE	Shin-Etsu Silicones of America, Inc.
P-88-1778	11/06/88	11/16/88	10	CA	GLENDALE	Products Research & Chemical Corporation
P-88-1799	11/06/88	02/14/89	100	CA	TORRANCE	Shin-Etsu Silicones of eamrica, Inc.
P-88-2161	12/20/88	03/14/89	84	CA	TORRAME	Shin-Etsu Silicones of America, Inc.
P-88-2301	12/25/88	03/08/90	438	CA	GLENDALE	Products Research & Chemical Corporation
P-88-2306	12/25/88	02/19/89	56	CA	GLENDALE	Products Research & Chemical Corporation
P-88-2307	12/25/88	01/16/89	22	CA	GLENDALE	Products Research & Chemical Corporation
P-88-2312	12/25/88	03/15/89	80	CA	GLENDALE	Products Research & Chemical Corporation
P-88-2379	12/28/88	04/15/89	108	CA	TORRANCE	Shin-Etsu Silicones of Amprica
P-88-2520	12/27/88	06/30/89	185	CA	GLENDALE	Products Research & chmical Corporation
P-89-0250	04/08/89	07/12/89	95	CA	TORRENCE	Shin-Etsu Silicones of America, Inc.
P-89-0251	04/08/89	07/12/89	95	CA	TORRENCE	Shin-Etsu Silicones of America, Inc.
P-89-0252	04/08/89	07/12/89	95	CA	TORRANCE	Shin-Etsu Silicones of America, Inc.
P-89-0306	04/29/89	07/19/89	81	CA	TORRANCE	Shin-Etsu Silicones of eamrica, Inc.
P-89-0307	04/29/89	08/03/89	96	CA	TORRANCE	Shin-Etsu Silicones of America, Inc.
P-89-0308	04/29/89	07/12/89	74	CA	TORRANCE	Shin-Etsu Silicones of America, Inc.
P-89-0327	04/30/89	09/16/89	139	CA	TORRANCE	Shin-Etsu Silicones of America, Inc.
P-89-0425	05/22/89	07/12/89	48	CA	TORRANCE	Shin-Etsu Silicones of America, Inc.
P-89-0520	01/16/90	06/03/90	138	CA	TORRANCE	Shin-Etsu Silicones of America, inc.
P-89-0573	06/28/89	12/15/89	170	CA	TORRANCE	Shin-Etsu Silicones of America, Inc.
P-89-0707	08/07/89	08/31/89	24	CA	SAN DIEGO	Moritex USA, Inc.
P-89-0857	09/26/89	02/25/90	152	CA	LOS ANGELES	Pacific Anchor Chemical Corporation
P-89-0872	09/30/89	11/22/89	53	CA	LOS ANGELES	Pacific Anchor Chemical Corporation
P-89-0874	10/02/89	11/22/89	51	CA	LOS ANGELES	Pacific Anchor Chemical Corporation
P-89-0879	10/02/89	10/16/90	381	CA	TORRANCE	Shin-Etsu Silicones of America, Inc.
P-89-0895	10/09/89	10/04/90	360	CA	TORRANCE	Shin-Etsu Silicones of America, Inc.
P-89-1132	12/21/89	03/26/90	93	CA	LOS ANGELES	Pacific Anchor Chemical Corporation
P-90-0190	02/21/90	06/20/90	119	CA	LOS ANGELES	Pacific Anchor Chemical Corporation
P-90-0407	04/20/90	01/02/91	249	CA	TORRANCE	Shin-Etsu Silicones of America, Inc.
P-90-0454	05/13/90	10/04/90	144	CA	TORRANCE	Shin-Etsu Silicones of America
P-90-0703	07/16/90	10/04/90	80	CA	TORRANCE	Shin-Etsu Silicones of America, Inc.
P-90-1389	08/11/90	11/08/90	89	CA	GLENDALE	Products Research & Chemical Corporation
Y-88-0051	04/29/85	06/06/86	403	CA	SAN MARCOS	MAPP SYSTEMS (USA), INC.

prepared by IMD/PDB/NCIBS

FIGURE 6-4

SAMPLE PRODUCT TREE



series, isolated intermediates as 20— series, and the final product as a 30— series.

- Verifying byproducts. The manufacturer or importer must include in the PMN any byproducts resulting from the manufacture, processing, use, and disposal of the new chemical substance. The inspector can generally find byproducts information in product files. These product files may appear in various forms, such as a product diagram or tree that lists the raw materials, isolated intermediates, and byproducts.

- Verifying proposed volume of production. The manufacturer or importer must include in the PMN an estimate of the maximum amount of the chemical to be manufactured or imported during the first year of production and the estimated maximum amount to be manufactured or imported during any 12-month period during the first three years of production. The inspector should verify these production or import numbers by reviewing the production or import records for the first three years of production or import. The inspector should document discrepancies in production numbers.

- Verifying proposed categories of use. The manufacturer or importer must describe the intended categories of use of the chemical substance by **function** and **application** in the PMN. In addition, the manufacturer or importer must include an estimate of the percent of production volume devoted to each category of use and the percentages of the new substance in the formulation for each commercial and consumer use. The inspector must verify the categories of use through review of general production, inventory, and sales records.

DEFINITIONS
***Function** is related to the inherent physical and chemical properties of the substance (e.g., degreaser, catalyst, plasticizer, ultraviolet absorber).* ***Application** refers to the use of the substance in particular processes or products (e.g., a degreaser may be used for cleaning of fabricated metal parts).*

TIPS
Examples of how the company may describe categories of use • *A disperse dye carrier for finishing polyester fibers* • *A cross-linking agent for epoxy-type coatings for metal surfaces* • *A flame retardant for surface application on cotton apparel, textile home furnishings, and exterior canvas products* • *A surfactant in automobile spray wax* • *A colorant for paper and other cellulosics* • *Fiber-reactive dye for nylon carpeting and upholstery* • *An antioxidant in fuel oils and lubricants.*

- Verifying process description. For sites controlled by the manufacturer who submits a PMN, the notice must include a process description of each manufacture, processing, and use operation containing a diagram of the major unit operations and chemical conversions, the identity and entry point of all feedstocks, and the points of release of the chemical substance. To verify the processes used to manufacture the subject chemical, the inspector should walk through the facility, inspecting every major unit process and the points of entry and release of the subject chemical and compare the manufacturing process diagram to in-plant operations. An example of a manufacturing process diagram is presented in Figure 6-5. Any discrepancies between what was provided in the PMN and the in-plant operations should be documented. If possible, the inspector should obtain a signed statement from company officials explaining the discrepancy.

- Verifying worker exposure. For sites controlled by the manufacturer, the PMN must supply worker exposure information including worker activities, the physical form of the new substance to which workers may be exposed, the number of workers, and the duration of the activities. The inspector should review records documenting worker exposure information (e.g., monitoring records). In addition, the inspector should tour the facility and interview employees to verify what tasks expose the workers to the chemicals (e.g., changing reactor vessels, sampling for quality control, bulk loading, changing filters, cleaning equipment). At this time, the inspector should also verify the use of protective equipment and engineering controls (e.g., gloves, goggles, respirators, closed containment system).

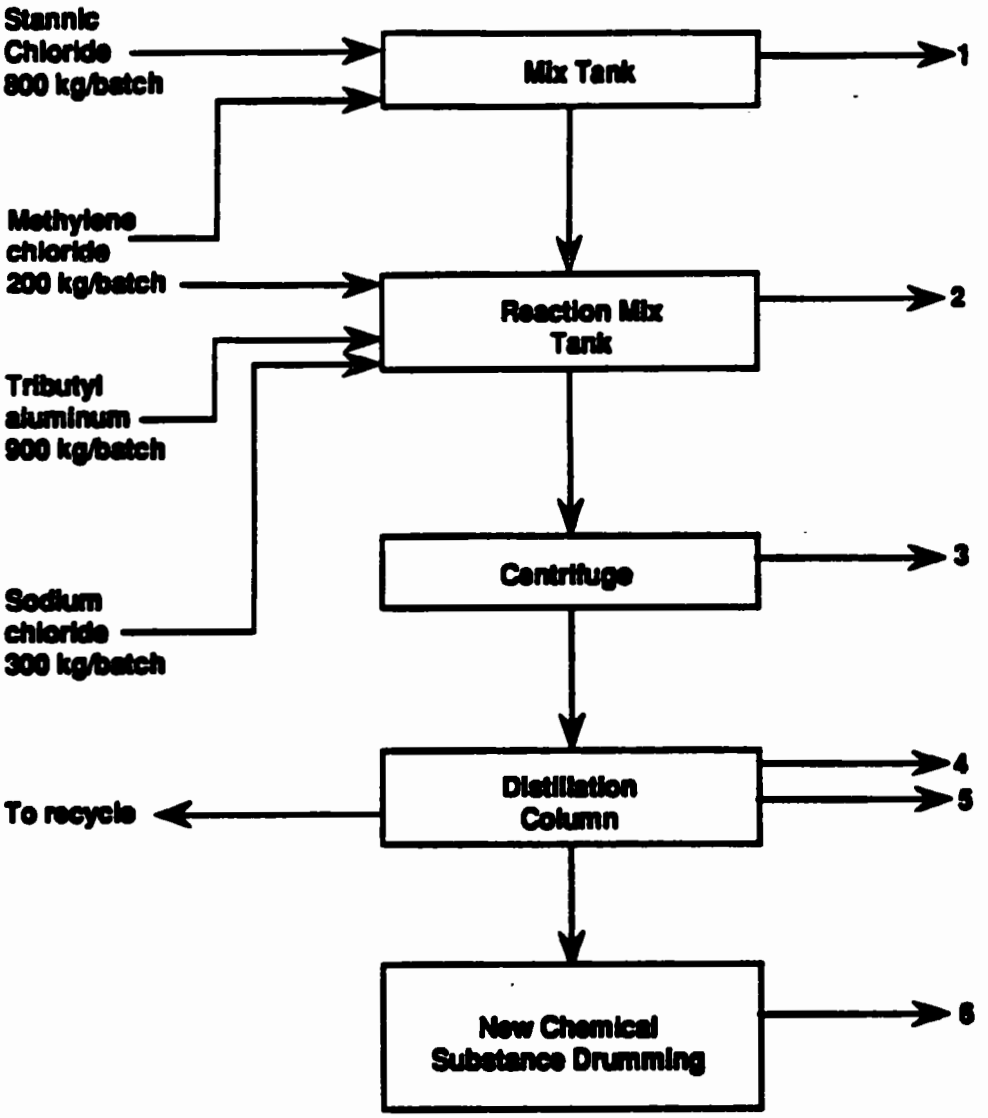
- Verifying release and disposal information. For sites controlled by the manufacturer or processor, the PMN must include information on the release of the new substance to the environment, including the quantity and media of release and the type of control technology used. The inspector should review records documenting the amount of chemical substance released (e.g., monitoring records). The inspector should note any discrepancies greater than 20 percent between the quantity specified in the monitoring records and the estimate provided in the PMN regarding the amount of chemical released. During a tour of the facility, the inspector should examine the control technologies in place as well as the points of and types of release.

- Verifying health and environmental effects testing data. All health and environmental effects testing data in the possession or control of the manufacturer or importer, as well as descriptions of health and environmental effects testing data known to or reasonably ascertainable by the manufacturer or importer, must be submitted as part of the PMN. The inspector should review the files containing health and environmental effects testing data. Examples of test data are provided in Figure 6-6. The inspector should note any testing data that were not submitted with the PMN and should obtain copies and attach them to the inspection record. The inspector should confirm that the dates of such submitted data or information are reliably documented in order to verify that these critical data were generated or available prior to the PMN submission.

- Verifying pollution prevention and recycling information (optional). If the company has provided information on any pollution prevention measures or recycling programs being implemented by the facility, the inspector may want to discuss and review these measures and/or programs. This is an ideal opportunity for the inspector to praise the company's efforts in these areas and to provide any additional pollution prevention outreach material being distributed by EPA.

FIGURE 6-5

MANUFACTURING OPERATION



The numbers represent points from which the chemical will be released into air, land, or water. They do not include accidental releases or fugitive emissions.

FIGURE 6-6

EXAMPLES OF TEST DATA

Physical and Chemical Properties and Environmental Fate Data	Health Effects Data	Environmental Effects Data
• Chromatograms • Spectra (ultraviolet, visible, infrared) • Density/relative density • Solubility in water • Melting temperature • Boiling/sublimation temperature • Softening point • Vapor pressure • Dissociation constant • Particle size distribution • Octanol/water partition coefficient • Henry's law constant • Volatilization from water • Volatilization from soil • pH • Flammability • Explodability • Adsorption/desorption characteristics • Photochemical degradation • Viscosity • Odor • Hydrolysis • Thermal analysis • Chemical analysis • Chemical oxidation • Chemical reduction • Biodegradation • Transformation to persistent or toxic products	• Mutagenicity • Carcinogenicity • Teratogenicity • Neurotoxicity/behavioral effects • Pharmacological effects • Mammalian absorption • Distribution • Metabolism and excretion • Cumulative, additive and synergistic effects • Acute, subchronic and chronic effects • Structure/activity relationships • Epidemiology • Reproductive effects • Clinical studies • Dermatoxicity • Phototoxicity • Irritation • Sensitization • Allergy • Skin staining	• Microbial bioassay • Algal bioassay • Aquatic macrophyte bioassay • Seed germination and root elongation • Seedling growth inhibition • Plant uptake • Acute toxicity to invertebrates • Life cycle test on invertebrates • Acute toxicity to fish • Early life stage (fish) • Avian dietary/reproduction • Bioaccumulation/ bioconcentration • Model ecosystem studies • Physical environment impairment effects • Flesh staining of aquatic organisms

6.2.3 PHASE 2 INSPECTION

To determine whether the manufacturer or importer has failed to submit the required PMN, the inspector should first compare the list of chemicals, isolated intermediates, and raw materials currently being manufactured, imported, or used by the company against the TSCA Inventory.

Before the inspection, the inspector should ask company officials to prepare a list of chemicals, isolated intermediates, and raw materials they currently manufacture, import, or use. The listing should contain the chemical name, CAS Registry Numbers, and trade name(s) for each chemical being manufactured or imported. The inspector should note that although the company is not required to prepare such a list for the inspection, the company should be encouraged to do so to facilitate the inspection process (discussed in Section 3.3.2).

The inspector should verify the accuracy and completeness of this list by reviewing inventory, production, batch, and sales records for the most recent 5 years. Any chemicals identified in these records that are not on the list prepared by the company should be documented, and the inspector should ask the facility officials to explain the deviation. The total production for the previous 5 years should be documented for any chemical potentially in violation of TSCA because the manufacturer or importer failed to submit a PMN. In addition, the inspector should document the customers who have received this chemical and the use of the chemical.

Once the inspector has verified the accuracy of this list, the inspector must determine if the chemicals are on the TSCA Inventory (both open and confidential sections). The CAS Registry Numbers are very important because these designations are the easiest way to verify a chemical's presence on the Inventory. This can be done through an Enforcement Request to Headquarters (see Section 3.2.4) or if the Region has on-line access to CUS. The inspector can use the Chemicals in Commerce Information System (CICIS) database to determine automatically if the chemicals are on the open Inventory. The EPA Regulated Chemicals System, which consists of the open Inventory and the Chemicals on Reporting Rules (CORR) database, is currently being developed and could be used by the inspector. If the chemicals are not on the open Inventory, the inspector must search the closed, or confidential, section of the Inventory. If possible, the inspector should obtain the chemical structure(s) of any chemical(s) not found on the open Inventory from the facility. If the inspector discovers that a particular raw material used, but not manufactured, by the company is not on the Inventory, s/he should document the supplier and the steps taken by the company to comply with TSCA. After the inspection, the inspector should request that the

Information Management Division (IMD) of OPPT conduct a search of the confidential section of the Inventory. Procedures for requesting this search are contained in Appendix 2.

6.3 TSCA SECTION 5(e)/5(f) ORDER

EPA can prevent or restrict the manufacturer of a new chemical substance at the end of the 90-day review period by means of a TSCA Section 5(e)/5(f) order. TSCA Section 5(e) orders are issued by EPA to provide restrictions that will minimize human exposure and/or environmental release when insufficient information is available to evaluate fully the potential hazards associated with a PMN chemical. Generally, a TSCA Section 5(e) order is issued based on structure-activity relationship, similarity to other known hazardous chemicals, and/or potential for significant exposure or release. To issue a Section 5(e) order, EPA must find (1) that available information is insufficient to permit a reasoned evaluation of the health and environmental effects of the new chemical substance, and either (2) that the substance may present an unreasonable risk to human health and the environment (a "risk-based" finding), or (3) that the substance will be produced in substantial quantities and may entail substantial environmental releases or significant or substantial human exposures. A TSCA Section 5(f) order is similar to the Section 5(e) order, except that sufficient data already exist to confirm an unreasonable risk associated with the chemical. A sample Section 5(f) order is shown in Figure 6-7.

If EPA is considering taking action under Section 5(e)/5(f), EPA will first request that the submitter of the PMN volunteer to suspend the 90-day review period in order to allow EPA time to develop the appropriate regulatory action. If the submitter is unwilling to cooperate, EPA can unilaterally extend the review period for "good cause" for up to 90 additional days.

EPA must propose a unilateral TSCA Section 5(e) order at least 45 days before the expiration of the review period, and the order becomes effective on the 91st day. A manufacturer subject to an impending TSCA Section 5(e) order has these three choices: (1) challenge the unilateral order; (2) negotiate a consent order; or (3) withdraw the PMN. Although TSCA Section 5(e) does not explicitly authorize EPA to enter into consent orders, EPA has employed this compromise mechanism to enable the manufacturer to proceed with planned operations while complying with certain EPA-imposed restrictions delineated in the order.

FIGURE 6-7

SAMPLE SECTION 5(f) ORDER

24658 Federal Register / Vol. 49, No. 118 / Thursday, June 14, 1984 / Rules and Regulations

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 747

[OPTS-61008; TSH-FRL 2569-6]

Triethanolamine Salt of a Substituted Organic Acid Restrictions on Use in Metalworking Fluids

AGENCY: Environmental Protection Agency (EPA).

ACTION: Immediately Effective Proposed Rule.

SUMMARY: EPA is proposing a rule under section 6(a) of the Toxic Substances Control Act (TSCA), which is effective immediately under section 5(f)(2) of TSCA. The proposed rule will remain in effect until EPA promulgates a final rule. The rule applies to the new chemical substance which was the subject of premanufacture notice (PMN) P-84-210, submitted under section 5(a) of TSCA. The rule prohibits the addition of any nitrosating agent, such as nitrites, to the chemical substance known generically as triethanolamine salt of a substituted organic acid when it is or could be used in metalworking fluids. The rule also requires distributors of the substance to notify customers of the restrictions of the rule through letters sent prior to shipment of the substance and to notify machine shop workers of the health hazard through labels on metalworking fluids containing the substance. EPA believes that the unrestricted distribution of the substance in commerce and its unrestricted processing and use in combination with nitrosating agents will present an unreasonable risk of injury to human health before a final rule can be promulgated under section 6 of TSCA to protect against this risk.

DATES: This rule is effective June 14, 1984. Written comments and requests for a public hearing must be submitted by August 13, 1984. A public hearing will be held, only if requested, beginning on August 27, 1984.

ADDRESS: Comments should be sent in triplicate to: Document Control Officer (TS-793), Office of Toxic Substances, Environmental Protection Agency, Rm. E-409, 401 M St., SW., Washington, D.C. 20460.

Comments must include the docket control number OPTS-61008. Non-confidential versions of comments received on this proposal will be available for reviewing and copying from 8:00 a.m. to 4:00 p.m., Monday through Friday, excluding legal holidays, in Rm. E-107 at the address given above.

Requests for a public hearing must be submitted to the above address and should reference the docket control number OPTS-61008. The time and location of the public hearing, if requested, will be announced in the future. Any person wishing information on the time and location of the hearing should contact the TSCA Assistance Office at the address and telephone number under "FOR FURTHER INFORMATION CONTACT" below.

FOR FURTHER INFORMATION CONTACT: Edward A. Klein, Director, TSCA Assistance Office (TS-798), Office of Toxic Substances, Environmental Protection Agency, Rm. E-543, 401 M St. SW., Washington, D.C. 20460, (Toll Free: 800-424-9065), (In Washington, D.C.: 554-1404), (Outside the USA: Operator—202-554-1404).

SUPPLEMENTARY INFORMATION:

I. Authority

Section 5(f)(2) of TSCA authorizes the Administrator to issue a proposed rule under section 6(a) of TSCA to apply to a chemical substance which is the subject of a premanufacture notice. Such a rule may be issued if the Administrator finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of the substance presents or will present an unreasonable risk of injury to health or the environment before a final rule promulgated under section 6 can protect against such risk. The section 6(a) rule may, among other things, require that a chemical substance be marked with or accompanied by clear and adequate warnings and instructions with respect to its use, distribution in commerce, or disposal as prescribed by the Agency; the Agency may also restrict the processing and use of the chemical substance. Pursuant to section 5(f)(2), a rule thus proposed under section 6(a) is immediately effective upon its publication in the Federal Register.

Substances covered by a proposed section 6(a) rule immediately effective upon publication pursuant to section 5(f)(2) are subject to the export reporting requirements of TSCA section 12(b). EPA regulations interpreting section 12(b) requirements appear at 40 CFR Part 707. Substances covered by such a proposed rule are also subject to TSCA section 13 import certification requirements at 19 CFR 12.119 through 12.127, and 127.8 (48 FR 34734, August 1, 1983). EPA regulations discussing TSCA's import requirements appear at 40 CFR Part 707, published in the Federal Register of December 13, 1982 (48 FR 55482).

II. Regulatory Background

A. Test Marketing Exemption T-83-81

Section 5(h)(1) of TSCA authorizes EPA to exempt persons from PMN requirements and to permit them to manufacture or import new chemical substances for test marketing purposes if the Agency finds that the manufacture, processing, distribution in commerce, use, and disposal of the substances for test marketing purposes will not present any unreasonable risk of injury to health or the environment. EPA may impose restrictions on test marketing activities. The Agency may rescind approval of an exemption, or modify the exemption, should any new information come to its attention which casts significant doubt on its finding that the test marketing activities will not present any unreasonable risk of injury to health or the environment.

On August 28, 1983, a test marketing exemption application was received by the Agency and subsequently designated T-83-81. The submitter identity, chemical identity, and use of the T-83-81 substance are identical to the submitter identity, chemical identity, and use of the substance regulated by this proposed rule. EPA announced receipt of the application in the Federal Register of September 9, 1983 (48 FR 40781).

The risk assessment performed on the T-83-81 substance identified it to be a moderate eye and skin irritant based on test data in the application. However, manufacturing workers were expected to wear appropriate protective equipment, including rubber gloves, aprons and safety glasses. Releases to the environment were expected to be insignificant. No other significant health or environmental effect concerns were identified. EPA therefore determined that test marketing of the T-83-81 substance as a corrosion inhibitor in aqueous systems under the conditions set out in the application for a time period not to exceed one year, would not present any unreasonable risk of injury to health or the environment.

EPA announced its approval of the exemption under these terms in the Federal Register of October 20, 1983 (48 FR 48710). Two additional restrictions were imposed. First, if the substance were shipped, the applicant was directed to maintain records of the date(s) of shipment(s) to each customer and the quantities supplied in each shipment, and to make these records available to EPA upon request. Second, the bill of lading accompanying each shipment was required to state that use

There are many TSCA Section 5(e) orders and some TSCA Section 5(f) orders in effect for chemicals for which commercial production has not been initiated and an NOC has not been submitted to EPA. If no NOC is recorded as filed, a TSCA Section 5(e)/5(f) inspection will normally not be conducted.

When conducting the TSCA Section 5(e)/5(f) order inspection, the inspector must ensure that s/he has a copy of the final version of any TSCA Section 5(e)/5(f) order, not a draft version that may have been prepared by EPA officials for negotiating purposes. The inspector should also check whether the order has been modified subsequent to its issuance.

6.3.1 INSPECTION OBJECTIVES

Before the inspection, the inspector should review copies of the final TSCA Section 5(e)/5(f) order, injunction, or rule and associated PMN(s), as well as copies of correspondence with EPA regarding the TSCA Section 5(e)/5(f) order, injunction, or rule. At the plant site, the inspector should verify the information contained in these documents by reviewing company records, interviewing company employees, and touring the facility. The inspection determines compliance with a TSCA Section 5(e)/5(f) order by verifying adherence to the constraints placed on the manufacturer by the TSCA Section 5(e)/5(f) order.

6.3.2 INSPECTION GUIDELINES

Most TSCA Section 5(e)/5(f) orders include, but are not limited to, the following elements:

- Testing trigger
- Permeability testing
- Personal protective equipment and environmental release controls
- Employee training
- Disposal
- Labeling
- Customer notification and compliance.

A TSCA Section 5(e)/5(f) order inspection will be most productive if the subject chemical is actually being manufactured or processed at the time of the inspection (i.e., so that the use of required protective

equipment and controls can be fully evaluated). Therefore, the inspector should attempt to arrange the inspection during such activities.

- Verifying testing trigger. Some TSCA Section 5(e) orders require "testing triggers." If a certain aggregate production (or import) volume of the subject PMN chemical is reached (i.e., the "testing trigger"), then the company must curtail manufacture until the test data have been submitted. Test triggers are usually expressed in terms of production volume, but some orders also express the trigger in terms of time (e.g., "20,000 kilograms or one year after the commencement of commercial manufacture, whichever is later"). Testing may be to determine health effects, environmental effects, chemical fate, physical fate, or all four. When EPA believes that a risk may be adequately mitigated through employment of human exposure and/or environmental release controls pending the development of adequate toxicity data, it will permit manufacturers to commence commercial production and submit the data by a given production volume.

  The inspector must establish total production and/or import volume for the PMN chemical of interest and determine whether the specified testing trigger volume has been attained or not. If the figure was reached, then the inspector will need to verify that the company submitted information within a certain time period of reaching that specified volume. That determination may depend on the language in the consent order. The inspector may also need to verify that specified testing had been initiated by the company if future manufacture or import was anticipated. The initiation or completion of testing should be documented, including the identification of the testing laboratory or laboratories and the anticipated starting and completion dates. A determination of whether the tests are being conducted according to the Good Laboratory Practice (GLP) Standards regulations will not be made during the TSCA Section 5(e)/5(f) inspection, but during a GLP inspection conducted by OCM.

  If testing has been initiated, the inspector should also ascertain whether any preliminary and/or final reports have been received by the company from the testing laboratory and whether the reports have been submitted to the EPA. Unsubmitted reports should be reviewed (and copies taken as exhibits, if necessary) to determine if there was a potential TSCA Section 8(e) substantial risk violation (discussed in Chapter 7).

- Verifying permeability testing. Many TSCA Section 5(e)/5(f) orders contain a requirement that the company or facility test and/or evaluate chemical protective clothing for imperviousness to the PMN chemical. The scope of this testing has been put forth as an updated EPA Inspection Guideline, dated May 1985 (included in Appendix 9).

  The inspector should document if, when, and by whom such testing/evaluation was performed and whether it was conducted according to the EPA criteria. A copy of the permeability testing/evaluation report or summary for the PMN chemical should be collected and attached to the inspection report.

  The inspector should also verify and document, if necessary, that employees use protective gloves during production, handling, transfer, and/or processing of the chemical in question, and that the gloves are identical or have been determined to be equivalent to those tested for imperviousness. The inspector should interview employees to verify the use of gloves, and s/he should also look at company purchase orders to determine whether the company is buying enough gloves for its employees.

- Verifying personal protective equipment and environmental release controls. Many TSCA Section 5(e)/5(f) orders carry a requirement that certain protective equipment be worn by workers and other personnel coming into contact with the PMN chemical and/or that environmental release controls on production-related equipment be employed. A key aspect of the TSCA Section 5(e)/5(f) order inspection will be to determine if these protective and/or safety measures have been established and are in active (and effective) use during the production and other handling of the PMN chemical(s). The inspector should recognize that the generic TSCA Section 5(e) language refers to the Occupational Safety and Health Administration (OSHA) requirements listed at 19 CFR Part 1200. However, any violations of these requirements found by the inspector are violations of the consent order, not of OSHA because they are part of the consent order requirements.

  To determine effectively the compliance with this aspect of a TSCA Section 5(e)/5(f) order, the inspector should attempt to conduct the inspection when the subject PMN material is actually being manufactured (or processed, in the case of imports). The inspector can directly observe the use of personal protective equipment and controls and can document noncompliance accordingly. If the new chemical substance has been manufactured or processed, but not during the on site inspection, the inspector should interview employees (and others, if necessary) to determine if the required equipment and controls are being used.

  If protective equipment is not being (or has not been) worn, as required by the TSCA Section 5(e)/5(f) order, then the inspector will need to determine if:

  - The clothing and equipment have not been made available (along with training).

  - The clothing and equipment have been made available, but are not being used.

  - The clothing and equipment have been supplied, but proper training for their use has not been provided.

  - The clothing and equipment have been supplied, but they have not been properly maintained.

  If any of these three situations are found to be the case during the inspection, the inspector should attempt to obtain a signed statement from the employee(s), or alternatively obtain a signed statement from a responsible management official documenting the situation. If a second member of the inspection team is present and a signed statement cannot be obtained, the employee's or manager's interview responses should be noted in the field notebook, signed by the interviewing inspector, and signed by the second team member as witness.

  The inspector should document with photographs (if possible) or signed statements from knowledgeable or responsible individuals a lack of protective equipment or employment of engineering practices contrary to the TSCA Section 5(e)/5(f) order.

- Verifying employee training. Most TSCA Section 5(e)/5(f) orders specify training in the handling of the subject PMN substance(s), as well as the use of protective clothing and devices. This training is to be provided at the time of each employee's initial assignment to a work area containing the substance and whenever the PMN substance is introduced into the employee's work area for the first time.

If the company has provided training in the handling of a PMN chemical subject to a TSCA Section 5(e)/5(f) order, the inspector should review a prospectus of the training and a list of the employees who attended the course (i.e., a "sign-in" sheet). The inspector should verify that the scope of the training corresponds with the TSCA Section 5(e)/5(f) order requirements, and s/he should check that the list of attendees corroborates the list of employees required to take the training course; verification can be achieved through employee and management interviews. The inspector should substantiate any commercial production of the subject chemical that has taken place prior to the date of the training session with dated copies of documents related to the training, as well as with documentation of the first date of commercial production.

If the TSCA Section 5(e) order refers to the OSHA requirements listed at 19 CFR Part 1200 then the employees must also be trained to be knowledgeable of and to implement the OSHA requirements. However, any violations of these training requirements found by the inspector are violations of the consent order, not of OSHA.

- Verifying disposal. If the TSCA Section 5(e)/5(f) order contains requirements for the disposal of waste, excess, and/or unsold chemical, then the inspector should determine how all wastes for the subject PMN chemical are being disposed. The inspector should fully document any disposal that was inconsistent with the order is to be fully documented with copies of invoices, manifests, correspondence, bills of lading, receipts, or other records. The inspector should also document fugitive emissions and/or other uncontrolled waste releases.

- Verifying labels and MSDSs. The TSCA Section 5(e)/5(f) order will normally contain a requirement for MSDSs and labels for the subject PMN chemical, advising workers and customers of the potential health and/or environmental hazard associated with the chemical and of the precautionary measures that should be taken when handling the chemical.

  The inspector should examine the labeling for all shipments of the subject chemical(s) sent to customers, particularly those ready for shipment. To document any non-compliance of labeling with the TSCA Section 5(e)/5(f) order requirements, the inspector should obtain bin labels, photographs of actual labels of materials released for shipment, and copies of correspondence and shipping records. The inspector should also obtain written statements from company officials and/or shipping personnel, if needed.

- Verifying customer notification and compliance. TSCA Section 5(e)/5(f) orders may also contain requirements that customers or other processors of the associated PMN chemical(s) are to be notified that the substance is the subject of a TSCA Section 5(e)/5(f) order and that they should take certain precautions when handling the chemical. In older orders, this notification normally will consist of a form letter, which must be transmitted to a customer via return receipt mail prior to the first shipment of the chemical. In most orders issued after 1988, manufacturers are required to convey safety information via an MSDS accompanying the customer's first shipment of the PMN substance. Consent orders require distributors to send to the company (i.e., the signatory) prior to distribution, a statement that they will adhere to the same restrictions as contained in the order. The company must keep records that document the fulfillment of this obligation. The inspector should verify that for all commercial shipments of the PMN chemicals subject to the TSCA Section 5(e)/5(f) order, the customer has been notified by copying the information that the company sent to customers and by checking for records of communication with customers about company directives to take certain steps. If the company did not meet this requirement, the inspector should obtain written statements from company officials as to whether they were aware

of the requirement and/or why they did not follow it. The inspector should document that no one received notification, if that is the case. If the inspector has reason to believe that the customer or processor was not adequately informed and/or is not complying with handling restrictions, the inspector may want to consider a secondary inspection (i.e., of the customer or processor).

6.4 SIGNIFICANT NEW USE RULE

6.4.1 RULE-MAKING PROCEDURES

SNUR requirements are found at 40 CFR Part 721 and consist of the following five subparts:

- Subpart A defines the terms found in other subparts
- Subpart B lists standardized significant new uses that EPA can apply to any existing chemical by rule
- Subpart C establishes recordkeeping requirements that EPA can impose upon manufacturers, importers, or processors
- Subpart D establishes expedited rule-making procedures that EPA can use to establish SNURs for chemical substances that have completed PMN review, limits the circumstances under which EPA can use these procedures to promulgate SNURs on chemicals that were not the subject of TSCA Section 5(e) orders, and creates a procedure by which persons affected by an expedited SNUR can petition EPA to modify or revoke it
- Subpart E lists the chemicals that are subject to 40 CFR Part 721 and the new uses for each chemical that EPA has designated as "significant."

EPA may use Subpart D's expedited procedures to promulgate a SNUR by publishing a single notice in the *Federal Register* that lists all the standard significant new uses that correspond to the restrictions in a particular TSCA Section 5(e) consent order. When the SNUR is promulgated, any subsequent manufacturers (or processors) of the chemical substance must either abide by the restrictions of the consent order or terminate operations and submit a Significant New Use Notice (SNUN) (See Section 6.4.2). In the course of EPA's review of the SNUN, it may investigate any manufacture or processing of the chemical that is not in compliance with the terms of the consent order and the SNUR. EPA may also address other TSCA Section 5(e) consent orders applicable to these new uses. In addition, EPA can use the expedited SNUR procedures to regulate any chemical that completed the PMN process but was not subject to a TSCA Section 5(e) consent order, provided the chemical meets the "concern criteria" listed in Subpart D. These criteria apply to chemicals of suspect toxicity and to chemicals structurally similar to toxic chemicals.

6.4.2 SNUN REQUIREMENTS

Although EPA may have already placed a chemical substance on the TSCA Inventory, the original manufacturer or another manufacturer may use the chemical in a different way that could substantially increase human or environmental exposure to the chemical.

The SNUR essentially converts an "existing" chemical into a "new" chemical with regard to the designated significant new use. A SNUR applies to a broader spectrum of submitters than the PMN regulations because it can apply to processors as well as to manufacturers and importers, and it can require everyone to whom the SNUR applies to file a SNUN, not just the first manufacturer or importer of the chemical substance, as is the case with the PMN. In accordance with 40 CFR Part 721, when EPA issues a SNUR (see Section 6.4.1), manufacturers and processors of the subject chemical substance must give 90 days prior notice to EPA in the form of a SNUN. The SNUN is the functional equivalent of a PMN, and information required in a SNUN mirrors the information that must be submitted in a PMN. Any manufacturer or processor submitting a SNUN shall not manufacture or process a chemical substance for a significant new use until the notice review period, including all extensions and suspensions, has expired. EPA will process the SNUN in the same manner as it processes a PMN, unless such procedures are inconsistent with 40 CFR Part 721.

Any manufacturer or processor subject to a SNUR must retain documentation of the information contained in the SNUN for 5 years from the date of its submission. Failure to keep any of these records constitutes a violation of 40 CFR §721.40. When the inspector is arranging an inspection involving a SNUN, s/he should ask the company to consolidate the supporting records prior to the inspection. The records of each manufacturer or processor of a chemical substance for a significant new use should include the following:

- Documentation of the information in any SNUN. This information must be kept for five years.
- Any other records required by the terms in individual rules.

The inspector should not simply accept the records provided at the facility. S/he should become familiar with other names and designations for the chemical substance and look for mention of the substance in any other records and data reviews, as well as watch for its potentially illegal manufacture, sale, storage, or use during the inspection.

6.4.3 INSPECTION OBJECTIVES

When conducting a SNUR inspection, the inspector's objectives are as follows:

- For a Section 5(e) order SNUR, identifying that a facility is not in compliance with a TSCA Section 5(e) order because it is manufacturing or processing a chemical substance in a way that is considered to be a new use and it had not submitted the required SNUN
- Checking the accuracy and technical content of a SNUN submitted by a manufacturer or processor.

In the first situation, to determine if a manufacturer or processor is manufacturing or processing in such a manner that it would be considered a significant new use, the inspector should first check the list of chemicals manufactured or processed by the facility to ascertain if any of these chemicals are listed in 40 CFR 721 Subpart E (i.e., Significant New Uses for Specific Chemicals). Before the inspection, the inspector should have asked company officials to prepare a list of the chemicals, isolated intermediates, and raw materials they currently manufacture or import. The listing should contain the chemical name, trade name(s), and CAS Registry Numbers for each chemical manufactured or imported. The inspector should note that although the company is not required to prepare such a list for the inspection, the company should be encouraged to do so to facilitate the inspection process (discussed in Section 3.3.2).

If the chemical is listed, but no SNUN has been submitted, the inspector should determine whether the chemical substance is being manufactured or processed in compliance with the restrictions of the TSCA Section 5(e) order (i.e., it is considered a significant new use). The persons required to submit a SNUN are summarized in Table 6-4 and the persons exempt from this requirement are summarized in Table 6-5.

6.4.4 INSPECTION GUIDELINES

The SNUN must include, but is not limited to, the following elements:

- Commercial production dates (not including NOC)
- Chemical identification and structure
- Impurities
- Byproducts
- Proposed volume of production
- Proposed categories of use

TABLE 6-4 PERSONS REQUIRED TO SUBMIT A SIGNIFICANT NEW USE NOTICE

Authority (40 CFR)	FR Publication	Requirements
721.5	53 FR 28359 July 27, 1988	The following persons must submit a Significant New Use Notice (SNUN):
721.5(a)(1)	53 FR 28359 July 27, 1988	• A person who intends to manufacture, import, or process for commercial purposes a chemical substance identified in Subpart E and who intends to engage in a significant new use of that substance
721.5(a)(2) 721.5(a)(2)(i) 721.5(a)(2)(ii) 721.5(a)(2)(iii)		• A person who intends to manufacture, import, or process for commercial purposes a chemical substance identified in Subpart E and who intends to distribute the substance in commerce; person not required to submit SNUN if he can document one or more of the following about the recipient: (1) he has notified the recipient in writing of the appropriate section in Subpart E; (2) the recipient has knowledge of the section in Subpart E; or (3) the recipient cannot undertake any significant new use described in the section in Subpart E
721.5(b)	53 FR 28359 July 27, 1988	• The person [721.5(a)(2)] who has knowledge at the time of commercial distribution of the substance identified in Subpart E that a recipient intends to engage in a significant new use without submitting a SNUN
721.5(c) 721.5(c)(1) 721.5(c)(2)	53 FR 28359 July 27, 1988	• A person who processes a chemical substance identified in Subpart E must submit a SNUN unless he can document that: (1) the person does not know the specific chemical identity of the substance being processed; and (2) the person is processing the chemical substance without knowledge that the substance is identified in Subpart E
721.5(d)(1) 721.5(d)(1)(i) 721.5(d)(1)(ii) 721.5(d)(1)(iii) 721.5(d)(2) 721.5(d)(2)	53 FR 28359 July 27, 1988	• After commencing distribution in commerce, the person [721.5(a)(2)] who has knowledge that the recipient is engaging in a significant new use without submitting a SNUN must cease distribution and submit a SNUN, unless he can document that: (1) the person has notified the recipient and EPA in writing within 15 working days of learning of the recipient's lack of a SNUN; (2) within 15 working days of notifying the recipient, the person received a written statement of assurance of the recipient's awareness of terms in Subpart E and a promise not to engage in the significant new use; and (3) the person promptly provided EPA with a copy of the recipient's statement • A person who manufactures, imports, or processes and then distributes to a recipient a chemical substance used by the recipient for a significant new use without a SNUN even after the recipient provided statements of assurance to the contrary; this person must cease distribution and then submit a SNUN • The recipient described above.

TABLE 6-5 PERSONS EXEMPT FROM THE SNUN REPORTING REQUIREMENTS

Authority (40 CFR)	FR Publication	Requirements
721.45	53 FR 28361 July 27, 1988	The persons identified in 721.5 are not required to submit a SNUN for a chemical substance identified in Subpart E if:
721.45(a)		• A person has been granted a test marketing exemption
721.45(b)		• A person manufactures, imports, or processes the chemical substance only in small quantities for R&D
721.45(c)		• A person has been granted an exemption under TSCA Section 5(h)(5) - "zero exposure" exemption
721.45(d)		
721.45(e)		• A person manufactures, imports, or processes the chemical substance only as an impurity
721.45(f)		• A person manufactures, imports, or processes the chemical substance only as a byproduct which is used only by public or private organizations that burn it as a fuel, dispose of it as a waste, or extract component substances from it for commercial purposes
721.45(h)		
721.45(h)(1)		• A person imports or processes the chemical substance as part of an article
721.45(h)(2)		• A person manufactures or processes the chemical substance solely for export and, when distributing the substance in commerce, labels the substance accordingly
721.45(i)		• A person submits a SNUN prior to the promulgation date of the relevant section in Subpart E, which identifies the chemical substance, and the person receives written notification of compliance from EPA prior to the effective date of the section if one of the following occurs: (1) EPA is unable to make the finding that the activities described in the SNUN will or may not present unreasonable risk of injury to health or the environment under reasonably foreseeable circumstances; or (2) EPA and the person negotiate a TSCA Section 5(e) consent order, with such order taking effect on the effective date of the section in Subpart E.
		• A person operating under the terms of a TSCA Section 5(e) consent order that has provisions inconsistent with a significant new use identified in Subpart E; the person abides by the consent order.

- Process description
- Worker exposure
- Release information
- Health and environmental effects testing data.

Before the inspection, the inspector should review a copy of the specific SNUR and the associated TSCA Section 5(e) order (if applicable), as well as copies of any correspondence with EPA. In some instances, EPA may approve alternative control measures (worker exposure or environmental release) for a particular facility that has submitted a request for a determination of equivalency. If EPA approves the request, the submitter may commence manufacture, import, or processing in accordance with the specifications identified in the submitter's request. Therefore, the inspector should review the appropriate correspondence documenting the approval either found in the company's records or through OPPT.

The following guidelines should assist the inspector in assessing compliance with the above listed elements of a SNUN and its implementation:

- Verifying commercial production date (NOT including NOC). As is the case for the PMN, confirming the accuracy of a particular date is the most important element of the SNUN inspection from a compliance standpoint. The inspector should know the 90-day review date for each SNUN under compliance review prior to a specific SNUN compliance inspection.

  If a SNUN under review has been formally withdrawn, the 90-day review period is terminated, eliminating the 90-day review date. In this case, no commercial manufacture or processing should have occurred, and any such commercial manufacture or processing violates TSCA. Unlike the PMN review, the inspector reviewing a SNUN for compliance does not need to concern himself with an NOC since the manufacturer (or processor) of a chemical substance for a significant new use does not have to notify EPA of the date of commencement of manufacture (or processing) as long as EPA has not initiated any action under TSCA Sections 5, 6, or 7 before the 90-day review period has elapsed.

  The 90-day review period begins on the date of receipt of the SNUN by the Office of Pollution Prevention and Toxics (OPPT) DCO.[1] The inspector must confirm that the submitter has waited until the final day of the 90-day review period before beginning to manufacture or process the chemical substance in the manner in which it is considered a significant new use. The inspector will obtain this information through:

  - Interviews with company officials.

[1] The Office of Toxic Substances (OTS) has changed its name to the Office of Pollution Prevention and Toxics (OPPT).

- Review of production and batch records.

Sales records may also need to be reviewed and copied to substantiate commercialization of the chemical substance.

- Verifying chemical identification and structure. The manufacturer or importer must specify whether the chemical substance is a Class 1 or a Class 2 substance or a polymer. The chemical name, the molecular formula, the CAS Registry Number (if available), and a structural diagram of the chemical substance are required on the SNUN. OPPT verifies the chemical identification and structure. Therefore, the inspector should only check the MSDS (if available), chemical composition or formulation data, or product literature to verify the chemical identity.

- Verifying impurities. The manufacturer or importer must list in the SNUN the impurities anticipated in the chemical substance by name, CAS Registry Number, and weight percent of the total substance. The inspector should review facility records to verify the impurities in the chemical substance against the information provided in the SNUN. Information on the impurities can generally be found in the quality control analyses or specifications for the product. It may also be possible for the inspector to find information about the impurities by analyzing the reactants and raw materials employed during the manufacturing process.

- Verifying byproducts. The manufacturer or importer must include in the SNUN any byproducts resulting from the manufacture, processing, use, and disposal of the new chemical substance. The inspector can generally find byproducts information in product files. These product files may appear in various forms, such as a product diagram or tree that lists the raw materials, isolated intermediates, and byproducts.

- Verifying proposed volume of production. The manufacturer or importer must include in the SNUN an estimate of the maximum amount of the chemical to be manufactured or imported during the first year of production and the estimated maximum amount to be manufactured or imported during any 12-month period during the first 3 years of production. The inspector should verify these production or import numbers by reviewing the production or import records for the first 3 years of production or import. The inspector should document discrepancies in production numbers.

- Verifying proposed categories of use. The manufacturer, importer, or processor must describe the intended categories of use of the chemical substance by function and application in the SNUN. In addition, the manufacturer, importer, or processor must include an estimate of the percent of production volume devoted to each category of use and the percent of the chemical substance in the formulation for each commercial and consumer use. The inspector must verify the categories of use through review of general production, inventory, and sales records.

- Verifying process description. For sites controlled by the manufacturer or processor who submits a SNUN, the notice must include a process description of each manufacture, processing, and use operation that includes a diagram of the major unit operations and chemical conversions, the identity and entry point of all feedstocks, and the points of release of the chemical substance. To verify the processes used to manufacture or process the subject chemical, the inspector should walk through the facility, inspecting every major unit process and the points of entry and release of the subject chemical and compare the manufacturing process diagram to in-plant operations. An example of a manufacturing operation is presented in Figure 6-5. Any discrepancies between

what was provided in the SNUN and the in-plant operations should be documented. If possible, the inspector should obtain a signed statement from company officials explaining the discrepancy.

- Verifying worker exposure. For sites controlled by the manufacturer or processor, the SNUN must supply worker exposure information, including worker activities, the physical form of the chemical substance to which workers may be exposed, the number of workers, and the duration of the activities. The inspector should review records (e.g., monitoring records) documenting worker exposure information. In addition, the inspector should tour the facility and interview employees to verify how the workers are exposed to the chemicals (e.g., changing reactor vessels, sampling for quality control, bulk loading, changing filters, cleaning equipment). At this time, the inspector should also verify the use of protective equipment and engineering controls (e.g., gloves, goggles, respirators, closed containment system).

- Verifying release and disposal information. For sites controlled by the manufacturer or processor, the SNUN must include information on the release of the new substance to the environment, including the quantity and media of release and the type of control technology used. The inspector should review records documenting the amount of chemical substance released (e.g., monitoring records). The inspector should document any discrepancies greater than 20 percent that s/he finds between the quantity specified in the monitoring records and the estimate provided in the SNUN regarding the amount of chemical released. During a tour of the facility, the inspector should examine the control technologies in place as well as the points of and types of release.

- Verifying health and environmental effects testing data. All health and environmental effects testing data in the possession or control of the manufacturer, importer, or processor, as well as descriptions of health and environmental effects testing data known to or reasonably ascertainable by the manufacturer, importer, or processor must be submitted as part of the SNUN. The inspector should review the files containing health and environmental effects testing data. Examples of test data are provided in Figure 6-6. The inspector should note any testing data that were not submitted with the SNUN and should obtain copies of them and attach them to the inspection record.

  The inspector should note that a search for health and environmental effects testing data is very difficult and time consuming (i.e., it can take up to 2 to 4 days). If during an inspection the inspector suspects the company has not submitted the required health and environmental effects testing data, s/he may want to consider such a search in a second followup inspection.

6.5 LOW VOLUME EXEMPTION

Under TSCA Section 5(h)(4), the manufacturer or importer of a new chemical substance can apply to EPA for an LVE if s/he plans to manufacture or import the substance in quantities of 1,000 kg or less per year. To manufacture or import a new chemical substance under the terms of this exemption, a manufacturer or importer must submit an LVE notice. LVE substances are not added to the TSCA Inventory, but EPA maintains a separate inventory of LVEs granted. A copy of this list is not readily

available, but EPA can produce one upon request. EPA only grants one LVE per substance; all subsequent manufacturers or importers must submit a PMN.

If, during pre-inspection preparation, the inspector learns that EPA has found the subject chemical to be ineligible for an LVE, the inspector should confirm that the facility complied with the regulatory procedures regarding ineligibility. Once EPA has made the determination of ineligibility, the company should have ceased manufacture, import, processing, distribution in commerce, or use of the new chemical substance within 24 hours of notification of EPA's determination. The inspector should confirm that the company did not resume any of the previously mentioned activities until the company submitted a PMN and the notice review period ended. The inspector should review company correspondence with EPA and company records from the period during which the ineligibility was being processed.

The submission requirements for LVE notices are delineated in Table 6-2. The regulatory requirements that apply to the LVE are summarized in Table 6-6.

6.5.1 INSPECTION OBJECTIVES

The inspection objectives to determine compliance with the LVE are as follows:

- To verify the accuracy and completeness of the information contained in the LVE notice
- To verify adherence by the manufacturer or importer to the LVE specifications.

The inspector should note that the LVE recordkeeping requirements specify the retention of records to document the accuracy of the information provided in the LVE notice and to document adherence to the LVE specifications. Failure to keep any of these records is a violation of 40 CFR §723.50(o). The inspector should encourage the company to consolidate the supporting records (which may be at corporate headquarters or the production site) when arranging the inspection.

The inspector should not accept at face value the LVE records as provided by the facility. S/he should ascertain all of the names and designations for the LVE chemical and note its mention in any other records and data reviews, as well as watch for its potentially illegal manufacture, sale, storage, or use during the plant tour.

TABLE 6-6 LOW VOLUME EXEMPTION

Authority (40 CFR)	FR Publication	Regulatory Requirements
723.50(e)(1) 723.50(e)(1)(i) 723.50(e)1)(ii) 723.50(e)1)(iii) 723.50(e)1)(iv) 723.50(e)1)(v) 723.50(e)1)(vi) 723.50(e)1)(vii) 723.50(e)1)(viii)	50 FR 16489-90 April 26, 1985	Notice must include: • Name and address of manufacturer and name and telephone number of a technical contact • Type of exemption • Chemical identification and structure • Description of use • Name and address of site of manufacture (except for imported chemical substances) • Certification that chemical will be manufactured or imposed in compliance with LVE terms • Test data in submitter's possession or control • Exposure controls may be submitted; if submitted, manufacturer must maintain the controls throughout LVE period.
723.50(i)	50 FR 16491 April 26, 1985	• Any change in site of manufacture or use of chemical must be submitted to EPA in notice.
723.50(j)	50 FR 16491 April 26, 1985	• Manufacturer must notify processors and users of use restrictions and of any controls specified in LVE notice. Notification may be made by means of a container labeling system, written notification, or any other method that adequately informs.
723.50(o) 723.50(o)(1) 723.50(o)(2) 723.50(o)(2)	50 FR 16492 April 26, 1985	Recordkeeping: • Annual production volume of chemicals under LVE • Documentation of information in exemption notice and compliance with LVE terms • Records must be retained for 5 years after their date of preparation.

6.5.2 INSPECTION GUIDELINES

Before the inspection, the inspector should review a copy of the LVE notice, a copy of the LVE *Federal Register* notice, and copies of correspondence with EPA regarding the exemption (including a copy of the *bona fide* inquiry, if applicable). At the plant site, the inspector will verify the information contained in these copies by reviewing company records, interviewing company employees, and touring the facility.

The following elements generally constitute the LVE components that require compliance verification during an inspection, as appropriate:

- Manufacturer's name and technical contact
- Type of exemption
- Chemical identification and structure
- Description of use
- Site of manufacture
- Health and environmental effects testing data
- Customer notification
- Exposure controls.

The following guidelines should assist the inspector in assessing compliance with the above-listed elements of an LVE notice and its implementation:

- Verifying manufacturer's name and technical contact and type of exemption. The inspector generally verifies these two items when reviewing records during pre-inspection planning. If during an inspection the inspector discovers that the company is manufacturing a chemical under an LVE, the inspector should note this information to include it in the inspection report.

- Verifying chemical identification and structure. The inspector should compare the identity (structure) of the chemical actually manufactured or imported and sold during the LVE period to information and/or data contained in the LVE notice. The inspector will want to look for the identification of the chemical substance as either a Class I or Class II substance or as a polymer, impurities anticipated in the new chemical substance, and a generic name for a new chemical substance claimed confidential. The chemical identity and structure should be verified by OPPT. Therefore, the inspector should check the MSDS (if available), chemical composition and formulation data, or product literature for the subject chemical to verify its identity. If the inspector finds any discrepancies, s/he should note them and obtain copies of supporting data for followup with EPA Headquarters.

- Verifying description of use. The inspector should review the LVE notice to confirm that the notice includes a description of the intended use of the new chemical substance by function and application and describes whether the use is **industrial, commercial,** or **consumer**. The inspector should verify that the actual use(s) of the LVE chemical accurately reflects the information in the LVE notice.

DEFINITIONS

***Consumer** - The new chemical substance or products containing the substance will be used by private individuals in or around a residence, or during recreation, or for any other personal use or enjoyment (e.g., automotive polish, dyed wearing apparel, household cleaners, etc.) If a consumer use is identified, then the EPA requests the following information be provided on an attached continuation sheet: a detailed description of the use of the new chemical substance expected in consumer products and any reactions that cause the substance to lose its identity in the consumer product.*

***Industrial** - The new chemical substance or products containing the substance will be used at the site of other manufacturers, importers, or processors (e.g., textile dyeing, paint formulation, use of a curable resin to manufacture an article).*

***Commercial** - The new chemical substance or products containing the substance will be used by a commercial enterprise providing a consumer service (e.g., use by commercial dry cleaning establishments, use by painting contractors, or use by roofers in commercial building construction).*

To do this, the inspector should review shipping, sales, and customer records and particularly watch for changes in the use category (e.g., the LVE notice indicates an industrial use, but company records indicate a consumer use) because the resulting exposure to the chemical can be significantly different. If the inspector finds a discrepancy, s/he should determine whether a new notice has been submitted that indicates a change from the original, reported use of the chemical substance. If no new LVE notice has been completed, the inspector should obtain copies of the supporting documentation and signed statements from company officials.

- Verifying site of manufacture. The LVE notice must specify the site of manufacture, and this information legally binds the company. Therefore, the inspector should verify that the actual site of the manufacturing activity matches the site specified in the LVE notice or in subsequent notices indicating a site change.

  Any change in the manufacturing site (or use) of the LVE chemical substance must be submitted to EPA by means of a new notice that indicates, in addition to the new site (or use), the identity of the new chemical substance, the manufacturer's name, and the name and telephone number of a technical contact. However, this notice need not include other information submitted to EPA in the previous exemption notice.

- Verifying health and environmental effects testing data. The regulations require that all health and environmental effects testing data in the submitter's possession or control and descriptions of other data that are known to or reasonably ascertainable by the submitter and that concern the health and environmental effects of the new chemical substance be submitted to EPA as part of the LVE notice. The inspector should review the files containing health and environmental effects testing data. To verify that these critical data were generated or available prior to the LVE submission, the inspector should confirm that the dates of such submitted data or information are reliably documented.

The inspector should note that a search for health and environmental effects testing data is very difficult and time consuming (i.e., it can take up to 2 to 4 days). Therefore, if during an inspection the inspector suspects the company has not submitted the required health and environmental effects testing data, s/he may want to consider conducting such a search in a second followup inspection.

- Verifying customer notification. The inspector should verify that the manufacturer or importer has notified processors and industrial users of the use restrictions and controls applicable to the chemical substance as specified in the LVE notice. The inspector can verify that the manufacturer or importer has fulfilled the customer notification requirements by checking for the means by which such notification was made, which could include the following:

  - A container labeling system

  - Written notification

  - Any other method that adequately informs.

  If the manufacturer or importer has not complied with the notification requirement, the inspector should obtain written statements from the facility officials as to whether they were aware of the requirement and/or why it was not followed. If the inspector has reason to believe that the customer was not adequately informed and/or is not complying with the use restrictions or controls, the inspector may consider a secondary inspection (i.e., of the customer).

- Verifying exposure controls. In the event the manufacturer chooses to provide information on exposure controls or other controls for the new chemical substance to support the exemption notice (information deemed optional in the regulations), the inspector should verify that the manufacturer has maintained the legally binding controls throughout the period during which the manufacturer is operating under the LVE. Such controls might include limits on the number of workers exposed and the duration of the exposure. The inspector should examine the manufacturing area to verify these controls, and if exposure levels have been specified the inspector should check the appropriate monitoring records. The inspector should also interview company employees, if necessary.

6.6 RESEARCH & DEVELOPMENT EXEMPTION

To engage in R&D activity, a manufacturer or importer is not required by TSCA Section 5(h)(3) to apply for an R&D exemption. The manufacturer or importer only needs to demonstrate that small quantities of the new chemical substance are being used solely for scientific experimentation or analysis, for chemical research on, or for analysis of such substance or another substance, including research or analysis for the development of a product. Neither the statute nor the regulations define "small quantities," but the manufacture or import of a low volume of a new chemical substance does not automatically qualify for the R&D exemption. A technically qualified person must supervise the R&D activity and the manufacturer or importer must notify all persons engaged in the experimentation,

research, or analysis of any risk to health that the manufacturer or importer has reason to believe may be associated with the chemical substance.

As specified in Table 6-2, to be eligible for an R&D exemption, a manufacturer or importer is not required to submit an application or a notice to EPA. The specific regulatory requirements that apply to the R&D exemption are summarized in Table 6-7.

6.6.1 INSPECTION OBJECTIVES

The objective of this type of inspection is to verify that the company is manufacturing or importing the new chemical substance to meet the criteria for the R&D exemption.

6.6.2 INSPECTION GUIDELINES

To determine compliance by any facility employing (knowingly or unknowingly) the TSCA R&D exemption, the TSCA inspector should assess the following information, either from company officials or through review of company records: whether a discrete R&D laboratory or operation is at or near the facility being inspected; whether new chemicals (according to the TSCA definition) are being synthesized for eventual commercialization and, if so, the different kinds of chemicals being synthesized (from the standpoints of general chemical structure and intended use); and, for any written company policy that addresses the development of new chemicals, whether the policy addresses notification of risk requirements, sample labeling and other customer notification procedures, recordkeeping requirements, the amount of R&D material that can be produced, designation of technically qualified individuals, procedures for risk evaluation and required health risk notification, and prudent laboratory practices.

- Verifying company policy. Ideally, compliance verification relative to the use of the TSCA R&D exemption should be conducted for all new commercially-intended chemicals synthesized since May 13, 1983 (the date of the promulgation of the PMN regulations); however, emphasis should be placed on those compounds synthesized since August 4, 1986, when the stayed R&D provisions became effective. In addition to reviewing the company's R&D policy, the inspector should review facility operations and recordkeeping practices to establish the typical or normal pathway of a new chemical from initial benchtop synthesis through pilot-plant scale-up to final commercial production. The major items that the inspector should identify and review are the responsible person for specific R&D activities (the technically qualified individual), the policies and procedures for recordkeeping and notification, and health risk assessments.

The inspector should collect a copy of the R&D policy if one of the following situations arises:

- Additional time is needed for its review

TABLE 6-7 RESEARCH AND DEVELOPMENT EXEMPTION

Authority (40 CFR)	FR Publication	Requirements
720.36	48 FR 21746 May 13, 1983	To qualify for exemption: • Chemical must be manufactured or imported in small quantities solely for R&D • Manufacturer or importer must notify all persons associated with R&D of health risks • Chemical must be used by or supervised by technically qualified individual [defined in 720.3(ee)]
720.36(a)(2) 720.36(c)(2)(i) 720.36(c)(2)(ii)	51 FR 15102 April 22, 1986	Manufacturer or importer notification of person employed by the firm and persons not employed by the firm: • Substance is to be used for R&D only • Health risks associated with the R&D chemical (See Table 6-8 for specific requirements)
720.36(b)(l)(i)–(iv)	48 FR 21746 May 13, 1983 51 FR 15102 April 1986	Manufacturer or importer must determine if any potential health risks exist by evaluating: • Information on significant adverse reaction by persons exposed to chemical reasonably associated with such exposure • Information provided by supplier or other person of health risk • Health and environmental effects data • Information on health effects accompanying any EPA rule or order issued under TSCA Sections 4, 5, or 6.
720.78(b)(l)(i)–(iv)	51 FR 15102-15103 April 22, 1986	Manufacturer or importer recordkeeping requirements (See Table 6-9 for specific requirements).
720.78(b)(3)	51 FR 15103 April 22, 1986	R&D records must be retained for 5 years after they are developed
720.36(e)	51 FR 15102 April 22, 1986	After completion of R&D, chemical may be disposed of in accordance with applicable regulations or used commercially (1) in burning as a fuel or (2) in reacting or in processing to form other chemicals for commercial purposes.
720.36(f)	51 FR 15102 April 22, 1986	Once R&D has been completed, R&D substances existing as impurities in a product or incorporated into an article are not subject to notification requirements in 720.36(a), (b), and (c).
720.36(g)	51 FR 15102 April 22, 1986	R&D activities done exclusively to determine potential use of chemical as a pesticide are exempt from requirements of Section 720.36.

- There are deviations from the requirements of TSCA

- There are operational deviations from the policy's provisions.

Through interviews with appropriate laboratory personnel at the site, the inspector should identify the senior product development or research chemists responsible for the various product lines of commercial interest. In this respect, it may assist the inspector in preparing a chart of all use and/or chemically discrete classes of compounds and then individually ascertain:

- Whether research on each new chemical is ongoing or not.

- The location of any research.

- Whether research is taking place locally (i.e., at or near the inspected facility or under immediate contract) and the person who is responsible for its undertaking.

Once this information is obtained and the total R&D scope is established, the inspector may want to perform either a total or a limited verification, as appropriate. To do this, the inspector should review laboratory notebooks and interview research chemists. At a minimum, the inspector should select several chemicals from various use and/or chemical categories for further inquiry. S/he should note the synthesis of potentially new commercial compounds in the laboratory, including dates, starting materials, and proposed target compound. The inspector should also note additional purification steps and any subsequent identity or property determinations. S/he should track the selected new compounds through interviews, and records, and risk evaluation to their current status.

The inspector should confirm all chemicals subject to *bona fide* inquiries not found on the TSCA Inventory for compliance with the R&D exemption. Thus, the inspector should obtain copies of all such *bona fide* inquiries before inspecting each facility. Semiannual printouts from EPA can include the list of *bona fide* inquiries if the inspector specifically asks the Office of Compliance Monitoring (OCM) to add the list to the printout.

Determining if newly synthesized or imported chemicals at a facility truly meet the R&D exemption may be difficult to establish immediately. If company records indicate that the chemical is manufactured for a purpose other than R&D, but the company is claiming the R&D exemption, the inspector should copy the R&D records and other records that document the use of the manufactured chemical, including batch records, volume of the chemical manufactured, customer lists, invoices, and shipping records.

- Verifying the technically-qualified individual. The inspector should identify and interview the person(s) responsible for the R&D program (generally, the R&D Director or Laboratory Supervisor). More than one such person may supervise activities involving a particular chemical substance. The inspector should document her/his technical background (i.e., education, training, and work experience) and her/his responsibilities in the position.

- Verifying recordkeeping and notification. The inspector should review the facility records to verify that the facility is complying with the recordkeeping and notification requirements. Any new TSCA chemical covered by the R&D exemption that was synthesized or imported by a facility after August 5, 1986, must meet the recordkeeping and notification requirements presented in

Tables 6-8 and 6-9. If these requirements are not met, or if records or notifications appear to be incorrect or missing, then the inspector should fully document these potential violations through copies of substantiating documents and/or statements from company officials. The inspector should obtain a list of customers to whom the chemical was sold.

TABLE 6-8 NOTIFICATION OF RISKS-R&D EXEMPTION

Who must be Notified	Method of Notification	Content of Notification	Authority (40 CFR)
Persons employed by a firm for R&D work	Any appropriate means that adequately informs	1. Risks associated with R&D substance	720.36(a)(2); 720.36(c)(1)
Persons not in a firm's employ to whom it distributes R&D substances	In writing	1. Risks associated with R&D substance 2. Requirement that substance be used only for R&D	720.36(a)(2); 720.36(c)(2)

6.7 TEST MARKETING EXEMPTION

TSCA Section 5(h)(i) authorizes EPA to provide an exemption for manufacturers who produce or import new chemical substances for test marketing purposes if the chemical substances do not present an unreasonable risk of injury to health or the environment. This is not an automatic exemption; the manufacturer or importer must apply for it to EPA. The submission requirements for the TME are summarized in Table 6-2. The intent of a TME is to allow a company to determine market capability in a competitive situation for a definite period of time. Generally, all conditions set forth in the TME application are to be followed by the applicant. In addition, EPA may impose restrictions on the test marketing activities with which the facility must comply.

The regulatory requirements that apply to the TME are summarized in Table 6-10.

6.7.1 INSPECTION OBJECTIVES

The inspection objectives to determine compliance with the TME are:

- To verify the accuracy and completeness of the information provided in the TME application.

TABLE 6-9 RECORDKEEPING-R&D EXEMPTION

Who Must Keep Records	Requirements	Authority (40 CFR)
All manufacturers using the R&D exemption (except labs using prudent lab practices)	1. Copies of or citations to information reviewed to determine risks	720.78(b)(1)(i)
	2. Documentation of the nature and method of risk notification	720.78(b)(1)(ii)
Labs using prudent lab practices	1. Documentation of prudent lab practices	720.78(b)(1)(iii)
Manufacturers distributing R&D substances to persons outside their employ	1. Names and addresses of those who received substance	720.78(b)(1)(iv)
	2. Identity of substance	
	3. Amount distributed	
	4. Copies of written notification	
Producers of more than 100 kg/year	1. Record of identity of substance	720.78(b)(2)
	2. Production volume	
	3. Disposition of substance	

TABLE 6-10 TEST MARKETING EXEMPTION (TME)

Authority (40 CFR)	FR Publication	Regulatory Requirements
720.38(b) 720.38(b)(1) 720.38(b)(2) 720.38(b)(3) 720.38(b)(4) 720.38(b)(5)	48 FR 21746-47 May 13, 1983	Application must include: • Existing health and environmental effects data including chemical/physical properties; if no data exists, discussion of toxicity based on structure-activity relationships (SAR) and relevant data on chemical analogues • Maximum quantity of substance to be manufactured or imported • Maximum number of persons who may be given the chemical during test marketing • Maximum number of persons to be exposed and duration and routes of exposure • Description of test marketing activity, its length, and how it will be distinguished from R&D and full-scale commercial production.
720.38(e)	48 FR 21747 May 13, 1983	EPA may impose restrictions on the exemption.
720.78(c)	48 FR 21751 May 13, 1983	Recordkeeping: • Documentation of information in the TME application and of compliance with EPA-imposed restrictions must be retained. • Records must be kept for 5 years from final date of manufacture or import under TME.

- To verify adherence by the manufacturer or importer to the TME conditions and to any additional EPA-imposed restrictions.

The inspector should keep in mind that TME recordkeeping requirements specify the retention of records to document the accuracy of the information contained in the TME application and to document compliance with any EPA-imposed restrictions. Failure to keep any of these records is a violation of 40 CFR §720.78(c). The supporting records for the TME may be consolidated by the company in one file, or they may be distributed at different production sites. The inspector should encourage the company to consolidate these records for review when arranging the inspection.

The inspector should not accept at face value the TME records as provided by the facility. S/he should ascertain all of the names and designations for the TME chemical and note its mention in any other records and data reviews, as well as watch for any potentially illegal manufacture, sale, storage, or use during the plant tour.

6.7.2 INSPECTION GUIDELINES

Before the inspection, the inspector should review a copy of the TME application, a copy of the *Federal Register* notice, and copies of any correspondence with EPA regarding review and/or approval of the application. At the plant site, the inspector should verify the information contained in these documents by reviewing company records, interviewing company employees, and touring the facility.

The following elements generally constitute the TME components that will require compliance verification during an inspection:

- Period of applicability
- Health and environmental effects testing data
- Chemical identification and structure
- Maximum quality of the chemical substance and number of customers
- Maximum number of persons exposed and duration and routes of exposure
- Description of the test marketing activity
- EPA-imposed restrictions.

The following guidelines should assist the inspector in assessing compliance with the above-listed elements of the TME:

- Verifying period of applicability. The inspector should review general production, batch, inventory, and sales records to verify that all commercial manufacture or import of the TME chemical was done during the period of time designated in the TME application. The inspector should start the review of these records with records dated approximately one month prior to EPA's receipt of the TME application. If the inspector finds deviations from the period of applicability in the TME application, s/he should document the deviations with copies of appropriate records and/or signed statements from company officials.

- Verifying health and environmental effects testing data. The inspector should review the files containing health and environmental effects testing data. The regulations require that all existing health and environmental effects testing data be supplied to EPA as part of the TME application. The inspector should verify with the person responsible for the test marketing program that all records containing health and environmental effects data have been provided for review. These test data may be in the form of health effects data, ecological data, physical and chemical properties data, environmental effects characteristics, monitoring data, or any data related to human exposure to or environmental release of the chemical substance.

  This requirement also includes the results of all determinations of chemical and physical properties. Therefore, the inspector should review R&D files, notebooks, and benchsheets for TME chemicals to ascertain if all testing data were submitted with the TME application. The inspector should collect copies of any documents discussing toxicity based on structure-activity relationships or analogue data that were not included with or referenced in the application to document a potential violation. To verify that these critical data were generated or available prior to the TME submission, the inspector should confirm that the dates of such submitted data or information are reliably documented.

- Verifying chemical identification and structure. The inspector should compare the identity and structure of the chemical actually produced or imported and sold during the TME period to information and/or data contained in the application. Since the chemical identity and structure are verified by OPPT, the inspector should not check chemical or instrumental analyses, such as mass or ultraviolet spectra. Rather, the inspector should only check the MSDS, chemical composition or formulation data, or product literature for the subject chemical to verify its identity. If the inspector finds any discrepancies, s/he should note them and obtain copies of supporting data for followup with EPA Headquarters.

- Verifying maximum quantity of the chemical substance and number of customers. The inspector should review inventory, batch, and sales records for a facility to determine the maximum quantity of the chemical substance the applicant may manufacture or import for test marketing and the maximum number of persons who may be given the chemical substance during test marketing. Thus, the inspector must be familiar with all trade, generic, and code names of the TME chemical substance, including processed materials in which it was used. The inspector should find that this information is consistent with that in the TME notice. If the inspector discovers any deviations, s/he should thoroughly document the deviation and copy the appropriate records. The inspector should note that the the maximum quantities in the TME are binding; any excess quantities above the maximum wuantity are a violation and should be documented.

- Verifying maximum number of persons exposed and duration and exposure routes. The inspector should review facility monitoring records, production schedules, and employee records to determine the maximum number of persons who may be exposed to the chemical substance as a result of the test marketing program. The inspector should find that these records also provide some information regarding the duration and route(s) of such exposure. The inspector should discuss with the manufacturer or importer how these numbers were estimated for the TME application.

- Verifying description of the test marketing activity. The inspector should carefully review the description in the TME application of the proposed use(s) and other activities for the subject chemical substance. The inspector should review customer correspondence, shipping records, and sales records to determine whether the use, processing, final products, and potential exposure exceed that stated or implied in the TME application. The inspector should also discuss the test marketing activities with the lead person responsible for the test marketing, as well as with employees involved in the test marketing program. S/he should document potential violations with copies of records and signed statements from the appropriate employees, as necessary.

- Verifying EPA-imposed restrictions. The inspector also verifies compliance with any EPA-imposed restrictions or limitations during the inspection. These restrictions are noted in the *Federal Register* notice that grants the exemption (see Figure 6-8 for a sample notice). In addition to reviewing the *Federal Register* notice, the inspector should review (and discuss with the OPPT Notice Manager) all additional correspondence with EPA. The OPPT Notice Manager can be found by in MITS. Each TME will have different restrictions, varying in number and type depending on EPA's concern for that chemical substance. These restrictions often apply to the elements already described (i.e., reductions in the proposed production volume, number of customers, or time period of applicability); limitations on other elements may also apply. For example, a TME may impose a requirement that worker protection equipment (e.g., goggles, gloves, or NIOSH-approved respirators) be worn by personnel coming into contact with the TME chemical. The inspector should document potential violations by copying records that support the violation and by obtaining signed statements from company officials, if necessary.

FIGURE 6-8

SAMPLE *FEDERAL REGISTER* NOTICE GRANTING TEST MARKETING EXEMPTION

ENVIRONMENTAL PROTECTION AGENCY

[OPTS-59135B TSH-FRL 2454-6]

Certain Chemicals; Approval of Test Marketing Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces EPA's approval of TM-83-60. and TM-83-61. two applications for test marketing exemptions (TMEs) under section 5(h)(6) of the Toxic Substances Control Act (TSCA). The test marketing conditions are described below.

EFFECTIVE DATE: October 7. 1983.

FOR FURTHER INFORMATION CONTACT: Wendy Cleland-Hamnett. Notice Review Branch. Chemical Control Division (TS-794). Office of Toxic Substances. Environmental Protection Agency. Rm. E-208. 401 M St. SW.. Washington DC. 20460 (202-382-3736).

SUPPLEMENTARY INFORMATION: Section 5(h)(1) of TSCA authorizes EPA to exempt persons from premanufacture nonification (PMN) requirements and to permit them to manufacture or import new chemical substances for test marketing purposes if the Agency finds that the manufacture. processing. distribution in commerce. use and disposal of the substances for test marketing purposes will not present any unreasonable risk of injury to health or the environment. EPA may impose restrictions on test marketing activities.

EPA has determined that test marketing of the new chemical substances described below. under the conditions set out in the applications. and for the time periods specified below. will not present any unreasonable risk of injury to health or the environment. Production volume. number of workers exposed to the new chemical. and the levels and duration of exposure must not exceed that specified in the applications. All other conditions described in the applications must be met. The following additional restrictions apply:

1. If the substance is shipped. the applicant must maintain records of the date(s) of shipment(s) to each customer and the quantities supplied in each shipment. and must make these records available to EPA upon request.

2. A bill of lading accompanying each shipment must state that use of the substance is restricted to that approved in the TME.

TME 83-60

Date of Receipt: August 29. 1983.

Notice of Receipt: September 9. 1983 (48 FR 40781).

Applicant: Confidential.

Chemical: (Generic) Polyether acid phosphate.

Use: (Generic) Additive for cutting fluids.

Production Volume: 7500 kg.

Number of Customers: 1.

Exposure Information: Confidential.

Test Marketing Period: 1 year.

Commencing on: October 7. 1983.

Risk Assessment: No significant health or environmental concerns were identified. The estimated worker exposure to the test market substance is expected to be low. Due to expected low releases. the test market substance should not pose an unreasonable environmental risk.

Public Comments: None.

TME 83-61

Date of Receipt: August 29. 1983.

Notice of Receipt: September 9. 1983 (48 FR 40781).

Applicant: Confidential.

Chemical: Amine salt of a substituted organic acid (generic).

Use: Corrosion inhibitor (generic).

Production Volume: 4000 kg.

Number of Customers: 1.

Worker Exposure: Confidential.

Test Marketing Period: 1 year.

Commencing on: October 7. 1983.

Risk Assessment: Based on test data. the test market substance is a moderate eye and skin irritant. However. workers are expected to wear appropriate protective equipment. including rubber gloves. apron and safety glasses. Releases to the environment are expected to be insignificant. No other significant health or environmental effect concerns were identified.

Public Comments: None.

The Agency reserves the right to rescind approval of an exemption should any new information come to its attention which casts significant doubt on its finding that the test marketing activities will not present an unreasonable risk to health or the environment.

Dated: October 7. 1983.

Marcia E. Williams.

Acting Director. Office of Toxic Substances.

[FR Doc. 83-28297 Filed 10-19-83. 8:45 am]

BILLING CODE 6560-50-M

TIPS
Examples of EPA-imposed restrictions and how to verify compliance
Production limits: *Examine manufacturing and processing records. Identify those records that show each day of production, dates, and amount produced. Note when production began and ended.*
Distribution/shipping records requirements: *Examine records that indicate customers, amounts shipped, and sales volume.*
Use limits: *Examine bill of lading for statement of use of the substance.*
Worker exposure limits: *Observe plant operations. Inspect manufacturing area for number of workers exposed and for exposure duration. If exposure levels are specified, check monitoring records.*
Manufacturing records: *Examine the manufacturing process to determine if the substance is produced in a closed system, including packaging facilities and storage and transfer lines.*
Safety requirements: *Determine if the company has MSDSs and/or labeling on specified products. Observe workers to see if worker protection measures are being implemented.*
Test data: *Ask to see any test data on the substance in question.*
Disposal requirements: *Examine records and describe the manner or method of disposal.*

6.8 POLYMER EXEMPTION

Under TSCA Section 5(h)(4), the manufacturer or importer of a new chemical substance can apply to EPA for a PE if the chemical substance:

- Meets the definition of a polymer molecule found in 40 CFR §723.250(b)(12), which is "a molecule that includes at least four covalently linked subunits, at least two of which are internal subunits."
- Is not specifically excluded under 40 CFR §723.250(d) because it is characterized as being or as having one of the following:
  - Cationic polymer
  - Polymer containing less than 32 percent carbon by weight

- Elemental limitations: polymer that does not contain at least two of the elements carbon, hydrogen, nitrogen, oxygen, silicon, or sulfur as an integral part of its composition, or polymer that contains as an integral part of its composition, except as impurities, any elements other than (i) carbon, hydrogen, nitrogen, oxygen, silicon, and sulfur; (ii) sodium, magnesium, aluminum, potassium, or calcium as the monatomic counterions Na^{+}, Mg^{+2}, Al^{+3}, K^{+}, or Ca^{+2}; and, (iii) less than 0.20 weight percent of any combination of lithium, boron, phosphorous, titanium, manganese, iron, nickel, copper, zinc, tin, and zirconium

- Biopolymer, synthetic equivalent of a biopolymer, or a derivative or a modification of a biopolymer if the initial biopolymer is substantially intact

- Polymer manufactured from reactants containing halogen atoms or cyano groups

- Polymer containing reactive functional groups

- Polymer that degrades, decomposes, or depolymerizes.

- Meets one of the following two criteria:

  - Has a number-average molecular weight greater than 1,000

  - Is a polyester as defined in 40 CFR §723.250(b)(10) and is manufactured solely from one or more of the reactants from a specified list.

The submission requirements for a PE are summarized in Table 6-2. Unlike the other exemptions, substances subject to PEs are added to the TSCA Inventory. An NOC must be submitted when commercial production begins.

If during pre-inspection preparation the inspector learns that EPA has found the subject chemical to be ineligible for the PE, the inspector should confirm that the facility complied with the regulatory procedures regarding ineligibility. Once EPA makes the determination of ineligibility, the company ceases manufacture, import, processing, distribution in commerce, or use of the new chemical substance within 24 hours of notification of EPA's determination. The inspector should confirm that the company did not resume any of the previously mentioned activities until the company submitted a PMN and the notice review period ended. The inspector should review company correspondence with EPA and company records from the period during which the ineligibility was being processed.

The regulatory requirements that apply to a polymer exemption are summarized in Table 6-11.

TABLE 6-11 POLYMER EXEMPTION (PE)

Authority (40 CFR)	FR Publication	Requirements
723.250(f) 723.250(f)(2)(i) 723.250(f)(2)(ii) 723.250(f)(2)(iii) 723.250(f)(2)(iv) 723.250(f)(2)(v) 723.250(f)(2)(vi) 723.250(f)(2)(vii) 723.250(f)(2)(viii) 723.250(f)(2)(ix) 723.250(f)(2)(x) 723.250(f)(2)(xi) 723.250(f)(2)(xii)	49 FR 46088-89 November 21, 1984	Notice must include: • Name and address of manufacturer and name and telephone number of a technical contact • Type of exemption • Name and address of site(s) of manufacture (except for imported chemical substances) • Chemical identification • Number average molecular weight • Residual monomer and other reactants and low molecular weight species content • Impurity information • Maximum annual production volume • Category of use • Generic chemical identity and use • Test data and other data • Certification.
723.250(r)(1) 723.250(r)(1) 723.250(r)(2)(i) 723.250(r)(2)(i) 723.250(r)(2)(i) 723.250(r)(2)(ii)(A) 723.250(r)(2)(ii)(B)	49 FR 46091 November 21, 1984	Recordkeeping: • Records must be retained for 5 years from the date of commencement of manufacture • Production volume for first 3 years of manufacture • Date of commencement of manufacture • Documentation of first two items • Information to demonstrate that the new polymer is not specifically excluded from exemption • Information to demonstrate that the polymer meets the exemption criteria: (1) > 1,000 number average molecular weight; (2) polyester polymer.

6.8.1 INSPECTION OBJECTIVES

Before the inspection, the inspector should review a copy of the PE notice, a copy of the PE *Federal Register*, and copies of any correspondence with EPA regarding the exemption. At the plant site, the inspector will verify the information contained in these documents by reviewing company records, interviewing company employees, and touring the facility.

The inspection objectives to determine compliance with the PE are as follows:

- To verify the accuracy and completeness of the information contained in the PE notice
- To verify adherence by the manufacturer or importer to the PE specifications.

The inspector should note that the PE recordkeeping requirements specify the retention of records to document the accuracy of information provided in the PE notice and to document compliance with its terms. Failure to keep any of these records constitutes a violation of 40 CFR §723.250(r). The supporting records may be consolidated by the company in one file (perhaps at corporate headquarters) or they may be at the production site. The inspector should encourage the company to consolidate these records for review when arranging the inspection.

The inspector should not accept at face value the PE records as provided by the facility. S/he should ascertain all of the names and designations for the PE chemical and note its mention in any other records and data reviews, as well as watch for its potentially illegal manufacture, sale, storage, or use during the plant tour.

6.8.2 INSPECTION GUIDELINES

In general, the inspector reviews all of the above-listed elements for compliance. The following guidelines should assist the inspector in assessing this compliance with the PE:

- Verifying manufacturer's name and technical contact and type of exemption. The inspector generally verifies these two items when reviewing records during pre-inspection planning. If an inspector discovers that the company is manufacturing a chemical under a PE, the inspector should note this for inclusion in the inspection report.
- Verifying site of manufacture. The inspector should verify that the actual site of the manufacturing activity matches the site listed in the PE notice.

- Verifying chemical identification and structure, and related information. The inspector should compare the identity of the chemical substance actually manufactured or imported and sold against information and/or data contained in the PE. The inspector should review information and records that include the following items: the chemical name; the CAS Registry Number of the substance; the maximum percent (by weight) of each reactant used at any weight percent to manufacture the polymer; a structural diagram, if possible; the number-average molecular weight; and the residual monomer and other reactants and low molecular weight species content. These records could be in the form of chemical composition or formulation records or MSDSs. The manufacturer or importer is also required to specify any reactants used at 2 weight percent or less that should be included as part of the polymer description on the Inventory. The inspector should compare synonyms and trade names of the chemical substance identified in the PE notice to those used in company records. If chemical identity information is claimed confidential in the PE notice, the inspector should find a generic, nonconfidential description of the identity.

- Verifying impurity information. The inspector should check the identity of each impurity, by chemical name and CAS Registry Number, and the estimated maximum weight percent of each impurity anticipated to be present in the polymer. If there are unidentified impurities, the inspector should verify the estimate of their total weight percent.

- Verifying production volume. The inspector should review production records to verify the maximum production volume during the first 12-month period of production and the maximum production volume for any consecutive 12-month period during the first 3 years of production.

- Verifying category of use. The PE notice must include a description of each intended use of the new chemical substance by function and application and describe whether the use is industrial, commercial, consumer, and/or site-limited. The inspector should confirm that the actual use(s) of the polymer accurately reflect the information in the PE notice. If category of use information is claimed confidential in the PE notice, the inspector should find a nonconfidential generic use description.

DEFINITIONS
***Generic Use Description** - The generic use description should reveal the intended category of use to the maximum extent possible. For example, the specific use of a new substance as an antioxidant in a lubricant could be described generically as a lubricant additive; a fiber-reactive dye for nylon carpeting could be described generically as a dye for fibers. If such a generic description does not provide a sufficient indication of potential exposure, the description can also describe the degree of containment of the new chemical substance, as shown in the list below; however, a generic use description that solely describes the degree of containment, such as "open, non-dispersive use," is not acceptable.*

- Verifying health and environmental effects testing data. The regulations require that all health and environmental effects testing data in the submitter's possession or control, descriptions of other data that are known to or reasonably ascertainable by the submitter and that concern the health and environmental effects of the polymer, and a description of data on related chemicals all be supplied

to EPA as part of the PE notice. The inspector should review the files containing the health and environmental effects testing data. Copies of any documents discussing structure-activity relationships or analogue data that were not included with or referenced in the notice are also to be collected so as to document a potential violation. The inspector should confirm that the dates of such submitted data or information are reliably documented. To verify that these critical data were generated or available prior to the PE submission, information should be reliably documented.

The inspector should note that a search for health and environmental effects testing data is very difficult and time-consuming (i.e., it can take up to 2 to 4 days). Therefore, if during an inspection the inspector suspects the company has not submitted the required health and environmental effects testing data, s/he may want to consider conducting such a search in a followup inspection.

6.9 INSTANT FILM CHEMICAL EXEMPTION (IFCE)

As a result of a petition from the Polaroid Corporation, EPA established an exemption for new chemical substances used in or for the manufacture or processing of instant photographic and peel-apart film articles. To manufacture or import a new chemical substance under the terms of the Instant Film Chemical Exemption (IFCE), a manufacturer must submit an exemption notice when manufacture begins, limit manufacture and processing of a new chemical substance to the site(s) listed in the IFCE notice, and also comply with requirements to limit exposure to the new chemical substance. A manufacturer is not permitted to distribute in commerce or use a peel-apart film article containing a new chemical substance until the manufacturer submits a PMN and until the 90-day review period for the notice has ended without EPA having taken any action to prevent the distribution or use of the chemical.

A new chemical substance manufactured under the terms of the IFCE will not be added to the TSCA Inventory. However, a firm may elect to submit a PMN for a chemical covered by the exemption, and the chemical will be placed on the Inventory after the notice review period ends and manufacturing begins unless EPA takes action, such as by issuing a TSCA Section 5(e) or Section 5(f) order.

The submission requirements for the IFCE notice are delineated in Table 6-2. The regulatory requirements for the IFCE are summarized in Table 6-12.

6.9.1 INSPECTION OBJECTIVES

The inspection objectives to determine compliance with the IFCE are as follows:

TABLE 6-12 INSTANT FILM CHEMICAL EXEMPTION (IFCE)

Authority (40 CFR)	FR Publication	Requirements
723.175(a)(1)	47 FR 24317 June 4, 1982	To qualify for exemption: • The new chemical substance must be used in or for the manufacture or processing of an instant photographic and peel-apart film article.
723.175(e) 723.175(e)(1) 723.175(e)(2) 723.175(e)(3) 723.175(e)(4) 723.175(e)(5) 723.175(e)(6) 723.175(e)(7) 723.175(e)(8) 723.175(e)(9) 723.175(e)(10)	47 FR 24317-18 June 4, 1982	All manufacturing, processing, and use operations must be performed in a special production area (SPA) under specified conditions, including: • Exposure limits • Respiratory protection • Monitoring • Engineering controls and exposure safeguards • Training, hygiene, and work practices • Personal protection devices • Caution signs • Procedures for removal of a new chemical substance for storage or transportation • Labeling • Exposure limits and monitoring apply to areas immediately adjacent to the SPA.
723.175(f) 723.175(f)(1) 723.175(f)(2)(i-iii) 723.175(f)(3)	47 FR 24319 June 4, 1982	A manufacturer or processor may incorporate a wet mixture into a photographic article or an instant photographic or peel-apart film article outside the SPA under specified conditions, including: • Engineering controls and exposure safeguards • Training, hygiene, and work practices • Personal protection devices.
723.175(g)	47 FR 24319 June 4, 1992	A manufacturer may incorporate a photographic film article into an instant photographic or peel-apart film article outside the SPA as long as he takes the same precautions required by 723.175(f).

TABLE 6-12 INSTANT FILM CHEMICAL EXEMPTION (IFCE) (Continued)

Authority (40 CFR)	FR Publication	Requirements
723.175(h) 723.175(h)(1) 723.175(h)(2) 723.175(h)(3)	47 FR 24319-20 June 4, 1982	Additional conditions of processing outside the SPA regulate: • Release to land of process waste • Release to water of wastewater or discharge • Release to air of process emissions.
723.175(i)(1) 723.175(i)(1)(i) 723.175(i)(1)(ii) 723.175(i)(1)(iii) 723.175(i)(1)(iv) 723.175(i)(1)(v) 723.175(i)(1)(vi) 723.175(i)(1)(viii) 723.175(i)(1)(ix) 723.175(i)(1)(vii) 723.175(i)(1)(viii) 723.175(i)(1)(ix) 723.175(i)(1)(x)	47 FR 24320 June 4, 1982	Notice must include: • Name of manufacturer and sites and locations where manufacturing and processing occur • Chemical identification and structure • Impurities • Physical-chemical properties • Byproducts • Anticipated maximum annual production volume • Identity of article(s) containing new chemical substance • Description of methods used to control and treat releases to water • Health and environmental effects test data • Identity of the article that will contain the new chemical substance • Description of the methods used to control and treat wastewater or discharge • Certification.
723.175(l)	47 FR 24321 June 4, 1982	Amendment and repeal of substantive terms of the exemption requires formal rule-making procedures.
723.175(m)	47 FR 24321 June 4, 1982	Prohibition of use of the exemption does not require formal rule-making procedure.

- To verify the accuracy and completeness of the information contained in the IFCE notice
- To verify adherence by the manufacturer or processor to the IFCE.

The inspector should note that the IFCE recordkeeping requirements specify not only the retention of production records, but also the retention of exposure monitoring records, training and exposure records, and treatment records. Any failure to keep these records is a violation of 40 CFR §723.175(j). The supporting records for the IFCE may be consolidated by the company in one file or they may be distributed at different production sites. The inspector should encourage the company to consolidate these records for review when arranging the inspection.

The inspector should not simply accept at face value the IFCE records as provided by the facility. S/he should identify all of the names and designations for the subject chemical substance and note its mention in any other records and data reviews, as well as watch for its potentially illegal manufacture, sale, storage, or use during the plant tour.

The inspector should note that under 40 CFR §723.175(j)(2) the manufacturer or processor must make these records available to EPA within 15 working days of receipt of a written request by the Director of the Office of Pollution Prevention and Toxics.

In accordance with 40 CFR §723.175(l), EPA may amend or repeal any substantive terms of the IFCE through formal rule-making procedures. Pursuant to 40 CFR §723.175(m), EPA may also prohibit the manufacture, processing, distribution, use, or disposal of any new chemical substance under the terms of the IFCE if it makes the determination that any one of these activities may present an unreasonable risk of injury to health or the environment. Unlike the amendment or repeal, prohibition does not require a rule.

6.9.2 INSPECTION GUIDELINES

Before the inspection, the inspector should review a copy of the IFCE notice, a copy of the IFCE *Federal Register* notice, and copies of correspondence with EPA regarding the exemption. At the plant site, the inspector should verify the information contained in these documents by reviewing company records, interviewing company employees, and touring the facility.

The following elements generally constitute the ICFE components that require compliance verification during an inspection:

- Conditions of manufacture and processing in the special production area (SPA)
- Conditions of processing outside the SPA
- Environmental release and waste treatment
- Manufacturer and sites
- Chemical identification and structure
- Impurities
- Physical-chemical properties
- Byproducts
- Production volume
- Health and environmental effects testing data
- Identity of the article
- Release to water.

The following guidelines should assist the inspector in assessing compliance with the above-listed elements of the IFCE:

- Verifying conditions of manufacture and processing in the SPA. Under the IFCE, all manufacturing, processing, and use operations involving the new chemical substance must be performed in an SPA under specified conditions until the new chemical substance has been incorporated into a wet mixture, photographic article, or instant photographic peel-apart film article. The manufacturer must take precautions in the SPA, which include the following, to safeguard against worker exposure:

  - Exposure limits
  - Respiratory protection
  - Monitoring (by means of air samples) to ensure compliance with the exposure limits
  - Engineering controls and exposure safeguards (e.g., isolation, enclosure, local exhaust ventilation, and dust collection)
  - Training, hygiene, and work practices
  - Personal protection devices

- Clearly posted caution signs

- Procedures for removal of a new chemical substance for storage or transportation

- Labeling of the chemical substance

- Exposure limits for and periodically monitoring areas immediately adjacent to the SPA

A vital aspect of the IFCE inspection will be to determine if the manufacturer has established these protective and safety measures and if the manufacturer uses them actively and effectively during the production, processing, and handling of the new chemical substance. To determine compliance with most of the conditions delineated above, the inspector should visit the site(s) when the subject chemical substance is actually being manufactured or processed. The inspector can spot the use of engineering controls, personal protection devices (such as protective clothing or equipment, chemical-resistant coveralls, protective eyewear, and gloves), caution signs, and labeling, as well as adherence to hygienic standards and worker practices. In a walk-through of the facility, the inspector can document noncompliance through direct observation.

If the new chemical substance has been manufactured, but not during the on site inspection, the inspector should interview employees (and others, if necessary) to ascertain whether the required protective clothing devices were in full use during manufacture. Although production may not be under way during the site visit, the inspector can still check compliance with the exposure limits by means of the monitoring records. The inspector should note that the company is required to keep monitoring data for each monitoring location.

- Verifying conditions of processing outside the SPA. The manufacturer may incorporate either (1) a wet mixture into a photographic article or an instant photographic or peel-apart film article or (2) a photographic article into an instant photographic or peel-apart film article outside the SPA under conditions similar to those required of the manufacturer inside the SPA. The inspector should assess the conditions of processing outside the SPA in the same way s/he evaluates the conditions within the SPA. When touring the facility, the inspector should determine whether the manufacturer is using or implementing the following:

  - Engineering controls and exposure safeguards

  - Training, hygiene, and work practices

  - Personal protection devices.

  If the inspector is unable to observe the new chemical substance being manufactured on site, s/he should interview employees (and others, if necessary) to ascertain compliance with the above-listed requirements.

- Verifying environmental release and waste treatment. Another condition of the IFCE specifies that any wastes containing the new chemical substance that are released to land, water, and air must be appropriately treated and/or disposed of. For specific details on waste treatment, the inspector can check the IFCE notice, which includes such information. The inspector should review with company officials the waste treatment or disposal activities. The inspector should observe these activities during a walk-through of the facility. If during the inspection the inspector suspects or

finds problems with the treatment or disposal of the wastes containing the new chemical substance, s/he should contact the appropriate Regional staff responsible for those specific activities. For example, if the inspector suspects that the manufacturer is disposing of hazardous solid wastes containing the chemical substance without using proper procedures, the inspector should document the situation and notify Regional staff responsible for the Resource Conservation and Recovery Act (RCRA) program.

- Verifying chemical identification and structure. The manufacturer is required to classify the new chemical substance as either a Class 1 or a Class 2 substance, or as a polymer. The inspector should compare the identity and structure of the chemical substance by reviewing chemical composition or formulation data and product literature. The inspector should review structural diagrams representing the chemical substances, if available.

- Verifying impurities. The manufacturer is required to identify impurities that are reasonably expected to be present in the new chemical substance by name, by CAS Registry Number, by class, and by process or source. The notice must also estimate the maximum percent (by weight) of each impurity in the new chemical substance and the percent of unknown impurities present. The inspector should also review these same items to verify the impurities in the new chemical substance. The inspector should document any discrepancies between the information in the IFCE notice and the company's records and obtain copies of supporting data obtained for followup with EPA Headquarters.

- Verifying physical-chemical properties. Since the physical-chemical properties should have been reviewed by EPA Headquarters, the inspector should simply check the MSDS or chemical information provided by the company. Any discrepancies should be documented for followup with OPPT.

- Verifying byproducts. In the notice, the manufacturer must identify the name, CAS Registry Number (if available), and the volume of each byproduct that would be produced during manufacture of the new chemical substance. The inspector should review the product diagram, product process schematic, and/or process information to confirm the byproducts. The inspector should document any discrepancies for inclusion in the inspection report.

- Verifying production volume. Through a review of general production, inventory, and sales records, the inspector should verify that the manufacturer has included in the IFCE notice both an estimate of the anticipated maximum annual production volume and the initial commercial production date. The inspector should document any discrepancies for inclusion in the inspection report.

- Verifying health and environmental effects testing data. The inspector should review the files containing the health and environmental effects testing data. The manufacturer must submit to EPA as part of the IFCE notice all health and environmental effects testing data in the submitter's possession or control and descriptions of other data that are known to or are reasonably ascertainable by the submitter and that concern the health and environmental effects of the new chemical substance. To verify that these critical data were generated or available prior to the IFCE notice submission, the inspector should confirm that the dates of such submitted data or information are reliably documented.

The inspector should note that a search for health and environmental effects testing data is very difficult and time consuming (i.e., it can take up to 2 to 4 days). Therefore, if during an inspection the inspector suspects the company has not submitted the required health and environmental effects testing data, s/he may want to consider such a search in a second followup inspection.

- Verifying identity of the article. The inspector should confirm the type of instant photographic film article(s) or peel-apart film article(s) that contains the new chemical substance as it is described in the IFCE notice. The inspector can do this by observing manufacture of the article, looking at the manufactured article, or reviewing product literature.

- Verifying release to water. The inspector should review the methods used to control and treat wastewater or discharge released to a Publicly-Owned Treatment Work (POTW) or any other receiving body of water. The manufacturer must provide this information, as well as the name of the POTW or the receiving water body to which the wastewater is discharged, in the IFCE notice. The inspector can verify this information by reviewing the facility's permit issued under the National Pollutant Discharge Elimination System (NPDES) permit either by the State or EPA, or its permit issued under the Pretreatment Program by the POTW. The inspector may want to notify the Regional staff responsible for the NPDES program (if the facility discharges directly to a receiving water body) or for the municipal pretreatment program (if the facility discharges to a POTW).

6.10 ZERO EXPOSURE

Under TSCA Section 5(h)(5), EPA may exempt any chemical substance that "(A) exists temporarily as a result of a chemical reaction in the manufacturing or processing of a mixture or another chemical substance, and (B) to which there is no, and will not be, human or environmental exposure." This exemption requires that an application be filed with EPA.

Chapter Seven

TSCA Section 8 Inspections

Page

7.0 TSCA SECTION 8 INSPECTIONS 7-1

7.1 INTRODUCTION 7-1

7.2 SECTION 8(a) 7-4

7.2.1 PRELIMINARY ASSESSMENT INFORMATION RULE (PAIR) 7-4

7.2.1.1 INSPECTION OBJECTIVES 7-5
7.2.1.2 PHASE 1 INSPECTION 7-6
7.2.1.3 PHASE 2 INSPECTION 7-15

7.2.2 COMPREHENSIVE ASSESSMENT INFORMATION RULE (CAIR) 7-16

7.2.2.1 INSPECTION OBJECTIVES 7-18
7.2.2.2 PHASE 1 INSPECTION (TO BE COMPLETED) 7-18
7.2.2.3 PHASE 2 INSPECTION 7-18

7.3 SECTION 8(a): INVENTORY UPDATE RULE (IUR) 7-21

7.3.1 INSPECTION OBJECTIVES 7-23
7.3.2 PHASE 1 INSPECTION 7-23
7.3.3 PHASE 2 INSPECTION 7-24

7.4 SECTION 8(c): ALLEGATIONS OF SIGNIFICANT ADVERSE HUMAN HEALTH OR ENVIRONMENTAL EFFECTS 7-26

7.4.1 INSPECTION OBJECTIVES 7-28
7.4.2 INSPECTION GUIDELINES 7-30

7.5 SECTION 8(d): HEALTH AND SAFETY STUDIES 7-32

7.5.1 INSPECTION OBJECTIVES 7-34
7.5.2 INSPECTION GUIDELINES 7-34

7.6 SECTION 8(e): NOTIFICATION OF SUBSTANTIAL RISKS 7-35

7.6.1 INSPECTION OBJECTIVES 7-39
7.6.2 INSPECTION GUIDELINES 7-39

LIST OF FIGURES

Page

FIGURE 7-1 ORGANIC CHEMICAL MANUFACTURE SCHEMATIC - BENZOIC ACID AND BENZALDEHYDE 7-8
FIGURE 7-2 ORGANIC CHEMICAL MANUFACTURE SCHEMATIC PERCHLOROETHYLENE-CHLORINATION OF CHLORINATED HYDROCARBONS 7-9
FIGURE 7-3 HOW TO CALCULATE QUANTITIES OF CHEMICAL PROCESSED BY PROCESS CATEGORY 7-10
FIGURE 7-4 HOW TO CALCULATE WORKER EXPOSURE HOURS AND WORKER HOURS 7-12
FIGURE 7-4 HOW TO CALCULATE WORKER EXPOSURE HOURS AND WORKER HOURS (continued) 7-13
FIGURE 7-5 HEALTH AND SAFETY STUDIES 7-36

LIST OF TABLES

TABLE 7-1 SUMMARY OF SECTION 8 REPORTING AND RECORDKEEPING REQUIREMENTS 7-2
TABLE 7-2 SECTION 8(c) ALLEGATIONS THAT MUST BE RECORDED 7-27
TABLE 7-3 SECTION 8(c) RECORDKEEPING REQUIREMENTS 7-29
TABLE 7-4 SECTION 8(d) REPORTING REQUIREMENTS 7-33
TABLE 7-5 SECTION 8(e) INFORMATION THAT MUST BE REPORTED 7-38

7.0 TSCA SECTION 8 INSPECTIONS

7.1 INTRODUCTION

This chapter contains background information and guidance to assist the inspector in conducting inspections for the reporting and recordkeeping requirements for existing chemicals under the Toxic Substance Control Act (TSCA) Section 8. The inspector should keep in mind that for the purposes of Section 8 the terms "chemical substance," "mixture," and "articles" are defined within the applicable regulations. These definitions have been included within the text to assist the inspector in understanding to what substances or products the regulations apply. The Section 8 reporting and recordkeeping requirements are summarized in Table 7-1.

The various sections of this chapter describe how the inspector can determine if a firm that is manufacturing or importing (and in some cases processing) an existing chemical is complying with the applicable reporting or recordkeeping requirements as follows:

- Section 7.2 - Preliminary Assessment Information Rule (PAIR) and Comprehensive Assessment Information Rule (CAIR) reporting [TSCA Section 8(a)]
- Section 7.3 - Inventory Update Rule (IUR) reporting [TSCA Section 8(a)]
- Section 7.4 - Recordkeeping for allegations of significant adverse human health or environmental effects [TSCA Section 8(c)]
- Section 7.5 - Reporting of health and safety studies [TSCA Section 8(d)]
- Section 7.6 - Notification of substantial risks [TSCA Section 8(e)].

Throughout the chapter, the inspector will find tips and examples to help explain the interpretation and application of the regulations. In addition, the tables found throughout the chapter provide summaries of the regulations as a quick reference for the inspector. However, the inspector should note that these summaries are not intended to substitute for the regulations published in the *Code of Federal Regulations* and *Federal Register*, and thus the appropriate citations are included in these tables for the inspector's use.

The inspector should note that Section 8 inspections are generally done in conjunction with Section 5 inspections. This is because when the inspector is reviewing the general inventory of chemicals

TABLE 7-1. SUMMARY OF SECTION 8 REPORTING AND RECORDKEEPING REQUIREMENTS

Section	Citation	Effective	Who Required	Reporting Requirements	Recordkeeping Requirements
8(a)	40 CFR 704 Subpart B	Substance specific	Manufacturers, importers, and processors	• Dependent on chemical.	• Dependent on chemical.
8(a) PAIR	40 CFR 712.20	June 1982 (Substance specific)	Manufacturers and importers	• 2-page report for each plant manufacturing a chemical listed in 40 CFR §712.30 • Cover latest corporate fiscal year • Due 60 days from effective date.	• No recordkeeping requirement.
8(a) CAIR	40 CFR 704.11 704.206	December 1988 (Substance specific)	Manufacturers, importers, and processors	• Chemical specific parts of 141-page report for each facility manufacturing, importing, or processing any chemicals listed in 40 CFR 704 Subpart D • Report corporate fiscal year that falls within CAIR coverage period.	• Copies of all CAIR forms submitted • Materials that verify the report, and copies of all notices sent to customers who distribute a listed substance.
8(a) IUR	40 CFR 710.33 710.37	August-December 1986	Manufacturers and importers	• Initial and recurring (every 4 years) reporting to TSCA Inventory • Manufacture or import chemical in the fiscal year prior to reporting period.	• All TSCA Inventory data submissions (kept for 4 years after reporting period) • Site-specific production records • Records that verify small business exemption.

TABLE 7-1. SUMMARY OF SECTION 8 REPORTING AND RECORDKEEPING REQUIREMENTS (Continued)

Section	Citation	Effective	Who Required	Reporting Requirements	Recordkeeping Requirements
8(c)	40 CFR 717	1983	Manufacturers and certain processors	• Records must be reported when required by letter to firms or notice in the *Federal Register*.	• Record of all allegations (the original document and abstract).
8(d)	40 CFR 716	1982 (Substance specific)	Manufacturers, importers, and processors	• Submit information within 60 days after effective date of chemical placed on 40 CFR §716.120 list. • 10-year continuing obligation to report certain information.	• No recordkeeping requirement.
8(e)	43 FR 11110 (Policy Statement)	Statute: January 1977 Policy Statement: March 1978	Manufacturers, importers, processors, and distributors	• Substantial risk information reported immediately: - Emergency - within 24 hours (oral) - Nonemergency - within 15 working days (written).	• No recordkeeping requirement.

manufactured or imported by the company under the Section 5 inspection (see Section 6.3 for additional details), the inspector can concurrently identify any chemicals being manufactured or imported that are subject to any of the Section 8 requirements.

7.2 SECTION 8(a)

TSCA Section 8(a) grants EPA the authority to require companies to document their chemical manufacturing, importing, and processing activities. Under Section 8(a), EPA may set recordkeeping and reporting requirements for specific chemicals. The Agency's most significant use of Section 8(a) has been the issuance of model rules that apply to multiple chemicals. Subpart B of 40 CFR Part 704 sets out the chemical-specific reporting and recordkeeping requirements under Section 8(a) of TSCA. EPA issued the PAIR in June 1982 (40 CFR Part 712 Subpart B) and the CAIR in December 1988 (40 CFR Part 704 Subpart C). While the PAIR is the predominately used form, because of its comprehensiveness, it is anticipated that the CAIR will eventually replace the PAIR. The following subsections describe the PAIR and CAIR rules. (A copy of the PAIR form is found in Appendix 10).

7.2.1 PRELIMINARY ASSESSMENT INFORMATION RULE (PAIR)

The PAIR, found at 40 CFR 712 Subpart B, is designed to gather information to support the preliminary stage of chemical assessment. All persons who manufacture or import in bulk any of the chemicals listed in 40 CFR §712.30 for commercial purposes are required to submit a PAIR report. Also included as subject manufacturers are miners and oil refiners that apply any method of extraction, refinement, or purification of a mined substance to make it marketable. These maufacturers are also required to report the manufacturing steps and uses of the extracted chemical. Processors are not subject to the PAIR.

The following manufacturers and importers are exempt from reporting under the PAIR (40 CFR §712.25):

- Companies that manufactured or imported the chemical substance, during the reporting period, only for scientific experimentation, analysis, or research, including research or analysis for product development (i.e., R&D).
- Companies that manufactured or imported less than 1,100 pounds (500 kilograms) of a chemical at a single plant site during the reporting period (small quantity exemption).
- Small manufacturers or importers, defined as companies whose total annual sales taken together from all sites owned by the foreign or domestic parent company were below $30 million for the reporting

period, and who produced less than 100,000 pounds (45,400 kilograms) of the listed substance at the plant site. However, the exemption does not apply to any chemical listed in 40 CFR §712.30 designated by an asterisk.

- Companies that manufactured the chemical as a non-isolated intermediate, an impurity, or a byproduct that was not used or sold, or formed as described in 40 CFR §710.4(d) (3) through (7).

With these exceptions, manufacturers and importers subject to PAIR must submit the two-page report for each plant site manufacturing a chemical listed in 40 CFR §712.30. Information submitted for a chemical substance or mixture must cover the respondent's latest complete corporate fiscal year as of the effective date of the rule adding the substance to PAIR. In accordance with 40 CFR §712.30(c), companies generally have 60 days from the effective date to submit complete PAIR reports.

The elements of the PAIR report include:

- Quantity of chemical manufactured or imported for sale or use
- Quantity lost to the environment and in wastes
- Manufacturing processes and worker exposure
- Manufacturer products
- Customer uses and products
- Trade names
- Customer's process categories.

7.2.1.1 INSPECTION OBJECTIVES

The inspection objectives to determine compliance with 40 CFR Part 712 are:

- To verify the accuracy and completeness of information contained in the PAIR form (Phase 1)
- To identify firms which have failed to submit a PAIR report for chemicals that are subject to PAIR (Phase 2).

The second phase of the inspection (i.e., identify failure to submit a PAIR report) is usually done in conjunction with the Section 5 general inventory part of the inspection (discussed in Section 6.2.3). In addition, a Section 4 (see Chapter 5) and Section 8(d) review (see Section 7.5) will also normally be conducted at this time.

The inspector should be aware that no recordkeeping requirement exists for this rule.

7.2.1.2 PHASE 1 INSPECTION

The inspector should review official copies of the PAIR reports before the inspection. At the plant site, the inspector will verify the information contained in the PAIR report by reviewing company records, interviewing company employees, and touring the facility. The inspector should determine the applicable reporting period (i.e., the latest complete corporate fiscal year) and when reviewing the PAIR elements, ensure that these elements have been derived from the applicable period.

The following guidelines should provide assistance to the inspector in verifying the accuracy and completeness of the various elements of the PAIR report.

- Verifying quantity of chemical manufactured. The inspector should review batch records, production records, manufacturing and process records, inventory records, invoices, and annual sales reports for the applicable reporting period. If the reported figures were based on or derived from other information, the inspector should ask the company official to clarify the source of the figures. Any significant discrepancies (typically, greater than 20 percent) should be documented by copying pertinent records and/or obtaining a signed statement from the company official.

- Verifying quantity of chemical imported. The inspector should review invoices and shipping records for the applicable reporting period. If the reported figures were based on or derived from other information, the inspector should ask the company official to clarify the source of the figures. Any significant discrepancies (typically, greater than 20 percent) should be documented by copying pertinent records and/or obtaining a signed statement from the company official.

- Verifying quantity lost to the environment and in wastes. The inspector should review monitoring records including emission (air) records, National Pollutant Discharge Elimination System (NPDES) permits, wastewater Discharge Monitoring Reports (DMRs), shipment and disposal records [e.g., Resource Conservation and Recovery Act (RCRA) manifests], and EPCRA Section 313 reports for the applicable reporting period. The inspector should also tour the facility and should check the points in the facility where discharges and releases occur and check that monitoring is actually taking place to verify that all monitoring records have been provided. If the reported figures were based on or derived from other information, the inspector should ask the company official to clarify the source of the figures. Any significant discrepancies (typically, greater than 20 percent) should be documented by copying pertinent records and/or obtaining a signed statement from the company official.

- Verifying manufacturing processes and worker exposure. The inspector should review the manufacturing processes and evaluate whether the manufacturer has correctly classified each unit process as enclosed, controlled release, or open.

DEFINITIONS (40 CFR §712.28)

***Enclosed process** is defined as a process which is designed and operated in a controlled manner to minimize release of the chemical. In this category, only fugitive or routine releases occur and special measures are taken to prevent worker exposure and environmental contamination. "Special measures" include procedures and equipment that are monitored and used to prevent worker exposure, and scrubbers and other recovery equipment employed to prevent environmental release. Equipment with emergency relief venting would be included in this category, but routine venting would not.*

***Controlled release process** is defined as a process operated in a controlled manner to minimize release of the chemical into the workplace. Releases would generally be prescribed within limits, which may be dictated by government regulations or by company guidelines. If the chemical is vented or otherwise discharged outside the plant process, the process is a "controlled release" process. General space ventilation fans are not counted in this category.*

***Open process** is defined as a process in which the chemical is routinely in direct contact with the atmosphere (workplace or outside the plant) and no measures are taken to prevent release. For example, reaction vats are open, the chemical is transported or stored in open containers, or the chemical is freely vented into the workplace.*

For each process category (i.e., enclosed, controlled release, and open), the inspector must verify the total quantity of chemical processed, the number of worker exposure hours, and the number of workers exposed for the applicable reporting period.

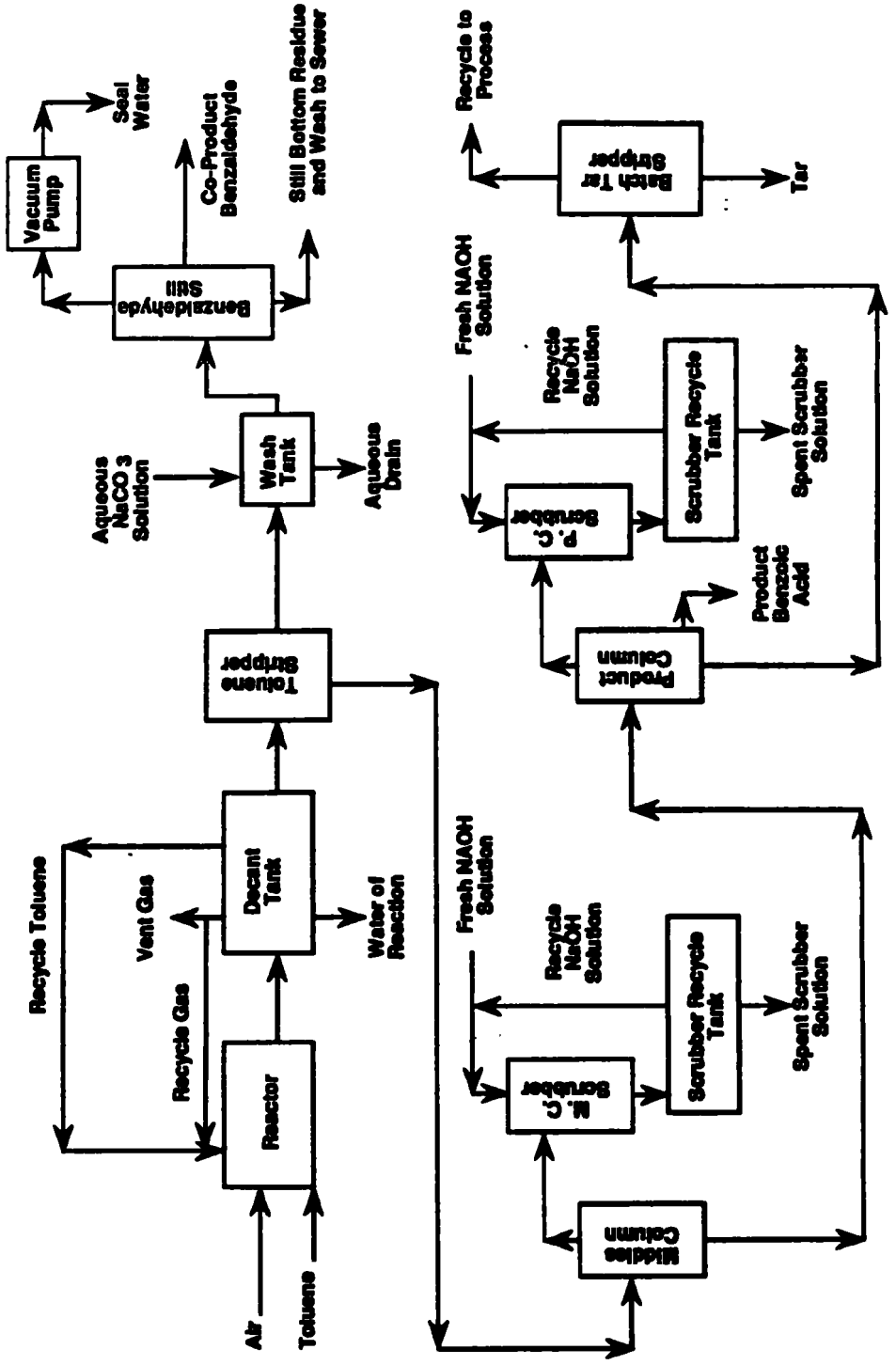
To review the manufacturing processes, the inspector should tour the facility, reviewing each unit process and discussing with the company representative any questions or issues that arise. Alternatively, if there is insufficient time for a tour, the inspector should request a facility process schematic or site layout plan, and review it with the company representative as to how each unit process was categorized for the PAIR report. (Sample process schematics for an organic chemicals manufacturer are given in Figures 7-1 and 7-2.) The inspector should review production records, manufacturing operating procedures or operating quality control procedures, and documentation of how the company calculated the total quantity of material processed in each process category. An example illustrating how this number should be calculated is presented in Figure 7-3.

The inspector should note that this facility tour or facility process review presents an ideal opportunity for the inspector to discuss pollution prevention. The objective is to raise the company's awareness of pollution prevention and how it could be applied to the company's operations, not to provide technical advice. The inspector can do this by inquiring whether the company has examined any options for making open processes into enclosed processes. In addition, the inspector could provide the name of the EPA contact person who can provide additional pollution prevention information and materials to the company. A list of EPA Region pollution prevention contacts is found in Appendix 6.

To verify the worker exposure hours and number of workers for each process category, the inspector should review documentation of how the company calculated these numbers (if available). These numbers can sometimes be verified by reviewing production schedules, costing (or budget) figures,

FIGURE 7-1

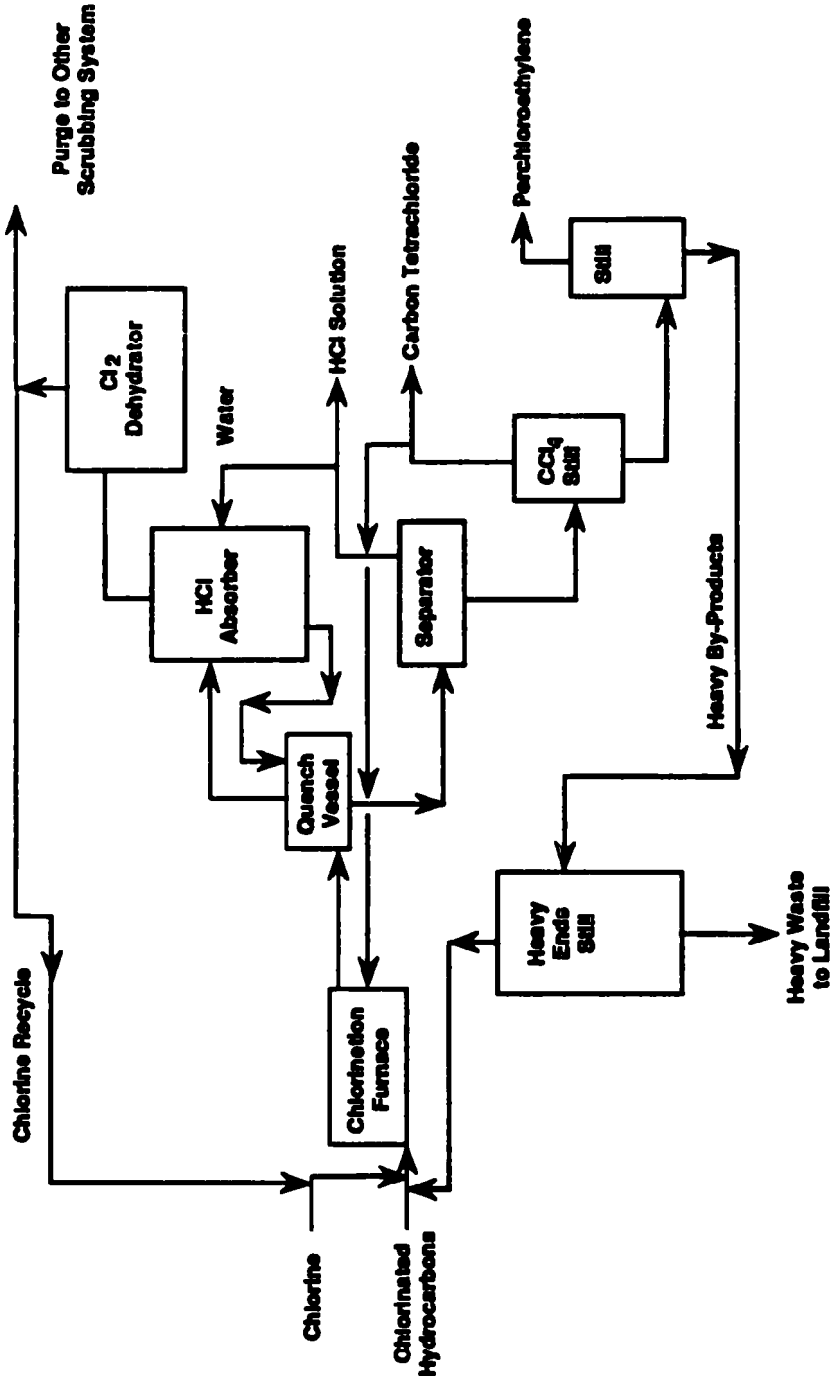
ORGANIC CHEMICAL MANUFACTURING SCHEMATIC - BENZOIC ACID AND BENZALDEHYDE



Source: Development Document for Interim Final Effluent Limitations and New Source Performance Standards for the Significant Organic Product Segment of the Organic Chemicals Manufacturing Point Source Category. U.S. EPA [illegible]ember, 1975

FIGURE 7-2

ORGANIC CHEMICAL MANUFACTURE SCHEMATIC -
PERCHLOROETHYLENE-CHLORINATION OF CHLORINATED HYDROCARBONS



Source: Development Document for Interim Final Effluent Limitations and New Source Performance Standards for the Significant Organic Product Segment of the Organic Chemicals Manufacturing Point Source Category. U.S. EPA, November, 1975

FIGURE 7-3

HOW TO CALCULATE QUANTITIES OF CHEMICAL PROCESSED BY PROCESS CATEGORY

Example 1

A company manufactures technical grade chemical x in four steps.

350,000 kg →	350,000 kg →	350,000 kg →	200,000 kg
Open	Enclosed	Open	Enclosed

The company would report:

Enclosed	350,000 kg
Controlled release	0
Open	350,000 kg

Example 2

A company produces the same chemical in a reagent and technical grade with the following steps.

Technical grade process:

350,000 kg →	350,000 kg →	350,000 kg →	200,000 kg
Open	Enclosed	Open	Enclosed

Reagent grade process:

650,000 kg →	500,000 kg →	500,000 kg →	400,000 kg
Controlled Release	Controlled Release	Open	Open

The company would report:

Enclosed	350,000 kg
Controlled release	650,000 kg
Open	850,000 kg

(The open process amount is the total of the maximum quantity in the open process category from each grade.)

and employee time sheets and records. Examples illustrating how these numbers should be calculated are given in Figure 7-4. The inspector should note that any employees who have contact with the subject chemical (including the process supervisor, clean-up crew, and maintenance people) should be included in these calculations.

Significant discrepancies (typically, greater than 50 percent) from reported values should be documented with copies of the appropriate records and/or signed statements from company officials.

- Verifying on site use of the chemical as a reactant. This item applies to the use of chemicals at the facility as a reactant in the manufacture of another chemical substance, where the molecular structure of the chemical is altered by breaking chemical bonds or making new chemical bonds between the original substance and some other substance. The inspector should review the processing steps and determine whether each step is classified as enclosed, controlled release, or open. The inspector should follow the procedures described for manufacturing processes to verify the information provided in the PAIR report, except that in place of the production records, the inspector should review the processing records.

- Verifying on site nonreactant use of the chemical. This item applies to the nonreactant use of chemicals at the facility, including use as a cleaning solvent, dielectric fluid, emulsifier, or lubricant. The inspector should review each use of the chemical and determine whether it is classified as enclosed, controlled release, or open. The inspector should follow the procedures described for manufacturing processes to verify the information provided in the PAIR report, except that in place of production records, the inspector should review documentation of how and where the chemical is being used. This may be found in inventory records. If no documentation is available, the inspector may need to obtain signed statements from company officials regarding the use of the chemical.

- Verifying on site preparation of products. This item applies to the processing of the chemical at the facility into products for on site use or sale and includes all the steps the chemical passes through to produce the product. This item also includes the quantity of chemical substance incorporated into a mixture or article. The inspector should note that this does not include manufacture of the chemical. The inspector should review the processing steps and determine whether each step is classified as enclosed, controlled release, or open. The inspector should follow the procedures described for manufacturing processes to verify the information provided in the PAIR report, except that in place of the production records, the inspector should review the processing records.

- Verifying manufacturer's products. This item requires the quantity of chemical prepared for industrial or consumer (domestic and export) use that the customer will not further process. *Industrial use means use by the manufacturing and service industries covered by the Standard Industrial Classification (SIC) Codes. Consumer use means use primarily by the general population.* Within these two categories, there are three types of products. The inspector must verify that each of the manufacturer's products has been correctly placed in one of the three product types: chemical substances or mixtures, articles or products with no release, or articles or products with some release. The three produced types are defined below.

  The inspector should verify that each product type has been correctly categorized and determine the total amount for each product type by reviewing sales reports, invoices, and shipping orders, and sales brochures. Sometimes the company will have customer work orders containing this information. Any significant discrepancies (typically, greater than 20 percent) from the reported

FIGURE 7-4

HOW TO CALCULATE WORKER EXPOSURE HOURS AND WORKER HOURS

Example 1

A company manufactured 1,000,000 kg of a chemical substance in 1980. It manufactured the chemical for all 12 months of the year and did so in an enclosed process.

In order to run the production line, 10 workers were present working 40-hour weeks; thus over the course of the year 20,800 worker-hours were used to run the production line.

Over the course of the year, 12 different workers worked on the production of the chemical.

The form would then be filled out as follows:

Process category	Quantity (kg)	Worker-hours	Total workers
Open	0	0	0
Controlled release	0	0	0
Enclosed	1,000,000 kg	20,800	12

FIGURE 7-4

HOW TO CALCULATE WORKER EXPOSURE HOURS AND WORKER HOURS (continued)

Example 2

A company manufactured 1,000,000 kg of a chemical substance in 1980. It manufactured the chemical for the entire year in a 24 hour/day process consisting of three steps in the open, controlled release, and open process categories. The production line was shut down for maintenance for 2 weeks of the year. The production line had three 8-hour shifts. Each shift in step 1 required 5 workers, while 7 and 10 workers were needed per shift in steps 2 and 3, respectively. The total worker-hours required for each step follows:

Process category	(Shifts/day x hours/shift x workers x days/week x weeks/year)	Worker-hours
Open (Step 1)	(3 x 8 x 5 x 7 x 50)	42,000
Controlled (Step 2)	(3 x 8 x 7 x 7 x 50)	58,800
Open (Step 3)	(3 x 8 x 10 x 7 x 50)	84,000

Analysis of the personnel records showed that a total of 75 individuals worked on the production of the chemical during 1980. After examining the personnel records, the company was able to fill in the following table:

Process category	Total workers
Open (Step 1)	21
Controlled (Step 2)	19
Open (Step 3)	35
	75

Note that workers are not double counted or split even though some jobs may require moving from one step of the process to another step of the same process. An employee working on both step 1 and step 2 is counted only in step 1 if s/he spends most of her/his time at that step. After adding together steps in the same process category, the company would report as follows:

Process category	Quantity (kg)	Worker-hours	Total workers
Open	1,000,000	126,000	56
Controlled release	1,000,000	58,800	19
Enclosed	0	0	0

figures should be documented by copying pertinent records and/or obtaining a signed statement from the company official.

DEFINITIONS (40 CFR §712.28)

***Chemical substance or mixture** is defined as a chemical, or mixture containing the chemical, that is used directly by the persons using the product (e.g., cleaners, paints, inks, deodorizers, solvents, etc.). This includes chemicals or mixtures in containers or other articles whose sole purpose is to release the chemical (e.g., cans of spray paint, ink pens, and other applications).*

***Articles or products with no release** are articles constructed to prevent human exposure to or release to the environment of the chemical substance during normal use and storage (e.g., chemical coatings on internal components, and chemicals inside sealed articles such as thermometers and batteries).*

***Articles or products with some release** are articles whose material components are made of chemicals that come in direct contact with persons using the article, the atmosphere, land, or water (e.g., exposure can come from leaching, evaporation, or surface contact). This includes such articles as plastic containers, chemically treated textiles, printed paper, coated appliances, etc. If the chemical itself is sold in a bottle or other container it should be reported under "Chemical substance or mixture," not as an article. Only the container itself is an article for purposes of this form; the substance it contains is not a component of the article.*

- Verifying customers' uses and products. This applies to how the customers are using or processing the manufacturer's chemical. The uses or products must also be categorized into the three product types described under the previous component: chemical or mixture, article with some release, or article with no release. Since the customer processing information is generally not readily available, the manufacturer probably estimated these numbers. Therefore, the inspector should discuss with the company official how the customers' uses and products were categorized and how the amount in each category was calculated. The inspector should also consider reviewing the customer list or sales records with the company official to ensure that all customers and all quantities sold to the customers were accounted for in the estimated numbers.

- Verifying market names. If the manufacturer or importer reported that more than 20 percent of the customers' uses or products are unknown, then the manufacturer must provide all the market or trade names for the chemical. The inspector should verify these names through review of annual sales reports, invoices, sales brochures, and product literature. If there is a discrepancy (e.g., name that was not provided is found on invoices), the inspector should copy all pertinent records and obtain a signed statement from the company official clarifying the reason for the discrepancy.

- Verifying customers' process categories. The manufacturer must attempt to provide an estimate of the process types (i.e., enclosed, controlled release, or open) used by the customers to process the manufacturer's chemical. Since this information is estimated by the manufacturer, the inspector should discuss it with the company official and document how the reported numbers were derived.

The inspector should note that, in general, whenever there are any discrepancies between what was reported and what is found during the review of records, the inspector should copy the appropriate records indicating the discrepancy and include them as part of the inspection report (discussed in Chapter 10).

7.2.1.3 PHASE 2 INSPECTION

The second phase of the inspection verifies that all chemicals listed in the Chemical Information Rules (40 CFR Part 712) that are manufactured or imported by the facility have been reported within the timeframe specified in the regulation (unless the manufacturer or importer is exempt).

Before the on site inspection, the inspector should identify any PAIR and IUR reports that have been submitted by the company. EPA Headquarters provides the Regions with a Confidential Business Information (CBI) summary of PAIR and IUR submittals derived from EPA databases (discussed in Section 3.2.3). The inspector may also use the Chemicals in Commerce Information System (CICIS) database and the IUR database [i.e., Chemical Update System (CUS)], if the Region has access, to identify any suspect chemicals manufactured by the company which might be subject to PAIR reporting but for which the company has not submitted PAIR reports.

During the inspection, the inspector should compare the company's current list of manufactured and/or imported chemicals (see Section 6.2.3) against the latest Chemicals on Reporting Rules (CORR) list (see Appendix 7). If the TSCA Inventory, IUR database, or the company's current inventory indicate the production of a PAIR chemical for which a PAIR report was not submitted, the inspector should request the company's records for the designated reporting period (which is found in the CORR list and in 40 CFR §712.30) to confirm that the PAIR chemical was in fact manufactured or imported during that period. If the chemical is subject to PAIR reporting and the company has not claimed an exemption (listed in Section 7.2.1), the inspector should obtain copies of records that indicate the total volume of chemical manufactured or imported and the estimated worker exposure hours. If the company is claiming an exemption from PAIR reporting, the inspector should verify that the company meets the criteria listed in 40 CFR §712.25 for exemptions as described below.

- Verifying R&D exemption. The inspector should review R&D notebooks, reports, production records, and sales records to ensure that the chemical was in fact produced only for R&D purposes.

- Small quantity exemption. The inspector should review production records for the company site being inspected for the designated reporting period. *(For purposes of this exemption, a site means a contiguous property unit. Property divided only by a public right-of-way is considered one site. There may be more than one plant on a single site.)* If the site produces or imports more than 1,100 pounds (500 kilograms), the site does not meet the criteria for the small quantity exemption. Records documenting the production in excess of 1,100 pounds at the site should be copied for inclusion in the inspection report.

- Verifying small manufacturer exemption. The inspector should review production records and annual sales reports or records for the whole company (i.e., all sites) for the reporting period. If the records indicate sales by the company of $30 million or more, or production of 100,000 or more pounds (45,400 or more kilograms) of the listed chemical at the plant site being inspected, the company does not qualify for the small manufacturer exemption. Records documenting these exceedances should be copied for inclusion in the inspection report.

- Verifying chemical manufactured as non-isolated intermediate, an impurity, or byproduct. The inspector should review the manufacturing flow diagram for the product of which the listed chemical is a component (i.e., non-isolated intermediate, impurity, or byproduct) if available. If no such diagram is available, then the inspector should review the production records and sales records to ensure that the chemical was not manufactured and sold and also ask company officials to explain and produce confirming documentation (if possible) describing where the chemical is a component in the manufacturing process. The inspector should review sales records to verify that a chemical is manufactured as a non-isolated intermediate or impurity.

DEFINITIONS (40 CFR §712.3)
***Non-isolated intermediate** is defined as an intermediate that is not intentionally removed from the equipment in which it is manufactured, including the reaction vessel, equipment that is ancillary to the reaction vessel, and any equipment through which the substance passes during a continuous flow process, but not including tanks or other vessels used for storage after manufacture.* ***Impurity** is defined as a chemical substance unintentionally present with another chemical substance or mixture.* ***Byproduct** is defined as any chemical substance or mixture produced without a separate commercial intent during the manufacture, processing, use, or disposal of another chemical substance or mixture. [For the purposes of PAIR, the definition of byproduct also includes the description found in 40 CFR §710.4(d)(3) through (7)].*

7.2.2 COMPREHENSIVE ASSESSMENT INFORMATION RULE (CAIR)

Certain Section 8(a) Information Gathering Rules are found in 40 CFR Part 704. Subpart A of 40 CFR Part 704 specifies general reporting and recordkeeping provisions for Section 8(a) Information Gathering Rules. Subparts C and D of 40 CFR 704 address CAIR and list the 19 chemicals currently subject to the rule. PAIR and CAIR differ not only in length (2- page and 141-page reports respectively, though

]only certain questions are required for specific chemicals), but also in application. While PAIR applies only to manufacturers and importers, CAIR covers manufacturers, importers, and processors. The design of the CAIR form enables EPA to use one form for many TSCA Section 8(a) reporting industries, thereby increasing EPA's ability, and decreasing the necessary time and energy, to capture relevant information.

The following manufacturers, importers, and processors are exempt from reporting under CAIR (40 CFR §704.5):

- Companies that manufacture, import, or process small quantities of the CAIR chemical solely for R&D
- Companies that are small manufacturers, importers, and processors. However, the definition of "small manufacturer" differs from PAIR and also applies to importers and processors. A small manufacturer under CAIR manufactures, imports, or processes less than 100,000 pounds (45,400 kg) per year at any individual site, and has total annual sales of less than $40 million when combined with those of its parent company. Also, a manufacturer, importer, or processor with total annual sales of less than $4 million is exempt regardless of the amount of listed chemical produced, imported, or processed (40 CFR §704.3)
- Companies that manufacture, import, or process the chemical solely as a non-isolated intermediate, an impurity, or a byproduct
- Companies that solely repackage the chemical.
- Companies that have previously used a CAIR reporting form to submit information about a substance subject to CAIR to EPA, or another Federal agency, are partially exempt from reporting requirements.

With the CAIR reporting form, EPA can tailor data requests to meet its specific needs for particular information on a chemical. The CAIR specifies the time period during which the reportable activity must have taken place. To determine the period during which reportable activity has taken place to trigger reporting requirements, each facility should:

- Determine which corporate fiscal years fall completely within any CAIR-designated coverage period (listed in the matrix in 40 CFR §704.225)
- Determine whether it engaged in an activity subject to that CAIR listing during any of those fiscal years.

Facilities should report activities that took place during the most recent coverage period (40 CFR §704.214).

The CAIR form contains 10 different classes of information:

- General manufacturer, importer, and processor information
- Manufacturer, importer, and processor volume and use
- Processor raw material identification
- Physical/chemical properties
- Environmental fate
- Economic and financial information
- Manufacturing and processing information
- Residual treatment, generation, characterization, transportation, and management
- Worker exposure
- Environmental release.

Respondents must keep a copy of all CAIR forms submitted to the Agency for 3 years. Also, materials that verify the report and copies of all notices sent to, and return receipt from, customers of those who distribute a listed substance under a trade name must also be retained (40 CFR §704.11).

7.2.2.1 INSPECTION OBJECTIVES

The inspection objectives that determine compliance with 40 CFR 704 Subpart C are:

- To verify the accuracy and completeness of information provided in the CAIR form (Phase 1)
- To identify firms that have failed to submit a CAIR report for a chemical subject to CAIR (Phase 2).

7.2.2.2 PHASE 1 INSPECTION (TO BE COMPLETED)

7.2.2.3 PHASE 2 INSPECTION

The second phase of the inspection verifies that all chemicals listed in 40 CFR Part 704 (i.e., subject to CAIR reporting) that are manufactured, imported, or processed by the facility have been reported within the timeframe specified in the regulation (unless the manufacturer, importer, or processor is exempt).

Before the on site inspection, the inspector should identify any CAIR reports that have been submitted by the company. These CAIR reports can be obtained from EPA Headquarters through an enforcement request as discussed in Section 3.2.4. The inspector may also use the CICIS database and the IUR

database (i.e., CUS), if the Region has access, to identify any suspect chemicals manufactured by the company which might be subject to CAIR reporting but for which the company has not submitted CAIR reports.

During the inspection, the inspector should compare the company's current list of manufactured, imported, or processed chemicals (see Section 6.2.3) against the latest CORR list (see Appendix 7). If CICIS, IUR database, or the company's current inventory indicate the production of a CAIR chemical for which a CAIR report was not submitted, the inspector should request the company's records for the designated reporting period (which is found in the CORR list and in 40 CFR §704.223) to confirm that the CAIR chemical was in fact manufactured, imported, or processed during that period. If the chemical is subject to CAIR reporting and the company is not subject to an exemption (listed in Section 7.2.2), the inspector should obtain copies of records that indicate the total volume of chemical manufactured, imported, or processed and the estimated worker exposure hours. If the company is claiming an exemption from CAIR reporting, the inspector should verify that the company meets the criteria listed in 40 CFR §704.5 and §704.210 for exemptions as described below.

- Verifying R&D exemption. The inspector should review R&D notebooks, reports, production records, and sales records to ensure that the chemical was in fact produced only for R&D purposes.

- Verifying small manufacturer exemption. The inspector should review production records and annual sales reports or records for the whole company (i.e., all sites) for the reporting period. If the records indicate sales by the company of $40 million or more, or production of 100,000 or more pounds (45,400 or more kilograms) of the listed chemical at the plant site being inspected, the company does not qualify for the small manufacturer exemption. Records documenting these exceedances should be copied for inclusion in the inspection report.

Small Manufacturer and Small Processor Exemption Criteria (40 CFR §704.3 and §704.203)

If the company's total sales combined with its parent company's sales are between $4 million and $40 million, the company must submit CAIR reports for manufacture, importation, or processing of 100,000 pounds or more of each particular chemical at any individual site.

If the company's total annual sales combined with the parent company's sales are less than $4 million, then the company is exempt from CAIR reporting as a small manufacturer, importer, or processor regardless of the quantity of substance manufactured.

- Verifying chemical manufactured as non-isolated intermediate, impurity, or byproduct. The inspector should review the manufacturing flow diagram for the product of which the listed chemical is a component (i.e., non-isolated intermediate, impurity, or byproduct) if available. If no such diagram is available, then the inspector should review the production records and sales records to ensure that the chemical was not manufactured and sold and also ask company officials to explain and produce confirming documentation (if possible) describing where the chemical is a component in the manufacturing process. The inspector should review sales records to verify that a chemical is manufactured as a non-isolated intermediate or impurity.

DEFINITIONS (40 CFR §704.3)
***Non-isolated intermediate** is defined as an intermediate that is not intentionally removed from the equipment in which it is manufactured, including the reaction vessel, equipment that is ancillary to the reaction vessel, and any equipment through which the substance passes during a continuous flow process, but not including tanks or other vessels used for storage after manufacture. Mechanical or gravity transfer through a closed system is not considered intentional removal, but storage or transfer to shipping containers "isolates" the substance by removing it from the process equipment in which it is manufactured.* ***Impurity** is defined as a chemical substance unintentionally present with another chemical substance or mixture.* ***Byproduct** is defined as any chemical substance or mixture produced without a separate commercial intent during the manufacture, processing, use, or disposal of another chemical substance or mixture.*

- Verifying repackager exemption. The inspector should review facility operating procedures and walk through the plant and repackaging areas to verify that the chemical is only being transferred to another container for purposes of sale.

DEFINITION (40 CFR §704.203)
***Repackager** is defined as a person who buys a CAIR substance or mixture, removes the substance or mixture from the container in which it was bought, and transfers this substance, as is, to another container for sale.*

- Verifying company previously submitted data. The inspector should review copies of CAIR forms previously submitted by the facility to EPA or another Federal agency to verify that the facility is subject to a partial exemption from current reporting requirements for the chemical and the site. The previously submitted report must have covered a complete corporate fiscal year that ended no more than 3 years before the effective date of the current reporting requirements for the chemical and the data must be accurate. The inspector should verify that the facility submitted a completed Section

1 of the CAIR reporting form and signed the certification in Section 1 that pertains to the use of the exemption.

7.3 SECTION 8(a): INVENTORY UPDATE RULE (IUR)

TSCA Section 8(a) requires EPA to maintain and update the TSCA Inventory of existing chemical substances. The purpose of the TSCA Inventory is to index current existing chemicals in commerce. The Inventory is a living document that EPA updates through involved processes of adding and deleting listed chemicals. When a new chemical has successfully completed review under the TSCA Section 5 Premanufacture Notice (PMN) process and the PMN submitter issues a Notice of Commencement (NOC) of non-exempt commercial manufacture or import, EPA adds this chemical to the Inventory. If a chemical is not currently produced by any manufacturers, EPA removes the chemical from the Inventory through the delisting process.

In 1986, EPA published the IUR (40 CFR 710 Subpart B). IUR requires manufacturers and importers of chemicals on the TSCA Chemical Substances Inventory to report current data on chemical identity, production volume, plant site, and site-limited status (unless exempt). To be subject to reporting requirements under Section 8(a), a person must manufacture at, or import to, any single site 10,000 pounds (4,540 kilograms) or more during the latest complete corporate fiscal year immediately prior to the reporting period. The initial 120-day reporting period lasted from August 25, 1986, to December 23, 1986. The succeeding reporting periods last for 120 days (August 25 to December 23) and occur every 4 years (since 1986). However, due to a reporting extension, the 1990 reporting period was extended to February 21, 1991.

TIPS
For the purposes of the reporting requirement, the site for an importer is the site of the operating unit within the person's organization that is directly responsible for importing the substance and that controls the import transaction. In some cases, the import site may be the organization's headquarters.

The following facilities are exempt from IUR reporting (40 CFR §710.28 and 710.29):

- Producers of less than 10,000 pounds (4,540 kilograms) of substance at a particular site during the corporate fiscal year preceding the reporting period

- Small manufacturers under the definition of the rule (see Section 7.3.3).

The following activities are exempt from IUR reporting (40 CFR §710.30):

- Production of a substance solely for R&D
- Import of a substance as part of an article
- Manufacturing a substance as an impurity, byproduct, non-isolated intermediate, or incidental to another operation or upon end use of another substance or mixture.

Finally, the following substances are exempt from reporting under the IUR (40 CFR §710.26):

- Certain polymers, inorganic substances, microorganisms, and naturally occurring substances.

A chemical substance that falls into one of the exempt categories must still be reported if it is the subject of a rule proposed or promulgated under Section 4, 5(a)(2), 5(b)(4), or 6 of TSCA, of an order in effect under Section 5(e) or 5(f) of TSCA, or of relief that has been granted under a civil action under Section 5 or 7. (The inspector should check CORR to verify the status of a chemical for these types of regulatory actions.)

The elements of the IUR report include:

- Chemical identity
- Production volume
- Plant site
- Site-limited status.

Manufacturers and importers must maintain the following records:

- All Inventory data submissions and records that document the information in the submission, for 4 years beginning with effective date of reporting period.
- Production or import records to verify a reporting exemption because the production or importation is less than 10,000 pounds (4,540 kilograms).

7.3.1 INSPECTION OBJECTIVES

The inspection objectives to determine compliance with Section 8(b) are:

- To verify the accuracy and completeness of information submitted in the IUR form (Phase 1)
- To identify chemicals reported on the IUR form that are not on the TSCA 8(b) Inventory (Phase 1)
- To identify firms that have failed to submit the IUR (Phase 2).

7.3.2 PHASE 1 INSPECTION

The inspector should review official copies of the IUR reports before the inspection. At the plant site, the inspector will verify the information contained in the IUR report by reviewing company records and interviewing company employees.

The following guidelines should provide assistance to the inspector in verifying the accuracy and completeness of the various elements of the IUR report.

- Verifying production volume. The inspector should review the production records for the subject chemical for the applicable reporting period (i.e., latest complete corporate fiscal year prior to August 25, 1990) to verify that the production numbers reported in the IUR report are accurate. Any discrepancies (greater than 10 percent) should be documented by copying the pertinent records and/or obtaining a signed statement from the company official.
- Verifying plant site. The inspector should verify that the production records that are being reviewed for the chemicals reported on the IUR are from the site of manufacture of the reported chemicals.
- Verifying site-limited status. If a company has listed a chemical or chemicals as site-limited, the inspector should review sales records to verify that the chemical or chemicals have not been distributed for commercial purposes. However, it should be noted that reviewing the sales records could be difficult and time consuming depending on the size of the site. The inspector should ask the facility's representatives how the chemical is used and what makes that use site-limited.

DEFINITIONS (40 CFR §710.23)
***Site-limited** is defined as a chemical that is manufactured and processed only within a site and is not distributed for commercial purposes as a substance or as part of a mixture or article outside the site. Imported substances are never site-limited.*

The inspector should note that, in general, whenever there are any discrepancies between what was reported and what is found during the review of records, the inspector should copy the appropriate records that document the discrepancy and include them as part of the inspection report (see Chapter 10).

7.3.3 PHASE 2 INSPECTION

The second phase of the IUR inspection verifies that all chemicals on the TSCA Section 8(b) Inventory that are manufactured or imported by the facility during the applicable reporting period have been reported within the specified timeframe (unless the manufacturer or importer is exempt).

During the inspection, the inspector should compare the company's list of manufactured and/or imported chemicals against the TSCA Section 8(b) Inventory. [This part of the inspection is generally done in conjunction with the Section 5 General Inventory inspection (see Section 6.2.2).] A comparison of these two lists could result in the following two situations:

- The company manufactured or imported a chemical during the applicable reporting period that is not on the Inventory and the company has not submitted an IUR or included the chemical on its IUR.
- The company manufactured or imported a chemical during the applicable reporting period that is on the Inventory but the company has not submitted an IUR report because it is claiming an exemption to IUR reporting.

In the first situation the inspector generally should not find (during an inspection) a chemical on the IUR that is not already on the TSCA Inventory because EPA Headquarters would find this discrepancy first when the company submits its IUR report. However, this may occur when the inspector does not have access to the CUS database and instead uses the published *TSCA Chemical Substance Inventory: 1985 Edition* (January 1986) when checking the chemicals on the IUR. In this case, the identified chemical that is not on the published Inventory (hard copy) will be in the up-to-date CUS database that contains confidential and public information. The inspector will not be able to confirm that the chemical is on the TSCA Inventory until s/he can search the database.

In the second situation, the chemical being manufactured or imported by the company is subject to IUR reporting because it is found on the Inventory but the company is claiming an exemption. The inspector should verify that the company meets the criteria listed in 40 CFR §710.29 and §710.30 for exemptions as described below.

- Verifying reportable quantities. The inspector should review the production records for each company site to verify that at any single site the chemical was not manufactured, imported, or processed in an amount of 10,000 pounds or more during the corporate year preceding the reporting period. In cases where the site has produced more than 10,000 pounds and the company is not exempt from reporting for any other reason, the inspector should copy the pertinent records.

- Verifying small manufacturer exemption. The inspector should review sales records to determine the total annual sales for the company and its parent company. If the company official is reluctant to provide such data because it is privately owned, the inspector should explain to company officials that such information can be claimed as Confidential Business Information (CBI). The inspector should also review the production records to determine the production in pounds for each chemical subject to IUR reporting. If the production records for a liquid chemical are expressed in gallons rather than pounds, the inspector needs to multiply the specific gravity for that chemical (expressed in pounds per gallon) by the gallons to obtain the production in pounds.

Small Manufacturer Exemption Criteria (40 CFR §710.29)
If the company's total sales combined with its parent company's sales exceed $40 million, the company must submit IUR reports for the manufacture or importation of 10,000 pounds or more of each particular chemical at any individual site. *If the company's total sales combined with its parent company's sales are between $4 million and $40 million, the company must submit IUR reports for manufacture or importation of 100,000 pounds or more of each particular chemical at any individual site.* *If the company's total annual sales combined with the parent's company sales are less than $4 million, then the company is exempt from IUR reporting as a small manufacturer or importer.*

If the company does not meet the small manufacturer criteria, the inspector should copy records documenting this finding and include them as part of the inspection report.

- Verifying R&D exemption. The inspector should review R&D notebooks, reports, production records, and sales records to ensure that the chemical was in fact produced only for R&D purposes.

- Verifying chemical imported as part of an article. The inspector should review documentation describing the imported article and how the subject chemical is incorporated into the article. This documentation may be in the form of sales brochures or product descriptions.

DEFINITION (40 CFR §710.2)
***Article** means a manufactured item (1) which is formed to a specific shape or design during manufacture, (2) which has end use function(s) dependent in whole or in part upon its shape or design during end use, and (3) which has either no change of chemical composition during its end use or only those changes of composition which have no commercial purpose separate from that of the article, and that result from a chemical reaction that occurs upon end use of other chemical substances, mixtures, or articles; except that fluids and particles are not considered articles regardless of shape or design.*

- Verifying manufactured or imported chemical is a polymer, inorganic substance, microorganism or naturally occurring substance. The inspector should review records substantiating that the chemical meets the criteria for inorganic chemical substance [40 CFR §710.26(a)]; polymer [40 CFR §710.26(b)]; microorganism [40 CFR §710.26(c)]; or naturally occurring substance [40 CFR §710.26(d)]. These types of records may include the production files, sales files, sales brochures, or others, depending on which criteria applies to the chemical. The inspector should gather all questionable data regarding exemptions and send it through the ER process for a technical opinion.

  However, the inspector should note that not every polymer or inorganic chemical identified is listed on the TSCA Inventory. The inspector should solely use the Inventory as a means to determine whether a substance is exempt.

7.4 SECTION 8(c): ALLEGATIONS OF SIGNIFICANT ADVERSE HUMAN HEALTH OR ENVIRONMENTAL EFFECTS

Under TSCA Section 8(c), companies are required to record allegations of previously unknown significant adverse reactions to any substance or mixture they manufacture, import, process, or distribute. EPA may require the reporting of these allegations, on a chemical or company-specific basis, by notice in the *Federal Register* or by letter to specific companies.

The Section 8(c) rule became effective on November 21, 1983 (40 CFR Part 717). This Section 8(c) rule provides a mechanism to identify previously unknown chemical hazards. It may reveal (to EPA or an individual recordkeeper) patterns of adverse effects that otherwise may not be noticed or detected. The rule describes the types of allegations to be recorded by any manufacturer or importer of a chemical substance or mixture subject to the rule. The types of allegations that must be documented as well as the types of allegations that are exempt from the recordkeeping requirements are summarized in Table 7-2. No exemptions exist for small manufacturers and processors.

Allegations that are subject to the rule implicate a chemical in an adverse reaction by:

TABLE 7-2. SECTION 8(c) ALLEGATIONS THAT MUST BE RECORDED

Keep Records	Cite	Type of Reaction	Type of Allegation
Required	40 CFR 717.12(a)	Human health	• Long-lasting or irreversible damage, such as cancer or birth defects • Partial or complete impairment of bodily functions, such as reproductive disorders, neurological disorders, or blood disorders • An impairment of normal activities experienced by all or most of the persons exposed at one time • An impairment of normal activities experienced each time an individual is exposed.
Not required	40 CFR 717.12(b) 40 CFR 717.3(c)(1) 40 CFR 717.3(c)(2)	Human health	• Exemption for known human health effects. Defined as commonly recognized human health effects of a particular substance or mixture as described in scientific articles or publications, the firm's product labeling, or the firm's material safety data sheets. An effect is not a known human health effect if it: - Was a significantly more severe toxic effect than previously described in scientific articles or publications - Was a manifestation of a toxic effect after a significantly shorter exposure period or lower exposure level than described - Was a manifestation of a toxic effect by an exposure route different from that described.
Required	40 CFR 717.12(c)	Environmental	• Gradual or sudden changes in the composition of animal life or plant life, including fungal or microbial organisms, in an area • Abnormal number of deaths of organisms (for example, fish kills) • Reduction of the reproductive success or the vigor of a species.
Not required	40 CFR 717.12(d)	Environmental	• Alleged cause of significant adverse reaction can be directly attributed to an accidental spill or other accidental discharge, emission exceeding permitted limits, or other incident of environmental contamination that has been reported to the Federal Government under any applicable authority.

- Naming the specific substance
- Naming a mixture or article that contains a specific substance
- Naming a company process or operation in which a specific substance is involved
- Naming an effluent, emission, or other discharge from a site of manufacturing, processing, or distribution of a specific substance.

Allegations may be submitted in writing or made orally. If oral, the company may either transcribe the allegation, or inform the alleger that the allegation may be subject to the Section 8(c) rule and suggest that the alleger submit the allegation in writing. The company is not obligated to record the allegation if, after requesting, the alleger does not put the oral allegation into writing. In addition, the company is not required to record reports of known adverse health effects (Table 7-2).

No automatic reporting provision exists under Section 8(c). The rule states that when the reporting of records is required, firms will be notified by letter, or by a notice in the *Federal Register*, of what chemical, when, and where to report.

Records of all allegations are to be maintained as referenced in the rule (40 CFR §717.15). A summary of the recordkeeping requirements is presented in Table 7-3.

The following persons are exempt from maintaining allegation files (40 CFR §717.7):

- Persons whose manufacturing activities consist of mining or other solely extractive functions
- Persons who are solely distributors. If a distributor also repackages chemicals or mixtures, then the distributor is a processor and not exempt from the rule
- Persons who are retailers of a chemical substance, unless such persons are also manufacturers or processors who are subject to the rule.

7.4.1 INSPECTION OBJECTIVES

The objectives of the inspection to determine compliance with Section 8(c) are:

- To check the company's awareness of the Section 8(c) rule

TABLE 7-3. SECTION 8(c) RECORDKEEPING REQUIREMENTS

Citation (40 CFR)	Allegation Record	Requirement
717.15(a)	Location	• Records of significant adverse reactions should be kept at the firm's headquarters or at any other appropriate location central to the firm's chemical operations.
717.15(b)	Content	The record must contain the following: • Original allegation and abstract • Name and address of plant or facility • Date allegation received • Implicated substance, mixture, or article • Process, operation, or site discharge • Description of alleging party • Description of alleged health effects • Description of nature of environmental effects • Results of internal or company investigations of allegation • Copies of required records or reports.
717.15(c)	Structure	Records must be retrievable by the alleged cause of the significant adverse reaction: • Chemical • Mixture or article • Company process or operation • Site emission, effluent, or other discharge.
717.15(d)	Retention Period	• Allegation records received from employees must be kept for 30 years. • All other allegation records must be kept for 5 years.
717.15(e)	Transfer	• If a firm ceases to do business, the successor must keep all records. • If a firm ceases to do business and no successor exists, these records must be transferred to EPA.

- To verify the accuracy and completeness of information contained in the allegation files
- To identify firms with no allegations on file when adverse effects have been reported
- To identify firms who have not submitted allegations under a Section 8(c) call-in.

7.4.2 INSPECTION GUIDELINES

The following guidelines should provide assistance to the inspector in assessing compliance with Section 8(c) allegation recordkeeping requirements.

- Verifying company awareness. This item applies to determining the company's general awareness of the Section 8(c) rule. While not an enforceable requirement, verifying the extent of company awareness of Section 8(c) requirements can improve future industry compliance. The inspector should review and obtain a copy of the company's policy or procedures for keeping records (i.e., records setup and maintenance procedures). The inspector should review documentation (if any) of how the company informs employees of the 8(c) rule. If no documentation exists, the inspector should discuss with company officials the company's general knowledge of the Section 8(c) rule and methods of how employees can be informed.

- Verifying allegation records not kept as required (see Table 7-3 for specific requirements). This item applies to the location, content, and structure of the file. The company must keep records at corporate headquarters or other appropriate location. If any elements are missing, incomplete, or inaccurate, the inspector should copy the entire allegation file to substantiate any suspected violation.

- Verifying allegation records not reported as required by EPA. This item applies to reporting of allegation records. The inspector should check the CORR list to determine whether allegations for a specific chemical were required to be reported to EPA [i.e., an 8(c) call-in]. If allegation records for the chemical are subject to an 8(c) call-in and the company has not reported its records, the inspector should copy the appropriate records and discuss with company officials the reason for non-submittal.

SUMMARY

The company must keep the following items in its files:

- *Original allegation*
- *Abstract of the allegation along with:*
  - *The name and address of the plant site that received the allegation*
  - *The date the allegation was received at that site*
  - *The implicated substance, mixture, article, company process or operation, or site discharge*
  - *A description of the alleger. If the allegation involves a health effect, the sex and year of birth of the individual should be recorded.*
  - *A description of the alleged health effects. The description must relate how the effects became known and the route of exposure, if explained in the allegation.*
  - *A description of the nature of the alleged environmental effects, identifying the affected plant and/or animal species, or contaminated portion.*

In addition, Section 8(c) files must be retrievable by the alleged substance, process, or emission, and not by any other designation, such as the alleger's name or site. If records are not accessible in this manner, the filing system and specific deficiencies should be documented in detail. In addition, the inspector should copy file folder titles. Additional information that the inspector should obtain are the number of allegations that are on file and the chemical(s) involved. Copies of multiple allegations for the same chemical or process should be obtained for review by EPA Headquarters. For example, if severe headaches and shortness of breath have been reported by two or more employees working on the same process, copies of these allegations should be collected. The inspector should also refer to Section 8(e) submissions. Depending on the pattern of Section 8(c) allegations, Section 8(e) violations may also have occurred.

- Verifying no allegations on file. This item applies to the difficult task of establishing the existence of nonrecorded allegations. First of all, if no adverse health allegations are on file, the inspector must determine if any allegations were reported for which the company concluded that the allegations were not subject to recordkeeping requirements under 40 CFR §717.12(c) or (d). To do this, the inspector should review incident and consumer complaint files, along with spill, release, OSHA 200/100, safety, and general employee medical and health records. If these or other records contain information that suggests an allegation was not recorded, the inspector should record the name of the alleger; date(s) of the incident(s); symptoms and effects; the chemical, mixture, or process involved; expert opinions; and the company's response. Most importantly, the inspector should attempt to obtain any copies of correspondence to the company or a written statement from the alleging party.

- Verifying records not retained for the required length of time. The company should retain employee allegations for 30 years, and all other allegations for 5 years. The inspector should document all allegations on file at a company for compliance verification during future inspections. When participating in a first-time inspection, the inspector should ask the company representative about the company's retention procedures to verify that they are aware of requirements. Any indication that prior allegations have not been retained should be documented as well as possible (e.g., with a signed statement). During the re-inspection of the location where Section 8(c) allegation files are kept, the inspector should review all previous listings or copies of allegations from previous inspections. The inspector should investigate any suspected disappearance or alteration of allegations. If an employee submitted the missing or altered allegation, the inspector should attempt to interview the employee (or relatives or associates) to document recent medical history and other pertinent facts. Intentional alteration or destruction of Section 8(c) allegation files may warrant a criminal referral.

7.5 SECTION 8(d): HEALTH AND SAFETY STUDIES

Generally, under TSCA Section 8(d), rules may be promulgated to require manufacturers, importers, or processors (or prospective manufacturers, importers, and processors) to submit to the Administrator lists and/or copies of ongoing and completed health and safety studies. Under this authority, EPA has promulgated a model health and safety data reporting rule (40 CFR 716).

The model Health and Safety Data Reporting Rule was developed to gather data on chemical substances and mixtures for which EPA requires health and safety information in fulfilling the goals of TSCA. Persons who must report under the rule include:

- Current and prospective manufacturers, processors, and importers
- Those persons who, in the 10 years preceding the effective date that a substance or mixture is added to 40 CFR §716.120, either has proposed to manufacture, import, or process, or has actually manufactured, imported, or processed the substance or mixture.

A list of studies subject to, and exempt from, the Section 8(d) rule is found in Table 7-4. Copies of studies in a person's possession at the time of a chemical's listing on the rule and copies of completed studies ongoing when listed on the rule or subsequently initiated must be submitted. The following categories of studies must be listed:

- Studies ongoing at the time a substance is listed
- Studies initiated after the date a chemical becomes subject to the rule
- Studies that are known but not possessed, and
- Studies previously sent to another Federal agency without confidentiality claims.

TABLE 7-4. SECTION 8(d) REPORTING REQUIREMENTS

Citation (40 CFR)	Report	Requirements
716.10	Health & Safety Studies	Health and safety studies on any substance or mixture listed in 40 CFR §716.120 that are unpublished are reportable. This requirement has limitations according to the nature of the material.
716.20	Exemptions from Reporting	• Studies published in scientific literature • Studies previously submitted to EPA-OPPT • Studies previously submitted to another Federal agency (must still be listed) • Studies conducted or initiated by or for another person who will report the studies • Studies of chemical substances not on the TSCA Chemical Inventory • Studies when substance or mixture is an impurity • Studies of chemical substances or mixtures previously submitted by trade associations • The following types of studies for a mixture: - acute oral toxicity - acute dermal toxicity - acute inhalation toxicity - primary eye irritation - primary dermal irritation - dermal sensitization - physical and chemical properties • Analyzed aggregations of monitoring data acquired more than 5 years before added to list • Analyzed aggregations of monitoring data on mixtures when the data are not analyzed to determine the exposure or concentration levels of the substances in the mixture.
716.30	Copies of Studies	Persons must send copies of any health and safety studies in their possession for listed chemicals and mixtures (unless exempt).
716.35	List of Studies	• Ongoing Studies • Initiated Studies • Studies that are known but without possession of copies • Studies previously sent to Federal agencies without confidentiality claims.

The rule, however, does limit several of the requirements for submitting studies. For example, the rule limits the file search to studies in the company's currently active files. The firm does not have to search files retired prior to December 31, 1979. In addition, companies can restrict the search for information to files in which such information is expected to be found in the ordinary course of business.

The rule requires all persons subject to the rule to submit information within 60 days after the effective date of the placement of a chemical on the list. The rule also contains a sunset provision, which states that the reporting period on the listed substance will terminate no later than 10 years after the effective date on which the substance is listed in 40 CFR §716.120. However, ongoing studies must be submitted whenever they are completed. The inspector should note that no mandatory recordkeeping requirements exist for this rule.

7.5.1 INSPECTION OBJECTIVES

The objectives of the inspection to determine compliance with Section 8(d) are:

- To check the company's awareness of the 8(d) rule
- To verify the accuracy and completeness of health and safety data reported
- To identify firms that have not reported health and safety studies.

7.5.2 INSPECTION GUIDELINES

The following guidelines should provide assistance to the inspector in assessing compliance with Section 8(d) health and safety study reporting requirements.

- Verifying company awareness. This item applies to determining the company's general awareness of the Section 8(d) rule. While not a regulatory requirement, if the company does not manufacture or import a chemical subject to Section 8(d), ascertaining the company's awareness can improve future industry compliance. To determine the company's awareness, the inspector should discuss the following items with the company officials:

  - Whether the company has a contact person responsible for (1) keeping track of the Section 8(d) rule, (2) being aware of the chemicals that are added to the existing list in 40 CFR §716.120, and (3) knowing which of their chemicals are subject to the reporting requirements. The inspector should report the name, position title, and phone number of the contact person.

- Whether the company has a central file or office where a copy of the Section 8(d) rule and amendments are maintained. The inspector should review this file and record the dates of *Federal Register* notices or other directives, notices, or directives relative to Section 8(d).

- Whether the company has internal procedures for monitoring/tracking any studies to determine when the company must report under Section 8(d). If so, the inspector should obtain a copy for inclusion in the inspection report. If no copy is available, the inspector should describe in the inspection report any procedures that are provided verbally.

- Whether the company has a testing facility on site or at the headquarters site, or whether contractors are used to conduct testing. The inspector should document the name and address of the testing facility if it is not located at the site being inspected.

- Verifying health and safety studies information as inaccurate or incomplete. The inspector should review copies of Section 8(d) submissions before the inspection (if possible). The inspector should request the list of studies submitted to EPA. (Generally, a company submits these studies to EPA with a cover letter listing each study.) The inspector should review all testing, monitoring, and risk assessment files for the subject chemical to verify that the list of submitted studies is complete and accurate. If the inspector is unsure of which files to review, s/he should discuss with the company official what types of studies are of concern and ask in which company files these studies would be found. The inspector should then search the identified files for the studies; however, the inspector should not be limited to these files if s/he believes that other files may contain health and safety studies. This type of review is very difficult and time-consuming to conduct because the type of information and data being reviewed is highly technical (see Figure 7-5). If studies are found that appear to meet the criteria in 40 CFR Part 716, the inspector should make copies of such studies and obtain a statement from the company official explaining why the studies were not submitted.

  The inspector should record the dates and titles of studies that appear to have been published in the scientific literature, or otherwise submitted to the EPA. The inspector should also check for any ongoing testing of Section 8(d) chemicals, including any physical/chemical testing. Examples of health and safety studies are listed in Figure 7-5.

- Verifying reports not submitted. During the inspection, the inspector should compare the company's list of manufactured and/or imported chemicals against the latest CORR list. Any chemical listed on CORR as subject to Section 8(d) reporting for which no health and safety studies were submitted should be noted. The inspector should then attempt to identify if the company has any reportable health and safety studies that meet the criteria of 40 CFR Part 716 and have not been submitted. The inspector should note that a search for health and safety studies is very difficult and time consuming (it can take from 2 to 4 days). If the inspector suspects or has reason to believe that the company has not submitted the required health and safety studies, s/he may want to consider such a search in a second followup inspection.

7.6 SECTION 8(e): NOTIFICATION OF SUBSTANTIAL RISKS

The self-implementing provisions of Section 8(e) went into effect on January 1, 1977. Section 8(e) requires any person who manufactures, imports, processes, or distributes in commerce a chemical substance or mixture and who obtains information that reasonably supports the conclusion that such

FIGURE 7-5

HEALTH AND SAFETY STUDIES

For the purposes of 40 CFR Part 716, the Health and Safety Data Reporting Rule, a health and safety study means "any study of any effect of a chemical substance or mixture on health or the environment or on data, including underlying data and epidemiological studies, studies of occupational exposure to a chemical substance or mixture, toxicological, clinical, and ecological or other studies of a chemical substance or mixture, and any test performed under TSCA."

Examples of studies (40 CFR §716.3) include:

- Long- and short-term tests of mutagenicity, carcinogenicity, or teratogenicity; data on behavioral disorders; dermatoxicity; pharmacological effects; mammalian absorption, distribution, metabolism, and excretion; cumulative, additive, and synergistic effects; and acute, subchronic, and chronic effects

- Ecological or other environmental effects on invertebrates, fish, or other animals and plants, including acute toxicity tests, chronic toxicity tests, critical life-stage tests, behavioral tests, algal growth tests, seed germination tests, plant growth or damage tests, microbial function tests, bioconcentration or bioaccumulation tests, and model ecosystem (microcosm) studies.

- Assessments of human and environmental exposure, including workplace exposure, and impacts of a particular chemical substance or mixture on the environment, including surveys, tests, and studies of the following: biological, photochemical, and chemical degradation; structure/activity relationships; air, water, and soil transport; biomagnification and bioconcentration; and chemical and physical properties, e.g., boiling point, vapor pressure, evaporation rates from soil and water, octanol/water partition coefficient, and water solubility

- Monitoring data, when they have been aggregated and analyzed to measure the exposure of humans or the environment.

substance or mixture presents a substantial risk of injury to health or environment to report that information to EPA immediately, unless EPA already has knowledge of the information. Such information need not establish conclusively that such a risk exists. In general, the chemical industry derives its Section 8(e) reports from two sources: (1) results of human, animal, and environmental studies; and (2) incidents involving chemicals, mixtures, effluents, or processes.

While EPA was not required to publish any regulations or rules for Section 8(e), EPA did issue a Policy Statement in the *Federal Register* on March 16, 1978 (43 FR 11110), which is included in Appendix 11. This continues to serve as the primary source of guidance to companies subject to Section 8(e). Also, in June 1991, EPA published a Section 8(e) reporting guide, as well as numerous Section 8(e)-related Question and Answer (Q&A) documents (See Appendix 12). Table 7-5 summarizes the types of substantial risk information that must be reported.

In reviewing enforcement cases, EPA found that some companies might have been misinterpreting TSCA Section 8(e). EPA announced in February 1991 (56 FR 4128) the TSCA Section 8(e) Compliance Audit Program (CAP). The CAP was a one-time, voluntary compliance program designed to encourage companies to audit their files voluntarily for studies reportable under Section 8(e). CAP was developed to encourage industry reporting by setting guidelines that identified in advance EPA's enforcement response and allowed companies to assess liability prior to electing to participate. After minor modifications in the original February 1, 1991, agreement, EPA set the final report submission date for February 28, 1992 (56 FR 19514). However, EPA has granted reporting extensions on a case-by-case basis. In reviewing existing guidance in connection with CAP, EPA determined that guidance on the release of chemical substances to and the detection of chemical substances in environmental media needed additional clarification to avoid potential over-reporting under CAP and to improve general compliance with Section 8(e). To this end, EPA extended the reporting deadline to 6 months after the publication of final refined reporting guidance for this type of information. (To date, no final guidance has been released.) (Reporting guidance is found in Appendix 12). As of the final reporting date, 123 companies enrolled in CAP.

Persons who obtain information that appears to constitute substantial risk information, but who do not manufacture, process, or distribute the subject chemical are not required to report under Section 8(e).

TABLE 7-5. SECTION 8(e) INFORMATION THAT MUST BE REPORTED

Citation	Type of Reaction	Type of Substantial Risk Information
43 FR 11112	Human health	• Any instance of cancer, birth defects, mutagenicity, death, or serious or prolonged incapacitation, including the loss or inability to use a normal bodily function with a consequently relatively serious impairment of normal activities, if one (or a few) chemical(s) is strongly implicated • Any pattern of effects or evidence that reasonably supports the conclusion that the chemical substance or mixture can produce cancer, mutation, birth defects, or toxic effects resulting in death, or serious or prolonged incapacitation.
43 FR 11112	Environmental	• Widespread and previously unsuspected distribution in environmental media[1] • Pronounced bioaccumulation. Measurements and indicators of pronounced bioaccumulation previously unknown to the Administrator should be reported when coupled with potential for widespread exposure and any nontrivial adverse effect. • Any nontrivial effect, previously unknown to the Administrator, associated with a chemical known to have bioaccumulated to a pronounced degree or to be widespread in environmental media • Ecologically significant changes in species' interrelationships (changes in population behavior, growth, survival, etc., that in turn affect other species' behavior, growth, or survival) • Facile transformation or degradation to a chemical having an unacceptable risk.
43 FR 11112	Emergency[1]	Any environmental contamination by a chemical substance or mixture to which any of the above adverse effects have been ascribed and which because of the pattern, extent, and amount of contamination: • Seriously threatens humans with cancer, birth defects, mutation, death, or serious or prolonged incapacitation, or • Seriously threatens nonhuman organisms with large-scale or ecologically significant population destruction.

[1] In 56 FR 28459, EPA suspended the applicability of Part V(b)(1) (i.e., widespread and previously unsuspected distribution in environmental media) and Part V(c) (i.e., emergency incidents of environmental contamination) of the TSCA 8(e) Policy Statement in determining the type of information to be submitted under Section 8(e).

Section 8(e) requires substantial risk information to be reported to EPA immediately. EPA considers information immediately reported for a nonemergency situation if they receive information within 15 working days. A company must report information concerning an emergency situation within 24 hours by telephone. Supplemental information received after the submission of a Section 8(e) notification should also be immediately reported.

No mandatory recordkeeping requirements exist for Section 8(e) submissions.

7.6.1 INSPECTION OBJECTIVES

The objectives of the inspection to determine compliance with Section 8(e) are:

- To check the company's awareness of Section 8(e)
- To verify the accuracy, completeness, and timeliness of substantial risk submissions
- To identify firms that have failed to report substantial risk information.

7.6.2 INSPECTION GUIDELINES

The following guidelines should provide assistance to the inspector in assessing compliance with Section 8(e) substantial risk information reporting requirements.

- Verifying company awareness. This item applies to determining the company's general awareness of Section 8(e). While company awareness is not an enforceable requirement, verifying the extent of company awareness of Section 8(e) requirements can increase compliance with the Section 8(e) substantial risk information reporting requirements. To determine the company's awareness, the inspector should discuss the following with company officials:

  - Whether the company maintains copies of the Section 8(e) requirement, the Statement of Interpretation (1978), and/or other relevant Section 8(e) guidance documents in its files.

  - Whether the company has a contact person at the site responsible for tracking/monitoring studies or events to determine whether information is reportable under Section 8(e). If so, the inspector should record the name, position title, and phone number of that person.

  - Whether the company has internal procedures on file outlining its policy for recognizing substantial risk information and reporting under Section 8(e). If so, the inspector should obtain a copy of that procedure and include it as an attachment to the inspection report. If no copy is available, the inspector should describe in the inspection report any procedures that are provided verbally.

- Whether the company has a testing facility on site or elsewhere, or whether contract laboratories are used to conduct testing. The inspector should document the name and address of the testing facility if it is not located at the site being inspected.

- Verifying substantial risk submission inaccurate, incomplete, or late. If possible, the inspector should review copies of any Section 8(e) reports and supporting documentation submitted by the company before the inspection. The inspector should conduct the search for reports at the corporate headquarters, since most substantial risk reports are submitted from this site. The key aspect in assessing compliance is to determine the date the company (or knowledgeable officials) first became aware of the substantial risk information. The inspector should examine all records, correspondence, and data to determine if the 15- working day (or 24-hour emergency) deadline was met. The inspector should review interim and/or preliminary reports for long-term health and environmental studies, as observations of harmful effects may be documented by knowledgeable persons before the completion of a study (and the preparation of a final report). If the inspector suspects that earlier harmful effects have been observed, copies of the interim reports and other supporting evidence (correspondence, laboratory notes, etc.) should be taken to determine a late submittal. Other potential sources include studies that were aborted due to deaths or poor health of study animals, or studies that are ongoing at the time of the inspection for which harmful effects are evident, but for which no Section 8(e) report has yet been submitted.

- Verifying substantial risk information not reported. This item applies to the difficult task of determining if a company failed to report substantial risk information.

DEFINITION (43 FR 11110)

Substantial risk information means information that reasonably supports the conclusion that a chemical substance or mixture presents a substantial risk of injury to health or environment. A substantial risk of injury to health or the environment is a risk of considerable concern because of the seriousness of the effect and the fact or probability of its occurrence. (Economic or social benefits of use, or costs of restricting use, are not to be considered in determining whether a risk is substantial.)

To gather information, the inspector should primarily interview company officials and review ongoing and completed health effects, environmental impact, and chemical fate studies. The inspector should also review epidemiology, monitoring, and other workplace studies. When a company registered for the Section 8(e) CAP program, a reporting guide was provided to the company. This reporting guide is included in Appendix 12. Other sources of information include Section 8(c) allegation records, incident records, OSHA records, health and safety data, and complaint records. The inspector should make pre-inspection arrangements to view copies (or summaries) of studies known by the company that have been conducted on chemicals manufactured or imported, but for which copies are not locally available. Currently, if the inspector finds information or data that may indicate a substantial risk, the inspector should document and obtain copies of the supporting information and data. During inspection followup, such information and data will be sent to EPA Headquarters for a determination of substantial risk.

Chapter Eight

TSCA Sections 12 and 13 Inspections

Page

8.0 TSCA SECTIONS 12 AND 13 8-1

8.1 INTRODUCTION 8-1

8.2 TSCA SECTION 12 EXPORT NOTIFICATION RULE 8-1

8.2.1 INSPECTION OBJECTIVES 8-2
8.2.2 INSPECTION GUIDELINES 8-2

8.3 TSCA SECTION 13 IMPORT RULE 8-3

8.3.1 INSPECTION OBJECTIVES 8-5
8.3.2 IMPORTER INSPECTION 8-5
8.3.3 DOCUMENTATION OF TSCA SECTION 13 VIOLATIONS 8-8
8.3.4 ENTRY REVIEW BY CUSTOMS 8-8

LIST OF FIGURES

FIGURE 8-1 EXAMPLE IMPORT CERTIFICATION STATEMENTS 8-5

BLANK PAGE

8.0 TSCA SECTIONS 12 AND 13

8.1 INTRODUCTION

This chapter contains background information and guidance to assist the inspector in conducting inspections of importers and exporters of chemicals subject to the Toxic Substances Control Act (TSCA). Section 8.2 contains the requirements under TSCA for exporters and describes how the inspector can determine whether exporters are complying with those requirements. Section 8.3 contains the requirements for importers under TSCA, describes the responsibilities of U.S. Customs in reviewing shipment, and explains procedures for the inspector to conduct investigations of shipments referred by Customs.

8.2 TSCA SECTION 12 EXPORT NOTIFICATION RULE

Section 12(b) of TSCA requires any person who exports, or intends to export, a chemical substance or mixture to notify the U.S. Environmental Protection Agency (EPA) of such export to a foreign country if any of the following actions have been taken under TSCA with respect to that chemical substance or mixture:

- Data are required under TSCA Sections 4 or 5(b)
- An order has been issued under TSCA Section 5
- A rule has been proposed or promulgated under TSCA Sections 5 or 6
- An action is pending, or relief has been granted under TSCA Sections 5 or 7.

DEFINITION (40 CFR §707.63)
Exporter means the person who, as the principal party of interest in the export transaction, has the power and responsibility for determining and controlling the sending of the chemical substance or mixture to a destination out of the customs territory of the United States.

EPA issued a final export reporting rule on December 16, 1980 (45 FR 82844; 40 CFR Part 707). Under this rule, an exporter must submit to EPA a written notice of the first export, per calendar year and per country of export, for the substance or mixture. Notice is required for the first export or intent to export to each foreign country of import in a calendar year. The notice must be postmarked within

7 days of acceptance of a definite contractual obligation to export or an equivalent intracompany agreement to export. Where the actual export occurs less than 7 days after the export obligation or agreement has been executed, the notice must be submitted to EPA no later than the same day as the export.

After EPA has received the first annual notification from the exporter, EPA must then notify the importing country's government of the availability of test data on the chemical submitted to EPA under TSCA Sections 4 or 5(b), and of any rule, order, action, or relief under TSCA Sections 5, 6, or 7. The Environmental Assistance Division (EAD) of the Office of Pollution Prevention and Toxics (OPPT) is responsible for notifying the country's government, generally by contacting that country's embassy.

8.2.1 INSPECTION OBJECTIVES

The inspection objectives to determine compliance are:

- To verify that notice of export was submitted
- To determine that export information submitted is accurate and complete.

8.2.2 INSPECTION GUIDELINES

- Verifying no submission of notice to export. Verification may require reviewing records at the exporter's establishment. The inspector should compare the exporter's list of the exported chemicals against the Chemicals on Reporting Rules (CORR) list.

- Verifying accuracy and completeness of information. The inspector should obtain copies of all notices of export through an Office of Compliance Monitoring (OCM) Enforcement Request (ER) process, and verify that they contain the following information:

  - Name and address of the exporter
  - Name of the chemical substance or mixture
  - Date(s) of export or intended export
  - Country (countries) of import
  - Section of TSCA (i.e., 4, 5, 6, or 7) under which EPA has taken action.

DEFINITION (45 FR 82846)
Country of import is defined as the country where the goods are to be consumed, further processed, or manufactured, as known to the shipper at the time of exportation. If the exporter does not know the country of ultimate destination, the shipment is credited to the last country to which the exporter knows that the merchandise will be shipped.

In addition, the inspector should determine whether the notice of export was sent to EPA within 7 days after a definite obligation to export was accepted.

8.3 TSCA SECTION 13 IMPORT RULE

TSCA Section 13 requires the U.S. Department of Treasury (Customs) to refuse entry into the customs territory of the United States of any chemical substance or mixture offered for entry if it fails to comply with any rule in effect under TSCA, or if it is offered for entry in violation of TSCA Sections 5 or 6, a TSCA Section 5 or 6 rule/order, or a TSCA Section 7 order. In addition, because TSCA defines importers as manufacturers, importers may be subject to testing requirements under TSCA Section 4 (discussed in Chapter 5), PMN requirements under TSCA Section 5 (discussed in Chapter 6), and reporting requirements under TSCA Section 8 (discussed in Chapter 7).

The U.S. Customs Service (Customs) published a rule concerning TSCA Section 13 on August 1, 1983, in 48 FR 34734 (19 CFR §12.118). The Customs rule sets forth general certification requirements and detention procedures. However, it does not address how a chemical shipment and its import would comply with TSCA. EPA issued a policy statement December 13, 1983, in 48 FR 55462 (40 CFR Part 707). It explains how EPA interprets and executes its responsibilities outlined in the Customs' Chemical Substances Import Rule. The main purpose of the EPA policy statement is to describe what compliance with TSCA means.

DEFINITION (40 CFR §707.20)

TSCA defines "manufacture" to include importation in addition to domestic production and manufacture. Consequently, importers are responsible for ensuring that chemical importation complies with TSCA, just as domestic manufacturers are responsible for ensuring that chemical manufacture complies with TSCA.

For the purposes of TSCA Section 13, the Customs Rule also defines an importer as:

> *The person primarily liable for the payment of any duties on the merchandise, or an authorized agent acting on his behalf. The importer may be:*
>
> - *The consignee*
> - *The importer of record*
> - *The actual owner of the merchandise, if an actual owner's declaration and superseding bond has been filed*
> - *The transferee of the merchandise, if the right to withdraw merchandise in a bonded warehouse has been transferred in accordance with Subpart C of 19 CFR Part 144 (Chapter I).*

Under the Customs rule, the importer of a chemical shipment must certify at the port of entry for shipments entering commerce in the U.S. either that the shipment is subject to TSCA and complies with all applicable rules and orders or that the shipment is not subject to TSCA. An importer can accomplish the certification and discharge her/his obligations related to the import by signing a briefly typed or reprinted statement on an entry document, invoice, or attachment. An example is found in Figure 8-1.

Certification of compliance with TSCA is required for chemical substances imported in bulk or as part of mixtures. Because some chemicals (e.g., pesticides) are not chemical substances subject to TSCA, the Customs rule requires importers to certify that such chemicals are not subject to TSCA. The rule does not require certification for chemical substances imported as part of articles, unless EPA requires reporting under a specific TSCA rule.

FIGURE 8-1

EXAMPLE IMPORT CERTIFICATION STATEMENTS

Positive certification for shipments subject to TSCA:

"I certify that all chemical substances in this shipment comply with all applicable rules or orders under TSCA and that I am not offering a chemical substance for entry in violation of TSCA or any applicable rule or order under TSCA."

Negative certification for other shipments:

"I certify that all chemicals in this shipment are not subject to TSCA."

(40 CFR §707.20)

8.3.1 INSPECTION OBJECTIVES

The inspection objectives to determine compliance of importers with TSCA are:

- To identify the applicable TSCA Section 4, 5, or 8 requirements for the chemical(s) being imported.
- To verify that shipments of the imported chemical(s) are in compliance with the TSCA Section 13 requirements.

8.3.2 IMPORTER INSPECTION

In inspecting an importer to determine compliance with the applicable requirements of TSCA Sections 4, 5, and 8, the inspector should follow the procedures contained in Chapters 5, 6, and 7, respectively, of this manual. For example, in conducting the general Inventory Section 5 inspection as described in Chapter 6 of the manual, the inspector should compare the list of chemicals imported by the company to the TSCA Inventory to determine if any of the imported chemicals are not on the Inventory. If the inspector finds an imported chemical not on the TSCA Inventory, then s/he should copy the import records for that chemical for inclusion in the inspection report. To avoid taking the Inventory on the inspection, the inspector could perform such a comparison after the inspection. If an imported chemical

is identified at that time as not being listed on the TSCA inventory, the inspector could then request by mail the import records for that specific chemical. Likewise, to determine whether one of the imported chemicals is subject to PAIR reporting and whether the importer has submitted the PAIR form, the inspector should follow the procedures in Chapter 7. The inspector should note that when the Chemical Abstract Service (CAS) Registry Number is available for the imported chemical, s/he can check the following documents:

- Chemicals on Reporting Rules (CORR) database report
- Section 12(b) Export Notification report
- *BNA's Chemical Regulation Reporter: Index to Government Regulations*, which lists for each chemical all proposed and final TSCA regulations.

In addition to determining compliance with TSCA Sections 4, 5, and 8, the inspector should also determine an importer's compliance with TSCA Section 13. To do this, the inspector would review shipping (import) records and review the certification provided with each shipment. The following guidelines should assist the EPA inspector in assessing compliance of shipments with TSCA Section 13:

- No certification statement present. In this case, shipping documents bore no certification statement and were not clearly Federal Food, Drug, and Cosmetic Act (FFDCA) or pesticide products accompanied by the appropriate Federal Drug Administration (FDA) or Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) forms. The inspector should have already established whether the imported chemicals in the shipment are subject to TSCA Sections 4, 5, or 8. However, if the inspector was unable to determine their compliance status and they were not accompanied by the appropriate arrival forms, their intended use may be in doubt. The inspector can verify that the chemical is for non-TSCA use by consulting the following reference materials:

  For FFDCA uses:

  - Merck Index
  - The Condensed Chemical Dictionary
  - Physicians Desk Reference
  - Harmonized Tariff Schedule.

For FIFRA uses:

- The Farm Chemicals Handbook
- The Condensed Chemical Dictionary
- Harmonized Tariff Schedule.

Cases involving shipments of chemicals that bear no certification statements, that are clearly FFDCA or pesticide products, and that are not accompanied by FDA or FIFRA forms should be forwarded to the FDA or to the Regional Pesticides and Toxic Substances Branch Chief for further action. (As a general policy, EPA does not require negative TSCA certification for a shipment that is accompanied by FDA or FIFRA forms.)

Shipments of chemicals that bear no certification and are subject to TSCA are in violation of Section 13. In this case, the inspector should document the information described in Section 8.3.3 of this chapter.

- Negative certification statement present. In this case, entry documents showed that the chemicals in these shipments were certified as not subject to TSCA but were not clearly FFDCA or pesticide products accompanied by FDA or FIFRA forms.

  The inspector should have already established whether the chemicals in such shipments are subject to TSCA. The inspector should verify that the imported chemical is for non-TSCA use by consulting the reference materials listed above for determining FFDCA or pesticide usage. FFDCA or pesticide products without accompanying forms but bearing negative certification statements are in compliance with TSCA Section 13. However, these cases should be forwarded to FDA or the Regional Pesticides and Toxics Branch Chief for possible further action.

  Shipments of chemicals that are not FFDCA or pesticide products and that bear negative certification statements may have received false certification under TSCA Section 13. If the inspector has already established that these shipments are subject to TSCA Sections 4, 5, or 8 requirements, the inspector should document the information described in Section 8.3.3 of this chapter.

- Positive certification statement present. The inspector should have determined whether the imported chemicals are not FFDCA or pesticide products and whether they have positive certification. If the inspector has found a shipment bearing positive certification to be in violation of some applicable rule or order under TSCA, then the shipment has received "false certification." This is the most serious violation of the TSCA Section 13 rule. The inspector should document the information described in Section 8.3.3 of this chapter.

  Some imported products may be multi-use chemicals that are subject to either FFDCA or FIFRA and TSCA. Cases involving FFDCA and pesticide products with positive TSCA certification that are not accompanied by the appropriate FDA or FIFRA forms should be referred to the FDA or the Regional Pesticides and Toxics Branch Chief for possible further action.

8.3.3 DOCUMENTATION OF TSCA SECTION 13 VIOLATIONS

In documenting a TSCA Section 13 violation, the inspector should prepare a summary that includes the following items:

- Importer
- Date of entry
- Entry number
- Customs Broker's name and address
- Certification status (positive, negative, or none)
- Forms attached (FDA or FIFRA form present)
- Specific chemical information name, formula, CAS Registry Number, uses
- Inventory status
- Applicable TSCA regulations.

This summary will be used in the preparation of inspection reports (discussed in Chapter 10) and will provide the necessary documentation for case development.

8.3.4 ENTRY REVIEW BY CUSTOMS

Customs may check chemical imports to determine whether shipments and their import comply with the certification requirements and the substantive mandates of TSCA. Customs may refuse entry to any shipment until certification is properly submitted. Customs may also detain a shipment if reasonable grounds exist to believe that such shipment or its import violates TSCA regulations or orders. A violative shipment must be brought into compliance, exported, destroyed, or voluntarily abandoned within the time periods prescribed in 19 CFR §12.124.

Customs may check the shipments using the following procedures.

- No certification statement present. Entry documents with no certification statements will be examined by the customs inspector for the presence of forms required by FFDCA or FIFRA. Chemicals regulated by FFDCA or FIFRA are not subject to TSCA, and so they would not require positive certification but should be accompanied by a negative certification, unless they are accompanied by the appropriate FDA or FIFRA forms. (As a general policy, EPA does not require negative certification for a shipment that is accompanied by FDA or FIFRA forms.) The Customs inspector may contact the EPA Regional office concerning shipments that bear no TSCA certification and are not clearly destined for FFDCA or pesticide use.

- False negative certification. Products regulated by FFDCA or FIFRA and imported solely for drug or pesticide use are not chemical substances subject to TSCA. Under the Customs Rule, importers are required to certify that these chemicals are not subject to TSCA unless they are accompanied by FDA Form 701 or EPA Form 3540-1. (As a general policy, EPA does not require negative certification for a shipment that is accompanied by FDA or FIFRA forms.) A shipment is falsely certified if it bears negative certification but is destined for non-FFDCA or non-FIFRA use.

  To verify that a chemical is subject to TSCA, Customs may check the Item number on the Harmonized Tariff Schedule assigned to the shipment because it will reflect the intended use of the chemical substance. Usage may also be indicated by the terms "USP," "pharmaceutical," or "pesticide" on the entry documents. The Customs inspector may contact the EPA Regional office concerning shipments that bear negative certification and are not clearly destined for non-TSCA use.

- False positive certification. Customs may consult the TSCA Inventory to determine whether all of the chemicals in a shipment are on the "open" Inventory. The Customs inspector may also compare the shipped chemicals to the list of chemicals subject to specific final regulations under TSCA Sections 5 and 6, and chemicals subject to proposed TSCA Sections 5 and 6 regulations (found in the CORR database and the Section 12(b) Export Notification report). If the chemical is not on the open inventory, Customs can flag it as a potential false certification and may refer it to EPA.

- "Blanket" Certification. "Blanket" certification may be authorized by the appropriate District Director of Customs to cover several shipments of the same chemical made over a 1-year period. Such a certification is subject to renewal. Importers authorized to use blanket certifications must also include a statement on the commercial invoice or entry document referring to the blanket certification. Separate blanket certifications are required for chemicals subject and not subject to TSCA. Since blanket certifications may be either positive or negative, the verification processes described above should be applied.

After Customs has completed the initial review and has determined that the shipment should be detained, it may notify EPA that the shipment is being held for further investigation and provide EPA with the entry documentation. If Customs does provide EPA with this information, then EPA will review this documentation and identify the reasons for the detention and the necessary actions for an importer to bring the shipment into compliance with TSCA. However, a shipment should not be detained if it is accompanied by a certification and is apparently in compliance with TSCA. If EPA is unable to determine the applicable TSCA requirements from the documentation provided, the EPA inspector should schedule and conduct an inspection of the importer.

The EPA inspector should note that further investigation of a shipment referred by U.S. Customs may become complicated because the shipment may enter the country through a port-of-entry in one EPA Region, while the importer-of-record is located in another Region. Since the importer-of-record is

responsible for certifying compliance, enforcement actions resulting from these investigations should be initiated in the Region in which the importer-of-record is located. Therefore, entry documents for shipments for which the importer-of-record is located in a Region other than the Region conducting the entry review at Customs should be forwarded to the Region in which the importer-of-record is located for further investigation. Entry review for shipments for which the importer-of-record is located in the Region should be conducted by that Region.

Chapter Nine

TSCA Biotechnology Regulation

Page

9.0 BIOTECHNOLOGY REGULATION 9-1

9.1 INTRODUCTION 9-1

9.2 BACKGROUND 9-1

9.3 CURRENT POLICY 9-2

9.3.1 MICROORGANISMS ARE CHEMICAL SUBSTANCES 9-2
9.3.2 DEFINING "NEW MICROORGANISM" FOR TSCA SECTION 5 9-2
9.3.3 MANDATORY PMN REPORTING 9-3
9.3.4 R&D EXEMPTION 9-3
9.3.5 VOLUNTARY PMN REPORTING 9-4
9.3.6 VOLUNTARY SNUR REPORTING 9-4

9.4 OTHER ISSUES 9-4

9.5 SUMMARY 9-5

BLANK PAGE

9.0 BIOTECHNOLOGY REGULATION

9.1 INTRODUCTION

The purpose of this chapter is to provide inspectors with basic information about the status of biotechnology regulation and, specifically, the current biotechnology program under the Toxic Substances Control Act (TSCA). EPA is currently operating its TSCA section 5 biotechnology program under a 1986 policy statement made as part of an interagency Coordinated Framework for Biotechnology (51 FR 23313, see Appendix 14). That policy statement will remain in effect until EPA promulgates final rules to fully implement its biotechnology program. This chapter does not provide a "how to" guide for inspectors, but instead provides basic information about the status of TSCA biotechnology regulation. This knowledge will allow inspectors to answer questions and provide general information, as necessary, on the subject.

9.2 BACKGROUND

Biotechnology, as defined by the U.S. Senate's Office of Technology Assessment, is any technique that uses living organisms or substances from those organisms to make or modify a product and perform services, to improve plants or animals, or to develop microorganisms for specific uses. Such genetic manipulation is not a new science and is used daily to enhance the characteristics of food (e.g., hybrid corn, selective breeding), manufactured food (e.g., bread, cheese, yogurt), waste disposal (e.g., bacterial sewage treatment), medicine (e.g., vaccines, hormones), and pesticides (e.g., Bacillus thuringiensis). In addition to these more common applications, biotechnology also includes the new molecular techniques of genetic modification, such as recombinant DNA, recombinant RNA, and cell fusion.

Federal regulation of biotechnology research and products was formalized in 1986 with the issuance of the Coordinated Framework for Regulation of Biotechnology. Coordinated by the White House Office of Science and Technology Policy, this framework is a combination of agency policy statements that were based on existing statutes and were formulated to govern the rapidly growing biotechnology industry. The notice included policy statements by EPA, the Food and Drug Administration (FDA), the National Institutes of Health (NIH), the National Science Foundation (NSF), the Occupational Safety and Health Administration (OSHA), and the U.S. Department of Agriculture (USDA). The primary purpose of the policy statements is to ensure the safety of the public and prevent unreasonable risk to the environment.

In its 1986 policy statement, EPA indicated that it had authority under both Federal Insecticide Fungicide and Rodenticide Act (FIFRA) and TSCA to regulate certain uses of microorganisms. The policy statement explained how and why certain biotechnology products would be subject to the review and reporting requirements under FIFRA and TSCA. Microbial pesticides are subject to FIFRA. TSCA coverage of biotechnology products will be discussed below.

Certain requirements became immediately effective upon issuance of the 1986 policy statement. Other aspects of TSCA coverage required rulemaking. Currently, EPA's Office of Pollution Prevention and Toxics is developing proposed rules to address the issues from the 1986 policy statement and fully implement its section 5 biotechnology program. The remainder of this chapter discusses both the voluntary and mandatory portions of the 1986 policy statement, which will remain in effect until final rules are promulgated.

9.3 CURRENT POLICY

9.3.1 MICROORGANISMS ARE CHEMICAL SUBSTANCES

The TSCA section 3 definition of "chemical substance" is broad enough to cover living organisms, including microorganisms. Similar to traditional chemicals, a microorganism is subject to premanufacture notification (PMN) reporting under TSCA section 5 when it is manufactured for a TSCA use and for commercial purposes. The definition of chemical substance in TSCA excludes pesticides, tobacco and tobacco products, food, food additives, drugs, cosmetics, and substances that are used as medical devices. Other than the exceptions described, all microorganisms produced for environmental, industrial or consumer uses potentially may be regulated under TSCA. Potential TSCA uses of microorganisms include bioremediation of hazardous waste sites, enhanced oil recovery, metal extraction and concentration, and specialty chemical production.

9.3.2 DEFINING "NEW MICROORGANISM" FOR TSCA SECTION 5

Only a new microorganism triggers PMN reporting just as a new chemical substance does. The definition of "new microorganism" in the 1986 policy statement became immediately effective. "New microorganisms" were considered to be intergeneric microorganisms not listed on the TSCA Inventory, with the exception of those intergeneric microorganisms in which the transferred material is only a well-characterized, non-coding regulatory region. Intergeneric microorganisms are formed from combinations of genetic material from source organisms in different genera (see discussion of intergeneric at 51 FR

23352). Therefore, under the current program naturally occurring microorganisms and genetically modified microorganisms that are not considered by EPA to be intergeneric are considered to be automatically included on the Inventory and thus are not new.

In a 1987 letter, EPA further clarified the applicability of its intergeneric policy to products containing mobile genetic elements (MGEs) or parts of MGEs, such as plasmids and transposons. The major consideration is the source of the original isolation of the MGE. Microorganisms will be considered intergeneric, and thus subject to PMN reporting as new microorganisms, if they contain an MGE isolated from a microorganism in a genus different from the recipient genus. Microorganisms will be considered intrageneric, and not subject to PMN reporting as new microorganisms, if the MGE is isolated from a microorganism in the same genus as the recipient.

9.3.3 MANDATORY PMN REPORTING

Similar to the traditional chemicals program, under the 1986 policy statement, PMNs must be submitted for new microorganisms 90 days prior to commencement of manufacture, processing, or distribution of the new microorganisms. The 1986 policy statement included information on preparing a PMN submission for new microorganisms. In addition, submitters are encouraged to obtain from the Biotechnology Program and use the guidance in the document entitled "Points to Consider in the Preparation and Submission of TSCA Premanufacture Notices (PMNs) for Microorganisms."

9.3.4 R&D EXEMPTION

The biggest difference between the traditional chemicals and the biotechnology programs is in the way research and development (R&D) activities are treated. TSCA section 5(h)(3) allows EPA to exempt from PMN reporting requirements chemical substances manufactured in small quantities solely for R&D. Under the traditional chemicals program, most R&D activities are exempt from review as long as researchers comply with the requirements of 40 CFR § 720.36. The small quantities definition developed for traditional chemicals cannot be applied with the same expectations to living microorganisms, which have the ability to multiply and spread in the environment. In 1986, EPA indicated that it would distinguish between R&D activities involving microorganisms used under contained conditions and those released to the environment. EPA stated its intention to develop rules which would revoke the R&D exemption for R&D activities involving the release of new microorganisms to the environment.

The 1986 policy statement indicated that microorganisms would be considered contained if they are used in a laboratory that complies with the NIH Guidelines or are used in a contained greenhouse, fermenter, or other contained structure (see criteria for "contained structure" at 51 FR 23335). R&D activities involving new microorganisms used under contained conditions continue to be eligible for the R&D exemption if the requirements of 40 CFR § 720.36 were followed.

9.3.5 VOLUNTARY PMN REPORTING

A rule must be promulgated to change the R&D exemption. Therefore, in the interim, EPA asked researchers intending to release new living microorganisms into the environment to voluntarily submit PMNs to the Agency prior to commencing their activities. While researchers working in contained structures would be subject to the requirements of 40 CFR § 720.36, EPA also specifically encouraged them prior to the time of voluntary reporting, to keep records describing the containment procedures used in their R&D activities.

9.3.6 VOLUNTARY SNUR REPORTING

In 1986, EPA indicated that it intended to supplement its PMN requirements by requiring persons to report prior to the introduction of pathogenic microorganisms (including microorganisms containing genetic material from pathogens) into the environment. EPA planned to use its TSCA section 5(a)(2) Significant New Use Rule (SNUR) authority to implement these requirements. In the interim, EPA asked persons to voluntary submit SNUR notices for (1) any new, non-agricultural use involving environmental release of engineered pathogens, and (2) any new, non-agricultural use involving environmental release of nonengineered pathogens on more than 10 acres of land. These provisions included a request for voluntary SNUR reporting of R&D activities involving release of engineered pathogens into the environment. While EPA does not currently plan to develop a specific SNUR for pathogens, the voluntary SNUR provisions will remain as part of the interim policy until a final rule is promulgated.

9.4 OTHER ISSUES

In setting forth its policy in 1986, EPA made several statements indicating how it planned to develop rules to fully implement its biotechnology program. As EPA has gained more experience reviewing biotech PMNs and as general scientific knowledge about genetically modified microorganisms has increased, EPA has made some changes in its plans for the biotechnology program. EPA's plans, which are subject to change and require notice and comment rulemaking, are briefly summarized in this section.

As indicated in 1986, EPA still plans to limit the R&D exemption to contained uses of new microorganisms. EPA has been developing an abbreviated reporting process tailored to specific R&D activities involving release to the environment.

In 1986, EPA also indicated that it was going to explore the possibility of using the provisions of TSCA section 5(h)(4) to develop exemptions from PMN reporting for certain general commercial uses of microorganisms in contained structures. EPA has pursued this approach and is planning to propose a flexible exemption process that will be able to accommodate additional microorganisms as EPA gains additional experience. EPA is also exploring use of a similar flexible exemption in conjunction with its abbreviated R&D reporting process for environmental releases to exempt specific categories of microorganisms.

As noted above, EPA had intended to develop specific SNUR requirements for certain uses of pathogens. While EPA does plan to propose a SNUR framework for microorganisms, at this time EPA does not plan to promulgate a SNUR for pathogens. In 1986, EPA also indicated an intention to develop a TSCA section 8(a) rule to collect general information about microorganisms that are subject to TSCA but not subject to PMN or SNUR reporting. At this time, EPA does not plan to develop section 8(a) reporting rules, because EPA has gained additional information regarding environmental uses of microorganisms through its PMN reviews and because of the general increase in scientific knowledge about microorganisms.

9.5 SUMMARY

The regulation of commercial biotechnology research and products is still a relatively new process under TSCA and is currently based on fundamental uncertainties associated with the use and characteristics of new microorganisms. Until EPA gains greater knowledge of TSCA uses of genetically modified microorganisms in the environment, EPA believes it prudent to screen R&D environmental releases as well as general commercial uses of certain genetically modified microorganisms. The 1986 policy statement and any subsequent regulations under TSCA, are intended to assist EPA in its effort to prevent unreasonable risks to human health and the environment. For current information on biotechnology regulation, the inspector should contact David Giamporcaro (FTS 202-260-6362) or Ellie Clark (FTS 202-260-3402) of the Biotechnology Program in the Chemical Control Division.

BLANK PAGE

Chapter Ten

Post-Inspection Activities

Page

10.0 POST-INSPECTION ACTIVITIES 10-1

10.1 INTRODUCTION 10-1

10.2 FOLLOWUP 10-1

10.3 THE INSPECTION REPORT 10-2

10.3.1 OBJECTIVES 10-3
10.3.2 CONFIDENTIAL BUSINESS INFORMATION CONSIDERATIONS 10-3
10.3.3 ELEMENTS OF THE INSPECTION REPORT 10-3
10.3.4 INSPECTION SUMMARY 10-9

10.4 WHAT TO DO WITH COMPLETED INSPECTION REPORT 10-9

LIST OF FIGURES

FIGURE 10-1 INSPECTION RESULTS SECTION OF REPORT - EXAMPLE 1 10-6
FIGURE 10-2 INSPECTION RESULTS SECTION OF REPORT - EXAMPLE 2 10-7
FIGURE 10-3 TIPS FOR DEVELOPING NARRATIVE LANGUAGE 10-10

BLANK PAGE

CBI PRINTOUTS

A. TSCA Section 5 Submitter Information (December 1989 - to present)
(PMNs, TMEAs, LVEAs, PEAs, and Bonafides)

1. Submitters should be sorted on the PLANT SITE Address data (manufacturing site taken from page 7) by Region and then by zip.

FORMAT:

REG. CO. Tech Contact Tech Phone Plant Site Address Submission #

2. Please break the pages by Region so that each Region will have the information pertaining to their Region only. For example, provide Region I with only Region I information, Region II with only Region II information, and so on for Regions I through X. One complete copy (all regional data) should be provided to OCM.

B. PAIR Submitter Information (December 1989 - to present)

1. Please sort submissions on Plant Site information, first by Region and then by zip code.

FORMAT:

Form #: CAS #: Chemical Name:
Company Name:
PLANT SITE Address:
Technical Contact: Tech's Phone:

2. Two complete printouts should be provided. One complete printout for OCM and one separated printout to be forwarded to each Region.

C. IUR Submitter Information (December 1989 - to present)

1. Provide a printout that shows who submitted an IUR form after 12/23/86. The printout should provide what CAS #s and Chemical Names were reported, and the production and importation value reported per chemical.

2. Submissions should be sorted on PLANT SITE information first by Region and then by zip code. (If there is more than one form per company do not try to merge the data, just display the forms in sequence.

FORMAT:

Company Name:
PLANT SITE Address:
Duns Number:
UPD-Form #:
Postmark:
Identifying #: Prod-Vol: MFG/IMP:
Chemical Name:
Identifying #: Prod-Vol: MFG/IMP:
Chemical Name:
Etc.:

3. Each Region should be provided with information for their Region only. Therefore, each Region should have a printout of late submitters. OCM should have all regional data for late submitters.

D. WITHDRAWN PMNs or PMNs which were followed by a 5(e)/(f) order Information (December 1989 - to present)

1. Submissions should be sorted on technical contact data first by Region and then by zip code. Please provide OCM with two complete printouts.

FORMAT:

Region:
PMN#: Company Name-Street Address: City: ST: Zip:
Received Date: NOC Date: Disp. Date: Disp.Code:
Tech. Contact Name: Tech's Phone:
Chemical Name:

E. WITHDRAWN, DENIED, INVALID TMEAs Information (December 1989 - to present)

1. SAME AS ABOVE:

F. WITHDRAWN, DENIED, INVALID LVEAs Information (December 1989 - to present)

1. SAME AS ABOVE:

G. WITHDRAWN, DENIED, INVALID PEAs Information (December 1989 - to present)

1. SAME AS ABOVE:

H. CAIR Submitter Information (December 1989 - to present)

1. Please sort submissions on PLANT SITE information, first by Region and then by State.

FORMAT:

Received Date: CAS #: Chemical Name:
Company Name:
PLANT SITE City and State:
Technical Contact: Tech's Phone: (If possible)

2. Two complete printouts should be provided. One complete printout for OCM and one separated printout to be forwarded to each Region.

NCBI PRINTOUTS

I. PMN/NOC Information (NCBI and CBI Data)

1. Printout 1: The information provided in this printout should be sorted by Region first then by PMN case number. Additionally, information is required for NOC dates June 1, 1989 - to present.

FORMAT:

Case#	End of PMN Review	NOC Date	Elapsed NO. of Days	PLANT SITE State	PLANT SITE City	CO Name

2. PRINTOUT 2: The information provided in this printout should only be sorted by the PMN case number. Additionally, information is required for NOC dates June 1, 1989 - to present.

FORMAT:

Case#	End of PMN Review	NOC Date	Elapsed Number of Days

3. Please provide a total of 11 copies of PRINTOUT #2 and two complete copies (one copy separated Region) of PRINTOUT #1.

J. TSCATS Information

1. Please provide eleven (11) TSCATS printouts (or DBase III diskettes, whichever is simplest or quickest). If it is possible, sort the information by Region. If this is possible, only two hardcopy documents are needed. The first copy will be used by OCM and the second copy needs to be separated and forwarded to the appropriate Region. Please provide the printouts/diskettes for, Date Received: June 1, 1989 or later.

FORMAT:

REGION #:

Dunn & Bradstreet Number:
CAS Number:
Chemical Name:
TSCA Section:
Title of Report/Study:
Date Received:
Submitter/Company Name:
Plant Site Address/Location:

APPENDIX 7

GUIDANCE FOR REQUESTING TSCA SECTION 8 AND 4 ENFORCEMENT REQUESTS (ERs)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D C. 20460

VAR

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: Guidance for Requesting TSCA Section 5 and 8 Enforcement Requests (ERs)

FROM: Maureen T. Lydon, Chief
Compliance Branch, OCM (EN-342)

Frank V. Caesar, Chief
Confidential Data Branch, OPPT (TS-793)

TO: Regional Toxics Branch Chiefs

During the FY 1991 TSCA Section 5 and 8 Conference held on June 4-6, 1991, there were concerns expressed by the Regions about inefficiencies associated with the Enforcement Request (ER) process. As you know, an action plan for streamlining the process for handling TSCA Section 5 and 8 ERs has been finalized. The goal is to transfer responsibility for receiving and tracking Section 5 and 8 ERs to IMD/OPPT by May 1, 1992. The transition date has been delayed somewhat due to organizational responsibility considerations within OPPT.

In the action plan, OCM committed to developing/enhancing guidance to the regions on requesting information. Attached you will find guidance which may be valuable in assisting you when requesting certified statements from IMD. It is important to keep these guidelines in mind when making a request in order to facilitate a prompt response.

If you have any questions about this memorandum or the attached guidance, please feel free to contact either of us or Ann Clavin of OCM's Compliance Branch at FTS-260-9438. Thank you for your attention to this guidance document.

Attachment

cc: Michael Stahl
Mark Greenwood
Michael Wood
Jerry Stubbs
Michael Walker
Joe Carra
Regional TSCA Section 5 & 8 Coordinators
Regional Toxics Section Chiefs

Printed on Re

GUIDANCE FOR SUBMITTING TSCA ENFORCEMENT REQUESTS

TSCA Inventory Searches/Certified Statements

o Confirm that the substance in question is used for a TSCA regulated purpose. (FDA and FIFRA chemicals and uses will not be reflected in the TSCA Inventory). If the use is questionable, submit information on the use with the request for the search or certified statement.

o Do not accept a company's assertion that what they may be making is excluded from TSCA reporting requirements under a specific exemption. If such an assertion is made, require the company to provide a detailed description of the manufacturing process used to produce the substance so that it can be reviewed at headquarters.

o When requesting a search or a certified statement, be sure to first check the public inventory. This information is available in the five volume January 1985 Edition of the "TSCA Chemical Substance Inventory" and June 1990 supplement or the EPA regulated Chemicals System database (which should be on-line by mid-April).

o Be sure to secure a chemical name, Chemical Abstracts Service Registry Number (CASRN), and/or chemical structure whenever possible. If possible, have a company representative transcribe the information him/herself; this makes them accountable for all transcriptions. DO NOT submit CASRN's that clearly identify items that are NOT searchable against the TSCA Inventory Master File such as hydrates, Colour Index Names, tradenames, etc.

o If you are provided with a CASRN only, have the company representative associate it with a chemical name or structure in case the CASRN is invalid. This way, the name and/or structure can be searched. Inspectors who have access to the chemical substance search service, CAS on-line, should determine if a CASRN is valid and matches the chemical name. All invalid CASRN's will be returned. Check with your library or a university library to determine if they have CAS on-line.

o Determine if the company can identify the manner in which they believe the substance became included in the TSCA Inventory (i.e. PMN, Initial Inventory Report Form Submission such as A, B, C, or E). If the company is not sure, see if a competitor's product name or designation (for the "same" substance) can be obtained for purposes of comparison by headquarters personnel)

o If the company obtains the substance in question from someone else in the U.S., secure the name of the other company.

o A search should suffice if the substance has not been manufactured or imported for commercial purposes. If the substance has been manufactured or imported for commercial purposes, a certified statement will be necessary (see Attachment 1: Form for Requesting Inventory Searches).

o Be sure to provide a copy of a generic Certified Statement with your request (see Attachment 2 for an example)

PMN and PMN Exemptions

o Be sure to include in your request a copy of the generic Certified Statement which addresses your needs (see Attachments 3, 4, 5, 6 and 7).

o Provide as much information as possible (i.e., Case Numbers, DCNs, dates of submission, company names, and chemical identity). Although non-CBI requests are preferable, you must make sure that enough information has been provided to complete the certified statement.

Section 8 (PAIR, CAIR, IUR, etc.)

o Be as specific as possible concerning company name, dates of submission, DCNs and chemical identities.

o Provide a copy of a generic Certified Statement (see Attachments 8, 9 and 10)

Technical Assistance/Opinion

o Be as specific as possible concerning the request. Include the reason, determination to be made and the timeframe for providing the information.

o Provide IMD with as much background information as possible.

Company Specific - Pre-inspection information

o Determine the exact documents, including the timeframe you want covered, about which you are concerned. For instance, if you are interested in all submissions made by a particular company, list each type (i.e., PMN, PMN exemption applications, Bona fides, IURs, etc.).

o Determine if you need actual copies of documents or if a listing will be adequate.

To the extent possible, try to anticipate the need for certified statements and request them in advance so that they are not sent in at the last minute. Also, do not request certified statements unless they are necessary.

General - Administrative

o Requests for certified statements or document requests addressing TSCA Sections 4, 6 or 12 should continue to be sent to OCM. If there is a CBI document (i.e. possibly TSCA Section 12(b)), OCM will request the appropriate information from IMD/CDB

o REMINDER - Multiple requests within a single request (i.e. a document search and a certified statement) lengthen the turnaround time for the request. If you have that situation, please separate the requests into two or more different requests and identify which one needs to be completed first.

SEARCH OF COMPLETE TSCA INVENTORY
EPA-Region ___

OCM Received ___/___/___
ER No. _____

Priority _____ Date _____

Inspector _____

Phone Number _____

Certified Statement ☐ YES ☐ NO CAS No. _____

SPECIAL NOTE FOR DYES: At a minimum, you must provide a valid chemical name (not trade name) and/or chemical structure.

☐ Substance is not a Colour Index name

☐ Substance is not a hydrate

CHEMICAL NAME

_____

_____

_____

STRUCTURE

_____

MOLECULAR FORMULA

_____

USE

_____

_____

COMPANY NAME

_____

INVENTORY REFERENCE
(Inventory Form No.)

IMD RESPONSE SECTION

Search completed on _____
Date placed on inventory _____
PMN # (if applicable) _____
Notice of commencement _____

☐ - Not on inventory
☐ Invalid CAS number
☐ Valid CAS number is not equivalent to submitted chemical name

CERTIFIED STATEMENT

I, Linda A. Travers, am the Director of the Information Management Division in the Office of Pollution Prevention and Toxics. The Information Management Division is responsible for maintaining and updating the list of chemical substances compiled under Section 8(b) of the Toxic Substances Control Act (TSCA) known as the TSCA Chemical Substance Inventory (TSCA Inventory). I certify that the substance identified below has completed the Agency's PMN review process and was included in the TSCA Inventory as of the data specified (or was not included in the TSCA Inventory as of the date of signature). I also certify that the chemical substance was not subject to TSCA Section 5(e) or 5(f).

PMN Case Number:

PMN Submitter:

CAS Registry Number:

Specific Chemical Name:

Date PMN Received for Agency Review:

Date PMN Review Period Expired:

Date Notice of Commencement of Manufacture for PMN Substance Submitted to Agency:

Date Notice of Commencement of Manufacture for PMN Substance Received by Agency:

Date PMN Substance Included in TSCA Inventory:

_____

Linda A. Travers, Director
Information Management Division

_____

Date

CERTIFIED STATEMENT

I, Linda A. Travers, am the Director of the Information Management Division. The Information Management Division of the Office of Pollution Prevention and Toxics is responsible for the inclusion of chemical substances on the list compiled and published under Section 8(b) of the Toxic Substances Control Act. I certify that the chemical substance identified below was submitted for review, reviewed, and included on the list compiled under Section (8) as of the date specified under the terms specified in the 5(e) Consent Order.

SUBMITTER:

PMN NUMBER:

CAS REGISTRY NUMBER:

CHEMICAL NAME:

DATE PMN RECEIVED FOR AGENCY REVIEW:

EFFECTIVE DATE OF 5(e) CONSENT ORDER:

DATE PMN REVIEW PERIOD EXPIRED:

DATE NOTICE OF COMMENCEMENT SUBMITTED:

DATE NOTICE OF COMMENCEMENT RECEIVED:

DATE CHEMICAL SUBSTANCE INCLUDED ON THE INVENTORY:

_____

Linda A. Travers, Director
Information Management Division

_____

Date

CERTIFIED STATEMENT

I, Linda A. Travers, am the Director of the Information Management Division in the Office of Pollution Prevention and Toxics. The Information Management Divsion is responsible for maintaining, and updating the list of chemical substances compiled under Section 8(b) of the Toxic Substances Control Act (TSCA) known as the TSCA Chemical Substance Inventory (TSCA Inventory). I certify that the substance identified below has not been submitted to the Agency for Premanufacture Notification (PMN) review and not included in the TSCA Inventory as of the date specified.

CAS Registry Number:

Specific Chemical Name:

_____

Linda A. Travers, Director
Information Management Division

_____

Date

CERTIFIED STATEMENT

I, Linda A. Travers, am the Director of the Information Management Division in the Office of Pollution Prevention and Toxics (OPPT). The Information Management Division is responsible for maintaining and updating the list of chemical substances compiled under the Toxic Substances Control Act (TSCA) known as the TSCA Chemical Substance Inventory (TSCA Inventory). I certify that the substance identified below has completed the Agency's Low Volume Exemption Application (LVEA) review process and been included in the confidential LVEA File of the TSCA Inventory as of the date specified.

LVEA Case Number:

LVEA Submitter:

CAS Registry Number:

Specific Chemical Name:

Date LVEA Received for Agency Review:

Date LVEA Review Period Expired:

Date LVEA Substance Included in LVEA File of TSCA Inventory:

_____

Linda A. Travers, Director
Information Management Division

_____

Date

CERTIFIED STATEMENT

I, Linda A. Travers, am the director of the Information Management Division. The Information Management Division of the Office of Pollution Prevention and Toxics is responsible for maintaining, and updating the list of chemical substances compiled under the Toxics Substances Control Act (TSCA) known as the TSCA Chemical Substance Inventory (TSCA Inventory). I certify that the substance identified below has completed the Agency's Test Marketing Exemption Application (TMEA) review process and has been included in the confidential/non-confidential TMEA file of the TSCA Inventory as of the date specified.

TMEA Case Number:

TMEA Submitter:

CAS Registry Number
Specified Chemical Name:

Date TMEA Received for Agency Review:

Date TMEA Review Period Expired:

Date TMEA Substance Included in LVEA File of TSCA Inventory:

_____
Linda A. Travers, Director
Information Management Division

_____
Date

CERTIFIED STATEMENT

I, Linda A. Travers, am the Director of the Information Management Division in the Office of Pollution Prevention and Toxics. The Information Management Division is responsible for maintaining, and updating the list of chemical substances compiled under Section 8(b) of the Toxic Substances Control Act (TSCA) known as the TSCA Chemical Substance Inventory (TSCA Inventory). I certify that the substance identified below has completed the Agency's Polymer Exemption Application (PEA) review process and has been included in the confidential/non-confidential TSCA Inventory as of the date specified.

PEA Case Number:

PEA Submitter:

Specified Chemical Name:

Date PEA Received for Agency Review:

Date PEA Review Period Expired:

Date Notice of Commencement of Manufactur/Import for PEA Substance Submitted to Agency:

Date Notice of Commencement of of Manufacuter/Import for PEA Substance Submitted to Agency:

Date PEA Substance Included in TSCA Inventory:

_____

Linda A. Travers, Director
Information Management Divsion

_____

Date

CERTIFIED STATEMENT

Partial Updating of the Inventory Data Base Rule
Search and Status

I, Linda A. Travers, am the Director of the Information Management Division. The Information Management Division of the Office of Pollution Prevention and Toxics is responsible for receiving, maintaining, and managing information submitted under the Partial Updating of the Inventory Data Base Rule (40 CFR 710 Subpart B), Inventory Update Rule, published under Section 8(a) of the Toxic Substances Control Act.

I certify that the information set out below is complete and accurate.

Submitter Name:

DUNS Number:

[ ] Did Submit

[ ] Did Not Submit
an Inventory Update Report

Chemical Name:

CAS Registry No.
(or Identification No.):

Postmark Date:

Date Form U Received:

Further, this substance is not encompassed by the Inventory Update Rule's reporting exclusions (40 CFR Part 710.26)

_____

Linda A. Travers, Director
Information Management Division

_____

Date

CERTIFIED STATEMENT

I, Linda A. Travers, am the Director of the Information Management Division. The Information Division of the Office of Pollution Prevention and Toxics is responsible for the compilation of data from reports submitted pursuant to 40 CFR 7122, Subpart B, Manufacturers Reporting--Preliminary Assessment Information.

I certify that the following PAIR information was submitted:

SUBMITTER:

CAS NUMBER:

CHEMICAL NAME:

DATE PAIR SUBMITTED:

DATE PAIR RECEIVED:

_____

Linda A. Travers, Director
Information Management Division

_____

Date

CERTIFIED STATEMENT

I, Linda A. Travers, am the Director of the Information Management Division. The Information Management Division of the Office of Pollution Prevention and Toxics is responsible for the compilation of data from reports submitted pursuant to 40 CFR 704.2, Subpart C--CAIR: Comprehensive Assessment Information Rule-General Reporting and Recordkeeping Provisions.

I certify that the following CAIR information was submitted:

SUBMITTER:

CAS NUMBER:

CHEMICAL NAME:

DATE CAIR SUBMITTED:

DATE CAIR RECEIVED:

_____

Linda A. Travers, Director
Information Management Division

_____

Date

TSCA GUIDELINES, STRATEGIES AND ENFORCEMENT RESPONSE POLICIES

DOCUMENT	DATE ISSUED
GENERAL TSCA PENALTY GUIDANCE	
Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation or Suspension of Permits [45 FR 24360]	04/09/80
Guidelines for Assessment of Civil Penalties under Section 16 of the Toxic Substances Control Act; PCB Penalty Policy [45 FR 59770]	09/10/80
Memorandum: Routine Use of SEC '10-K' Statements in TSCA and FIFRA Civil Penalty Actions	10/17/80
TSCA Settlement with Conditions	11/16/83
TSCA Compliance/Enforcement Strategy	11/22/83
Memorandum: Settlement With Conditions (SWC)	12/20/85
TSCA TECHNICAL GUIDANCE	
General	
Neutral Administrative Inspection Schemes for TSCA Enforcement	11/07/79
Use of TSCA Section 11(c) Subpoenas	12/04/79
TSCA §4	
Strategy for the Enforcement of the Good Laboratory Practice Regulations under TSCA and FIFRA	01/15/85
TSCA Good Laboratory Practice Enforcement Response Policy	04/09/85
TSCA §4 Test Rules Enforcement Response Policy	05/29/86

TSCA §5: Premanufacture Notices

Enforcement Facts and Strategy: Premanufacture Notification (PMN) (ERP portion is Obsolete).	08/80
Compliance Strategy for TSCA §5(h)(4) Premanufacture Notice Exemption for Chemicals Used in or for Instant Photographic or Peel-Apart Film Articles	11/15/83
TSCA §5 Enforcement Response Policy	08/05/88

TSCA §6: Asbestos

Memorandum from A. E. Conroy to Regions: Asbestos in Schools Rule Transmits Two Legal Opinions from the Office of General Counsel Re: 1) Enforcement under Title I of TSCA after Title II was in Effect, and 2) Enforcement of the Title I Asbestos in Schools Rule for schools which opened or commenced operation after June 28, 1983	11/25/86

Worker Protection

TSCA §6 Interim Strategy and Enforcement Response Policy for the Asbestos Worker Protection Rule (Strategy replaced 09/09/86)	07/09/85
OSHA Interpretations for the Asbestos Abatement Projects Rule	10/03/85
Asbestos Abatement Projects Rule Compliance Monitoring Strategy (modifies Strategy for Asbestos Worker Protection Rule of 07/09/85)	09/09/86
Asbestos Abatement Projects; Worker Protection; Final Rule [52 FR 5618]	02/25/87
Final Compliance Monitoring Strategy for the Asbestos Abatement Projects; Worker Protection Final Rule	11/14/88

AHERA: Asbestos

Enforcement Policy for the Transition from AIS to AHERA	01/29/88
Amendment to the Enforcement Policy for the Transition from AIS to AHERA	09/02/88

Memorandum: Integration of Agency Asbestos Activities (Can be found in the appendix to the Compliance Monitoring Strategy for AHERA	09/29/88
Compliance Monitoring Strategy for AHERA	10/05/88
Interim Final Enforcement Policy for the Asbestos Hazard Emergency Response Act	01/31/89
AHERA May 9th Deferral Deadline	05/09/89

TSCA §6: Chlorofluorocarbons

Enforcement Facts and Strategy: Chlorofluorocarbons	11/15/79

TSCA §6: Polychlorinated Biphenyls (PCBs)

Guidelines for Assessment of Civil Penalities Under Section 16 of the Toxic Substances Control Act; PCB Penalty Policy [45 FR 59770] (Document found under "TSCA Penalty Guidance" Section)	09/10/80
Memorandum: Civil Penalty Cases Involving Use of PCBs in Hydraulic Systems	09/14/81
Compliance Monitoring Strategy for TSCA §6(e) - PCBs	05/23/85
Amendment to the Compliance Monitoring Strategy for TSCA §6(e) Polychlorinated Biphenyls (PCBs)	06/13/86
Final Second Compliance Monitoring Amendment for TSCA Section 6(e) Polychlorinated Biphenyls and TSCA Section 6 PCB Enforcement Response Policy Clarification	05/02/88

TSCA §§8, 12, and 13: Reporting Requirements

Inventory Enforcement Strategy	04/25/79
Compliance Strategy for Preliminary Assessment Information Reporting Rule (Level A)	07/22/82
Asbestos Reporting Rule Compliance Strategy	08/30/82
Compliance Strategy for TSCA §8(d)	12/12/83
Compliance Monitoring Strategy for TSCA §8(c) Rule	05/18/83

TSCA §13 [redacted]liance Monitoring Strategy	07/12/84
Evaluation of the Pilot Program for Monitoring Compliance with §13	01/18/85
Recordkeeping and Reporting Rules for TSCA §§8, 12, and 13; Final Enforcement Response Policy	05/15/87
Final Compliance Strategy for the TSCA §8(a) Inventory Update Rule	06/09/87
TSCA §§8, 12, and 13 Enforcement Policy Clarification	07/13/87

TSCA STATE RELATED GUIDANCE

Memorandum: Maryland's Application for a TSCA Pilot Cooperative Enforcement Agreement: Issues of Preemption	06/18/81
Memorandum: Supplemental Guidance Procedures for State Inspectors Acting Under the Authority of TSCA §11	06/19/81
Memorandum: Preemption Provisions Under the Toxic Substances Control Act (TSCA)	04/05/85
Final TSCA Cooperative Agreement Guidance for FY89	03/10/88
Guidance for the FY89 State/EPA Enforcement Agreement Process	06/20/88

TSCA COMPLIANCE PROGRAM POLICY COMPENDIUM

6-ASB-1: When to Wear Protective Clothing and Equipment for Asbestos Regulations Compliance Monitoring Inspections	07/15/83
6-ASB-2: [redacted]ment of Catholic Dioceses as Local Education[redacted]ncies	07/02/84
6-ASB-3: Qualification for Exemption from the Asbestos in Schools Rule Based on the Asbestos Abatement Programs	07/02/84
6-ASB-4: Asbestos in Schools: "For Profit Schools"	05/21/85
6-ASB-5: Enforcement Response for Small Local Education Agencies Without Friable Materials	09/10/85
6-ASB-6: Recordkeeping Requirements for Schools with Friable Asbestos Containing Materials	09/10/85

6-WPR-1: [redacted]r Protection Requirement During Asbestos Abatement [redacted]ects Using Glove Bag Procedures	04/01/88
6-CFC-1 Product Labeling for Both Essential and Non-Essential CFC Aerosol Propellent Uses	08/30/82
6-PCB-1: Responsibility for Compliance with PCB Rule	03/04/82
6-PCB-2: Distillation, Solvent Extraction, Filtration, and Other Physical Separation Methods for PCBs	08/16/83
6-PCB-3: Residual PCBs in Processed Liquids and Solids	08/16/83
6-PCB-4: Disposal Methods for PCBs in Sludge	08/13/85
6-PCB-6: Allocation of Enforcement Liability for Violations of the One-Year Disposal Deadline for PCB Articles or PCB Containers	08/16/83
6-PCB-7: Reference Date for Violations of the One-Year Storage for Disposal Deadline for PCB Waste Resulting from Physical Separation	08/16/83
6-PCB-10 First In/First Out Standard for Meeting the PCB One-Year-Storage-for-Disposal Requirement	08/13/85

ADDITIONAL SOURCES OF TSCA COMPLIANCE ENFORCEMENT INFORMATION

General Enforcement Policy Compendium

See page 4 of this listing for Table of Contents

TSCA MISCELLANEOUS SOURCES

(These sources are not in the TSCA Compendium but may be obtained from Headquarters.)

State and Local Assistance [47 FR 44946] (40 CFR Part 35)	10/12/82
EPA Policy on Performance-Based Assistance	05/31/85
OECM Memorandum: Issuance of Enforcement Considerations for Drafting and Reviewing Regulations and Guidelines for Developing New or Revised Compliance and Enforcement Strategies	08/15/85
OECM Memorandum: Policy on Publicizing Enforcement Activities	11/21/85
TSCA §4 Data Self Auditing Program Events	11/22/85
Final Policy Statement on Environmental Auditing	06/13/86
Uniform Administrative Requirements for Grants and Cooperative Agreements with State and Local Governments [53 FR 8075] (40 CFR Part 31)	03/11/88 (Effective 10/01/88)

MANUALS

Multi-Media Compliance Audit Inspection Procedures

TSCA Compliance/Enforcement Guidance Manual

TSCA Compliance/Enforcement Guidance Manual-Policy Compendium

05/01/89

OBSOLETE DOCUMENTS

Enforcement Facts and Strategy: Polychlorinated Biphenyls (PCBs)	02/80
Inventory Penalty Policy	06/23/80
PCB Enforcement Policy Subsequent to Appellate Court Opinion Remanding Portions of the PCB Regulation	11/11/80
Guidance for Pilot TSCA Cooperative Enforcement Agreements	12/31/80
New Requirements for PCB Transformers Persuant to Appellate Court Order	03/09/81
Enforcement Facts and Strategy: PCB Interim Measures Program	08/81
Dioxin Contaminated Waste Compliance Strategy	01/82
Compliance Strategy for the Submission of Notices of Manufacture or Importation of Polybrominated Biphenyls (PBB) and Tris	03/30/82
Compliance Strategy for the Friable Asbestos-Containing Materials in Schools: Identification and Notification Regulation	06/24/82
Model Asbestos in Schools; Cooperative Compliance Program	09/21/82
Compliance Assistance Guidelines for the Asbestos-In-Schools Rule	12/15/82
Compliance Assistance Guidelines: Friable Asbestos containing materials in Schools; Identification and Notification Rule	
Dioxin Contaminated Waste Enforcement Response Policy	07/06/83
Enforcement Response Policy for the Friable Asbestos Containing Materials in Schools Identification and Notification Rule	07/06/83
General Regulation for Assistance Programs [48 FR 45056] (40 CFR Part 30)	09/30/83
Revised Asbestos-in-Schools Enforcement Response Policy (see 10/18/85 amendment)	07/02/84
Guidelines for assessment of Civil Penalties under Section 16 of the Toxic Substance Control act: PCB Penalty Guidance Section 9/10/80	05/01/89

Belongs on page 2

OBSOLETE DOCUMENTS (Page 2)

TSCA §§8, [redacted] and 13 Recordkeeping and Reporting Rules Enforcement Response Policy (Replaces the May 23, 1980 Inventory Penalty Policy)	07/30/84
TSCA §5 Enforcement Response Policy Supplement	01/09/85
Amendment to the Revised Asbestos-in-Schools Enforcement Response Policy	10/18/85
Memorandum to Regions: Reductions and Remittances of Penalties for Violations of the TSCA Asbestos-in-Schools Rule	04/15/85
Interim Final Amendments to the Enforcement Response Policy for TSCA §13 and Interim Final Amendments to the Enforcement Response Policy for TSCA §8(a) Violations Involving Falsification	05/28/86
Interim Compliance Monitoring Strategy for the Asbestos Abatement Projects Rule	05/30/86
Final TSCA Cooperative Agreement Guidance for FY86/87	02/86
Final TSCA Cooperative Agreement Guidance for FY88	03/12/87
Memorandum: Clarification of Section 5 Penalty Policy on Notice of Commencement Violations	04/02/87
Interim Final Enforcement Policy for Violations of the Immediately Enforceable Provisions of AHERA	01/29/88

APPENDIX 3

LIST OF INDUSTRIAL PROCESS REFERENCES

INDUSTRIAL REFERENCES

Bikales, N.M. (ed). 1964-1972. *Encyclopedia of Polymer Science and Technology - Plastics, Resins, Rubber Fibers*. Interscience, New York, NY. Supplemental volumes issued.

Sixteen volumes that five processes, processing techniques, theoretical aspects, and the properties for all polymers.

Groggins, P.H. 1958. *Unit Processes in Organic Synthesis, Edition 5*. McGraw-Hill, New York, NY.

A presentation of the processes and processing conditions for making organic chemicals.

Shreve, N.R. 1967. *Chemical Process Industries, Edition 3*. McGraw-Hill, New York, NY.

A presentation of the processes and processing conditions for producing most major chemicals.

Sittig, M. 1966. *Organic Chemical Process Encyclopedia*. Noyes Development Corporation, Park Ridge, NJ.

587 process flow sheets.

Standen, A. 1963-1972. *Kirk-Othmer Encyclopedia of Chemical Technology, Edition 2*. Interscience, New York, NY. Supplemental volumes issued.

Twenty-two volumes that give all aspects of chemical technology, including a comprehensive discussion of chemical processes and processing conditions and a listing or properties for all mass-produced chemicals.

APPENDIX 4

RECOMMENDED PROCEDURES FOR ENFORCEMENT PERSONNEL RESPONSIBLE FOR HANDLING SECTION 5 CONFIDENTIAL BUSINESS INFORMATION

Appendix 2

Recommended Procedures for Enforcement Personnel Responsible for Handling Section 5 Confidential Business Information

INTRODUCTION

great deal of information on new chemicals is considered sensitive by the chemical industry. Consequently, much of the information submitted to the agency under the Section 5 program -- including information in premanufacture notices and test marketing exemption applications -- is claimed TSCA Confidential Business Information (CBI). Because of the large volume of TSCA CBI which will be transferred and handled while conducting the Section 5 enforcement program, special procedures have been developed to supplement the procedures in the EPA TSCA CBI Security Manual and the TSCA Base Inspection Manual. These procedures should be followed by Document Control Officers (DCOs), inspectors, and all other EPA personnel who receive and/or review Section 5 information.

BACKGROUND

Unlike other TSCA inspection programs (particularly PCBs), the information used to target Section 5 inspections and the information that is obtained during the inspection will most likely be CBI. Section 5 premanufacture notification (PMN) forms and test marketing exemption (TME) requests are submitted to the Chemical Control Division in the Office of Pesticides and Toxic Substances (OPTS). PTSED reviews this information and prepares a series of Section 5 target inspection packages to be sent to the regions. Any TSCA CBI related to these packages will be sent by the DCO in PTSED directly to the DCO in each region. Under separate cover, a non-CBI memorandum will notify the person responsible for TSCA inspections in each region that a PMN/TME inspection package was sent to the DCO.

Initial coordination among the DCO, the inspectors and other reviewers of Section 5 CBI documents in the region is a major part of the inspection program. The DCO and the regional inspection coordinators should prepare an outline describing how the entire program will work, including organization of a uniform Section 5 CBI file system that will be effectively used throughout the program.

The remainder of this document outlines specific procedures that regional personnel handling CBI must follow prior, during, and following an inspection. Some of the procedures outlined in this package repeat the TSCA Confidential Business Information Security Manual and the TSCA Inspection Base Manual. However, these supplemental procedures stress the importance of effective coordination, communication and secure handling of sensitive information received and reviewed under the Section 5 inspection program. These procedures as well as the Interim Inspection Guidance prepared by PTSED, must be followed carefully during the Section 5 inspection program.

REGIONAL PROCEDURES FOR HANDLING SECTION 5 CBI

MAILING OF PMN DATA FROM PTSED

- PTSED Compliance Monitoring Section will oversee the mailing of PMN inspection targeting packages to each region. The package will consist of a summary Target Sheet and any other pertinent support documents. In most cases this information will be confidential.

- PTSED's DCO will mail all CBI related to the inspection targeting package directly to the regional DCO. A non-CBI letter of receipt will be included in each package for immediate review, signature, and return by the DCO.

- A non-CBI memorandum will be sent under separate cover to the region's Section 5 inspection coordinator notifying him or her that CBI data was sent.

- PTSED DCO will notify each regional DCO by phone when the CBI is to be mailed.

RECEIPT OF PMN DATA FROM PTSED

The Regional Document Control Officer/Assistant must:

- Review each CBI package received from PTSED to ensure that the document control numbers and number of pages match up as indicated in the letter of receipt. If there is a discrepancy, notify the PTSED DCO for clarification.

- Sign and return the letter of receipt immediately to the PTSED DCO. (A return address label will be included for prompt mailing.)

- Sign all document cover sheets and fill in the date.

- Be sure to use the OPTS document control number which will be assigned to each document. (Some regions assign sequential numbers within their own numbering system and attach a different cover sheet whenever a CBI document is received in their office; the OPTS document number should also appear on those cover sheets.)

- Participate in the pre-review meeting [see below: Pre-Inspection Activities - Pre-Review Meeting]. Brief all reviewers on security procedures for review of CBI and suggest that they refer to the appropriate sections of the TSCA CBI Security Manual and the TSCA Base Inspection Manual as a refresher.

In addition, the Regional Document Control Officer/Assistant should:

- Become familiar with proposed regulations, interim policy statements and enforcement policies under Section 5, including the types of information that may be submitted and collected as CBI during inspections.

- Become faimliar with security practices of each individual reviewer and establish working procedures for each person based on this knowledge.

- Request to be informed prior to any inspection activity of the persons that will be involved in each individually targeted inspection and/or review of a Section 5 CBI company file (inspectors, attorneys, Branch Chiefs, etc.). Also request to be informed of any major changes in program operation and/or program personnel in the event that Section 5 CBI procedures may be affected.

- Keep duplication of CBI to the bare minimum. The security manual states that the original should remain with the DCO. However, since the DCO will not receive the original, unless regional practice strictly prohibits it, the DCO's copy can be logged out without duplication. Also, the transfer of CBI documents among authorized persons in different divisions should be kept to a minimum. If more than one key person is involved in a Section 5 inspection and the individuals are in separate Divisions, it may be necessary to make two separate copies to be logged out by each Division instead of transferring documents. This procedure will help to keep the DCO/DCA in direct control of the chain-of-custody of the CBI.

PRE-INSPECTION ACTIVITIES

Prior to a Section 5 inspection, the inspectors should assemble and carefully review the information from PTSED concerning the company to be inspected. The information will include PTSED Section 5 Target Sheet (summary sheet of company) and attachments, including the PMN and TME forms and communications between the company and OPTS. Following are activities to be carried out by the inspectors.

Pre-Review Meetings

- Conduct pre-review meetings upon receipt of all target information from PTSED. Participants in the meeting should include inspectors, DCO/DCA, attorneys, secretaries who will type CBI, and all other persons who will review or receive CBI. The meeting should include discussions of the individual responsibilities of persons involved in the Section 5 Program, and of the following topics as they relate to CBI:

  - overall background and proposed objectives of the program;
  - number of inspections that will be performed;
  - who will perform which inspections;
  - who will need a copy of which document(s);
  - types of CBI documents that will be generated from the reviews;
  - types of information (especially CBI) that will be taken on the inspection;
  - typing load and typing system for CBI;
  - refresher CBI briefing by DCO/DCA; and
  - schedule for similar review meetings.

Review in CBI Room

- Request access to the CBI information from the DCO/DCA. Be sure to sign the document cover sheet of each document reviewed. Because of the sensitivity of the PMN information, the information should be reviewed in the DCO room or a room assigned for CBI reviews. Bring necessary regulations, guidances, and notepads for the review.

Signout of CBI Documents

- When it is impractical for review of the information in the DCO room, the documents may need to be logged out. Persons without approved storage must return the information to the DCO by close of business each day. Persons with approved storage can log information out overnight.

  In either situation, the following supplemental procedures and precautions should be followed:

  - Sign cover sheet and the DCO/DCA log out/sign out sheet. (This log sheet is maintained on file until the document is returned.)

  - Obtain a current list of authorized persons from the DCO to ensure that CBI data is shown only to other authorized personnel.

  - When the Section 5 information is logged out overnight, ensure that the DCO/DCA has the combination to the file in which the information will be secured. If that information will be filed in an approved storage where more than one other person has the combination or where other categories of CBI is filed, some type of identification should be present on the folder or envelope to flag the contents. This identification should help to avoid unnecessary handling of Section 5 information by authorized persons without a specific need to know.

  - Keep document(s) under constant surveillance so that direct security control can be exercised over the document when it is out of the file.

  - Lock the document in the approved storage area when it is not actually being reviewed.

  - Discuss CBI only with or in the presence of authorized persons.

  - Discuss PMN information with an authorized person only if there is an absolute need to know.

Review of CBI by Others

- After logging out a document from the DCO/DCA, ensure that all other persons reviewing it are identified on the cover sheet:

  - Ensure that all other persons who review the document, sign the cover sheet of each document reviewed. Coordinate group reviews with other persons involved with the inspection so that a minimum number of separate reviews is needed and fewer CBI notes are generated.

- Do not allow other persons to leave the room with the CBI document unless absolutely necessary. If the person must take it:

- Have that person sign a loan receipt which constitutes a record that the document is temporarily the responsibility of another person. (Even if a person will not keep the document overnight, a loan receipt must be signed when the document will be out of the direct surveillance of the person who logged it out.)

- Give a copy of the loan receipt to the DCO.

- Be sure that that the person is familiar with the supplemental review procedures under Section 5.

• Provide the DCO with all generated CBI notes to be stamped and logged into the system.

Discussion of CBI on the Telephone

A blanket waiver has been approved to allow discussions of Section 5 CBI by telephone. A copy is attached as Appendix 2-A. Although this waiver has been granted, certain steps must be followed for discusssions between EPA personnel:

• Identify at the beginning of the conversation that information about to be discussed is CBI. This will allow the other party to properly document the conversation.

• Maintain a log of all telephone conversations containing CBI.

Additional information for CBI telephone discussions is outlined below under NOTIFICATION OF COMPANY.

Travel With CBI

Decide if confidential information needs to be taken on the inspection. As a security measure, the inspector should take the minimum amount of CBI on travel. The Section 5 Target Sheet is designed to give the inspector all the summary information that may be needed on a company. If additional CBI information such as a test marketing exemption application will be needed during the inspection, it is suggested that the inspector request that the company make such information available. (See below -- NOTIFICATION OF COMPANY.) Before leaving on an inspection return confidential Section 5 document(s) that have been logged out and will not be taken on the inspection to the DCO before leaving.

If the inspector needs to take CBI on an inspection, adhere to the following procedures:

• Do not pack CBI in luggage that will be checked in at airport, train station, etc.

• Do not leave information in the briefcase or envelope unattended in the

hotel room. Information can be secured in a locked briefcase, in the trunk of a car. However, hotel safes are preferred for overnight storage.

- Do not carry CBI in a clearly marked "CBI" envelope in the event that the briefcase is opened and the envelope is exposed. Briefcases containing CBI can be carried into a restaurant. Do not, however, review or discuss the CBI in a public place. Information can be reviewed in the privacy of a hotel room when necessary.

Documents and Equipment

Assemble other appropriate CBI related forms and materials for the inspection, including:

- inspection credentials
- letter of authorization to access CBI
- TSCA Inspection Confidentiality Notice
- chain of custody records
- loose leaf note pad specifically for CBI notes
- envelopes addressed to OCO (registered return receipt card should be attached)
- Declaration of Confidential Business Information form
- briefcase with lock
- copy of security procedures as reference
- other forms as outlined in the TSCA Inspection Base Manual
- CBI stamp and ink pad (if available)

NOTIFICATION OF COMPANY

In general, the inspector will telephone the company in advance of the inspection. Contact should be made with the technical contact whose name appears on the Target Sheet to obtain information on where to conduct the inspection and appropriate personnel with whom to meet. An appointment should be arranged to ensure that the appropriate officials and records will be available at the time of the inspection. (See Interim Inspection Guidelines "Notification of Company" for more details.)

A blanket waiver has been granted to the regions so that, when necessary, CBI can be discussed with company officials as well as notice managers in OPTS headquarters. The following procedure should be followed when notifying the technical contact.

- Immediately upon phoning the technical contact, request permission to discuss CBI over the telephone.

- Give PMN number and date of submittal and/or the generic chemical name if PMN number is not familiar to the technical contact.

- The inspector should also ask the company representative, at this time, to make available during the inspection copies of the CBI documents submitted to EPA under the Section 5 Program which are the subject of the inspection. This procedure is a security measure which will limit the amount of CBI information which inspectors will need to carry.

- Ask if they want to claim any new information they have provided during the discussion as confidential.

- Fill out telephone log of the conversation. (This log is considered confidential.)

If the technical contact does not grant permission to discuss CBI over the telephone, explain why it is necessary to do so, making the following points:

- Inspection needs to be scheduled;
- Documents claimed CBI by the firm could be made available at the inspection site to avoid the need for EPA to travel with such information;
- Ensure that the location of the site to be inspected maintains the needed records or that appropriate records are transferred to the inspection site; and
- Ensure that a company official authorized to make confidentiality claims is available during the inspection.

If after explanation of need to discuss CBI, request is still not granted, the inspector should notify their Compliance Monitoring Coordinator in Headquarters, Compliance Monitoring Branch. (The inspector may have to submit questions in writing.)

ENTRY

The inspector should, in addition to other required inspection procedures, remember to:

- Have letter of authorization to access CBI readily available. (Letter should not be copied or leave the sight of the inspector.)

OPENING CONFERENCE

The inspector should clearly explain how EPA handles and documents information claimed CBI (A handout is attached for your use in Appendix 2-8). It is to the company's advantage to clearly and directly make confidentiality claims during the inspection so that those notes/documents can be written directly in CBI note books and placed in designated envelopes. Otherwise, the company has seven days after the inspection within which to make the claim. (This process will also make the closing conference and declaration of confidentiality process go smoothly, effectively and more securely.)

The official at this point also has the opportunity to withdraw any previous claims of confidentiality for information that has already been submitted to EPA. The company must submit a letter, waiving confidentiality claim, to the OPTS DCO in EPA for each document which no longer requires CBI treatment.

INSPECTION ACTIVITIES

During the examination of records, inspectors may view or copy documents that are considered confidential by the company. It is recommended that such documents be avoided unless they are essential to the documentation of violations. The inspector should:

- Clearly mark or stamp immediately each document claimed CBI during the inspection. Place documents inside an envelope also marked "confidential business information to be opened by addressee only." This envelope should be placed inside a plain envelope and mailed immediately by registered mail to the Document Control Officer in the regional office after the inspection when hand delivery is not possible.

- Information claimed or suspected to be claimed confidential (either orally or copied) obtained from facility records, should be referenced in a non-confidential statement in the field notebook and the information should be placed on separate sheets of paper that are then treated as CBI documents. Photocopied documents should be referenced in the same manner.

- To avoid difficulties arising from confidentiality claims surrounding photographs, it is recommended that all unnecessary background be shielded when photographs are taken, or the subject may be moved to another area. It is recommended that instant cameras which do not produce negatives be used.

CLOSING CONFERENCE

The inspector must, in addition to other required inspection procedures:

- Review the company documents and samples obtained during the inspection and list them on the "Receipt for Samples and Documents." Reference listed documents in a non-confidential statement. Review this list carefully with the company representative.

- Prepare a complete list of all items declared CBI on the Declaration of TSCA CBI form. Facility officials must review and make any further entries on the Declaration form.

- Mail CBI documents by registered mail from a post office immediately to the DCO when hand delivery is not possible.

INSPECTION REPORT

The inspector should coordinate with the DCO/DCA to be sure uniform typing procedures for CBI are followed and proper documentation of generated CBI reports are logged into the system.

MISCELLANEOUS REMINDERS

- No private contractor assistance is available under the Section 5 Inspection Program.
- Only DCOs/DCAs can make copies of CBI. However, the regional DCO is not to duplicate Section 5 CBI for distribution to another region. Contact the PTSED HQ in cases when Section CBI needs to be sent to additional regions.
- Inspectors must contact the HQ Compliance Monitoring Coordinator if they want to challenge a company's confidentiality claims. Declassification under Section 5 has not been redelagated to the regional counsel, therefore coordination must be made through HQ.
- Ask the DCO/DCA for any further information on CBI procedures. Violators of the security procedures by wrongful disclosure of CBI are subject to criminal penalty under TSCA Section 14(d) 15 U.S.C. Section 2613(d).

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUL 20 1981

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Authorization Request for Communication of TSCA Section 5 Confidential Business Information over the Telephone

TO: Ed Cull, Chief
Information Services Branch
Management Division

FROM: John S. Seitz, Chief
Compliance Monitoring Branch
Pesticides and Toxic Substances Enforcement Division

The majority of information submitted to the agency under Section 5, including Premanufacture Notices (PMN) and Test Marketing Exemption (TME) has been claimed Confidential Business Information (CBI). As such, this is the first TSCA enforcement program which will require the handling of large volumes of CBI.

PTSED is currently coordinating with OPTS to target the first group of companies for inspection under the Section 5 inspection program. These target inspection packages will be transmitted to the regions for review, coordination and implementation. Prior to each inspection, the region will need to contact the facility to ensure that appropriate officials and records will be available at the designated site. Also, the regions on occassion will need to contact HQ to gather additional information or to ask questions.

In both instances, the authorization to discuss CBI over the telephone would facilitate coordination efforts and expedite the transmitting of facts and information among authorized agency personnel and company personnel submitting the information.

The communication would involve:

Region to Region
Region to OPTS
OPTS to Region
PTSED to Region
Region to PTSED
PTSED/Region to Company

Upon approval of the authorization, the following procedure would be followed:

EPA employees authorized for access may, when necessary, discuss TSCA Confidential Business Information related to this Section 5 inspection program over the telephone with other authorized EPA employees or the representative of the firm who submitted the information. Any such information discussed would first be specifically identified as TSCA Confidential Business Information during the conversation.

E. Cull 7/22/81
Approved / / date

Disapproved date

Fact Sheet
TSCA Inspection Confidentiality

Right to Make Confidential Business Information Claims

Section 14 of the Toxic Substances Control Act (15 USC Sec. 2613) permits any manufacturer, processors, or distributor in commerce of chemical substances to claim as confidential business information (CBI) any information submitted under the Act to the U.S. Environmental Protection Agency (EPA). EPA regulations at 40 CFR Part 2 require that businesses be notified of this right when EPA requests or demands information which might be entitled to confidential treatment; the regulations also detail the notice and hearing procedures to be followed if a public request is made for such information.

Section 14 and the regulations are designed to protect confidential business information from unauthorized disclosure. Confidential business information includes information considered to be trade secrets (including chemical identity, process, formulation, or production data) that could damage a company's competitive position if it became publicly known.

Information collected during an inspection would be made available in response to a Freedom of Information Act (FOIA) request unless the information were determined to be exempt from release under strict FOIA criteria. However, if the data has been claimed confidential business information by the company, EPA would follow certain procedural steps prior to release of the information and the data would not be released at all if it was determined to be entitled to confidential treatment.

TSCA Inspection Confidentiality Notice

The TSCA Inspection Confidentiality Notice is the company's official notification of the right to make confidentiality claims for material collected during a TSCA inspection. It lists four criteria which must be met by any information the company claims confidential. The Notice should be signed by the facility owner or agent in charge at the time of the inspection to acknowledge receipt.

If no facility official is present at the inspection site who is authorized to make CBI claims, the Notice and accompanying forms (see below) will be sent within two days of the inspection to the Chief Executive Officer of the firm and another company official, if designated. In such instances, CBI claims can be made by the company within seven days of receipt of the Notice.

How CBI Claims Are Made

Information is officially claimed CBI at the close of the inspection. However, it is strongly suggested that, when available on-site, a company official authorized to make CBI claims accompany the inspector during the inspection to facilitate designation of confidential business data while the inspection is in progress; this official can also help the inspector avoid copying confidential information not necessary to the purpose of the inspection.

At the end of the inspection, the inspector will hold a closing conference with facility officials. At this time, all documents, photographs, or physical samples taken during the inspection will be listed in detail on a Receipt for Documents and Samples.

The authorized company official should carefully review this list and decide which of the items should receive confidential treatment. Each item to be claimed confidential must meet all of the following criteria:

- The company has taken measures to protect the confidentiality of the information and it intends to continue to take such measures;
- The information is not, and has not been reasonably obtainable without the company's consent by other persons (other than governmental bodies) by use of legitimate means (other than discovery based on a showing of special need in a judicial or quasi-judicial proceeding);
- The information is not publicly available elsewhere; and
- Disclosure of the information would cause substantial harm to the company's competitive position.

Such items should be listed on the Declaration of TSCA Confidential Business Information form and the facility official must sign the form certifying that each item meets the criteria.

If no authorized facility official is on-site during the inspection, the Notice, Receipt for Documents and Samples, and Declaration form will be sent by registered mail to the Chief Executive Officer (and other designated person) within two days of the inspection. CBI claims in such cases may be made by the company within seven days by registered mail.

Security Measures for Handling CBI

Any information claimed CBI is handled under stringent security procedures. The document control system for CBI includes logging of all information, secure physical storage of the material, and access only by authorized personnel who have undergone a security clearance procedure and have a need to know. Personnel given access to CBI are strictly accountable for any CBI in their possession. These procedures are detailed in the TSCA-CBI Security Manual. TSCA Section 14 provides a criminal penalty for wrongful disclosure of confidential business information, whether such disclosure is made by an EPA employee or employee under contract with EPA.

Data not immediately claimed confidential business information because no authorized person is available on-site during the inspection will be kept in locked storage and otherwise accorded confidential treatment. However, the material will not be entered into the document control system until an actual CBI claim is made (within the seven-day period).

Release of CBI

When EPA desires or needs to determine whether information claimed confidential is entitled to confidential treatment (such as if there is an FOIA request), will furnish the affected business an opportunity to substantiate its claim dance with 40 CFR § 2. If a determination is made that information claimed tial under TSCA is not entitled to confidential treatment, EPA will notify affected business that it will release the information on the thirty-first day after its receipt of the notice, unless the business first notifies EPA office that it has commenced a lawsuit to prevent disclosure of the informa

APPENDIX 3

SAMPLING PROCEDURES

SAMPLING PROCEDURES

The inspector does not routinely take samples during TSCA inspections. However, in some special situations, obtaining samples may be the only way to determine if a facility is in compliance. The inspector should have a clear defined reason for obtaining the sample and discuss it with her/his supervisor to determine if the sample should be taken.

If the inspector and her/his supervisor have determined that obtaining a sample of a chemical or mixture in question is necessary, then the inspector should develop a sampling plan to ensure that the sample is collected and analyzed in such a manner that it can be used as evidence in an enforcement action.

Sampling Plan

The sampling plan should contain the elements discussed below.

- *Represesentative sample* - The inspector must ensure that the sample collected is representative of the chemical substance or mixture. Therefore, the inspector must select the appropriate site (e.g., storage container, process tank, etc.) and the appropriate number of samples. The inspector should note the site selected for sampling and provide additional documentation such as photographs or drawings of the sampling site.

- *Proper equipment and procedures* - The inspector should use the appropriate equipment and sample container. Various substances and sample types require different types of equipment and sample containers, so the inspector should check with the laboratory which will be performing the analyses to determine what is necessary. When preparing and using the equipment, the inspector should be extremely careful not to contaminate such equipment. All steps which were followed in preparing the equipment and collecting the sample should be carefully noted in the inspector's notebook.

- *Sufficient sample volume* - The inspector should also check with the laboratory which will be performing the analyses to determine the amount of volume needed. The amount should be sufficient to perform all required analyses plus an additional amount for quality control and repeat analyses. Specific volumes vary with the type of sample and chemical substance or mixture to be analyzed. If the company wants a duplicate sample, the inspector should collect and handle the duplicate sample using the exact procedures used for collecting the official EPA sample.

- *Sample Identification* - The following information should be recorded in the inspector's notebook:

  Sample number
  Name of sampler
  Time and date of collection
  Collection method
  Description of sample, including color, texture, viscosity, etc.
  Analyses to be performed
  Duplicate sample and to whom it was provided.

A label should be affixed to the sample container with the following information:

Sample number
Time and date of collection
Inspector's (i.e., sampler's) initials
Sub-sample number if necessary.

After the sample has been collected and labeled, its container should be placed inside a plastic bag on which the inspector has written her/his initials, and the date. The bag should then be turned inside out to prevent any means of tampering with the contents. The bag is then taped in a secure manner with the Official Sample Seal (EPA Form 7500-2). The seal is completed by:

(1) Inserting the sample number;
(2) Inserting the date;
(3) Printing the locator of the collector's station;
(4) Printing the name and title of the person sealing the sample;
(5) Signature of the person sealing the sample; and
(6) If the company declares the sample as CBI, the seal should be marked "Confidential Business Information."

The sample container and wrapper should be sealed so that it may not be opened at any point without breaking the seal and/or original package. One seal should be used for one sample. If the seal is broken for any reason, the person breaking the seal should initial the seal and write on it the date it was broken, mount it on a piece of paper, and submit it with the sample records to provide a continuous history of the sample. The sample should then be resealed with a new seal.

- *Chain-of-Custody* - The inspector should complete the Chain-of-Custody record. The Chain-of-Custody record initiates the process that controls and records access to the sample once it has left the inspector's possession. The sample number relates the sample to the record that accompanies the sample through the handling and analyses stages. Chain-of-Custody is discussed in more detail in the next section.

- *Sample Handling* - Samples must be handled, stored, and shipped properly to avoid loss, contamination, danger to handlers, and tampering. Requirements for handling specific chemical or mixture samples include the following:

  Samples should be handled according to appropriate safety procedures for the specific chemical or mixture to be sampled.

  Provisions for sample preservation (refrigeration, chemical preservatives, proper packaging, etc.) should be planned in advance of the actual sampling so the inspector has the appropriate equipment and sample container available.

  The recommended holding times for specific samples should be determined and care taken to avoid delays in sample transit.

Highly toxic materials require special handling, and such arrangements should be made in advance of the actual sampling.

Security provisions should be appropriate for protecting the samples.

Samples should be delivered directly to the laboratory by the inspector whenever possible. If this is not possible, the inspector should ship the sample by the most economical means considering the need for rapid handling (i.e., the recommended holding time). All shipments must be in accordance with the US Postal Service and Department of Transportation regulations.

Handling and shipping procedures followed should be recorded to document the integrity of the sample. Copies of all shipping and handling documents (e.g., bills of lading, return receipts, etc.) should be obtained for inclusion in the inspection report as part of the sample documentation.

The inspector should ensure that all sampling activities have been clearly and adequately documented in her/his notebook. All documents relating to the sample (i.e., Seals, Chain-of-Custody record, drawings, photographs, etc.) should be clearly marked with the sample number.

Chain-of-Custody

In any activity that may be used to support litigation, EPA must be able to prove that any analytical data offered as evidence in a court accurately represent the conditions at the time of sample collection. It must be demonstrated that the samples collected were not tempered with or contaminated during collection, transit, storage, or analysis. An accurate written record must be maintained to trace the possession of each sample from the moment of collection through analyses to its introduction as evidence.

The procedures which are used to ensure the integrity of the sample are called chain-of-custody procedures. The chain-of-custody procedures begin with the identification of the sample and continue through the laboratory analyses. These procedures include the steps described below.

1. *Establishing Custody* - Sample custody is initialed at the time of collection by sealing the sample with the EPA Official Seal.

2. *Preparing Sample Documentation* - A major aspect of the chain-of-custody is the preparation and maintenance of written information describing the collection, shipment, and storage of the sample. Preparation of this documentation is the responsibility of the inspector, any other person involved in the transit of the sample, and the laboratory personnel. This documentation will serve as a clear, detailed account indicating that the sample remained intact from collection through laboratory analyses to introduction as evidence. The documentation includes the inspector's field notebook, the EPA Official Seal, and the Chain-of-Custody Record.

3. *Coordinating Sample and Documentation* - The inspector must ensure that the sample number, date, and inspector's initials appear on all documentation to ensure that the relationship between the sample and the documentation is clear, complete, and accurate. If the company has declared the sample as CBI, the Seal, Chain-of-Custody record, and

any analytical reports should be clearly marked as "Confidential Business Information" and treated as such. Also, the inspector should note that a sample claimed as CBI should only be delivered or sent to a laboratory individual who has been cleared for access to confidential information. Each person who handles the sample and analytical report must also be cleared for CBI access.

4. *Ensuring Custody During Transit* - Shipment of samples to the laboratory will involve the following procedures:

   - Samples must be accompanied by the Chain-of-Custody Record. Copies of documents should be retained by the originator.

   - If sent by common carrier, a bill of lading should be obtained.

   - All receipts and shipping documents should be included in the Chain-of-Custody documentation.

APPENDIX G

REGIONAL POLLUTION PREVENTION CONTACTS

Regional Pollution Prevention Contacts

Region I	
Mark Mahoney/Abby Swaine Pollution Prevention Program U.S. EPA Region I (PAS) John F. Kennedy Federal Building Boston, MA 02203 Mahoney: Telephone: 617-565-1155 FTS: 835-1155 FAX: 617-565-3346 Swain: Telephone: 617-565-4523 FTS: 835-4523 FAX: 617-565-3346	Marv Rosenstein 33/50 Program Chief, Pesticides and Toxic Substances Branch U.S. EPA Region I (APT) John F. Kennedy Federal Building Boston, MA 02203 Telephone: 617-565-3273 FTS: 835-3273 FAX: 617-565-4939
Region II	
Janet Sapadin Policy and Program Integration Branch Office of Policy Aid Management U.S. EPA Region II 26 Federal Plaza New York, NY 10278 Telephone: 212-264-1925 FTS: 264-1925 FAX: 212-264-9695	Barbara Metzger 33/50 Program Director, Environmental Services Division U.S. EPA Region II (MS 100) 2890 Woodgridge Avenue, Building 10 Edison, NJ 08837-3679 Telephone: 908-340-6754 FTS: 340-6754 FAX: 908-342-4381
Region III	
Roy Denmark Pollution Prevention Coordinator Environmental Assessment Branch Environmental Services Division U.S. EPA Region III 841 Chestnut Building (3ES43) Philadelphia, PA 19107 Telephone: 215-597-8327 FTS: 597-8327 FAX: 215-597-7906	Bill Reilly 33/50 Program Special Assistant Air, Radiation and Toxics Division U.S. EPA Region III (MS 3ATOO) 841 Chestnut Building Philadelphia, PA 19107 Telephone: 215-597-9302 FTS: 597-9302 FAX: 215-597-7906

Region IV	
Carol Monell Chief, Pollution Prevention Unit Policy, Planning, and Evaluation Branch Office of Policy and Management U.S. EPA Region IV 345 Courtland Street, NE Atlanta, GA 30365 Telephone: 404-347-7109 FTS: 257-7109 FAX: 404-347-1043	Jon D. Johnston 33/50 Program Chief, Title II and Toxics Section U.S. EPA Region IV 345 Courtland Street, NE Atlanta, GA 30365 Telephone: 404-347-1033 FTS: 257-1033 FAX: 404-347-1681
Region V	
Louis Blume Pollution Prevention Coordinator Planning and Budgeting Branch Policy and Management Division U.S. EPA Region V 77 West Jackson Blvd. Chicago, IL 60604-3590 Telephone: 312-353-4135 FTS: 353-2000 FAX: 312-886-5374	Dennis Wesolowski 33/50 Program Acting Chief, Asbestos Control Section Environmental Science Division U.S. EPA Region V (MS 5SPT) 230 S. Dearborn Street Chicago, IL 60604 Telephone: 312-886-6879 FTS: 886-6879 FAX: 312-886-2591
Region VI	
Laura Townsend Pollution Prevention Coordinator Office of Planning and Evaluation U.S. EPA Region VI 1445 Ross Avenue (6M-P) Dallas, TX 75270 Telephone: 214-655-6525 FTS: 255-6525 FAX: 214-655-2146	Lewis Robertson 33/50 Program U.S. EPA Region VI (MS 6T-P) 1445 Ross Avenue, Suite 1200 Dallas, TX 75202 Telephone: 214-655-7235 FTS: 255-7235 FAX: 214-655-2164

Region VII	
Alan Wehmeyer, Deputy Director Waste Management Division U.S. EPA Region VII 726 Minnesota Avenue Kansas City, KS 66101 Telephone: 913-551-7336 FTS: 276-7336 FAX: 913-551-7063	Carl Walter 33/50 Program Deputy Director, Air and Toxics Division U.S. EPA Region VII (MS ARIX) 726 Minnesota Avenue Kansas City, KS 66101 Telephone: 913-551-7020 FTS: 276-7020 FAX: 913-551-7063
Region VIII	
Don Patton, Chief Sharon Childs, Program Analyst Policy Office U.S. EPA Region VIII 999 18th Street, Suite 500 Denver, CO 80202-2405 Patton: Telephone: 303-293-1456 FTS: 330-1456 FAX: 303-293-1198 Childs: Telephone: 303-293-1454 FTS: 330-1454 FAX: 303-293-1198	Laura Lonowski 33/50 Program Toxic Release Inventory Program U.S. Region VIII (MS 8AT-TS) 999 18th Street, Suite 500 Denver, CO 80202-2405 Telephone: 303-293-1735 FTS: 330-1735 FAX: 303-293-1229
Region IX	
Jesse Baskir, Program Coordinator Alisa Green, Program Coordinator Pollution Prevention Program U.S. EPA Region IX 75 Hawthorne Street (H-1-B) San Francisco, CA 94105 Baskir: Telephone: 415-744-2189 FTS: 484-2189 FAX: 415-744-1796 Greene: Telephone: 415-744-2190 FTS: 484-2190 FAX: 415-744-1796	Mark Samolis 33/50 Program Environmental Scientist U.S. EPA Region IX (MS A-4) 75 Hawthorne Street San Francisco, CA 84105 Telephone: 415-744-1139 FTS: 484-1139 FAX: 415-744-1073

Region X	
Carolyn Gangmark Pollution Prevention Coordinator Policy, Planning, and Evaluation Branch U.S. EPA Region X 1200 Sixth Avenue (MD-142) Seattle, WA 98101 Telephone: 206-553-4072 FTS: 339-4072 FAX: 206-553-4957	Gil Haselberger 33/50 Program Chief, Toxic Substances Section U.S. EPA Region X (MS AT-083) 1200 Sixth Avenue Seattle, WA 98101 Telephone: 206-442-1094 FTS: 399-1094 FAX: 206-442-0110

APPENDIX 2

CHEMICALS ON REPORTING RULES (CORR) DATABASE

CHEMICALS ON REPORTING RULES DATABASE (CORR) - 06/30/90

Office of Toxic Substances (OTS)

Compiled by the
Existing Chemical Assessment Division
Chemical Screening Branch

The CORR database are lists of chemical substances, chemical categories, and mixtures that are or have been the subject of proposed or final OTS regulations.

Individual chemical substances that have a Chemical Abstracts Service (CAS) Registry Number are listed by CAS number in ascending order. Following the CAS number ordered list, is a list of Premanufacture Notice (PMN) substances listed in PMN number order. Following this PMN list, is an alphabetical list of categories, mixtures, and chemical substances with no assigned CAS number. Those category members that were individually listed in the Federal Register (FR) or in any subsequent question and answer document are included in the CAS number ordered list.

Each listed substance, mixture, and category is followed by one or more rule codes. For example:

- a = TSCA section 8(a) chemical-specific rules (final rule).
- c = TSCA section 8(c) requests for records and reports regarding significant adverse reactions.
- d = TSCA section 8(d) rules requiring the submission of unpublished health and safety studies (final rules).
- e = TSCA section 12(b) export notification rules (proposed and final rules).
- f = TSCA section 4(f) required actions.
- m = TSCA section 8(a) Comprehensive Assessment Information Rules (CAIR) (final rules).
- p = TSCA section 8(a) Preliminary Assessment Information Rules (PAIR) (final rules).
- r = Substances subject to reporting period terminations under model 8(d) rule.
- s = TSCA section 5 significant new use rules (SNURs) on new and existing chemicals (proposed and final rules).
- sr110 = List of hazardous substances under §104(i) of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or Superfund) as amended by SARA §110.
- sr313 = List of toxic chemicals under §313 of the Emergency Planning and Community Right-to-Know Act (EPCRA or SARA Title III).
- t = TSCA section 4 test rules and consent orders (proposed and final rules).
- x = TSCA section 6 risk management rules (proposed and final rules).

The rule codes are explained in the Index to the Rule Codes, which appears at the back of the CORR lists. The index provides: Federal Register (FR) citations, the Code of Federal Regulations (CFR) citation, and dates relevant to the rulemakings. The CORR database does not contain information on the number or content of Industry reports submitted in response to these rulemakings. This information is maintained by the OTS Information Management Division.

IMPORTANT NOTES: This document is intended to be an information resource. Since it may contain errors, omissions, etc.,.this document should not be used in lieu of FR documents or the CFR for purposes of compliance. For instance, CORR does not include many of the Inventory Update Rule substances. Please report any errors or omissions to Jerry Payer at (202) 382-3636.

Copies of CORR and the Index are available from the TSCA Hotline at (202) 554-1404 or you may request copies through the following address:

U. S. Environmental Protection Agency
OPTS/OTS/Environmental Assistance Division
Mail Code: TS-799
401 M Street, S.W.
Washington, DC 20460

PLEASE NOTE: You can also FAX your request for CORR or other TSCA publications by calling (202) 554 - 5603.

CHEMICAL ABSTRACT SERVICES (CAS) NUMBERS & CHEMICAL NAMES
LISTED BY CAS NUMBER

CAS NUMBER	CHEMICAL NAME	RULE CODE
)-00-0	Formaldehyde	sr110 f2 sr313
50-32-8	Benzo[a]pyrene	sr110
51-28-5	2,4-Dinitrophenol	sr110 sr313
51-75-2	Nitrogen mustard aka: Mechlorethamine	sr110 sr313
51-79-6	Urethane	s3 sr313
52-68-6	Trichlorfon	sr313
53-70-3	Dibenzo[a,h]anthracene	sr110
53-96-3	2-Acetylaminofluorene	sr313
54-11-5	Nicotine	t35*
55-18-5	N-Nitrosodiethylamine	sr31
55-21-0	Benzamide	sr313
-63-0	Nitroglycerin	sr313
56-23-5	Carbon tetrachloride	sr110 sr313
56-38-2	Parathion aka: DNTP	sr110 sr313
56-55-3	Benzo[a]anthracene	sr110
57-12-5	Cyanide	sr110 sr313
57-14-7	1,1-Dimethylhydrazine	sr313
57-56-7	Hydrazinecarboxamide	m1
57-57-8	beta-Propiolactone	sr313
57-74-9	Chlordane	sr313
58-89-9	Lindane	sr110 sr313

CHEMICAL ABSTRACT SERVICES (CAS) NUMBERS & CHEMICAL NAMES
LISTED BY CAS NUMBER

CAS NUMBER	CHEMICAL NAME	RULE CODE
59-50-7	p-Chloro-m-cresol	sr110
59-89-2	N-Nitrosomorpholine	sr313
60-09-3	4-Aminoazobenzene	sr313
60-11-7	4-Dimethylaminoazobenzene	sr313
60-34-4	Methylhydrazine	sr313
60-35-5	Acetamide aka: Ethanamide	m1 sr313
60-57-1	Dieldrin/aldrin	sr110
62-44-2	Phenacetin	t35*
62-53-3	Benzenamine aka: Aniline	d1 t42 sr110 sr313
62-55-5	Thioacetamide	sr313
62-56-6	Thiourea	sr313
62-73-7	Dichlorvos	sr313
62-74-8	Acetic acid, fluoro-, sodium salt	d16
62-75-9	N-Nitrosodimethylamine	sr110 sr313
63-25-2	Carbaryl aka: Sevin	sr110 sr313
64-67-5	Sulfuric acid, diethyl ester aka: Diethyl sulfate	p1 sr313
65-85-0	Benzoic acid	sr110
67-56-1	Methanol	sr110 sr313
67-63-0	2-Propanol aka: Isopropanol Isopropyl alcohol	t40 p15 d19 sr313 t52

CHEMICAL ABSTRACT SERVICES (CAS) NUMBERS & CHEMICAL NAMES
LISTED BY CAS NUMBER

CAS NUMBER	CHEMICAL NAME	RULE CODE
-64-1	Acetone	sr110 sr313
67-66-3	Methane, trichloro- aka: Chloroform	sr110* d20 sr313
67-72-1	Ethane, hexachloro-	sr110 p3 d3 r1 sr313
68-12-2	Dimethyl formamide aka: DMF Formamide, N,N-dimethyl-	p21 d25 sr110
68-76-8	Triaziquone	sr313
70-30-4	Hexachlorophene	t35*
71-36-3	n-Butyl alcohol	sr31
71-43-2	Benzene	sr110 sr313
-55-6	Ethane, 1,1,1-trichloro- aka: Methyl chloroform	sr110 p1 d1 t1 sr313
72-20-8	Endrin	t35
72-43-5	Methoxychlor	sr110 sr313
72-55-9	4,4'-DDE, DDT, DDD	sr110
72-57-1	2,7-Naphthalenedisulfonic acid, 3,3'-[(3,3'-dimethyl [1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[5-amino-4-hydroxy-tetrasodium salt aka: Trypan blue	t35* p1 d1
74-83-9	Methane, bromo- aka: Bromomethane Methyl bromide	p21 sr110 d20 sr313

CHEMICAL ABSTRACT SERVICES (CAS) NUMBERS & CHEMICAL NAMES LISTED BY CAS NUMBER

CAS NUMBER	CHEMICAL NAME	RULE CODE
74-85-1	Ethylene	sr313
74-87-3	Methane, chloro- aka: Methyl chloride	t35 sr110 t17 p1 d1 sr313 t50
74-88-4	Methyl iodide	sr313
74-90-8	Hydrogen cyanide aka: Hydrocyanic acid	p18 sr313
74-93-1	Methanethiol	t35 t50
74-95-3	Methane, dibromo- aka: Methylene bromide	t35 d20 sr313 t50
74-97-5	Methane, bromochloro-	sr110 d20
75-00-3	Ethane, chloro- aka: Ethyl chloride	p21 sr110 d20 sr313 t54
75-01-4	Vinyl chloride (monomer)	sr110 sr313
75-02-5	Ethene, fluoro- aka: Vinyl fluoride	t23 p3 d1 t52
75-04-7	Ethanamine	d20
75-05-8	Acetonitrile	p1 d1 sr313
75-07-0	Acetaldehyde	sr313
75-09-2	Methane, dichloro- aka: Methylene chloride	f4 sr110*

S NUMBER	CHEMICAL NAME	RULE CODE
		t21 p1 d1 sr313
75-12-7	Formamide	p1 d3
75-15-0	Carbon disulfide	sr110 sr313
75-21-8	Oxirane aka: Ethylene oxide	sr110 p1 d1 sr313
75-25-2	Methane, tribromo- aka: Bromoform	sr110 t35 d20 sr313
75-27-4	Methane, bromodichloro- aka: Dichlorobromomethane	sr110 d20 sr313
-29-6	Propane, 2-chloro-	d20
-34-3	Ethane, 1,1-dichloro-	sr110 t35 d20 t54
75-35-4	1,1,-Dichloroethylene aka: Vinylidene chloride 1,1-Dichloroethene	sr110 t20 sr313
75-37-6	Ethane, 1,1-difluoro-	p21 d25
75-38-7	Ethene, 1,1-difluoro- aka: Vinylidene fluoride	t23 p1 d1 t52
75-43-4	Methane, dichlorofluoro- aka: Dichloromonofluoromethane	p2 d2
75-44-5	Phosgene	sr t s

CHEMICAL ABSTRACT SERVICES (CAS) NUMBERS & CHEMICAL NAMES LISTED BY CAS NUMBER

CAS NUMBER	CHEMICAL NAME	RULE CODE
75-45-6	Chlorodifluoromethane	p21 d25 sr110
75-52-5	Methane, nitro-	p21 d25
75-55-8	Propyleneimine	sr313
75-56-9	Oxirane, methyl- aka: Propylene oxide	p1 d1 t5 sr313
75-63-8	Bromotrifluoromethane aka: Halon 1301	sr313#
75-65-0	tert-Butyl alcohol	sr313
75-68-3	Ethane, 1-chloro-1,1-difluoro-	p21 d25
75-69-4	Fluorotrichloromethane aka: Trichlorofluoromethane CFC-11	sr110 sr313#
75-70-7	Trichloromethanethiol	t35
75-71-8	Dichlorodifluoromethane aka: CFC-12	sr110 sr313#
75-86-5	Propanenitrile, 2-hydroxy-2-methyl-	d16
75-87-6	Chloral	t35*
75-88-7	Ethane, 2-chloro-1,1,1-trifluoro- aka: 2-Chloro-1,1,1-trifluoroethane HCFC-133a	s55 d28
76-01-7	Pentachloroethane	t35 s4
76-13-1	Ethane, 1,1,2-trichloro-1,2,2-trifluoro- aka: Freon 113 Chlorinated fluorocarbon	d25 sr110 sr313
76-14-2	Dichlorotetrafluoroethane aka: CFC-114	sr110

CHEMICAL ABSTRACT SERVICES (CAS) NUMBERS & CHEMICAL NAMES
LISTED BY CAS NUMBER

AS NUMBER	CHEMICAL NAME	RULE CODE
5-15-3	(Mono)chloropentafluoroethane aka: CFC-115	sr313#
76-44-8	Heptachlor (and for SARA section 110 Heptachlor/ Heptachlor epoxide)	sr110* sr313
77-47-4	1,3-Cyclopentadiene, 1,2,3,4,5,5-hexa-chloro-	sr110 r1* p1 d1 sr313
77-58-7	Dibutyltin dilaurate aka: Stannane, dibutylbis[(1-oxododecyl)oxy]-	p7 d2
77-78-1	Sulfuric acid, dimethyl ester	p1. sr313
77-83-8	Oxiranecarboxylic acid, 3-methyl-3-phenyl-,ethyl ester	p1 d1
78-30-8	Phosphoric acid, tris(2-methylphenyl) ester	p1 d1
78-32-0	Phosphoric acid, tris(4-methylphenyl) ester	p1 d1
78-33-1	Phenol, 4-(1,1-dimethylethyl)-, phosphate (3:1)	p1 d1
78-40-0	Phosphoric acid, triethyl ester	c2
78-42-2	Phosphoric acid, tris(2-ethylhexyl) ester	c2
78-51-3	Ethanol, 2-butoxy-, phosphate (3:1)	c2
78-59-1	2-Cyclohexen-1-one, 3,5,5-trimethyl- aka: Isophorone	sr110 p1 d1
78-83-1	1-Propanol, 2-methyl- aka: Isobutyl alcohol	d16
78-84-2	Isobutyraldehyde	sr313
78-87-5	Propane, 1,2-dichloro-	sr110 p1 d1 t11 sr313

CHEMICAL ABSTRACT SERVICES (CAS) NUMBERS & CHEMICAL NAMES
LISTED BY CAS NUMBER

CAS NUMBER	CHEMICAL NAME	RULE CODE
		t50
78-88-6	1-Propene, 2,3-dichloro-	sr313** d20
78-92-2	sec-Butyl alcohol	sr313
78-93-3	2-Butanone aka: Methyl ethyl ketone	sr110 p1 d1 sr313
78-97-7	Propanenitrile, 2-hydroxy-	d20
78-99-9	Propane, 1,1-dichloro-	d16
79-00-5	Ethane, 1,1,2-trichloro-	p21 sr110 d20 sr313
79-01-6	Trichloroethylene aka: Trichloroethene	sr110 sr313
79-06-1	2-Propenamide aka: Acrylamide	p1 d1 sr313
79-10-7	Acrylic acid	sr313
79-11-8	Chloroacetic acid	sr313
79-19-6	Thiosemicarbazide	t35*
79-21-0	Peracetic acid	sr313
79-22-1	Methyl chlorocarbonate	t35*
79-24-3	Ethane, nitro-	p21 d25
79-27-6	Ethane, 1,1,2,2-tetrabromo-	m1
79-34-5	Ethane, 1,1,2,2-tetrachloro-	sr110 d20 sr313 t54
79-44-7	Dimethylcarbamyl chloride	sr313

CHEMICAL ABSTRACT SERVICES (CAS) NUMBERS & CHEMICAL NAMES LISTED BY CAS NUMBER

CAS NUMBER	CHEMICAL NAME	RULE CODE
79-46-9	2-Nitropropane	sr313
79-94-7	Tetrabromobisphenol A aka: Phenol, 4,4'-(1-methylethylidene)bis [2,6-dibromo-	t31 t33 p12 d12
79-95-8	Tetrachlorobisphenol A	t31
80-05-7	Phenol, 4,4'-(1-methylethylidene)bis- aka: Bisphenol A	p6 d8 t12 sr313
80-15-9	Hydroperoxide, 1-methyl-1-phenylethyl-	d16 sr313
80-62-6	2-Propenoic acid, 2-methyl-, methyl ester aka: Methyl methacrylate	d25 sr110 p1 sr31
81-07-2	Saccharin (manufacturing)	t35* sr313
1-21-0	2,4-Methano-2H-indeno[1,2-b:5,6-b']bisoxirene, octahydro-	p1
81-88-9	C.I. Food Red 15s	sr313
82-28-0	1-Amino-2-methylanthraquinone	sr313
82-68-8	Quintozene aka: Pentachloronitrobenzene	sr313
83-32-9	Acenaphthene	sr
84-61-7	1,2-Benzenedicarboxylic acid, dicyclohexyl ester	r
84-64-0	1,2-Benzenedicarboxylic acid, butyl cyclohexyl ester	
84-65-1	Anthraquinone aka: 9,10-Anthracenedione	

CHEMICAL ABSTRACT SERVICES (CAS) NUMBERS & CHEMICAL NAMES LISTED BY CAS NUMBER

CAS NUMBER	CHEMICAL NAME	RULE CODE
84-66-2	1,2-Benzenedicarboxylic acid, diethyl ester aka: Diethyl phthalate	sr110 p1 d1 sr313
84-69-5	1,2-Benzenedicarboxylic acid, bis(2-methylpropyl) ester	d1
84-74-2	1,2-Benzenedicarboxylic acid, dibutyl ester aka: Dibutyl phthalate Di-n-butyl phthalate	t44 sr110 t35** p1 d1 sr313
84-75-3	1,2-Benzenedicarboxylic acid, dihexyl ester aka: Di-n-hexyl phthalate	t44 d1
84-76-4	1,2-Benzenedicarboxylic acid, dinonyl ester	d1
84-78-6	1,2-Benzenedicarboxylic acid, butyl octyl ester	d1
85-01-8	Phenathrene	m1 sr110
85-22-3	Benzene, pentabromoethyl-	s50 t30 p9 d10
85-44-9	Phthalic anhydride	t1[illegible] sr[illegible]
85-68-7	1,2-Benzenedicarboxylic acid, butyl phenylmethyl ester aka: Benzyl butyl phthalate BBP Butylbenzyl phthalate	sr[illegible] t[illegible] p[illegible] d[illegible]
85-69-8	1,2-Benzenedicarboxylic acid, butyl 2-ethylhexyl ester	
85-70-1	1,2-Benzenedicarboxylic acid, 2-butoxy-2-oxyethyl butyl ester	
86-30-6	N-Nitrosodiphenylamine	
86-73-7	Fluorene	

CHEMICAL ABSTRACT SERVICES (CAS) NUMBERS & CHEMICAL NAMES
LISTED BY CAS NUMBER

CAS NUMBER	CHEMICAL NAME	RULE CODE
86-74-8	9H-Carbazole	d16
87-10-5	3,4,5-Tribromosalicylanilide	t31
87-61-6	Benzene, 1,2,3-trichloro-	p1 d1 t8
87-62-7	2,6-Xylidine	sr313
87-63-8	Benzenamine, 2-chloro-6-methyl-	s49
87-65-0	2,6-Dichlorophenol	t31
87-68-3	1,3-Butadiene, 1,1,2,3,4,4-hexachloro-	sr110 p1 d1 sr313
87-86-5	Pentachlorophenol aka: PCP	sr1 sr3
88-04-0	Phenol, 4-chloro-3,5-dimethyl- aka: p-Chloro-m-xylenol	p21 d25
88-06-2	2,4,6-Trichlorophenol	sr110 sr313
88-74-4	Benzenamine, 2-nitro- aka: 2-Nitroaniline o-Nitroaniline	sr110 t42 p1 d1
88-75-5	2-Nitrophenol	sr110 sr313
88-89-1	Picric acid	sr313
89-13-4	1,2-Benzenedicarboxylic acid, 2-ethylhexyl-8-methylnonyl ester	d1
89-63-4	Benzenamine, 4-chloro-2-nitro-	p1 d1
90-04-0	o-Anisidine	sr313
90-13-1	Naphthalene, 1-chloro-	r2 a5 p1

CHEMICAL ABSTRACT SERVICES (CAS) NUMBERS & CHEMICAL NAMES LISTED BY CAS NUMBER

CAS NUMBER	CHEMICAL NAME	RULE CODE
		d1
90-42-6	[1,1'-Bicyclohexyl]-2-one	d20
90-43-7	2-Phenylphenol	sr313
90-94-8	Michler's ketone	sr313
91-08-7	Benzene, 1,3-diisocyanato-2-methyl- aka: Toluene-2,6-diisocyanate	m1 c2 d20 sr313
91-20-3	Naphthalene	sr110 d20 sr313
91-22-5	Quinoline	sr313
91-57-6	2-Methylnaphthalene	sr110
91-58-7	Naphthalene, 2-chloro-	a5 d1
91-59-8	beta-Naphthylamine	sr313
91-92-9	2-Naphthalenecarboxamide, N,N'-(3,3'-dimethoxy [1,1'-biphenyl]-4,4'-diyl)bis[3-hydroxy-	d1
91-94-1	3,3'-Dichlorobenzidine	sr110 sr313
91-96-3	Butanamide, N,N'-[3,3'-dimethyl(1,1'-biphenyl)-4,4' -diyl]bis[3-oxo-	d1
91-97-4	1,1'-Biphenyl, 4,4'-diisocyanato-3,3'-dimethyl-	c2 d20
92-49-9	Benzenamine, N-(2-chloroethyl)-N-ethyl-	p1
92-52-4	1,1-Biphenyl	p1 d3 t4 sr313 t50
92-66-0	1,1'-Biphenyl, 4-bromo- aka: 4-Bromobiphenyl	s5
92-67-1	4-Aminobiphenyl	sr313

CHEMICAL ABSTRACT SERVICES (CAS) NUMBERS & CHEMICAL NAMES
LISTED BY CAS NUMBER

CAS NUMBER	CHEMICAL NAME	RULE CODE
92-69-3	[1,1'-Biphenyl]-4-ol	d20
92-84-2	10-H-Phenothiazine	d20
92-86-4	1,1'-Biphenyl, 4,4'-dibromo- aka: 4,4'-Dibromobiphenyl	s5
92-87-5	[1,1'-Biphenyl]-4-4'-diamine aka: Benzidine	sr110 d20 sr313
92-93-3	4-Nitrobiphenyl	sr313
93-00-5	2-Naphthalene sulfonic acid, 6-amino- aka: Broenner's acid	m1
93-72-1	2,4,5-TP acid aka: Silvex	sr110
93-76-5	2,4,5-T	sr11
94-36-0	Benzoyl peroxide	sr31
94-58-6	Dihydrosafrole	t35 t50
94-59-7	Safrole	sr313
94-75-7	2,4-Dichlorophenoxyacetic acid aka: 2,4-D (sr110 includes salts and esters).	sr110 t35 sr313 t31*
94-82-6	2,4-Dichlorophenoxybutyric acid	t31*
95-14-7	1H-Benzotriazole aka: 1,2,3-Benzotriazole	p21 d25
95-39-6	2-Propenoic acid, bicyclo[2.2.1]hept-5-en-2-ylmethyl ester	p1
95-47-6	Benzene, 1,2-dimethyl- aka: o-Xylene	p1 d1 sr313
95-48-7	Phenol, 2-methyl- aka: o-Cresol	sr110 p1 d1 t9

CAS NUMBER	CHEMICAL NAME	RULE CODE
		sr313
95-49-8	Benzene, 1-chloro-2-methyl-	p1 d3
95-50-1	Benzene, 1,2-dichloro-	sr110 t35 p1 d1 t8 t10 sr313 t50
95-51-2	Benzenamine, 2-chloro- aka: 2-Chloroaniline	t42 p1 d1
95-53-4	Benzenamine, 2-methyl- aka: o-Toluidine	d16 sr313
95-54-5	1,2-Benzenediamine aka: o-Phenylenediamine o-Diaminobenzene o-PDA	t36 p1 d3 t52
9 -8	2-Chlorophenol	sr110
95-63-6	Benzene, 1,2,4-trimethyl-	p1 d3 sr313
95-69-2	Benzenamine, 4-chloro-2-methyl-	s49
95-70-5	1,4-Benzenediamine, 2-methyl- aka: 2,5-Diaminotoluene	p3 d3
95-76-1	Benzenamine, 3,4-dichloro- aka: 3,4-Dichloroaniline	t42 p1 d1
95-77-2	3,4-Dichlorophenol	t31
95-80-7	1,3-Benzenediamine, 4-methyl- aka: 1,3-Diamino-4-methylbenzene	p3 d3 sr313
95-82-9	Benzenamine, 2,5-dichloro-	p1 d1

CHEMICAL ABSTRACT SERVICES (CAS) NUMBERS & CHEMICAL NAMES
LISTED BY CAS NUMBER

CAS NUMBER	CHEMICAL NAME	RULE CODE
95-83-0	1,2-Benzenediamine, 4-chloro- aka: o-Phenylenediamine, 4-chloro-	p3 d3
95-94-3	Benzene, 1,2,4,5-tetrachloro-	t35 p1 d1 t10 t50
95-95-4	2,4,5-Trichlorophenol	sr110 t31 sr313
96-05-9	2-Propenoic acid, 2-methyl-, 2-propenyl ester	p1
96-08-2	7-Oxabicyclo[4.1.0]heptane, 1-methyl-4- (2-methyloxiranyl)-	p1
96-09-3	Oxirane, phenyl- aka: Styrene oxide	p1 sr313
96-12-8	Propane, 1,2-dibromo-3-chloro-	sr1 p1 sr3
96-18-4	Propane, 1,2,3-trichloro-	sr110 d20
96-23-1	1,3-Dichloropropanol	t35 t50
96-29-7	2-Butanone, oxime aka: Methyl ethyl ketoxime MEKO	p15 d19 t43
96-33-3	2-Propenoic acid, methyl ester	p1 sr313
96-37-7	Cyclopentane, methyl-	t26* p12 d12 t50 t52
96-45-7	Ethylene thiourea	sr[illegible]
97-02-9	Benzenamine, 2,4-dinitro- aka: 2,4-Dinitroaniline	t[illegible] p[illegible] d[illegible]

CHEMICAL ABSTRACT SERVICES (CAS) NUMBERS & CHEMICAL NAMES
LISTED BY CAS NUMBER

CAS NUMBER	CHEMICAL NAME	RULE CODE
9 -7	Phenol, 2,2'-thiobis[4,6-dichloro-	d20
97-23-4	Phenol, 2,2'-methylenebis[4-chloro-	d20
97-56-3	C.I. Solvent Yellow 3	sr313
97-63-2	2-Propenoic acid, 2-methyl-, ethyl ester aka: Ethyl methacrylate	t35 p1 t50
97-86-9	2-Propenoic acid, 2-methyl-, 2-methylpropyl ester	p1
97-88-1	2-Propenoic acid, 2-methyl-, butyl ester aka: Butyl methacrylate	d25 p1
97-90-5	2-Propenoic acid, 2-methyl-, 1,2-ethanediyl ester	p1
98-01-1	2-Furancarboxaldehyde	d20
98-06-6	Benzene, (1,1-dimethylethyl)-	d20
98-07-7	Benzene, trichloromethyl-	p1 sr313
98-09-9	Benzenesulfonyl chloride	d16
9 -1	Benzene, 1-(1,1-dimethylethyl)-4-methyl- aka: p-tert-Butyltoluene PTBT	a8 d17
98-56-6	Benzene, 1-chloro-4-(trifluoromethyl)-	p3 d3
98-73-7	Benzoic acid, 4-(1,1-dimethylethyl)- aka: p-tert-Butylbenzoic acid PTBBA	a8 d17
98-82-8	Benzene, (1-methylethyl)- aka: Cumene 1-Methylethylbenzene	t18 p9 d10 sr313 t50
98-83-9	Benzene, (1-methylethenyl)-	d20
98-86-2	Acetophenone	t35**
98-87-3	Benzene, dichloromethyl- aka: Benzal chloride	t3** p1 s:

CHEMICAL ABSTRACT SERVICES (CAS) NUMBERS & CHEMICAL NAMES LISTED BY CAS NUMBER

CAS NUMBER	CHEMICAL NAME	RULE CODE
98-88-4	Benzoyl chloride	p1 sr313
98-95-3	Benzene, nitro-	sr110 t27 p1 d1 sr313
99-09-2	Benzenamine, 3-nitro- aka: m-Nitroaniline	sr110 p1 d1
99-28-5	2,6-Dibromo-4-nitrophenol	t31
99-29-6	Benzenamine, 2-bromo-6-chloro-4-nitro-	d1
99-30-9	Benzenamine, 2,6-dichloro-4-nitro- aka: 2,6-Dichloro-4-nitroaniline	t42 p1 d1
99-35-4	1,3,5-Trinitrobenzene	sr11
99-56-9	1,2-Benzenediamine, 4-nitro- aka: o-Phenylenediamine, 4-nitro-	p1 d3
99-59-2	5-Nitro-o-anisidine	sr313
99-65-0	Benzene, 1,3-dinitro- aka: m-Dinitrobenzene	sr313**
99-87-6	Benzene, 1-methyl-4-(1-methylethyl)-	d20
100-01-6	Benzenamine, 4-nitro- aka: p-Nitroaniline 4-Nitroaniline	t42 t35** p1 d1
100-02-7	4-Nitrophenol aka: p-Nitrophenol	p21 d25 sr110 t35 sr313
100-21-0	Terephthalic acid	sr313
100-25-4	Benzene, 1,4-dinitro- aka: p-Dinitrobenzene	sr313**

CHEMICAL ABSTRACT SERVICES (CAS) NUMBERS & CHEMICAL NAMES
LISTED BY CAS NUMBER

CAS NUMBER	CHEMICAL NAME	RULE CODE
1)-3	Cyclohexene, 4-ethenyl aka: 4-Vinylcyclohexene	p18 d27 p23
100-41-4	Benzene, ethyl- aka: Ethyl benzene	sr110 p16 d21 p1 sr313
100-42-5	Benzene, ethenyl- (Styrene monomer) aka: Styrene	sr110 p1 sr313
100-44-7	Benzene, chloromethyl-	p1 sr313
100-48-1	4-Pyridinecarbonitrile	d20
100-51-6	Benzyl alcohol	sr110
100-54-9	3-Pyridinecarbonitrile	r2 d20
100-70-9	2-Pyridinecarbonitrile	d20
1 5-4	N-Nitrosopiperidine	sr313
101-14-4	4,4'-Methylenebis(2-chlorobenzenamine) aka: 4,4'-Methylenebis(2-chloroaniline) MBOCA	m1 sr110 a7 sr313
101-43-9	2-Propenoic acid, 2-methyl-, cyclohexyl ester	p1
101-55-3	1-Bromo-4-phenoxybenzene	sr110 t35*
101-61-1	4,4'-Methylenebis(N,N-dimethylbenzenamine)	sr313
101-68-8	Benzene, 1,1'-methylenebis[4-isocyanato- aka: Methylenebis(phenylisocyanate) MDI	c2 d20 sr313
101-77-9	Benzenamine, 4,4'-methylenebis- aka: 4,4-Methylenedianiline MDA	f1 p1 d1 sr313
101-80-4	4,4'-Diaminodiphenyl ether	sr313

CHEMICAL ABSTRACT SERVICES (CAS) NUMBERS & CHEMICAL NAMES LISTED BY CAS NUMBER

CAS NUMBER	CHEMICAL NAME	RULE CODE
101-84-8	Benzene, 1,1'-oxybis- aka: Diphenyl oxide	p21 d25
101-90-6	Oxirane, 2,2'-[1,3-phenylenebis(oxymethylene)]bis-	p1 d1
102-71-6	Ethanol, 2,2',2''-nitrilotris- aka: Triethanolamine	p21 d25
103-11-7	2-Propenoic acid, 2-ethylhexyl ester	p1
103-23-1	Bis(2-ethylhexyl) adipate	sr313
103-65-1	n-Propylbenzene	t54
103-71-9	Benzene, isocyanato-	p1
103-85-5	n-Phenylthiourea	t35*
104-49-4	Benzene, 1,4-diisocyanato-	c2 d20
104-51-8	Benzene, butyl-	d20
104-76-7	1-Hexanol, 2-ethyl-	t22 d20
104-94-9	p-Anisidine	sr313
105-16-8	2-Propenoic acid, 2-methyl-, 2-(diethylamino) ethyl ester	p1
105-60-2	2H-Azepin-2-one, hexahydro-	d21
105-67-9	2,4-Dimethylphenol	sr. sr
106-40-1	Benzenamine, 4-bromo-	
106-42-3	Benzene, 1,4-dimethyl- aka: p-Xylene	
106-43-4	Benzene, 1-chloro-4-methyl-	
106-44-5	Phenol, 4-methyl- aka: p-Cresol	

CHEMICAL ABSTRACT SERVICES (CAS) NUMBERS & CHEMICAL NAMES
LISTED BY CAS NUMBER

CAS NUMBER	CHEMICAL NAME	RULE CODE
		t9 sr313
106-46-7	Benzene, 1,4-dichloro-	sr110* t35** p1 d1 t8 t10 sr313
106-47-8	Benzenamine, 4-chloro- aka: 4-Chloroaniline	sr110 t42 p1 d1
106-49-0	Benzenamine, 4-methyl-	d16
106-50-3	1,4-Benzenediamine aka: p-Phenylenediamine p-Diaminobenzene p-PDA	t36 p1 d1 sr313 t52
106-51-4	2,5-Cyclohexadiene-1,4-dione aka: Quinone p-Benzoquinone	t35* t32 p1 d1 sr313
106-63-8	2-Propenoic acid, 2-methylpropyl ester	p1
106-71-8	2-Propenoic acid, 2-cyanoethyl ester	p1
106-74-1	2-Propenoic acid, 2-ethoxyethyl ester	p1
106-83-2	Oxiraneoctanoic acid, 3-octyl-, butyl ester	p1
106-84-3	Oxiraneoctanoic acid, 3-octyl-, octyl ester	
106-87-6	7-Oxabicyclo[4.1.0]heptane, 3-oxiranyl-	
106-88-7	Oxirane, ethyl-	
106-89-8	Oxirane, chloromethyl- aka: Epichlorohydrin	

CHEMICAL ABSTRACT SERVICES (CAS) NUMBERS & CHEMICAL NAMES
LISTED BY CAS NUMBER

CAS NUMBER	CHEMICAL NAME	RULE CODE
106-90-1	2-Propenoic acid, oxiranylmethyl ester	p1 d1
106-91-2	2-Propenoic acid, 2-methyl-, oxiranylmethyl ester	p1 d1
106-92-3	Oxirane, [(2-propenyloxy)methyl]-	p1 d1
106-93-4	1,2-Dibromoethane aka: Ethylene dibromide	sr110 sr313
106-99-0	1,3-Butadiene	f3 sr313
107-02-8	Acrolein	sr110 sr313
107-04-0	Ethane, 1-chloro-2-bromo- aka: CBE	s46
107-05-1	Allyl chloride	sr313
107-06-2	Ethane, 1,2-dichloro- aka: Ethylene dichloride	sr110 d20 sr313
107-10-8	1-Propanamine	t35* d16
107-12-0	Propanenitrile	t35*
107-13-1	Acrylonitrile	sr110 sr313
107-18-6	2-Propen-1-ol aka: Allyl alcohol	sr313**
107-19-7	2-Propyn-1-ol	d16
107-21-1	Ethylene glycol	sr110 sr313
107-30-2	Chloromethyl methyl ether aka: Methane, chloromethoxy-	sr313
107-98-2	2-Propanol, 1-methoxy-	p21 d25

CHEMICAL ABSTRACT SERVICES (CAS) NUMBERS & CHEMICAL NAMES
LISTED BY CAS NUMBER

CAS NUMBER	CHEMICAL NAME	RULE CODE
1 -4	Acetic acid, ethenyl ester	sr110
	aka: Vinyl acetate	d15
		sr313
108-10-1	2-Pentanone, 4-methyl-	sr110
	aka: Methyl isobutyl ketone	p1
		d1
		sr313
108-31-6	2,5-Furandione	t35*
	aka: Maleic anhydride	p1
		d6
		sr313
108-38-3	Benzene, 1,3-dimethyl-	p1
	aka: m-Xylene	d1
		sr313
108-39-4	Phenol, 3-methyl-	p1
	aka: m-Cresol	d1
		sr313
108-42-9	Benzenamine, 3-chloro-	p1
		d1
1 -2	1,3-Benzenediamine	t36
	aka: m-Phenylenediamine	p1
	m-Diaminobenzene	d3
	m-PDA	t52
108-60-1	Propane, 2,2'-oxybis[1-chloro-	t35
	aka: Bis(2-chloro-1-methylethyl) ether	d20
	Bis(2-chloroisopropyl) ether	sr313
108-67-8	Benzene, 1,3,5-trimethyl-	d5
		p7
		t54
108-70-3	Benzene, 1,3,5-trichloro-	p1
		d1
108-71-4	1,3-Benzenediamine, 5-methyl-	p3
	aka: 3,5-Diaminotoluene	d3
108-78-1	Melamine	sr313*
108-86-1	Benzene, bromo-	d20
108-88-3	Benzene, methyl-	sr110
	aka: Toluene	p1

CHEMICAL ABSTRACT SERVICES (CAS) NUMBERS & CHEMICAL NAMES
LISTED BY CAS NUMBER

CAS NUMBER	CHEMICAL NAME	RULE CODE
		d1 sr313
108-89-4	Pyridine, 4-methyl-	d6
108-90-7	Benzene, 1,2,3-trichloro- aka: 1,2,3-Trichlorobenzene	sr110 p1 d1 t10 sr313 t50
108-94-1	Cyclohexanone	sr110 p1 d1
108-95-2	Phenol	sr110 d20 sr313
108-98-5	Benzenethiol	d16
108-99-6	Pyridine, 3-methyl-	d6
109-06-8	Pyridine, 2-methyl- aka: 2-Picoline	t35** d6
109-16-0	2-Propenoic acid, 2-methyl-, 1,2-ethanediylbis (oxy-2,1-ethanediyl) ester	p1
109-66-0	n-Pentane	sr110
109-77-3	Propanedinitrile aka: Malononitrile	t35 d16 t50
109-86-4	2-Methoxyethanol	sr313
109-87-5	Methane, dimethoxy-	d20
109-89-7	Ethanamine, N-ethyl- aka: Diethylamine	d20 sr313**
109-99-9	Tetrahydrofuran	sr110
110-54-3	Hexane	sr110 t50 t52
110-75-8	Ethene, (2-chloroethoxy)	sr110

CAS NUMBER	CHEMICAL NAME	RULE CODE
	aka: 2-Chloroethyl vinyl ether	t35* d16
110-80-5	2-Ethoxyethanol	sr313
110-82-7	Cyclohexane	p13 d14 sr313
110-86-1	Pyridine	p1 d1 sr313
111-21-7	Ethanol, 2,2'-[1,2-ethanediylbis(oxy)]bis, -diacetate aka: Ethylene bisoxyethylene diacetate	r2 p5 d7
111-40-0	1,2-Ethanediamine, N-(2-aminoethyl)- aka: Diethylenetriamine	p1 d3 t3 t50
111-42-2	Ethanol, 2,2'-iminobis- aka: Diethanolamine	p21 d25 sr313
11[illegible]-4	Bis(2-chloroethyl) ether	sr110 sr313
111-54-4	Ethylenebisdithiocarbamic acid	t35*
111-65-9	Octane	sr110
111-69-3	Hexanedinitrile	d20
111-76-2	Ethanol, 2-butoxy-	p21 d25
111-77-3	Ethanol, 2-(2-methoxyethoxy)- aka: Diethylene glycol monomethyl ether	p21 d25
111-90-0	Ethanol, 2-(2-ethoxyethoxy)- aka: Diethylene glycol monoethyl ether	p21 d25
111-91-1	Ethane, 1,1'-[methylenebis(oxy)]bis[2-chloro- aka: Bis(2-chloroethoxy)methane	sr110 t35 d16 t50
111-92-2	1-Butanamine, N-butyl-	d20

CHEMICAL ABSTRACT SERVICES (CAS) NUMBERS & CHEMICAL NAMES LISTED BY CAS NUMBER

CAS NUMBER	CHEMICAL NAME	RULE CODE
112-34-5	Diethylene glycol butyl ether	t19 t50
112-35-6	Ethanol, 2-[2-(2-methoxyethoxy)ethoxy]- aka: Triethylene glycol monomethyl ether	t34 p12 d12
112-50-5	Ethanol, 2-[2-(2-ethoxyethoxy)ethoxy]- aka: Triethylene glycol monoethyl ether	t34 p12 d12
112-90-3	9-Octadecen-1-amine, (Z)- aka: Oleylamine ODA	t29 p5 d7 t52
114-26-1	Propoxur	sr313
114-49-8	Benzeneacetic acid, alpha-(hydroxymethyl)-, 9-methyl -3-oxa-9-azatricyclo[3.3.1.0 (2,4)]non-7-yl ester, hydrobromide, [7(S)-(1alpha,2beta,4beta,5alpha, 7beta)]	p1
115-07-1	Propylene aka: Propene	sr313
115-27-5	4,7-Methanoisobenzofuran-1,3-dione, 4,5,6,7,8,8- hexachloro-3a,4,7,7a-tetrahydro- aka: Chlorendic anhydride	c1 p1
115-28-6	Bicyclo[2.2.1]hept-5-ene-2,3-dicarboxylic acid, 1,4, 5,6,7,7-hexachloro- aka: Chlorendic acid	c1 p1 d3 r1
115-29-7	Endosulfan aka: Alpha, beta, sulfate	sr110
115-32-2	Dicofol	sr313
115-86-6	Phosphoric acid, triphenyl ester	p1 d1
115-96-8	Ethanol, 2-chloro-, phosphate (3:1) aka: Tris(2-chloroethyl) phosphate	m1 p2 d2
116-14-3	Ethene, tetrafluoro-	t1 p

CHEMICAL ABSTRACT SERVICES (CAS) NUMBERS & CHEMICAL NAMES
LISTED BY CAS NUMBER

CAS NUMBER	CHEMICAL NAME	RULE CODE
		d3 t52
116-15-4	1-Propene,1,1,2,3,3,3-hexafluoro-	t23 p1 d3 t52
117-79-3	2-Aminoanthraquinone	sr313
117-81-7	1,2-Benzenedicarboxylic acid, bis(2-ethylhexyl) ester aka: Bis(2-ethylhexyl) phthalate Di(ethylhexyl)phthalate DEHP	t44 sr110* p1 d1 sr313
117-84-0	1,2-Benzenedicarboxylic acid, dioctyl ester aka: Di-n-octyl phthalate	sr110 p1 d1 sr313
118-74-1	Hexachlorobenzene	sr110 sr313
118-75-2	2,3,5,6-Tetrachloro-2,5-cyclohexadiene-1,4-dione	t31
118-79-6	Phenol, 2,4,6-tribromo-	t31 p1 d27 p23
118-96-7	2,4,6-Trinitrotoluene	sr110
119-06-2	1,2-Benzenedicarboxylic acid, ditridecyl ester aka: Ditridecyl phthalate	t44 p1 d1
119-07-3	1,2-Benzenedicarboxylic acid, decyl octyl ester	p1 d1
119-90-4	3,3'-Dimethoxybenzidine	sr313
119-93-7	3,3'-Dimethylbenzidine aka: o-Tolidine	sr313
120-12-7	Anthracene	sr d sr
120-32-1	Phenol, 4-chloro-2-chlorophenol(phenylmethyl)-	p

CHEMICAL ABSTRACT SERVICES (CAS) NUMBERS & CHEMICAL NAMES
LISTED BY CAS NUMBER

CAS NUMBER	CHEMICAL NAME	RULE CODE
	aka: 2-Benzyl-4-chlorophenol	d25
120-36-5	2-2,4-(Dichlorophenoxy)propionic acid	t31
120-58-1	1,3-Benzodioxole, 5-(1-propenyl)-	sr313**
	aka: Isosafrole	t35*
120-71-8	p-Cresidine	sr313
120-80-9	Catechol	sr313
120-82-1	Benzene, 1,2,4-trichloro-	sr110
		p1
		d1
		t8
		t10
		sr313
120-83-2	2,4-Dichlorophenol	t31
		sr110
		sr313
121-14-2	2,4-Dinitrotoluene	sr110
		sr313
121-39-1	Oxiranecarboxylic acid, 3-phenyl-, ethyl ester	p1
		d1
121-44-8	Ethanamine, N,N-diethyl-	d20
121-45-9	Phosphorous acid, trimethyl ester	p1
121-47-1	Benzenesulfonic acid, 3-amino-	r2
		d20
121-69-7	N,N-Dimethylaniline	sr313
121-75-5	Malathion	sr110
121-82-4	Cyclonite	sr110
	aka: RDX	
121-87-9	Benzenamine, 2-chloro-4-nitro-	p1
		d1
122-07-6	Ethanamine, 2,2-dimethoxy-N-methyl-	p1
122-09-8	Benzeneethanamine, alpha, alpha-dimethyl-	t35*
	aka: alpha, alpha-Dimethylphenethylamine	d16

CHEMICAL ABSTRACT SERVICES (CAS) NUMBERS & CHEMICAL NAMES
LISTED BY CAS NUMBER

CAS NUMBER	CHEMICAL NAME	RULE CODE
12 -1	Oxirane, (phenoxymethyl)-	p1 d1
122-66-7	Hydrazine, 1,2-diphenyl- aka: Hydrazobenzene	sr110 d20 sr313
122-99-6	Ethanol, 2-phenoxy-	p4 d4
123-31-9	1,4-Benzenediol aka: Hydroquinone	d19 p1 t7 sr313
123-33-1	Maleic hydrazide	t35
123-38-6	Propionaldehyde	sr313
123-54-6	2,4-Pentanedione	s54
123-61-5	Benzene, 1,3-diisocyanato-	c2 d20
123-63-7	Paraldehyde	t35*
1: -8	Butyraldehyde aka: Butanal	p20 d24 sr313
123-91-1	1,4-Dioxane	sr110 sr313
124-16-3	2-Propanol, 1-(2-butoxyethoxy)- aka: 1-Butoxyethoxy-2-propanol	p21 d25
124-17-4	Ethanol, 2-(2-butoxyethoxy)-, acetate aka: Diethylene glycol butyl ether acetate 2-(2-Butoxyethoxy)ethyl acetate	t19 p5 d7
124-48-1	Methane, dibromochloro- aka: Chlorodibromomethane	sr110 d20
124-73-2	Dibromotetrafluoroethane aka: Halon 2402	sr313#
126-71-6	Phosphoric acid, tris(2-methylpropyl) ester	c2
126-72-7	Tris(2,3-dibromopropyl) phosphate	a2 s6

CHEMICAL ABSTRACT SERVICES (CAS) NUMBERS & CHEMICAL NAMES
LISTED BY CAS NUMBER

CAS NUMBER	CHEMICAL NAME	RULE CODE
		sr313
126-73-8	Phosphoric acid, tributyl ester aka: Tributyl phosphate	c2 t39 p14 d18
126-80-7	Disiloxane, 1,1,3,3-tetramethyl-1,3-bis[3-oxiranylmethoxy)propyl]-	d1
126-98-7	Methacrylonitrile	t35*
126-99-8	1,3-Butadiene, 2-chloro- aka: Chloroprene	p1 p9 d10 sr313
127-18-4	Ethene, tetrachloro- aka: Perchloroethylene Tetrachloroethylene	sr110 d20 sr313
128-39-2	Phenol, 2,6-bis(1,1-dimethylethyl)- aka: 2,6-Di-tert-butyl phenol DTBP	t38 p13 d14
128-66-5	C.I. Vat Yellow 4	sr313
128-86-9	2,6-Anthracenedisulfonic acid, 4,8-diamino-9,10-dihydro-1,5-dihydroxy-9,10-dioxo-	p17 d22
129-00-0	Pyrene aka: Benzo[def]phenanthrene	m1 sr113 t31
131-11-3	1,2-Benzenedicarboxylic acid, dimethyl ester aka: Dimethyl phthalate	t13
131-15-7	1,2-Benzenedicarboxylic acid, bis(1-methylheptyl) ester	
131-17-9	1,2-Benzenedicarboxylic acid, di-2-propenyl ester aka: Diallyl phthalate	
131-89-5	4,6-Dinitro-o-cyclohexylphenol	
132-64-9	Dibenzofuran	

CHEMICAL ABSTRACT SERVICES (CAS) NUMBERS & CHEMICAL NAMES
LISTED BY CAS NUMBER

CAS NUMBER	CHEMICAL NAME	RULE CODE
		sr313
133-06-2	Captan	sr313
133-90-4	Chloramben	sr313
134-29-2	o-Anisidine hydrochloride	sr313
134-32-7	alpha-Naphthylamine aka: 1-Naphthylamine	t35* sr313
135-20-6	Cupferron	sr313
135-98-8	Benzene, (1-methylpropyl)-	d20
137-09-7	Phenol, 2,4-diamino-, dihydrochloride	p3 d3
137-20-2	Ethanesulfonic acid, 2-[methyl(1-oxo-9-octadecenyl) amino]-, sodium salt, (Z)- aka: N-Methyl-N-oleoyltaurine, sodium salt	p9 d10
137-26-8	Thioperoxydicarbonic diamide, tetramethyl-	d20
139-13-9	Nitrilotriacetic acid	sr313
1[illegible]-3	Benzene, 1,1'-methylenebis[4-isocyanato-3-methyl-	c2 d20
139-65-1	4,4'-Thiodianiline	sr313
140-08-9	Tris(2-chloroethyl) phosphite	p1 d1 r1
140-30-4	2-Mercaptobenzothiazole	t35
140-57-8	Aramite	[illegible]
140-66-9	Phenol, 4-(1,1,3,3-tetramethylbutyl)-	
140-88-5	2-Propenoic acid, ethyl ester aka: Ethyl acrylate	
141-32-2	2-Propenoic acid, butyl ester	

CHEMICAL ABSTRACT SERVICES (CAS) NUMBERS & CHEMICAL NAMES LISTED BY CAS NUMBER

CAS NUMBER	CHEMICAL NAME	RULE CODE
141-38-8	Oxiraneoctanoic acid, 3-octyl-, 2-ethylhexyl ester	p1
141-79-7	3-Penten-2-one, 4-methyl- aka: Mesityl oxide	p8 d1 t6
141-85-5	Benzenamine, 3-chloro-, hydrochloride	p1 d1
142-04-1	Benzenamine, hydrochloride	p1
142-09-6	2-Propenoic acid, 2-methyl-, hexyl ester	p1
142-28-9	Propane, 1,3-dichloro-	p21 d16
142-82-5	Heptane	sr110
142-84-7	1-Propanamine, N-propyl-	d16
142-90-5	2-Propenoic acid, 2-methyl-, dodecyl ester	p1
143-22-6	Ethanol, 2-[2-(2-butoxyethoxy)ethoxy]- aka: Triethylene glycol monobutyl ether	t34 p12 d12
145-73-3	7-Oxabicyclo[2.2.1]heptane-2,3-dicarboxylic acid	p1
147-14-8	Copper, [29H,31H-phthalocyaninato(2-)-N (29),N (30), N (31),N (32)]-, (SP-4-1)- aka: C.I. Pigment Blue 15	sr313*
147-82-0	Benzenamine, 2,4,6-tribromo-	p1 d1
149-30-4	2(3H)-Benzothiazolethione aka: Mercaptobenzothiazole	t25 p9 d10 t50
149-57-5	Hexanoic acid, 2-ethyl-	p6 d8 t13
151-56-4	Ethyleneimine aka: Aziridine	sr313
155-41-9	3-Oxa-9-azoniatricyclo[3.3.1.0 (2,4)]nonane, 7-(3-hydroxy-1-oxo-2-phenylpropoxy)-9,9-dimethyl-, bromide, [7(S)-(1alpha,2beta,4beta,5alpha,7beta)]-	p1

CHEMICAL ABSTRACT SERVICES (CAS) NUMBERS & CHEMICAL NAMES
LISTED BY CAS NUMBER

NUMBER	CHEMICAL NAME	RULE CODE
156-10-5	p-Nitrosodiphenylamine	sr313
156-59-2	cis-1,2-Dichloroethylene	sr110
156-60-6	Ethene, 1,2-dichloro-, (E)- aka: 1,2-trans-Dichloroethene	sr110
156-62-7	Calcium cyanamide	sr313
191-24-2	Benzo[g,h,i]perylene	sr110
193-39-5	Indeno[1,2,3-cd]pyrene	sr110
205-99-2	Benzo[b]fluoranthene	sr110
206-44-0	Fluoranthene	sr110
207-08-9	Benzo(k)fluoranthene	sr110
208-96-8	Acenaphthylene	sr110
218-01-9	Chrysene	sr110
285-67-6	6-Oxabicyclo[3.1.0]hexane	p1
-20-4	7-Oxabicyclo[4.1.0]heptane	p1
298-04-4	Disulfoton	sr110
302-01-2	Hydrazine	sr11 sr31
306-83-2	Ethane, 2,2-dichloro-1,1,1-trifluoro- aka: 2,2-Dichloro-1,1,1-trifluoroethane HCFC-123	d28
309-00-2	Aldrin	sr313
319-84-6	Cyclohexane, 1,2,3,4,5,6-hexachloro-, (1alpha, 2alpha,3beta,4alpha,5beta,6beta)-	sr110
320-72-9	3,5-Dichlorosalicyclic acid	t31
328-84-7	Benzene, 1,2-dichloro-4-(trifluoromethyl)- aka: 3,4-Dichlorobenzotrifluoride DCBTF	t37 p10 d9 t50
334-88-3	Diazomethane	sr313

CHEMICAL ABSTRACT SERVICES (CAS) NUMBERS & CHEMICAL NAMES LISTED BY CAS NUMBER

CAS NUMBER	CHEMICAL NAME	RULE CODE
353-50-4	Carbonyl fluoride	t35*
354-33-6	Ethane, pentafluoro- aka: Pentafluoroethane HFC-125	d28
357-57-3	Strychnidin-10-one, 2,3-dimethoxy-	d16
359-11-5	Ethene, trifluoro-	p3 d3 r1
421-01-2	Bromochlorodifluoromethane aka: Halon 1211	sr313#
428-59-1	Oxirane, trifluoro(trifluoromethyl)- aka: Hexafluoropropylene oxide HFPO	t24 a9 d1 s9
463-58-1	Carbonyl sulfide	sr313
470-67-7	7-Oxabicyclo[2.2.1]heptane, 1-methyl-4-(1-methylethyl)-	p1
472-41-3	Phenol, 4-(3,4-dihydro-2,2,4-trimethyl-2H-1-benzopyran-4-yl)-	r2 d20
479-45-8	Trinitrophenylmethylnitramine	sr110
488-47-1	Tetrabromocatechol	t31
492-80-8	Auramine	sr313
494-03-1	Chlornaphazine	t35*
496-72-0	1,2-Benzenediamine, 4-methyl- aka: 1,2-Diamino-4-methylbenzene	p1 d3
505-60-2	Mustard gas aka: Ethane, 1,1'-thiobis[2-chloro-	sr110 sr313
506-68-3	Cyanogen bromide	t35*
506-96-7	Acetyl bromide	d20
510-15-6	Chlorobenzilate	sr313
512-56-1	Phosphoric acid, trimethyl ester	c2

CHEMICAL ABSTRACT SERVICES (CAS) NUMBERS & CHEMICAL NAMES
LISTED BY CAS NUMBER

CAS NUMBER	CHEMICAL NAME	RULE CODE
52[illegible]8	Benzene, 1,2,3-trimethyl-	d5 p7
528-29-0	Benzene, 1,2-dinitro- aka: o-Dinitrobenzene	sr313**
530-50-7	Hydrazine, 1,1-diphenyl-	d20
532-27-4	2-Chloroacetophenone	sr313
534-07-6	2-Propanone, 1,3-dichloro-	d20
534-15-6	Ethane, 1,1-dimethoxy-	p1
534-52-1	4,6-Dinitro-o-cresol aka: 4,6-Dinitro-2-methylphenol	sr110 sr313
540-54-5	Propane, 1-chloro-	d20
540-59-0	1,2-Dichloroethylene	sr110 sr313
540-84-1	Pentane, 2,2,4-trimethyl-	d20
54[illegible]-3	Ethyl chloroformate	sr313
54[illegible]-5	1,3-Benzenediamine, dihydrochloride aka: m-Phenylenediammonium dichloride	p3 d3
541-70-8	1,3-Benzenediamine, sulfate (1:1) aka: m-Phenylenediamine, sulfate salt m-PDA.(H)2 S(O)4	t36 p3 d3 t52
541-73-1	Benzene, 1,3-dichloro-	sr110 t35** p1 d1 sr313
542-75-6	1-Propene, 1,3-dichloro- aka: 1,3-Dichloropropylene	d20 sr313
542-76-7	Propanenitrile, 3-chloro-	t35*
542-88-1	Bis(chloromethyl) ether	sr110 sr313
554-00-7	Benzenamine, 2,4-dichloro-	p1

10.0 POST-INSPECTION ACTIVITIES

10.1 INTRODUCTION

The effectiveness of a TSCA compliance inspection is dependent on many factors, including the thoroughness of the inspection, the evidence collected by the inspector, and the cooperation of the facility being inspected. Critical to the success of the inspection process are two steps that follow the inspection itself:

- Conducting necessary followup activities (discussed in Section 10.2) at the conclusion of the inspection
- Preparing the inspection report (discussed in Section 10.3).

The guidance that follows includes discussion of followup activities and report preparation, including guidance on what to do with the inspection report once it is completed. Followup activities are necessary to ensure that any outstanding data pertaining to the facility and the inspection are obtained as soon as possible following the inspection for inclusion in the inspection report. The primary function of the inspection report is to serve as the main document upon which EPA Case Development Officers (CDOs) will base enforcement decisions concerning the facility. Each of these two steps is discussed below.

10.2 FOLLOWUP

Prior to preparing the inspection report, the inspector should gather all data collected during the inspection, including documents and other supporting evidence obtained before and during the inspection, such as photographs, inspection report forms, any inspection checklist used, and the field logbook or other inspection notes (if used). The inspector should review the information, noting any gaps or discrepancies, and refresh her/his memory of the entire inspection process. Gaps may need to be filled in by a phone call or, in unusual circumstances, a followup visit. Written requests may also be utilized to collect additional information. Such requests should always specify a timeframe for a response (usually 30 days).

The inspector should conduct the necessary followup to answer outstanding questions and obtain relevant documents. The inspector should focus on obtaining information necessary to fill in gaps in material already obtained from EPA records and/or the facility pertaining to facility operations and compliance

with TSCA. The inspector should also collect information that clarifies the data already in the inspector's possession. This additional and clarifying information should be included in the inspection report (see Section 10.3.3).

In order to obtain such information, the inspector should contact the facility representative by telephone and/or by letter and request that outstanding data be submitted. The inspector should keep in mind that s/he may have already requested the facility to provide additional or clarifying data at the closing conference (see Section 4.9). Therefore, the purpose of conducting followup activities is to ensure that facility representatives followup on requests by EPA to supply missing data concerning the inspection. Other followup can be through Headquarters (late reports, etc.), other contacts suggested on site, or other program offices, if warranted. For example, the inspector may need to search the confidential TSCA Inventory; this search would be performed by the Information Management Division (IMD) of the Office of Pollution Prevention and Toxics (OPPT).

10.3 THE INSPECTION REPORT

The following guidance on preparing the inspection report includes objectives of the report (Section 10.3.1), CBI considerations (Section 10.3.2), and report elements (Section 10.3.3).

The inspector should prepare the inspection report as soon as possible following the inspection. EPA recommends that the report be completed within 45 days of the inspection; however, the actual amount of time will depend on obtaining any additional required information in a timely fashion. This timeframe should allow the inspector sufficient time to conduct necessary followup and to append to the report (and mention in the narrative) any data obtained during followup.

The purpose of the inspection report is to present a complete and factual record of the inspection process from opening conference, to the inspection itself, to closing conference. The inspector should keep in mind that the report should contain enough information about the facility and the inspection (as well as observations made during the inspection) to enable CDOs to make enforcement decisions pertaining to the subject facility and to develop a case, as necessary.

10.3.1 OBJECTIVES

As the inspector prepares the report, s/he should have the following objectives in mind:

- To include in the report all of its basic elements (see Section 10.3.3), ensuring that the report not only contains copies of relevant forms and documents as appendices, but that the narrative component of the report references those forms and documents
- To substantiate with as much evidence as possible each potential violation of TSCA cited in the report, ensuring that any documents and/or photographs are not only appended to the report, but are referenced in the narrative component of the report. (This is necessary so that CDOs know how the data relates to the inspection.)
- To write the report in clear and concise language
- To present factual and accurate information pertaining to all steps in the inspection process from opening to closing conference and followup
- To make only those observations that are based on firsthand knowledge of the facility since enforcement personnel must be able to depend on the accuracy of all information
- To include only information that is relevant to the facility and its compliance with TSCA. (Irrelevant facts can interfere with enforcement decisionmaking.)

10.3.2 CONFIDENTIAL BUSINESS INFORMATION CONSIDERATIONS

While preparing the inspection report, the inspector should keep in mind that some or all of the data gathered during the inspection may be confidential business information (CBI), if properly claimed as such by the facility. Otherwise, the report may be released to the public in response to a Freedom of Information Act (FOIA) Request, unless the report falls under a FOIA exemption, such as law enforcement. Therefore, if the inspection report contains CBI, those portions of the inspection report must be treated in accordance with TSCA CBI procedures. However, the inspector may refer to CBI material in general terms (e.g., by a reference number assigned by the inspector) so that the report need not be treated as CBI. Additional information concerning the handling of CBI can be found in the *TSCA Business Information Security Manual*.

10.3.3 ELEMENTS OF THE INSPECTION REPORT

While inspection reports may vary in general content and format, there are certain elements that should be contained in each inspection report in order to ensure that necessary information is not inadvertently overlooked. The basic components of the inspection report are discussed below.

The inspection report should be a concise and chronological account of observations made and activities undertaken during the inspection, from opening conference to closing conference and followup. The inspector may find that the field logbook and/or an inspection checklist (if either were used) are useful tools for developing the narrative. These tools can help the inspector recall and include in the narrative important details concerning the inspection. The inspector should also include the reason for the inspection and any relevant historical information, such as Dun and Bradstreet (D&B) reports and any knowledge of prior violations obtained during the pre-inspection process. If the company learned of anything as a result of the inspection that it might decide to submit to EPA, it would be helpful if the company also sent copies of these documents to the inspector for inclusion in the inspection report.

Perhaps the most important guide to the inspector for writing the inspection report is the outline (discussed below) that the inspector should prepare prior to writing the narrative. The purpose of the outline is to serve as a blueprint for the development of the inspection report.

A well-developed outline will ensure that the inspector includes in the narrative all information pertinent to the inspection, and, ultimately, the outline can serve to support subsequent enforcement decisions relating to the facility. The inspector should keep in mind that the suggested outline may be modified based upon the particular circumstances of a given inspection.

- *Title Page*
- *Index*
- *Facility Information*

  The facility information should include:

  - Company name, address, and telephone number
  - Primary SIC code
  - DUNS number
  - Corporate fiscal year
  - Number of employees
  - Approximate sales (year)

- Type of facility
- Parent company name and address
- Parent company approximate sales (year)
- Primary areas of business

- *Inspection Conduct Information*

  Information under this heading should include:

  - Date of notification
  - Type of inspection conducted
  - Date and time of inspection
  - Responsible official's name, title, and telephone number
  - Name of EPA inspector
  - Other facility participants

- *Inspection results*

  This section should provide a brief summary of the inspection results and the factors that led to the inspector's conclusions. A sample of the Inspection Results section of a report is shown in Figure 10-1.

- *TSCA administrative exhibits*

  The inspector should attach, as exhibits to the inspection report, all documentary evidence, including photographs, that supports the observations made during the inspection (and which should be described in the report narrative, as appropriate). The inspector should be sure that any data attached to the report as an exhibit is labeled as such and is mentioned within the narrative. Also, the inspector should prepare an index of exhibits (or attachments) listing the name and the location of each exhibit. This index should precede the exhibits and serve as a reference for enforcement personnel.

  There are numerous forms pertaining to the inspection that should be labeled as exhibits and appended to the end of the inspection report. The most important exhibits are the forms and the notification letter relating to the TSCA inspection. They should be labeled and attached to the report as follows:

  - Exhibit 1: Notification Letter (see Figure 3-4)
  - Exhibit 2: Notice of Inspection (see Figure 4-1)

FIGURE 10-1

INSPECTION RESULTS SECTION OF REPORT - EXAMPLE 1

III. INSPECTION RESULTS

A. TSCA Section 5 Findings

1. General Inventory

The inspector determined, through a comprehensive review of [Company/Facility Name]'s records (19__ to 19__), that all chemicals commercially manufactured by the facility and all chemicals used as raw materials by the facility appear on the TSCA Section 8(b) Chemical Substance Inventory (TSCA Inventory). Additionally, R&D activities, as defined under TSCA, are conducted at the facility and were found to be consistent with 40 CFR 720.

2. Premanufacture Notification Review

No PMNs have been submitted since 1987.

B. TSCA Section 8 Findings

1. Partial Inventory Update Rule

A review of available Agency and corporate records did not reveal any noncompliance with regard to 40 CFR §710.33(a).

2. Section 8(a) Level A and 8(d)

The inspector verified that [Company/Facility Name] had not manufactured or imported chemicals for which a manufacturer's PAIR or a Section 8(d) report was required.

3. Section 8(c) and 8(e)

Verification was made that allegations have not been received indicating adverse effects upon human health or the environment. [Company/Facility Name] stated it had not received nor was it aware of information that would have required submission of a Notice of Substantial Risk. A review of [Company/Facility Name] records seemed to confirm this statement.

FIGURE 10-2

INSPECTION RESULTS SECTION OF REPORT - EXAMPLE 2

III. INSPECTION RESULTS

A. TSCA Section 5 Findings

1. General Inventory

During the inspection, the inspector determined that [Company/Facility Name] manufactured for commercial purposes, a chemical substance that is not found on the Section 8(b) Chemical Substance Inventory (TSCA Inventory). The chemical substance identified as [Company/Facility Name]'s product code XXX was manufactured between [Date] and [Date].

Manufacture of product XXX occurred on XX separate dates totaling 20 commercial batches and amounting to approximately 140,000 pounds as finished product.

The commercial manufacture of product XXX is inconsistent with the regulations for new chemical manufacture found in 40 CFR Section 720.22.

2. Premanufacture Notification Review

During the inspection, the inspector reviewed one chemical substance that was the subject of a PMN submitted by [Company/Facility Name]. The inspector verified the PMN's number to be XXX and that the manufacture was commenced at [Facility Name].

The chemical substance described in XXX has the chemical name [Insert name].

PMN XXX was submitted to the Agency on [Date]. The end of the 90-day review period was determined to be [Date]. The inspector verified that the first commercial production batch was manufactured on [Date]. The NOC was mailed to the Agency on [Date] within the 30 days allowed under the regulations found in 40 CFR Section 720.(b)(1).

FIGURE 10-2

SAMPLE OF INSPECTION RESULTS SECTION OF REPORT - EXAMPLE 2 (CONTINUED)

B. TSCA Section 8 Findings

1. Partial Inventory Update Rule

   During the inspection and follow-up investigation, the inspector determined that [Company/Facility Name] incorrectly used calendar year production volumes rather than corporate fiscal year production volumes in reporting to the IUR. This error resulted in incorrect production volumes being reported to the IUR for [Company/Facility Name].

2. Section 8(a) Level A and 8(d)

   The inspector verified that [Company/Facility Name] had not manufactured or imported chemicals for which a manufacturer's PAIR or a Section 8(d) report was required.

3. Section 8(c) and 8(e)

   Verification was made that allegations have not been received indicating adverse effects upon human health or the environment. [Company/Facility Name] stated it had not received nor was it aware of information that would have required submission of a Notice of Substantial Risk. A review of [Company/Facility Name] records seemed to confirm this statement.

- Exhibit 3: TSCA Inspection Confidentiality Notice (see Figure 4-2)
- Exhibit 4: Receipt for Samples and Documents (see Figure 4-4)
- Exhibit 5: Declaration of Confidential Business Information (see Figure 4-3).

In addition to the above forms, the inspector should attach to the report any inspection checklist used during the inspection. The inspector should keep in mind that not every Region has developed a checklist for use during the inspection process, but that if one was developed and used, it should be attached to the report and may serve as the basis upon which the narrative language of the report is developed.

Once the outline has been prepared, the inspector should write the narrative using the outline as a guide. The inspector should follow the tips in Figure 10-3 when writing the inspection report.

10.3.4 INSPECTION SUMMARY

The inspection summary is not an actual component of the inspection report, but rather a stand-alone document that can be produced in conjunction with the inspection report. The inspection summary should include the type of inspection conducted, specific inspection priorities, and any potential violations identified by the inspector. The potential violations are noted separately from the inspection report because they are pre-decisional [e.g., opinion(s) of an inspector prior to an actual enforcement decision]. Pre-decisional notes of violations are exempted from release pursuant to a request under FOIA. The actual report may be releasable, unless other exemptions under FOIA apply (such as CBI claims).

10.4 WHAT TO DO WITH COMPLETED INSPECTION REPORT

The inspection report is filed, reviewed by the TSCA coordinator or supervisor, and sent to the CDO. The CDO will draft a complaint if a violation exists. Most Regions also need concurrence by the Office of Compliance Monitoring (OCM) before case issuance. Initial case review, determination of possible violation, and case development will be conducted by the Regions. The developed case will be submitted to the appropriate Headquarters compliance officer per OCM concurrence policy until relaxation is granted.

FIGURE 10-3

TIPS FOR DEVELOPING NARRATIVE LANGUAGE

When developing the narrative language portion of an inspection report, the inspector should:

- Write the narrative in accordance with the report outline
- Ensure that the reader is able to readily ascertain the following information from the narrative:
  - The specific reason for the inspection
  - Who participated in the inspection (i.e., identity of each facility representative and inspector)
  - A brief description of the facility being inspected (i.e., what it imports and/or manufactures, physical size of plant, number of buildings, etc.)
  - That all required notices and receipts were completed and issued as required and are attached to the report
  - The actions taken during the inspection, in chronological order
  - What observations were made during the inspection
  - What evidence (e.g., documents, photographs) was collected during the inspection. The inspector should identify the evidence within the narrative and include copies of such evidence as exhibits. The inspector should be very careful not to draw conclusions as to the existence of any actual violations of TSCA, as this is the responsibility of the CDOs. However, if the inspector decides to write a summary of the violations, it should be done on a sheet of paper separate from the rest of the report.
- Include within the narrative the components of the suggested report format (see Section 10.3.3) identified as appropriate for inclusion within the narrative (e.g., general information, summary of findings, facility background, and inspection activities).

APPENDIX I

OCMC MEMO TO IMD REQUESTING TARGETING PRINTOUTS

MEMORANDUM

SUBJECT: Updated Targeting Printouts

From: Michael F. Wood, Director
Compliance Division (EN-342)

TO: Linda A. Travers, Director
Information Management Division (TS-793)

The Office of Compliance Monitoring is requesting an update of previously requested targeting data. These updated printouts will allow our inspectors to use current information when selecting their targets. Please note that the information OCM is requesting is substantially the same as the information requested in Enforcement Request (ER) Numbers 87-399, 88-011, 88-074, 89-021, 89-138, and 90-104.

Please provide these printouts to Phil Milton of my staff by September 21, 1990. Attached is a listing of the information for which we need updates. The information provided in response to ER 90-104 did not include Printout I or Plant Site Addresses. Please ensure that this information is included with this ER response or let us know as soon as possible if there is a problem providing this information. Thanks for your cooperation in this effort. If you have any questions, please call Phil Milton at 475-6732.

Attachment

cc: Sherry Sterling (EN-342)
Frank Caesar (TS-793)
Steve Newburg-Rinn (TS-793)

CAS NUMBER	CHEMICAL NAME	RULE CODE
		d1
556-52-5	Oxiranemethanol aka: Glycidol	p1 d1
556-67-2	Cyclotetrasiloxane, octamethyl- aka: OMCTS	t28 p9 d10
558-30-5	Oxirane, 2,2-dimethyl-	r2 d1
563-04-2	Phosphoric acid, tris(3-methylphenyl) ester	d1
563-41-7	Hydrazinecarboxamide monohydrochloride aka: Semicarbazide hydrochloride	m1
563-54-2	1-Propene, 1,2-dichloro-	r2 d16
563-58-6	1-Propene, 1,1-dichloro-	r2 d16
569-64-2	C.I. Basic Green 4	sr313
573-58-0	1-Naphthalenesulfonic acid, 3,3'-[[1,1'-biphenyl]-4,4'-diylbis(azo)]bis[4-amino-, disodium salt	d1
580-51-8	[1,1'-Biphenyl]-3-ol	d20
583-78-8	2,5-Dichlorophenol	t31
584-84-9	Benzene, 2,4-diisocyanato-1-methyl- aka: Toluene-2,4-diisocyanate	m1 c2 d20 sr313
591-08-2	Acetamide, N-(aminothioxomethyl)-	t35* d16
591-78-6	Methyl n-butyl ketone aka: 2-Hexanone	sr110 s7
593-60-2	Ethene, bromo-	p1 sr313
594-20-7	Propane, 2,2-dichloro-	d1
598-21-0	Acetyl bromide, bromo-	d1

CHEMICAL ABSTRACT SERVICES (CAS) NUMBERS & CHEMICAL NAMES
LISTED BY CAS NUMBER

CAS NUMBER	CHEMICAL NAME	RULE CODE
1-2	2-Propanone, 1-bromo- aka: Bromoacetone	t35* d16
603-35-0	Phosphine, triphenyl-	p1
606-20-2	2,6-Dinitrotoluene	sr110 t35** sr313
608-27-5	Benzenamine, 2,3-dichloro-	p1 d1
608-71-9	Pentabromophenol	t31
608-93-5	Benzene, pentachloro-	sr110 t35 p1 d1
611-14-3	o-Ethyltoluene aka: Benzene, 1-ethyl-2-methyl-	r2 d3
614-94-8	1,3-Benzenediamine, 4-methoxy-, dihydrochloride aka: m-Phenylenediamine, 4-methoxy-, dihydrochloride	r2 p3 d3
5-4	1,3-Benzenediamine, 4-methoxy- aka: m-Phenylenediamine, 4-methoxy-	p1 d3 sr313
615-28-1	1,2-Benzenediamine dihydrochloride aka: 1,2-Phenylenediamine dihydrochloride	p3 d3
615-45-2	1,4-Benzenediamine, 2-methyl-, dihydrochloride	p3 d3
615-46-3	1,4-Benzenediamine, 2-chloro-, dihydrochloride p-Phenylenediamine, 2-chloro-, dihydrochloride	r2 p3 d3
615-50-9	1,4-Benzenediamine, 2-methyl-, sulfate (1:1) aka: 2,5-Diaminotoluene sulfate	p3 d3
615-58-7	2,4-Dibromophenol	t31
616-23-9	1-Propanol, 2,3-dichloro-	t3 d1
620-14-4	Benzene, 1-ethyl-3-methyl- aka: m-Ethyltoluene	d1

CHEMICAL ABSTRACT SERVICES (CAS) NUMBERS & CHEMICAL NAMES LISTED BY CAS NUMBER

CAS NUMBER	CHEMICAL NAME	RULE CODE
621-64-7	1-Propanamine, N-nitroso-N-propyl- aka: Nitrosodipropylamine	sr110 sr313
622-96-8	Benzene, 1-ethyl-4-methyl- aka: p-Ethyltoluene	d3
624-18-0	1,4-Benzenediamine dihydrochloride aka: p-Phenylenediamine dihydrochloride	p1 d3
624-83-9	Methyl isocyanate	sr313
624-92-0	Disulfide, dimethyl-	m1
626-43-7	Benzenamine, 3,5-dichloro-	p1 d1
630-20-6	Ethane, 1,1,1,2-tetrachloro-	d20
632-79-1	Tetrabromophthalic anhydride	p23 d27
634-66-2	Benzene, 1,2,3,4-tetrachloro-	p1 d1
634-90-2	Benzene, 1,2,3,5-tetrachloro-	p1 d1
634-93-5	Benzenamine, 2,4,6-trichloro-	p1 d1
635-22-3	Benzenamine, 4-chloro-3-nitro-	p1 d1
636-21-5	o-Toluidine hydrochloride	t35* sr313
640-19-7	Acetamide, 2-fluoro-	t35
646-06-0	1,3-Dioxolane	p7 d2
677-21-4	Ethene, trifluoromethyl-	p3 d3 r1
680-31-9	Hexamethylphosphoramide	s2 sr313
684-93-5	N-Nitroso-N-methylurea	sr313

CHEMICAL ABSTRACT SERVICES (CAS) NUMBERS & CHEMICAL NAMES
LISTED BY CAS NUMBER

CAS NUMBER	CHEMICAL NAME	RULE CODE
685-91-6	Acetamide, N,N-diethyl-	d20
688-84-6	2-Propenoic acid, 2-methyl-, 2-ethylhexyl ester	p1
689-12-3	2-Propenoic acid, 1-methylethyl ester	p1
692-42-2	Arsine, diethyl-	d16
696-28-6	Arsonous dichloride, phenyl-	d16
757-58-4	Tetraphosphoric acid, hexaethyl ester aka: Hexaethyl tetraphosphate	t35* d16
759-73-9	N-Nitroso-N-ethylurea	sr313
765-34-4	Glycidyl aldehyde	t35*
811-97-2	Ethane, 1,1,1,2-tetrafluoro- aka: 1,1,1,2-Tetrafluoroethane HFC-124a	d28
812-03-3	Propane, 1,1,1,2-tetrachloro-	d20
818-61-1	2-Propenoic acid, 2-hydroxyethyl ester	p1
822-06-0	Hexane, 1,6-diisocyanato- aka: 1,6-Hexamethylene diisocyanate	t46 p19 c2 d20
823-40-5	1,3-Benzenediamine, 2-methyl- aka: 2,6-Diamino-1-methylbenzene	p1 d3
827-94-1	Benzenamine, 2,6-dibromo-4-nitro-	p1 d1
828-00-2	1,3-Dioxan-4-ol, 2,6-dimethyl-, acetate	d20
842-07-9	C.I. Solvent Yellow 14	sr313
868-77-9	2-Propenoic acid, 2-methyl-, 2-hydroxyethyl ester	p1
872-50-4	N-Methylpyrrolidone aka: NMP	t51
919-62-0	1-Butanol, 3-methyl-, phosphate (3:1)	c2
924-16-3	1-Butanamine, N-butyl-N-nitroso- aka: Nitrosodibutylamine	sr313

CHEMICAL ABSTRACT SERVICES (CAS) NUMBERS & CHEMICAL NAMES LISTED BY CAS NUMBER

CAS NUMBER	CHEMICAL NAME	RULE CODE
925-60-0	2-Propenoic acid, propyl ester	p1
930-22-3	Oxirane, ethenyl-	d1
930-37-0	Oxirane, (methoxymethyl)-	p1 d1
933-75-5	2,3,6-Trichlorophenol	t31
939-97-9	Benzaldehyde, 4-(1,1-dimethylethyl)- aka: p-tert-Butylbenzaldehyde PTBB	a8 d17
961-11-5	Tetrachlorvinphos	sr313
989-38-8	C.I. Basic Red 1	sr313
992-59-6	1-Naphthalenesulfonic acid, 3,3'-[(3,3'-dimethyl [1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[4-amino-, disodium salt	d1
1000-82-4	Urea, (hydroxymethyl)- aka: Methylolurea	p4 d4
1024-57-3	Heptachlor epoxide	sr110*
1070-78-6	Propane, 1,1,1,3-tetrachloro-	d20
1120-71-4	1,2-Oxathiolane, 2,2-dioxide aka: Propane sultone	sr313
1129-42-6	Urea, (hexahydro-6-methyl-2-oxo-4-pyrimidinyl)-	s59
1139-30-6	5-Oxatricyclo[8.2.0.0 (4,6)]dodecane, 4,12,12-trimethyl-9-methylene-, [1R-(1R*,4R*,6R*,10S*)]-	p1
1163-19-5	Decabromodiphenyl oxide aka: Decabromodiphenyl ether	
1185-81-5	Stannane, dibutylbis(dodecylthio)- aka: Dibutyltin bis(lauryl mercaptide)	
1197-37-1	1,2-Benzenediamine, 4-ethoxy- aka: o-Phenylenediamine, 4-ethoxy-	
1208-52-2	Benzenamine, 2-[(4-aminophenyl)methyl]-	

CHEMICAL ABSTRACT SERVICES (CAS) NUMBERS & CHEMICAL NAMES LISTED BY CAS NUMBER

CAS NUMBER	CHEMICAL NAME	RULE CODE
1241-94-7	Phosphoric acid, 2-ethylhexyl diphenyl ester	p1 d1
1300-71-6	Phenol, dimethyl-	d20
1309-64-4	Antimony oxide (Sb (2) O (3)) aka: Antimony trioxide	p1 d1
1313-13-9	Manganese oxide aka: Manganese dioxide	p18
1313-27-5	Molybdenum oxide aka: Molybdenum trioxide	p18 sr313
1314-20-1	Thorium dioxide	sr313
1314-62-1	Vanadium oxide aka: Vanadium pentoxide	p18
1319-77-3	Phenol, methyl- aka: Cresols	sr110 p1 sr313
1321-38-6	Benzene, diisocyanatomethyl- (unspecified isomer) aka: Unspecified toluene diisocyanate	m1 c2 d20
1321-64-8	Naphthalene, pentachloro-	a5 p1 d1
1321-65-9	Naphthalene, trichloro-	a5 p1 d1
1328-53-6	C.I. Pigment Green 7	[illegible]
1330-20-7	Benzene, dimethyl- (Total xylenes--sr110)	
1330-61-6	2-Propenoic acid, isodecyl ester	
1330-78-5	Phosphoric acid, tris(methylphenyl) ester	
1331-47-1	[1,1'-Biphenyl]-4,4'-diamine, dichloro-	
1332-21-4	Asbestos	

CHEMICAL ABSTRACT SERVICES (CAS) NUMBERS & CHEMICAL NAMES
LISTED BY CAS NUMBER

CAS NUMBER	CHEMICAL NAME	RULE CODE
	aka: Asbestiform mineral(s)	x6 a3 d1 sr313
1333-41-1	Pyridine, methyl-	r2 d6
1335-87-1	Naphthalene, hexachloro-	a5 p1 d1 sr313
1335-88-2	Naphthalene, tetrachloro-	a5 p1 d1
1336-36-3	Polychlorinated biphenyls aka: PCBs	x1 sr313
1344-28-1	Aluminum oxide	sr313*
1345-04-6	Antimony sulfide (Sb (2) S (3)) aka: Antimony trisulfide	p1 d1
1429-50-1	Phosphonic acid, [1,2-ethanediylbis[nitrobis (methylene)]]tetrakis- aka: EDTMPA	a12
1464-53-5	2,2'-Bioxirane	t35* p1 d1 sr313
1477-55-0	1,3-Benzenedimethanamine	p3
1582-09-8	Trifluralin	sr313
1623-19-4	Phosphoric acid, tri-2-propenyl ester	c2
1634-04-4	Propane, 2-methoxy-2-methyl- aka: Methyl tert-butyl ether	t41 p15 d19 sr313 t50
1649-08-7	Ethane, 1,2-dichloro-1,1-difluoro- aka: 1,2-Dichloro-1,1-difluoroethane HCFC-132b	d23 s55

CAS NUMBER	CHEMICAL NAME	RULE CODE
16[illegible]-4	2-Propenoic acid, 1,1-dimethylethyl ester	p1
1675-54-3	Oxirane, 2,2'-[(1-methylethylidene)bis(4,1-phenyleneoxymethylene)]bis-	d1
1717-00-6	Ethane, 1,1-dichloro-1-fluoro- aka: 1,1-Dichloro-1-fluoroethane HCFC-141b	d28
1746-01-6	Tetrachlorodibenzo-p-dioxin	sr110 x7
1817-73-8	Benzenamine, 2-bromo-4,6-dinitro-	p1 d1
1825-30-5	Naphthalene, 1,5-dichloro-	a5 d1
1825-31-6	Naphthalene, 1,4-dichloro-	a5 d1
1836-75-5	Nitrofen	sr313
1888-71-7	1-Propene, 1,1,2,3,3,3-hexachloro-	d16
18[illegible]5-6	Chlorothalonil	sr313
19[illegible]-4-9	Atrazine	sr110
1937-37-7	2,7-Naphthalenedisulfonic acid, 4-amino-3-[[4'-[(2,4-diaminophenyl)azo][1,1'-biphenyl]-4-yl]azo]-5-hydroxy-6-(phenylazo)-, disodium salt aka: C.I. Direct Black 38	sr313 p1 d1
1940-42-7	4-Bromo-2,5-dichlorophenol	t31
2050-69-3	Naphthalene, 1,2-dichloro-	a5 d1
2050-72-8	Naphthalene, 1,6-dichloro-	a5 d1
2050-73-9	Naphthalene, 1,7-dichloro-	a5 d1
2050-74-0	Naphthalene, 1,8-dichloro-	a5 d1
2050-75-1	Naphthalene, 2,3-dichloro-	a5 d1

CHEMICAL ABSTRACT SERVICES (CAS) NUMBERS & CHEMICAL NAMES
LISTED BY CAS NUMBER

CAS NUMBER	CHEMICAL NAME	RULE CODE
2052-07-5	1,1'-Biphenyl, 2-bromo- aka: 2-Bromobiphenyl	s5
2065-70-5	Naphthalene, 2,6-dichloro-	a5 d1
2082-81-7	2-Propenoic acid, 2-methyl-, 1,4-butanediyl ester	p1
2113-57-7	1,1'-Biphenyl, 3-bromo- aka: 3-Bromobiphenyl	s5
2136-89-2	2-Chlorobenzotrichloride	t35*
2150-54-1	2,7-Naphthalenedisulfonic acid, 3,3'-[(3,3'-dimethyl [1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[4,5-dihydroxy-, tetrasodium salt	d1
2156-96-9	2-Propenoic acid, decyl ester	p1
2164-17-2	Fluometuron	sr313
2198-75-6	Naphthalene, 1,3-dichloro-	a5 d1
2198-77-8	Naphthalene, 2,7-dichloro-	a5 d1
2210-28-8	2-Propenoic acid, 2-methyl-, propyl ester	p1
2210-79-9	Oxirane, [(2-methylphenoxy)methyl]-	d1
2223-82-7	2-Propenoic acid, 2,2-dimethyl-1,3-propanediyl ester	p1
2224-15-9	Oxirane, 2,2'-[1,2-ethanediylbis(oxymethylene)]bis-	d1
2234-13-1	Naphthalene, octachloro-	a5 p1 d1 sr313
2238-07-5	Oxirane, 2,2'-[oxybis(methylene)]bis-	p1 d1
2303-16-4	Diallate	sr313
2358-84-1	2-Propenoic acid, 2-methyl-, oxydi-2,1-ethanediyl ester	p1
2385-85-5	Mirex	sr313

CAS NUMBER	CHEMICAL NAME	RULE CODE
2[illegible]4-6	Oxirane, octyl-	r2 d1
2425-01-6	Oxirane, 2,2'-[1,4-phenylenebis(oxymethylene)]bis-	d1
2425-79-8	Oxirane, 2,2'-[1,4-butanediylbis(oxymethylene)]bis-	p1 d1
2426-08-6	Oxirane, (butoxymethyl)-	p1 d1
2426-54-2	2-Propenoic acid, 2-(diethylamino) ethyl ester	p1
2429-71-2	1-Naphthalenesulfonic acid, 3,3'-[(3,3'-dimethoxy [1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[4-hydroxy-, disodium salt	d1
2429-73-4	2,7-Naphthalenedisulfonic acid, 5-amino-3-[[4'-[(7-amino-1-hydroxy-3-sulfo-2-naphthalenyl)azo][1,1'-biphenyl]-4-yl]azo]-4-hydroxy-, trisodium salt	d1
2429-74-5	2,7-Naphthalenedisulfonic acid, 3,3'-[(3,3'-dimethoxy[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[5-amino-4-hydroxy-, tetrasodium salt	d1
2 79-0	Benzoic acid, 5-[[4'-[(1-amino-4-sulfo-2-naphthalenyl)azo][1,1'-biphenyl]-4-yl]azo]-2-hydroxy-, disodium salt	d1
2429-81-4	Benzoic acid, 5-[[4'-[[2,6-diamino-3-[[8-hydroxy-3,6-disulfo-7-[(4-sulfo-1-naphthalenyl)azo]-2-naphthalenyl]azo]-5-methylphenyl]azo] [1,1'-biphenyl]-4-yl]azo]-2-hydroxy-, tetrasodium salt	d1
2429-82-5	Benzoic acid, 5-[[4'-(7-amino-1-hydroxy-3-sulfo-2-naphthalenyl)azo][1,1'-biphenyl[-4-yl]azo]-2-hydroxy-, disodium salt	d1
2429-83-6	2,7-Naphthalenedisulfonic acid, 4-amino-3-[[4'[(2,4-diamino-5-methylphenyl)azo][1,1'-biphenyl]-4-yl]azo]-5-hydroxy-6-(phenylazo)-, disodium salt	d1
2429-84-7	Benzoic acid, 5-[[4'-(2-amino-8-hydroxy-6-sulfo-1-naphthalenyl)azo][1,1'-biphenyl]-4-yl]azo]-2-hydroxy-, disodium salt	d1
2432-99-7	11-Aminoundecanoic acid aka: 11-AA	a10 s8

CHEMICAL ABSTRACT SERVICES (CAS) NUMBERS & CHEMICAL NAMES
LISTED BY CAS NUMBER

CAS NUMBER	CHEMICAL NAME	RULE CODE
2455-24-5	2-Propenoic acid, 2-methyl-, [tetrahydro-2-furanyl] methyl ester	p1
2461-15-6	Oxirane, [[(2-ethylhexyl)oxy]methyl]-	d1
2461-18-9	Oxirane, [(dodecyloxy)methyl]-	p1 d1
2499-95-8	2-Propenoic acid, hexyl ester	p1
2528-36-1	Phosphoric acid, dibutyl phenyl ester	p1 d1
2530-83-8	Silane, trimethoxy[3-(oxiranylmethoxy)propyl]-	p1 d1
2530-85-0	2-Propenoic acid, 2-methyl-, 3-(trimethoxysilyl) propyl ester	p1
2536-05-2	Benzene, 1,1'-methylenebis[2-isocyanato-	c2 d20
2556-36-7	Cyclohexane, 1,4-diisocyanato-	c2 d20
2577-72-2	3,5-Dibromosalicylanilide	t31
2586-57-4	1,3-Naphthalenedisulfonic acid, 4-amino-5-hydroxy-6-[[4'-[(2-hydroxy-1-naphthalenyl)azo]-3,3'-dimethoxy [1,1'-biphenyl]-4-yl]azo-, disodium salt	d1
2586-58-5	Benzoic acid, 5-[[4'-[[2,6-diamino-3-methyl-5-[(4-sulfophenyl)azo]phenyl]azo][1,1'-biphenyl]-4-yl]azo] -2-hydroxy-, disodium salt	d1
2602-46-2	2,7-Naphthalenedisulfonic acid, 3,3'-[[1,1'-biphenyl]-4,4'-diylbis(azo)]bis[5-amino-4-hydroxy-, tetrasodium salt	p1 d1 sr313
2610-05-1	1,3-Naphthalenedisulfonic acid, 6,6'-[(3,3'-dimethoxy[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[4-amino-5-hydroxy-, tetrasodium salt	p1 d1
2650-18-2	C.I. Acid Blue 9, diammonium salt	sr[illegible]
2687-25-4	1,2-Benzenediamine, 3-methyl- aka: 1,2-Diamino-3-methylbenzene	p1 d1
2763-96-4	3(2H)-Isoxazolone, 5-(aminomethyl)-	c

CAS NUMBER	CHEMICAL NAME	RULE CODE
27 -9	Benzene, 1,3-bis(1-isocyanato-1-methylethyl)-	c2 d20
2832-40-8	C.I. Disperse Yellow 3	sr313
2855-19-8	Oxirane, decyl-	r2 p1 d1
2861-02-1	2,6-Anthracenedisulfonic acid, 4,8-diamino-9,10-dihydro-1,5-dihydroxy-9,10-dioxo-, disodium salt	p17 d22
2867-47-2	2-Propenoic acid, 2-methyl-, 2-(dimethylamino)ethyl ester	p1
2873-89-0	Ethane, 2-chloro-1,1,1,2-tetrafluoro- aka: 2-Chloro-1,1,1,2-tetrafluoroethane HCFC-124	d28
2893-80-3	Benzoic acid, 5-[[4'-[[2,4-dihydroxy-3-[(4-sulfophenyl)azo]phenyl]azo][1,1'-biphenyl]-4-yl]azo]-2-hydroxy-, disodium salt	d1
2897-60-1	Silane, diethoxymethyl[3-(oxiranylmethoxy)propyl]-	d1
29 5-9	Benzoic acid, 3-chloro-, methyl ester	p1
30 7-2	1-Tridecanol, phosphate (3:1)	c2
3076-04-8	2-Propenoic acid, tridecyl ester	p1
3083-25-8	Oxirane, (2,2,2-trichloroethyl)- aka: Trichlorobutylene oxide TCBO	p1 d1 s9
3101-60-8	Oxirane, [[4-(1,1-dimethylethyl)phenoxy]methyl]-	p1 d1
3118-97-6	C.I. Solvent Orange 7	sr313
3132-64-7	Oxirane, (bromomethyl)- aka: Epibromohydrin EBH	r2 p1 d1 s9
3165-93-3	Benzenamine, 4-chloro-2-methyl-, hydrochloride	s40
3173-72-6	Naphthalene, 1,5-diisocyanato-	c2 d2

CHEMICAL ABSTRACT SERVICES (CAS) NUMBERS & CHEMICAL NAMES LISTED BY CAS NUMBER

CAS NUMBER	CHEMICAL NAME	RULE CODE
3194-55-6	Cyclododecane, 1,2,5,6,9,10-hexabromo- aka: Hexabromocyclododecane	p1 d27 p23
3234-28-4	Oxirane, dodecyl-	r2 d1
3266-23-7	Oxirane, 2,3-dimethyl-	r2 d1
3288-58-2	Phosphorodithioic acid, O,O-diethyl-S-methyl ester aka: O,O-Diethyl-S-methyldithiophosphate	t35* d16
3296-90-0	1,3-Propanediol, 2,2-bis(bromomethyl)- aka: Dibromoneopentyl glycol	d20 p23
3319-31-1	1,2,4-Benzenetricarboxylic acid, tris(2-ethylhexyl) ester aka: Tris(2-ethylhexyl) trimellitate	p7 d2
3322-93-8	Cyclohexane, 1,2-dibromo-4-(1,2-dibromoethyl)-	r2 p6 d8
3389-71-7	Bicyclo[2,2,1]hepta-2,5-diene, 1,2,3,4,7,7-hexachloro- aka: 1,2,3,4,7,7-Hexachloronorbornadiene	a6 s1 p5 d7
3530-19-6	1,3-Naphthalenedisulfonic acid, 8-[[4'-[(4-ethoxyphenyl)azo][1,1'-biphenyl]-4-yl]azo]-7-hydroxy-, disodium salt	d1
3531-19-9	Benzenamine, 2-chloro-4,6,-dinitro-	d1
3567-65-5	1,3-Naphthalenedisulfonic acid, 7-hydroxy-8-[[4'-[[4-[[(4-methylphenyl)sulfonyl]oxy]phenyl]azo][1,1'-biphenyl]-4-yl]azo]-, disodium salt	d1
3618-72-2	Acetamide, N-[5-[bis[2-(acetyloxy)ethyl]amino]-2-[(2-bromo-4,6-dinitrophenyl)azo]-4-methoxyphenyl]- aka: C. I. Disperse Blue 79:1 DB-79:1	p16 d21 t48
3618-73-3	Acetamide, N-[5-[bis[2-(acetyloxy)ethyl]amino]-2-[(2-chloro-4,6-dinitrophenyl)azo]-4-methoxyphenyl]-	p16 d21
3626-28-6	2,7-Naphthalenedisulfonic acid, 4-amino-5-hydroxy-3-[[4'-[(4-hydroxyphenyl)azo][1,1'-biphenyl]-4-yl]azo]-6-(phenylazo)-, disodium salt	d1

CHEMICAL ABSTRACT SERVICES (CAS) NUMBERS & CHEMICAL NAMES
LISTED BY CAS NUMBER

CAS NUMBER	CHEMICAL NAME	RULE CODE
36 0-2	1,2-Benzenedicarboxylic acid, diundecyl ester aka: Diundecyl phthalate (branched and linear isomers)	t44 d1
3663-23-8	1,2-Benzenediamine, 4-butyl- aka: Benzenediamine, 4-butyl- o-Phenylenediamine, 4-butyl-	r2 p3 d3
3689-24-5	Tetraethyldithiopyrophosphate	t35*
3761-53-3	C.I. Food Red 5	sr313
3772-94-9	Pentachlorophenyl laurate	t31
3775-90-4	2-Propenoic acid, 2-methyl-, 2-[(1,1,-dimethylethyl) -amino]ethyl ester	p1
3844-45-9	C.I. Acid Blue 9, disodium salt	sr313*
3953-10-4	2-Propenoic acid, 2-ethylbutyl ester	p1
3956-55-6	Acetamide, N-[5-[bis[2-(acetyloxy)ethyl]amino]-2-[(2-bromo-4,6-dinitrophenyl)azo]-4-ethoxyphenyl]-	p15 d19
40[illegible]-11-9	Oxirane, (ethoxymethyl)-	p1 d1
4016-14-2	Oxirane, [(1-methylethoxy)methyl]-	p1 d1
4098-71-9	Cyclohexane, 5-isocyanato-1-(isocyanatomethyl)-1,3,3-trimethyl-	c2 d20
4162-45-2	Tetrabromobisphenol A bisethoxylate	t31
4170-30-3	2-Butenal aka: Crotonaldehyde	p19 d16 t47
4200-55-9	Phosphoric acid, tris(decyl) ester	c2
4335-09-5	2,7-Naphthalenedisulfonic acid, 4-amino-5-hydroxy-6[[4'-[(4-hydroxyphenyl)azo][1,1'-biphenyl]-4-yl]azo]-3-[(4-nitrophenyl)azo]-, disodium salt	d1
4549-40-0	N-Nitrosomethylvinylamine	sr313
4680-78-8	C.I. Acid Green 3	sr313

CHEMICAL ABSTRACT SERVICES (CAS) NUMBERS & CHEMICAL NAMES LISTED BY CAS NUMBER

CAS NUMBER	CHEMICAL NAME	RULE CODE
4835-11-4	1,6-Hexanediamine, N,N'-dibutyl-	p1
4889-45-6	Phosphoric acid, trioctadecyl ester	c2
5026-74-4	Oxiranemethanamine, N-[4-(oxiranylmethoxy)phenyl]-N-(oxiranylmethyl)-	d1
5042-55-7	1,3-Benzenediamine, 5-nitro- aka: m-Phenylenediamine, 5-nitro-	r2 p3 d3
5124-30-1	Cyclohexane, 1,1'-methylenebis[4-isocyanato-	c2 d20
5131-58-8	1,3-Benzenediamine, 4-nitro- aka: m-Phenylenediamine, 4-nitro-	r2 p3 d3
5131-60-2	1,3-Benzenediamine, 4-chloro- aka: m-Phenylenediamine, 4-chloro-	p3 d3
5131-66-8	2-Propanol, 1-butoxy-	p21 d25
5216-25-1	4-Chlorobenzotrichloride	t35
5255-75-4	Oxirane, [(4-nitrophenoxy)methyl]-	d1
5307-02-8	1,4-Benzenediamine, 2-methoxy- aka: p-Diaminoanisole	p3 d3
5307-14-2	1,4-Benzenediamine, 2-nitro- aka: p-Phenylenediamine, 2-nitro-	p3 d3
5344-82-1	Thiourea, (2-chlorophenyl)- aka: 1-(o-chlorophenyl)thiourea	t t
5388-62-5	Benzenamine, 4-chloro-2,6-dinitro-	
5455-98-1	1H-Isoindole-1,3(2H)-dione, 2-(oxiranylmethyl)-	
5470-11-1	Hydroxylamine hydrochloride aka: Hydroxylammonium chloride	
5493-45-8	1,2-Cyclohexanedicarboxylic acid, bis (oxiranylmethyl) ester	
5536-61-8	2-Propenoic acid, 2-methyl-, sodium salt	

CA[illegible]BER	CHEMICAL NAME	RULE CODE
58[illegible]-1	Benzene, 1-isocyanato-2-[(4-isocyanatophenyl) methyl]-	c2 d20
6033-05-2	Morphinan-3,6-diol, 7,8-didehydro-4,5-epoxy-17-methyl- [5alpha,6alpha]-, (Z)-9-octadecenoate (salt)	p1
6106-46-3	Benzeneacetic acid, alpha-(hydroxymethyl)-, 9-methyl -3-oxa-9-azatricyclo[3.3.1.0 (2,4)]non-7-yl ester, [7(S)-[1alpha,2beta,4beta,5alpha,7beta)]-, compound with methyl nitrate (1:1)	p1
6106-81-6	Benzeneacetic acid, alpha-(hydroxymethyl)-, 9-methyl -3-oxa-9-azatricyclo[3.3.1.0 (2,4)]non-7-yl ester, N-oxide, hydrobromide, [7(S)-(1alpha,2beta,4beta, 5alpha,7beta)]-	p1
6145-73-9	1-Propanol, 2-chloro-, phosphate (3:1)	p20 d24
6163-73-1	Ethanol, 2-methoxy-, phosphate (3:1)	c2
6178-32-1	Oxirane, [(4-nonylphenoxy)methyl]- aka: Propane, 1,2-epoxy-3-(p-nonylphenoxy)-	d1
6219-67-6	1,3-Benzenediamine, 4-methoxy-, sulfate aka: m-Phenylenediamine, 2-nitro-	r2 p3 d3
6219-71-2	1,4-Benzenediamine, 2-chloro-, sulfate aka: p-Phenylenediamine, 2-chloro-, sulfate	r2 p3 d3
6219-77-8	1,2-Benzenediamine, 4-nitro-, dihydrochloride aka: o-Phenylenediamine, 4-nitro-, sulfate	r2 p3 d3
6247-34-3	2-Anthracenedisulfonic acid-, 4-[[4-(acetylamino) phenyl]amino]-1-amino-9,10-dihydro-9,10-dioxo-	p[illegible] d[illegible]
6283-25-6	Benzenamine, 2-chloro-5-nitro-	[illegible]
6358-29-8	1,3-Naphthalenedisulfonic acid, 8-[[4'-[(4-ethoxyphenyl)azo]-3,3'-dimethyl[1,1'-biphenyl]-4-yl] azo]-7-hydroxy-, disodium salt	
6360-54-9	Benzoic acid, 5-[[4'-[[2,6-diamino-3-methyl-5-[(4-sulfophenyl)azo)phenyl]azo][1,1'-biphenyl]-4-yl]azo] -2-hydroxy-3-methyl-, disodium salt	

CHEMICAL ABSTRACT SERVICES (CAS) NUMBERS & CHEMICAL NAMES LISTED BY CAS NUMBER

CAS NUMBER	CHEMICAL NAME	RULE CODE
6369-59-1	1,4-Benzenediamine, 2-methyl-, sulfate	p1 d3
6422-86-2	1,4-Benzenedicarboxylic acid, bis(2-ethylhexyl) ester	p7 d2
6424-85-7	2-Anthracenesulfonic acid, 4-[[4-(acetylamino) phenyl]amino]-1-amino-9,10-dihydro-9,10-dioxo- monosodium salt	p17 d22
6449-35-0	1-Naphthalenesulfonic acid, 3-[[4'-[(6-amino-1-hydroxy-3-sulfo-2-naphthalenyl)azo]-3,3'-dimethoxy [1,1'-biphenyl]-4-yl]azo]-4-hydroxy-, disodium salt	d1
6484-52-2	Ammonium nitrate (solution)	sr313
6637-88-3	Benzoic acid, 5-[[4'-[(2,6-diamino-3-methyl-5-sulfophenyl)azo]-3,3'-dimethyl[1,1'-biphenyl]-4-yl] azo]-2-hydroxy-, disodium salt	d1
6656-03-7	Cuprate(3-), [mu-[7-[[3,3'-dihydroxy-4'-[[1-hydroxy-6-(phenylamino)-3-sulfo-2-naphthalenyl]azo][1,1'-bipenyl]-4-yl]azo]-8-hydroxy-1,6-naphthalene disulfonato(7-)]]di-, trisodium	d1
6739-62-4	Benzoic acid, 2-[[2-amino-6-[[4'-[(3-carboxy-4-hydroxyphenyl)azo]-3,3'-dimethoxy[1,1'-biphenyl]-4-yl]azo]-5-hydroxy-7-sulfo-1-naphthalenyl]azo]-5-nitro-, trisodium salt	d1
7005-72-3	4-Chlorophenyl phenyl	sr110
7195-45-1	1,2-Benzenedicarboxylic acid, bis(oxiranylmethyl) ester	d1
7221-93-4	Endrin aldehyde/endrin	sr110
7320-37-8	Oxirane, tetradecyl-	p1 d1
7328-97-4	Oxirane, 2,2',2'',2'''-[1,2-ethanediylidenetetrakis (4,1-phenyleneoxymethylene)]tetrakis-	d1
7332-46-9	Ethanol, 2-(2-butoxyethoxy)-, phosphate (3:1)	c2
7390-81-0	Oxirane, hexadecyl-	r2 d1
7422-52-8	Trisiloxane, 1,1,1,3,5,5,5-heptamethyl-3-[3-(oxiranylmethoxy)propyl]-	d1

CHEMICAL ABSTRACT SERVICES (CAS) NUMBERS & CHEMICAL NAMES
LISTED BY CAS NUMBER

CAS NUMBER	CHEMICAL NAME	RULE CODE
74[illegible]-5	Aluminum (fume or dust)	sr313
7439-92-1	Lead	sr110 sr313
7439-96-5	Manganese	sr110 sr313
7439-97-6	Mercury	sr110 sr313
7439-98-7	Molybdenum	sr110
7440-02-0	Nickel	sr110* sr313
7440-14-4	Radium	sr110
7440-22-4	Silver	p18 sr110 sr313
7440-24-6	Strontium	sr110
74[illegible]8-0	Thallium	sr110 d20 sr313
7440-29-1	Thorium	sr110
7440-31-5	Tin	sr110
7440-36-0	Antimony	sr110 p1 d1 sr313
7440-38-2	Arsenic	sr110* sr313
7440-39-3	Barium	sr110 sr313
7440-41-7	Beryllium	sr110* sr313
7440-42-8	Boron	sr110
7440-43-9	Cadmium	sr110*

CHEMICAL ABSTRACT SERVICES (CAS) NUMBERS & CHEMICAL NAMES
LISTED BY CAS NUMBER

CAS NUMBER	CHEMICAL NAME	RULE CODE
		sr313
7440-47-3	Chromium	sr110 sr313
7440-48-4	Cobalt	sr110 d20 sr313
7440-50-8	Copper	sr110 sr313
7440-61-1	Uranium	sr110
7440-62-2	Vanadium (fume or dust)	sr110 sr313
7440-66-6	Zinc (fume or dust)	sr110 sr313
7446-09-5	Sulfur dioxide	sr110
7446-81-3	2-Propenoic acid, sodium salt	p1
7534-94-3	2-Propenoic acid, 2-methyl-, 1,7,7-trimethylbicyclo [2.2.1]hept-2-yl ester, exo-	p1
7550-45-0	Titanium tetrachloride	sr313
7647-01-0	Hydrochloric acid	sr313
7647-10-1	Palladium chloride aka: Palladium(II) chloride	p18
7664-38-2	Phosphoric acid	sr313
7664-39-3	Hydrofluoric acid aka: Hydrogen fluoride	p18 sr313
7664-41-7	Ammonia	sr110 sr313
7664-93-9	Sulfuric acid	sr110 sr313
7665-72-7	Oxirane, [(1,1-dimethylethoxy)methyl]-	d1
7681-49-4	Sodium fluoride	p18
7697-37-2	Nitric acid	sr313

CHEMICAL ABSTRACT SERVICES (CAS) NUMBERS & CHEMICAL NAMES
LISTED BY CAS NUMBER

CAS NUMBER	CHEMICAL NAME	RULE CODE
7[illegible]4-0	Phosphorus	p18 sr313
7726-95-6	Bromine	p18
7757-82-6	Sodium sulfate (solution)	sr313*
7761-88-8	Nitric acid, silver(1+) salt aka: Silver nitrate	p18
7782-49-2	Selenium	p18 sr110 sr313
7782-50-5	Chlorine	m1 sr313
7783-06-4	Hydrogen sulfide	sr110
7783-20-2	Ammonium sulfate (solution)	sr313
7785-87-7	Sulfuric acid, manganese(2+) salt (1:1) aka: Manganese(II) sulfate	p18
7[illegible]9-8	Hydroxylamine aka: Oxammonium	m1
7803-55-6	Ammonium vanadate	t35*
8001-35-2	Toxaphene	sr110 sr313
8001-58-9	Creosote	sr313** sr110
8014-91-3	Benzoic acid, 3,3'-[(3,7-disulfo-1,5-naphthalenediyl)bis[azo(6-hydroxy-3,1-phenylene)azo[6 (or 7)-sulfo-4,1-naphthalenediyl]azo[1,1'-biphenyl]-4,4'-diylazo]]bis[6-hydroxy-, hexasodium salt	d1
9011-05-6	Urea, polymer with formaldehyde	p11 d11
9016-87-9	Isocyanic acid, polymethylenepolyphenylene ester	c2 d20
10028-17-8	Tritium	sr110

CHEMICAL ABSTRACT SERVICES (CAS) NUMBERS & CHEMICAL NAMES LISTED BY CAS NUMBER

CAS NUMBER	CHEMICAL NAME	RULE CODE
10034-93-2	Hydrazine sulfate	sr313
10039-54-0	Hydroxylamine sulfate (2:1) aka: Hydroxylammonium sulfate	m1
10043-92-2	Radon & compounds	sr110
10046-00-1	Hydroxylamine sulfate (1:1) aka: Hydroxylamine acid sulfate	m1
10049-04-4	Chlorine dioxide	sr313
10061-01-5	cis-1,3-Dichloropropene	sr110
10061-02-6	trans-1,3-Dichloropropene	sr110
10124-43-3	Sulfuric acid, cobalt(2+) salt (1:1) aka: Cobaltous sulfate Cobalt(II) sulfate	p18
10347-54-3	Cyclohexane, 1,4-bis(isocyanatomethyl)-	c2 d20
10361-37-2	Barium chloride	p18
10401-50-0	C.I. Direct Blue 218	d1
10427-00-6	2-Furanmethanol, tetrahydro-, phosphate	c2
10436-39-2	1-Propene, 1,1,2,3-tetrachloro-	d20
10588-01-9	Sodium dichromate	x8
11096-82-5	PCBs--Aroclor 1260	sr110
11097-69-1	PCBs--Aroclor 1254	sr110
11104-28-2	PCBs--Aroclor 1221	sr110
11141-16-5	PCBs--Aroclor 1232	sr110
12001-29-5	Chrysotile [(Mg (3))(H (2))((SiO (4)) (2))(H (2)O)] aka: Asbestiform mineral(s)	a3 d1
12001-85-3	Naphthenic acids, zinc salts	d2
12070-12-1	Tungsten carbide	p1
12122-67-7	Zineb	s1

CAS NUMBER	CHEMICAL NAME	RULE CODE
12001-73-5	Asbestos, grunerite aka: Asbestiform mineral(s)	a3 d1
12217-79-7	9,10-Anthracenedione, 1,5-diaminochloro-4,8-dihydroxy-	p17 d22
12427-38-2	Maneb	sr313
12513-27-8	Zinc borate hydrate aka: ZB-2335	sr313
12604-53-4	Ferromanganese	p18
12672-29-6	PCBs--Aroclor 1248	sr110
12674-11-2	PCBs--Aroclor 1016	sr110
13048-33-4	2-Propenoic acid, 1,6-hexanediyl ester	p1
13236-02-7	Oxirane, 2,2',2"-[1,2,3-propanetriyltris (oxymethylene)]tris-	p1 d1
13414-54-5	Benzene, 1-[(2-methyl-2-propenyl)oxy]-2-nitro-	p7 d5
13463-55-6	Benzofuran, 2,3-dihydro-2,2-dimethyl-7-nitro-	p7 d5
13463-67-7	Titanium dioxide	sr313*
13561-08-5	Oxirane, 2,2'-(oxiranylmethoxy)-1,3-phenylene]bis (methylene)]bis-	p1 d1
13654-09-6	1,1'-Biphenyl, 2,2',3,3',4,4',5,5',6,6'-decabromo- aka: Decabromobiphenyl	s5
13674-84-5	2-Propanol, 1-chloro-, phosphate (3:1)	p20 d24
13674-87-8	2-Propanol, 1,3-dichloro-, phosphate (3:1)	p20 d24
14228-73-0	Oxirane, 2,2'-[1,4-cyclohexanediylbis (methyleneoxymethylene)]bis- aka: Cyclohexane, 1,4-bis[(2,3-epoxypropoxy)methyl]-	d1
14302-13-7	Copper, [1,3,8,16,18,24-hexabromo-2,4,9,10,11,15,17, 22,23,25-decachloro-29H,31H-phthalocyaninato(2-)-N (29),N (30),N (31),N (32)]-, (SP-4-2)- aka: C.I. Pigment Green 36	sr313*

CAS NUMBER	CHEMICAL NAME	RULE CODE
14797-55-8	Nitrates/nitrites	sr110
15117-48-3	Plutonium-239	sr110
15142-96-8	Phosphonic acid, [1,2-ethanediylbis[nitrilobis (methylene)]]tetrakis-, hexasodium salt	a12
15646-96-5	Hexane, 1,6-diisocyanato-2,4,4-trimethyl-	c2 d20
15872-73-8	Phenol, 2,4-diamino-6-methyl- aka: 4,6-Diamino-o-cresol	r2 p3 d3
15965-99-8	Oxirane, [(hexadecyloxy)methyl]-	d1
16071-86-6	Cuprate(2-), [5-[[4'-[[2,6-dihydroxy-3-[(2-hydroxy-5-sulfophenyl)azo]phenyl]azo][1,1'-biphenyl]-4-yl]azo]-2-hydroxybenzoato(4-)]-, disodium	d1 sr313
16110-89-7	Benzenesulfonic acid, 4[(4,6-dichloro-1,3,5-triazin-2-yl)amino]-	p1
16143-79-6	Cuprate(4-), [mu-[[6,6'-[(3,3'-dihydroxy[1,1'-biphenyl]-4-4'-diyl)bis(azo)]bis[4-amino-5-hydroxy-1,3-naphthalenedisulfonato]](8-)]]di-, tetrasodium	d1
16245-77-5	1,4-Benzenediamine, sulfate (1:1) aka: p-Phenylenediamine, sulfate salt p-PDA.(H)2 S(O)4	t36 p3 d3 t52
16245-97-9	Oxirane, [(octadecyloxy)methyl]-	d1
16532-79-9	4-Bromobenzylcyanide	t35
16543-55-8	N-Nitrosonornicotine	sr313
16715-83-6	2-Propenoic acid, 2-methyl-, 2-[bis(1-methylethyl)amino]ethyl ester	p1
16938-22-0	Hexane, 1,6-diisocyanato-2,2,4-trimethyl-	c2 d20
16984-48-8	Fluorides/fluorine/hydrogen fluoride	sr110
17068-78-9	Anthopyllite aka: Asbestiform mineral(s)	a3 d1

CAS NUMBER	CHEMICAL NAME	RULE CODE
17[illegible]39-2	2-Propanamine, 1-chloro-N,N-dimethyl-, hydrochloride	p1
17418-58-5	9,10-Anthracene, 1-amino-4-hydroxy-2-phenoxy-	p19 d22
17557-23-2	Oxirane, 2,2'-[(2,2-dimethyl-1,3-propanediyl)bis-(oxymethylene)]bis-	d1
17963-04-1	Silane, ethoxydimethyl[3-oxiranylmethoxy)propyl]- aka: Silane, [3-(2,3-epoxypropoxy)propyl] ethoxydimethyl-	d1
17977-09-2	2-Propenoic acid, 2,2-dinitropropyl ester	p1
18266-52-9	1,4-Benzenediamine, 2-nitro-, dihydrochloride aka: p-Phenylenediamine, 2-nitro-, dihydrochloride	r2 p3 d3
18495-30-2	Propane, 1,1,2,3-tetrachloro-	r2 d20
18633-25-5	Oxirane, tridecyl-	d1
19660-16-3	2-Propenoic acid, 2,3-dibromopropyl ester	r2 d20
2[illegible]-09-7	1,4-Benzenediamine, 2,5-dichloro- aka: p-Phenylenediamine, 2,5-dichloro-	r2 p3 d3
20217-01-0	Oxirane, [(2,4-dibromophenoxy)methyl]-	d1
20282-70-6	[1,1'-Biphenyl]-4,4'-bis(diazonium), 3,3'-dimethoxy-	d1
20816-12-0	Osmium tetroxide	sr313
20830-81-3	Daunomycin	t35*
21429-43-6	Acetamide, N-[5-[bis[2-(acetyloxy)ethyl]amino]-2-[(2-chloro-4,6-dinitrophenyl)azo]-4-ethoxyphenyl]-	p16 d21
21850-44-2	Tetrabromobisphenol-A-bis-2,3-dibromopropyl ether	t31
22092-38-2	Oxirane, pentadecyl-	r2 d1
24442-57-7	Ethanol, 1,2-dibromo-, acetate	p1
25085-99-8	Oxirane, 2,2'-[(1-methylethylidene)bis(4,1-phenyleneoxymethylene)]bis-, homopolymer	p1 d1

CHEMICAL ABSTRACT SERVICES (CAS) NUMBERS & CHEMICAL NAMES
LISTED BY CAS NUMBER

CAS NUMBER	CHEMICAL NAME	RULE CODE
25134-21-8	4,7-Methanoisobenzofuran-1,3-dione, 3a,4,7,7a-tetrahydromethyl-	p1
25154-55-6	Nitrophenol	sr110
25155-23-1	Phenol, dimethyl-, phosphate (3:1)	p1 d1
25168-06-3	Phenol, (1-methylethyl)- aka: Isopropyl phenol	p21 d25
25168-21-2	Dibutyltin bis(isooctyl maleate) aka: 2-Butenoic acid, 4,4'-[(dibutylstannylene)bis (oxy)]bis[4-oxo-, diisooctyl ester, (Z,Z)-	p7 d2
25168-24-5	Acetic acid, 2,2'-[(dibutylstannylene)bis(thio)] bis-, diisooctyl ester aka: Dibutyltin S,S'-bis(isooctyl) mercaptoacetate	r2 p7 d2
25321-14-6	Benzene, methyldinitro- aka: Dinitrotoluene (mixed isomers)	sr313**
25321-22-6	Benzene, dichloro (mixed isomers)	sr313
25327-89-3	Allyl ether of tetrabromobisphenol A	t31
25376-45-8	Benzenediamine, ar-methyl- aka: Diaminotoluene	p3 d3 sr313
25498-49-1	Propanol, [2-(2-methoxymethylethoxy)methylethoxy]- aka: Tripropylene glycol monomethyl ether	p21 d25
25550-14-5	Benzene, ethylmethyl-	p1 d1
25550-98-5	Phosphorous acid, diisodecyl phenyl ester aka: Diisodecyl phenyl phosphite	p
25551-13-7	Benzene, trimethyl- (mixed isomers)	
25584-83-2	2-Propenoic acid, monoester with 1,2-propanediol	
25586-43-0	Naphthalene, chloro-	

CHEMICAL ABSTRACT SERVICES (CAS) NUMBERS & CHEMICAL NAMES
LISTED BY CAS NUMBER

CAS NUMBER	CHEMICAL NAME	RULE CODE
25637-99-4	Cyclodecane, hexabromo-	p1
25640-78-2	1,1'-Biphenyl, (1-methylethyl)- aka: Isopropyl biphenyl	p6 d8
25724-58-7	1,2-Benzenedicarboxylic acid, decyl hexyl ester	d1
25852-70-4	Acetic acid, 2,2',2"-[(butylstannylidyne)tris(thio)] tris-, triisooctyl ester aka: Monobutyltin tris(isooctyl) mercaptoacetate	p7 d2
26444-49-5	Phosphoric acid, methylphenyl diphenyl ester	p1 d1
26447-14-3	Oxirane, [(methylphenoxy)methyl]-	p1 d1
26447-40-5	Benzene, 1,1'-methylenebis[isocyanato-	c2 d20
26471-62-5	Benzene, 1,3-diisocyanatomethyl- aka: Toluene diisocyanate (mixed isomers)	sr313** m1 sr110 c2 d20
265 0-1	3(2H)-Isothiazolone, 2-octyl-	r2 d20
26636-01-1	Acetic acid, 2,2'-[(dimethylstannylene)bis(thio)] bis-, diisooctyl ester aka: Dimethyltin S,S'-bis(isooctyl) mercaptoacetate	r2 p7 d2
26761-40-0	1,2-Benzenedicarboxylic acid, diisodecyl ester aka: Diisodecyl phthalate	t44 p1 d1
26761-45-5	Neodecanoic acid, 2,3-epoxypropyl ester aka: Neodecanoic acid, oxiranylmethyl ester	p1 d1
26952-23-8	1-Propene, dichloro-	d2
27288-44-4	Antimony tris(iso-octyl mercaptoacetate) aka: ATOM	sr
27554-26-3	1,2-Benzenedicarboxylic acid, diisooctyl ester	d1
27753-52-2	Nonabromobiphenyl (unspecified location of bromines)	s

CHEMICAL ABSTRACT SERVICES (CAS) NUMBERS & CHEMICAL NAMES LISTED BY CAS NUMBER

CAS NUMBER	CHEMICAL NAME	RULE CODE
27858-07-7	Octabromobiphenyl, (ar,ar,ar,ar,ar',ar',ar',ar')-	s5
28108-99-8	Phosphoric acid, (1-methylethyl)phenyl diphenyl ester	d1
28553-12-0	1,2-Benzenedicarboxylic acid, diisononyl ester	d1
29385-43-1	1H-Benzotriazole, methyl- aka: Tolyltriazole	p21 d25
29761-21-5	Phosphoric acid, isodecyl diphenyl ester	p1 d1
32052-51-0	Isocyanic acid, trimethylcyclohexyl ester aka: Isocyanic acid, trimethylhexamethylene ester Hexane, 1,6-diisocyanato-2,2,4(or 2,4,4)-trimethyl-	c2 d20
32241-08-0	Naphthalene, heptachloro-	r2 a5 d1
32360-05-7	2-Propenoic acid, 2-methyl-, octadecyl ester	p1
32534-81-9	Pentabromodiphenyl oxide aka: Pentabromodiphenyl ether	t31 d27 p23
32536-52-0	Octabromodiphenyl oxide aka: Octabromodiphenyl ether	t31 d27 p23
32568-89-1	2,4-Imidazolidinedione, 5,5-dimethyl-3-[2-(oxiranylmethoxy)propyl]-1-(oxiranylmethyl)-	d1
32588-76-4	N,N'-Ethylenebis(tetrabromophthalimide) aka: 1H-Isoindole-1,3(2H)-dione, 2,2'-(1,2-ethanediyl)bis[4,5,6,7-tetrabromo-	p23 d27
33125-86-9	Phosphoric acid, 1,2-ethanediyl tetrakis (2-chloroethyl) ester	p20 d24
33791-58-1	2-Propenoic acid, 3a,4,5,6,7,7a-hexahydro-4,7-methano-1H-indenyl ester	p1
34274-30-1	Phosphonic acid, [1,2-ethanediylbis[nitrilobis (methylene)]] tetrakis-, potassium salt	a12
34364-42-6	Phosphoric acid, (1-methyl-1-phenylethyl)phenyl diphenyl ester	d1

CHEMICAL ABSTRACT SERVICES (CAS) NUMBERS & CHEMICAL NAMES
LISTED BY CAS NUMBER

CAS NUMBER	CHEMICAL NAME	RULE CODE
34[illegible]4-8	Propanol, (2-methoxymethylethoxy)- aka: Dipropylene glycol monomethyl ether	p21 d25
35243-89-1	Oxirane, [(1,2-dibromopropoxy)methyl]-	d1
36355-01-8	Hexabromobiphenyl (unspecified location of bromines)	s5
37853-59-1	Benzene, 1,1'-[1,2-ethanediylbis(oxy)]bis[2,4,6-tribromo- aka: 1,2-Bis(tribromophenoxy) ethane	t31 p1 d27 p23
37853-61-5	Bismethyl ether of tetrabromobisphenol A	t31
38304-52-8	2,4-Imidazolidenedione, 3,3'-[2-(oxiranylmethoxy)-1,3-propanediyl]bis[5,5-dimethyl-1-(oxiranylmethyl)-	d1
38565-52-5	Oxirane, (2,2,3,3,4,4,5,5,6,6,7,7,7-tridecafluoroheptyl)-	r2 d1
38661-72-2	Cyclohexane, 1,3-bis(isocyanatomethyl)-	c2 d20
38954-75-5	Oxirane, [(tetradecyloxy)methyl]-	p2 d1
39[illegible]1-7	1,3-Benzenediamine, 4-methoxy-, sulfate (1:1) aka: 2,4-Diaminoanisole sulfate	p3 d3 sr313
39817-09-9	Oxirane, 2,2'-[methylenebis(phenyleneoxymethylene)]bis- aka: 2,2'-[Methylenebis(phenyleneoxymethylene)]bisoxirane	d1
41291-34-3	Ethylene(5,6-dibromonorbornane-2,3-dicarboximide) aka: 4,7-Methano-1H-isoindole-1,3(2H)-dione, 2,2'-(1,2-ethanediyl)bis[5,6-dibromohexahydro-	p23 d27
42389-30-0	1,2-Benzenediamine, 5-chloro-3-nitro-	r2 p3 d3
51363-64-5	Phosphoric acid, diisodecyl phenyl ester	p1 d1
53469-21-9	PCBs--Aroclor 1242	sr11[illegible]
54208-63-8	Oxirane, 2,2'-[methylenebis(2,1-	d1

CAS NUMBER	CHEMICAL NAME	RULE CODE
	phenyleneoxymethylene)]bis-	
54849-38-6	Monomethyltin tris(isooctyl) mercaptoacetate aka: Acetic acid, 2,2',2"-[(methylstannylidyne)tris (thio)]tris-, triisooctyl ester	r2 p7 d2
55205-38-4	Tetrabromobisphenol A diacrylate	t31
56803-37-3	Phosphoric acid, (1,1-dimethylethyl)phenyl diphenyl ester	p1 d1
56827-95-3	1-Hexadecanol, phosphate (3:1)	c2
57011-27-5	Phosphonic acid, [1,2-ethanediylbis[nitrilobis (methylene)]] tetrakis-, ammonium salt	a12
57137-10-7	Tribrominated polystyrene	p23 d27
57344-01-1	Poly(oxy-1,2-ethanediyl), alpha,alpha'-[(octyloxy)phosphinylidene]bis[omega-hydroxy-	c2
57344-02-2	Poly(oxy-1,2-ethanediyl), alpha-[bis(octyloxy) phosphinyl]-omega-hydroxy-	c2
60501-41-9	Oxirane, [9-Octadecenyloxy)methyl]-,(Z)-	d1
61262-53-1	Ethylenebis(pentabromophenoxide) aka: Benzene, 1,1'-[1,2-ethanediylbis(oxy)]bis [2,3,4,5,6-pentabromo-	p23 d27
61386-02-5	Benzoic acid, 3,3'-methylenebis[6-amino-, di-2-propenyl ester	s28
61578-04-9	Oxirane, [[4-(1-methyl-1-phenylethyl)phenoxy] methyl]-	d1
61702-81-6	1,2-Benzenedicarboxylic acid, hexyl isodecyl ester	d1
61788-33-8	Terphenyl, chlorinated aka: Polychlorinated p-terphenyl	r2 a4 d1
61788-76-9	Alkanes, chloro-	d1
61789-36-4	Naphthenic acids, calcium salts aka: Calcium naphthenate	p4 d4
61789-51-3	Naphthenic acids, cobalt salts aka: Cobalt naphthenate	p4 d4

CAS NUMBER	CHEMICAL NAME	RULE CODE
6[illegible]14-5	Naphthenic acids, lead salts aka: Lead naphthenate	p4 d4
61886-60-0	1,2-Benzenedicarboxylic acid, isodecyl tridecyl ester	d1
62654-17-5	1,4-Benzenediamine, ethanedioate (1:1)	p3 d3
63449-39-8	Paraffin waxes and hydrocarbon waxes, chloro	d1
64131-07-3	1-Hexacosanol, phosphate (3:1)	c2
64131-08-4	1-Tetracosanol, phosphate (3:1)	c2
64131-09-5	1-Docosanol, phosphate (3:1)	c2
64131-10-8	1-Eicosanol, phosphate (3:1)	c2
64131-18-6	1-Octacosanol, phosphate (3:1)	c2
64502-13-2	Poly(oxy-1,2-ethanediyl), alpha,alpha',alpha"-phosphinylidynetris[omega-hydroxy-	c2
65[illegible]-44-9	Phenol, 2,4-diamino-6-methyl-, hydrochloride	r2 p3 d3
66108-37-0	Phosphoric acid, 2,2-bis(bromomethyl)-3-chloropropyl bis[2-chloro-1-(chloromethyl)ethyl] ester	p1
66422-95-5	Ethanol, 2-(2,4-diaminophenoxy)-, dihydrochloride	r2 p3 d3
67801-06-3	1,3-Benzenediamine, 4-ethoxy-, dihydrochloride	r2 p3 d3
67860-04-2	Oxirane, heptadecyl-	r2 d1
67924-23-6	Cobaltate(6-), [[[1,2-ethanediylbis[nitrilobis (methylene)]]tetrakis[phosphonato]](8-)]-, pentapotassium hydrogen, (OC-6-21)-	a12
67969-67-9	Cobaltate(6-), [[[1,2-ethanediylbis[nitrilobis (methylene)]]tetrakis[phosphonato]](8-)-N,N',O,O'', O'''',O''''''']-, pentasodium hydrogen, (OC-6-21)-	a12

CAS NUMBER	CHEMICAL NAME	RULE CODE
67989-89-3	Cuprate(6-), [[[1,2-ethanediylbis[nitrilobis (methylene)]]tetrakis[phosphonato]](8-)]-, pentapotassium hydrogen, (OC-6-21)-	a12
67989-89-3	Cuprate (6-), [[[1,2-ethanediylbis[nitrilobis(methyl ene)]]tetrakis[phosphonato]] (8-)]-,pentapotassium h ydrogen, (OC-6-21)-	a12
68015-98-5	1,3-Benzenediamine, 4-ethoxy-, sulfate (1:1)	r2 p3 d3
68025-39-8	Cobaltate(6-), [[[1,2-ethanediylbis[nitrilobis (methylene)]]tetrakis[phosphonato]](6-)-N,N',O,O'', O'''',O''''''']-, pentaammonium hydrogen, (OC-6-21)-	a12
68081-84-5	Oxirane, mono[(C (10-16)-alkyloxy)methyl] derivatives	d1
68122-86-1	Imidazolium compounds, 4,5-dihydro-1-methyl-2-nortallow alkyl-1-(2-tallow amidoethyl), methyl sulfates	p19 d23
68153-35-5	Ethanaminium, 2-amino-N-(2-aminoethyl)-N-(2-hydroxyethyl)-N-methyl-, N,N'-ditallow acyl derivatives, methyl sulfates (salts)	p19 d23
68188-98-8	Phosphonic acid, [1,2-ethanediylbis[nitrilobis (methylene)]] tetrakis-, tetrapotassium salt	a12
68239-80-5	1,3-Benzenediamine, 4-chloro-, sulfate (1:1) aka: m-Phenylenediamine, 4-chloro-, sulfate	r2 p3 d3
68239-82-7	1,2-Benzenediamine, 4-nitro-, sulfate (1:1)	r2 p3 d3
68239-83-8	1,4-Benzenediamine, 2-nitro-, sulfate (1:1)	r2 p3 d3
68298-46-4	7-Benzofuranamine, 2,3-dihydro-2,2-dimethyl-	r2 p7 d5
68309-98-8	Cadmate(6-), [[[1,2-ethanediylbis[nitrilobis (methylene)]]tetrakis[phosphonato]](8-)]-, pentapotassium hydrogen, (OC-6-21)-	a.

CAS NUMBER	CHEMICAL NAME	RULE CODE
68[illegible]88-8	Poly(oxy-1,2-ethanediyl), alpha-[2-[bis(2-aminoethyl)methylammonio]ethyl]-omega-hydroxy-, N, N'-dicoco acyl derivatives, methyl sulfates (salts)	p19 d23
68389-89-9	Poly(oxy-1,2-ethanediyl), alpha-[2-[bis(2-aminoethyl)methylammonio]ethyl]-omega-hydroxy-, N, N'-bis(hydrogenated tallow acyl) derivatives, methyl sulfates (salts)	d23 p19
68410-69-5	Poly(oxy-1,2-ethanediyl), alpha-[2-[bis(2-aminoethyl)methylammonio]ethyl]-omega-hydroxy-, N, N'-ditallow acyl derivatives, methyl sulfates (salts)	p19 d23
68413-04-7	Poly[oxy(methyl-1,2-ethanediyl)], alpha-[2-[bis(2-aminoethyl)methylammonio]methylethyl]-omega-hydroxy-, N,N'-ditallow acyl derivatives, methyl sulfates (salts)	p19 d23
68459-98-3	1,2-Benzenediamine, 4-chloro-, sulfate (1:1)	r2 p3 d3
68515-44-6	Diheptyl phthalate (branched and linear isomers)	t44
68[illegible]45-7	Dinonyl phthalate (branched and linear isomers)	t44
68[illegible]-47-9	Ditridecyl phthalate (mixed isomers)	t44
68515-49-1	Diisodecyl phthalate (mixed isomers)	t44
68515-50-4	Dihexyl phthalate (mixed isomers)	t44
68517-02-2	Oxirane, 2,2',2"-[propylidynetris(4,1-phenyleneoxymethylene)]tris-	d1
68554-06-3	Poly(oxy-1,2-ethanediyl), alpha-[3-[bis(2-aminoethyl)methylammonio]-2-hydroxypropyl]-omega-hydroxy-, N-coco acyl derivatives, methyl sulfates (salts)	p19 d23
68609-96-1	Oxirane, mono[C (8-10)-alkyloxy)methyl] derivatives	d1
68609-97-2	Oxirane, mono[(C (12-14)-alkyloxy)methyl] derivatives	d1
68611-64-3	Urea, reaction products with formaldehyde	p[illegible] d[illegible]

CHEMICAL ABSTRACT SERVICES (CAS) NUMBERS & CHEMICAL NAMES
LISTED BY CAS NUMBER

CAS NUMBER	CHEMICAL NAME	RULE CODE
68901-17-7	Phosphonic acid, [1,2-ethanediylbis[nitrilobis (methylene)]]tetrakis-, octaammonium salt	a12
68920-70-7	Alkanes, C (6-18), chloro-	d1
68958-86-1	Nickelate(6-), [[[1,2-ethanediylbis[nitrilobis (methylene)]]tetrakis[phosphonato]](8-)]-, pentaammonium hydrogen, (OC-6-21)-	a12
68958-87-2	Nickelate(6-), [[[1,2-ethanediylbis[nitrilobis (methylene)]]tetrakis[phosphonato]](8-)]-, pentapotassium hydrogen (OC-6-21)-	a12
68958-88-3	Nickelate(6-), [[[1,2-ethanediylbis [nitrilobis (methylene)]]tetrakis[phosphonato]](8-)]-, pentasodium hydrogen (OC-6-21)-	a12
68959-23-9	Oxirane, 2,2',2"-[1,2,6-hexanetriyltris (oxymethylene)]tris-	d1
68966-84-7	1,3-Benzenediamine, ar-ethyl-ar-methyl-	r2 p3 d3
68987-80-4	Oxirane, mono[C (6-12)-alkyloxy)methyl] derivatives	d1
69009-90-1	1,1 -Biphenyl, bis(1-methylethyl)- aka: Diisopropyl biphenyl	r2 p6 d8
69155-42-6	Tetrasiloxane, 1,1,1,3,5,7,7,7-octamethyl-3,5-bis [3-(oxiranylmethoxy)propyl]-	d1
69943-75-5	Poly(oxy-1,2-ethanediyl), alpha-[4-(oxiranylmethoxy) benzoyl]-gamma-[[4-(oxiranylmethoxy)benzoyl]oxy]-	d1
70776-03-3	Naphthalene, chloro derivatives	r2 a5 d1
70914-09-9	Poly(oxy-1,2-ethanediyl), alpha-[2-[bis(2-aminoethyl)methylammonio]ethyl]-omega-hydroxy-, N, N'-di-C (14-18) acyl derivatives, methyl sulfates (salts)	p19 d23
71033-08-4	Oxirane, 2,2'-[(1-methylethylidene)bis[4,1-phenyleneoxy[1-(butoxymethyl)-2,1-ethanediyl] oxymethylene]]bis-	d1
71808-64-5	Silane,(3-chloropropyl)dimethoxy[3-(oxiranylmethoxy)	d1

CAS NUMBER	CHEMICAL NAME	RULE CODE
	propyl]-	
7[illegible]-24-5	Oxirane, 2,2'-[(1-methylethylidene)bis[4,1-phenyleneoxy-3,1-propanediyloxy-4,1-phenylene(1-methylethylidene)-4,1-phenyleneoxymethylene]]bis-	d1
73070-47-0	Poly(oxy-1,2-ethanediyl), alpha,alpha',alpha"-phosphinylidynetris[omega-(tridecyloxy)-	c2
73980-60-8	Diphenyl-2,4,6-trimethylbenzoyl phosphine oxide	s48
74049-24-4	Poly(oxy-1,2-ethanediyl), alpha,alpha'-(methoxyphosphinylidene)bis[omega-hydroxy-	c2
75790-84-0	Benzene, 2-isocyanato-4-[(4-isocyanatophenyl)methyl]-1-methyl-	c2 d20
75790-87-3	Benzene, 1-isocyanato-2-[(4-isocyanatophenyl)thio]-	c2 d20
79771-08-7	Isopropylamine, distillation residues	s13
79771-09-8	Ethylamine, distillation residues	s13
84852-15-3	4-Nonylphenol, branched* * = Chemical Abstracts Service does not consider this registry number (CAS No.) to represent a unique chemical substance; therefore, this is denoted by an asterisk (*). aka: para-branched C9-Alkylphenols	t49*
85712-26-1	Potassium N,N-bis(hydroxyethyl) cocoamine oxide phosphate	s12
85712-27-2	Potassium N,N-bis(hydroxyethyl) tallowamine oxide phosphate	s12
94148-67-1	Benzenamine, 4,4'-[[1,1'-biphenyl]-2,5-diylbis(oxy)]bis-	s58
100545-50-4	Decanamine, N-decyl-N-methyl-N-oxide	s47
111381-89-6	Di(heptyl, nonyl) phthalate (branched and linear isomers)	t44
111381-90-9	Di(heptyl, undecyl) phthalate (branched and linear isomers)	t44
111381-91-0	Di(nonyl, undecyl) phthalate (branched and linear isomers)	t44

CHEMICAL ABSTRACT SERVICES (CAS) NUMBERS & CHEMICAL NAMES
LISTED BY CAS NUMBER

CAS NUMBER	CHEMICAL NAME	RULE CODE

CHEMICAL ABSTRACT SERVICES (CAS) NUMBERS & CHEMICAL NAMES LISTED BY PMN NUMBER

PMN NUMBER	CHEMICAL NAME	RULE CODE
8[illegible]	Isopropylamine, distillation residues *	s13
80-290	Ethylamine, distillation residues *	s13
81-69	Benzophenonetetracarboxylic acid dimethyl ester, reaction product with methylenedianiline and substituted pyridine.	s23
81-125	Benzophenonetetracarboxylic acid dimethyl ester, reaction product with methylenedianiline and alkylenediamine; and benzophenonetetracarboxylic acid dimethyl ester, reaction product with methylenedianiline, alkylenediamine and substituted pyridine.	s24
82-326	Substituted methylpyridine *	s16
82-400	Potassium N,N-bis(hydroxyethyl) cocoamine oxide phosphate	s12
82-409	Potassium N,N-bis(hydroxyethyl) tallowamine oxide phosphate	s12
82-438	Benzoic acid, 3,3'-methylenebis-[6-amino-di-2-propenyl] ester	s28
8[illegible]	Derivative of tetrachloroethylene *	s19
83-23	Sustituted 2-phenoxypyridine *	s15
83-24	Substituted methylpyridine *	s15
83-49	Substituted methylpyridine *	s15
83-75	Substituted 2-phenoxypyridine *	s15
83-105	1,2-Benzenediamine, 4-ethoxy-, sulfate	s[illegible]
83-237	Substituted methylpyridine *	s[illegible]
83-255	Dicarboxylic acid monoester *	
83-272	Substituted methylpyridine *	
83-330	Substituted 2-phenoxypyridine *	
83-370	8-Acetyl-3-dodecyl-7,7,9,9-tetramethyl-1-,3,-8-triaza-spiro-[4,5]-decane-2,4-dione	
83-394	Substituted polyglycidyl benzenamine *	

CHEMICAL ABSTRACT SERVICES (CAS) NUMBERS & CHEMICAL NAMES
LISTED BY PMN NUMBER

PMN NUMBER	CHEMICAL NAME	RULE CODE
83-769	Substituted bromothiophene *	s26
83-817	[(Dinitrophenyl)azo]-[2,4-diamino-5-	s29
83-818	Methoxybenzene derivatives	s30
83-822	Disubstituted diamino anisole *	s31
83-906	Brominated arylalkyl ether *	s25
83-908	Ethylated aminophenol *	s25
83-909	Amino phenol *	s25
83-910	Anilino ether *	s25
83-1005	Triethanolamine salt of tricarboxylic acid *	x3
83-1023	Alkylaryl phosphine *	s27
83-1062	Tricarboxylic acid *	x3
83-1085	Halogenated-N-(2-propenyl)-N-[substituted phenyl] acetamide	s37
84-7	N,N,N',N'-Tetrakis(oxiranylmethyl)-1,3-cyclohexanedimethanamine or N,N,N',N'-Tetraglycidyl-1,3-bisaminomethylcyclohexane	s41
84-27	Alkyl glycol ether acrylic acid derivative *	s32
84-105	Substituted tetrafluoroalkane *	s35
84-106	Disubstituted tetrafluoroalkane *	s35
84-107	Disubstituted tetrafluoroalkane *	s35
84-176	Alkanetriol dimethacrylate, substituted *	s33
84-180	Polyalkylene glycol monomethacrylate, substituted *	s34
84-181	Polyalkyl-alkane diol monoacrylate, substituted *	s34
84-182	Alkanetriol polyalkylene glycol ester acrylate, substituted *	s34
84-183	Alkylene glycol monomethacrylate, substituted *	s34
84-184	Polyalkylalkanediol monomethacrylate, substituted *	s34

PMN NUMBER	CHEMICAL NAME	RULE CODE
84	Poly(oxy-1,4-butanediyl)-alpha-(1-oxo-2-propenyl)-gamma-[(1-oxo-2-propenyl)-oxy]- *	s39
84-310	Triethanolamine salt of a substituted organic acid	x4
84-341	2-Oxepanone, homopolymer, ester with 3-hydroxy-2,2-dimethylpropanoic acid (2:1), di-2-propenoate;	s38
84-342	2-Oxepanone, homopolymer, 2-propenoate, (tetrahydro-2-furanyl) methyl ester;	s38
84-343	2-Oxepanone, homopolymer, 2-propenoate, ester with 2,2'-[oxybis(methylene)]bis-[2-(hydroxymethyl)-1,3-propanediol];	s38
84-344	2-Propenoic acid, [2-[1,1-dimethyl-2-[(1-oxo-2-propenyl)oxy]ethyl]-5-ethyl-1,3-dioxan-5-yl]methyl ester.	s38
84-417	Methylphenol, bis(substituted alkyl)- *	s36
84-482	Urea, condensate with poly[oxy(methyl-1,2-ethanediyl)]-alpha-(2-aminomethylethyl)-mu-(2-aminoethylethoxy) (generic name)	s59
84	Mixed mono- and diamides of an organic acid	x5
84	Sodium salt of an alkylated, sulfonated aromatic (generic name)	s59
84-660	Substituted benzenes, halogenated *	s42
84-704		s42
84-820	Phosphonium salt (generic name)	s60
84-824	Brominated aromatic compound (generic name)	s59
84-913	N,N'-Bis(2-(2-(3-alkyl)thiazoline)vinyl)-1,4-phenylenediamine methyl sulfate, double salt (generic name)	s59
84-954	Substituted aromatic (generic name)	s59
84-963	6-Nitro-2(3H)-benzoxazolone	s59
84-1007	3-Alkyl-2-(2-anilino)vinylthiazolinium salt (generic name)	s59

CHEMICAL ABSTRACT SERVICES (CAS) NUMBERS & CHEMICAL NAMES LISTED BY PMN NUMBER

PMN NUMBER	CHEMICAL NAME	RULE CODE
84-1042	Methylammonium, N-methyldithiocarbamate	s40
84-1054	Alkyl sulfonic acid, ammonium salt *	s43
84-1056		s43
84-1079	Alkylated diphenyl oxide (generic name)	s60
85-335	Benzenamine, 4,4'-[[1,1'-biphenyl]-2,5-diylbis(oxy)] bis-	s58
85-336	A reaction mixture consisting of 1,2,4,5-benzenetetracarboxylic acid, 1,4-diethyl ester compound with 4,4'-[[1,1'-biphenyl]-2,5-diylbis(oxy)]bis[benzeneamine] (1:1) and 1,2,4,5-benzenetetracarboxylic acid, 1,5-diethyl ester compound with 4,4'-[[1,1'-biphenyl]-2,5-diylbis(oxy)]bis[benzeneamine] (1:1)	s58
85-337	1,2,4,5-benzenetetracarboxylic acid, 1,4-diethyl ester, compound with 4,4'-[[1,1'-biphenyl]-2,5-diylbis(oxy)]bis[benzeneamine] (1:1), polymer with 4,4'-[[1,1'-biphenyl]-2,5-diylbis(oxy)]bis[benzeneamine]-1,5-diethyl-1,2,4,5-benzenetetracarboxylate (1:1)	s58
85-367	Haloalkyl substituted cyclic ethers (generic name)	s60
85-368	Haloalkyl substituted cyclic ethers (generic name)	s60
85-369	Haloalkyl substituted cyclic ethers (generic name)	s60
85-433	1-Propanol, 3-mercapto-	s53
85-605	Trisubstituted phenol (generic name)	s60
85-680	1,1-Dimethylpropyl peroxyester (generic name)	s60
85-730	Substituted phosphate ester (generic name)	s59
85-929	1,3-Benzenediamine, 4-(1,1-Dimethylethyl)-ar-methyl	s52
85-932	Disubstituted alkyl triazines (generic name)	s59
85-933	Disubstituted alkyl triazines (generic name)	s59
85-1331	Naphthalene, 1,2,3,4-tetrahydro(1-phenylethyl)	s60
86-83		s44

CHEMICAL ABSTRACT SERVICES (CAS) NUMBERS & CHEMICAL NAMES LISTED BY PMN NUMBER

PMN NUMBER	CHEMICAL NAME	RULE CODE
36-	Tetraglycidylamines (generic name)	s59
36-501	Aromatic diamines (generic name)	s60
36-502	Tetraglycidylamines (generic name)	s59
36-503	Aromatic diamines (generic name)	s60
86-542	Ethanol, 2-amino-, compound with N-hydroxy-N-nitrosobenzenamine (1:1)	s45
86-562	Perfluoroalkyl epoxide (generic name)	s59
86-628	Dimer acids, polymer with polyalkylene glycol, bisphenol A - diglycidyl ether, and alkylenepolyols polyglycidyl ethers (generic name)	s60
86-1043	Monosubstituted alkoxyaminotrazines (generic name)	s60
86-1044	Monosubstituted alkoxyaminotrazines (generic name)	s60
86-1153	1,2,4,5-Benzenetetracarboxylic acid, 1,4-diethyl ester, compound with 4,4'-[[1,1'-biphenyl]-2,5-diylbis(oxy)]bis[benzeneamine] (1:1), polymer with 4,4'-[[1,1'-biphenyl]-2,5-diylbis(oxy)]bis[benzeneamine]-1,5-diethyl-1,2,4,5-benzenetetracarboxylate (1:1), reaction products with phthalic anhydride	s58
86-1252	Boric acid, alkyl and substituted alkyl esters (generic name)	s60
86-1322	Mixture of 1,3-Benzenediamine, 2 (or 4)-* methyl-4,6 (or 2,6)-bis(methylthio)-	s51
86-1489	Alkylphenoxypolyalkoxyamine (generic name)	s59
86-1493	Substituted alkyl peroxyhexane carboxylate (mixed isomers) (generic name)	s60
87-304	Nitrothiophene carboxylic acid, ethyl ester, bis[[[[(substituted)]amino]alkylphenyl]azo] (generic name)	s60
87-502	Dialkenylamide (generic name)	s59
87-1265	2-Naphthalenecarboxamide-N-aryl-3-hydroxy-4-arylazo (generic name)	s60
87-1456	Polyamine ureaformaldehyde condensate (generic name)	s60

CHEMICAL ABSTRACT SERVICES (CAS) NUMBERS & CHEMICAL NAMES LISTED BY PMN NUMBER

PMN NUMBER	CHEMICAL NAME	RULE CODE
88-63	Substituted thiazino hydrazine salt (generic name)	s60
88-854	Polymer of alkenoic acid, substituted alkylacrylate, sodium salt (generic name)	s59
88-1658	Polymer of alkanepolyol and polyalkylpolyisocyanatocarbomonocycle, acetone oxime -blocked (generic name)	s59
89-279	Formaldehyde, polymer with bisphenol A and substituted phenol (generic name)	s59
89-292	Carboxy alkyl silyl salt (generic name)	s59
89-303	Urea, (hexahydro-6-methyl-2-oxo-4-pyrimidinyl)-	s59
89-448	Alkanepolyol phosphate ester (generic name)	s57
89-506	Alkylated diarylamine, sulfurized (generic name)	s59
89-596	Alkylene glycol terephthalate and substituted benzoate esters (generic name)	s59
89-650	Substituted ethylene diamine, methyl sulfate quaternized (generic name)	s57
89-653	Adipic acid, polymer with 1,4-Cyclohexanedimethanol, dipropylene glycol, alkanepolyol, substituted alkanolamines, and carbomonocyclic dicarboxylic acid (generic name)	s57
89-703	Reaction products of secondary alkyl amines with a substituted benzenesulfonic acid and sulfuric acid (generic name)	s57
89-755	Reaction products of secondary alkyl amines with a substituted benzenesulfonic acid and sulfuric acid (generic name)	s57
89-756	Reaction products of secondary alkyl amines with a substituted benzenesulfonic acid and sulfuric acid (generic name)	s57
89-770	Coconut oil, reaction products with tetrahydroxy branched alkane esters of trisubstituted benzene propanoic acid (generic name)	s57

	CATEGORY NAME AND CHEMICALS OR MIXTURES TO WHICH A CAS NUMBER HAS NOT BEEN ASSIGNED	RULE CODE
**********	Alkyl epoxides-- including all noncyclic aliphatic hydrocarbons with one or more epoxy functional groups. Representative alkyl epoxides are listed by CAS registry number. The 8(d) reporting period for this category, listed in 40 CFR 716.120(c), has been terminated. Certain substances within this category have been transferred to the individual listing (40 CFR 716.120(a)) and their original sunset dates remain in effect.	r2 d1
**********	Alkyl phthalates-- all alkyl esters of 1,2-benzenedicarboxylic acid (ortho-phthalic acid). Representative alkyl phthalates are listed by CAS registry number.	d1
**********	Alkyl phthalates (confidential)-- all alkyl esters of 1,2-benzenedicarboxylic acid (ortho-phthalic acid). Confidential category members only.	p2
**********	Alkylamine tetrachlorophenate--	t31
**********	Alkyltin compounds-- Representative alkyltin compounds are listed by CAS registry number. The 8(d) reporting period for this category, listed in 40 CFR 716.120(c), has been terminated. Certain substances within this category have been transferred to the individual listing (40 CFR 716.120(a)) and their original sunset dates remain in effect.	r2 d2
**********	Aniline and chloro-,bromo-, and/or nitroanilines-- Representative chemicals are listed by CAS registry number.	d1
**********	Antimony compounds--	sr[illegible]
**********	Aromatic C9 fraction-- from petroleum refining.	t[illegible]

	CATEGORY NAME AND CHEMICALS OR MIXTURES TO WHICH A CAS NUMBER HAS NOT BEEN ASSIGNED	RULE CODE
**********	Arsenic compounds--	sr313
**********	Aryl phosphates-- phosphate esters of phenol or of alkyl-substituted phenols. Triaryl and mixed alkyl and aryl esters are included but trialkyl esters are excluded. Representative aryl phosphates are listed by CAS registry number.	d1
**********	Aryl phosphates (Confidential)-- phosphate esters of phenol or of alkyl-substituted phenols. Triaryl and mixed alkyl and aryl esters are included but trialkyl esters are excluded. Confidential category members only.	p2
**********	Asbestos-- asbestiform varieties of chrysotile (serpentine); crocidolite (riebeckite); amosite (cummingtonite-grunerite); anthophyllite; tremolite; and actinolite.	x6 sr313 a3 d1
**********	Barium compounds--	sr110 sr313
**********	Beryllium compounds--	sr313
**********	Bisazobiphenyl dyes-- derived from benzidine and its congeners, ortho-toluidine (dimethylbenzidine) and dianisidine (dimethoxybenzidine). Representative bisazophenyl dyes are listed by CAS registry number.	d1
**********	Boron compounds--	sr110
**********	Cadmium compounds--	sr313
**********	Chlorinated benzenes-- mono, di-, tri-, tetra- and penta-. Representative chlorinated benzenes are listed by CAS registry	d1

	CATEGORY NAME AND CHEMICALS OR MIXTURES TO WHICH A CAS NUMBER HAS NOT BEEN ASSIGNED	RULE CODE
	number.	
**********	Chlorinated naphthalenes-- chlorinated derivatives of naphthalene (empirical formula) C (10)H (x)Cl (y), where x + y = 8. Representative chlorinated naphthalenes are listed by CAS registry number. The 8(d) reporting period for this category, listed in 40 CFR 716.120(c), has been terminated. Certain substances within this category have been transferred to the individual listing (40 CFR 716.120(a)) and their original sunset dates remain in effect.	r2 a5 d1
**********	Chlorinated paraffins-- chlorinated paraffin oils and chlorinated paraffin waxes, with chlorine content of 35 percent through 70 percent by weight. Representative chlorinated paraffins are listed by CAS registry number.	d1
**********	Chlorodibenzodioxins--	sr110
**********	Chlorodibenzofurans--	sr110
**********	Chlorophenols--	sr313
**********	Chromium compounds--	sr313
**********	Cobalt compounds--	sr110 sr313
**********	Commercial hexane-- for purposes of this rule, is a product obtained from crude oil, natural gas liquids or petroleum refinery processing which consists primarily of six-carbon alkanes or cycloalkanes and contains at least 50 liquid volume percent n-hexane (CAS No. 110-54-3) and at least 5 liquid volume percent methylcyclopentane (MCP; CAS No. 96-37-7).	t26
**********	Copper compounds--	sr313*

	CATEGORY NAME AND CHEMICALS OR MIXTURES TO WHICH A CAS NUMBER HAS NOT BEEN ASSIGNED	RULE CODE
**********	Cyanide compounds--	sr313
**********	Ethyltoluenes-- This category consists of ethyltoluene (mixed isomers) and the ortho-, meta-, and para-isomers. Representative ethyltoluenes are listed by CAS registry number. The 8(d) reporting period for this category, listed in 40 CFR 716.120(c), has been terminated. Certain substances within this category have been transferred to the individual listing (40 CFR 716.120(a)) and their original sunset dates remain in effect.	r2 d3
**********	Fluoroalkenes-- this category is defined as fluoroalkenes of the general formula: C (n)H (2n-x)F (x), where n equals 1 to 6. Representative fluoroalkenes are listed by CAS registry number.	d3
**********	Fully halogenated chlorofluoroalkane--	x2
**********	Glycidol (oxiranemethanol) & derivatives (confident)-- C (2)H (3)O-CH (2)O-R, where R is an alkyl, alkenyl, alkynyl, aryl, or acyl group. Any substituent or functional group may be present on the alkyl, etc. groups. Confidential category members only.	.p2
**********	Glycidol (oxiranemethanol) and its derivatives-- C (2)H (3)O-CH (2)O-R, where R is an alkyl, alkenyl, alkynyl, aryl, or acyl group. Any substituent or functional group may be present on the alkyl, etc. groups. Representative derivatives are listed by CAS registry number.	d:
**********	Glycol ethers--	
**********	Halogenated alkyl epoxides-- halogenated noncyclic aliphatic hydrocarbons with one or more epoxy functional groups. Representative halogenated alkyl epoxides are listed by CAS	

	CATEGORY NAME AND CHEMICALS OR MIXTURES TO WHICH A CAS NUMBER HAS NOT BEEN ASSIGNED	RULE CODE
	registry number. The 8(d) reporting period for this category, listed in 40 CFR 716.120(c), has been terminated. Certain substances within this category have been transferred to the individual listing (40 CFR 716.120(a)) and their original sunset dates remain in effect.	
**********	Lead compounds--	sr313
**********	Manganese compounds--	sr313
**********	Mercury compounds--	sr313
**********	Nickel compounds--	sr313
**********	Phenylenediamine-- this category is defined as all nitrogen-unsubstituted phenylenediamines and their salts with zero to two substituents on the ring selected from the same or different members of the group of halo, nitro, hydroxy, hydroxy-lower alkoxy, lower-alkyl, and lower alkoxy. For this purpose, the term "lower" is defined as a group containing between one and four carbons. The reporting period for certain individual members of the category will be terminated. This is represented by the rule code r2.	d3
**********	Polybrominated biphenyls-- brominated biphenyl molecules having the molecular formula C (12)H (x)Br (y), where x + y = 10 and y ranges from 1 to 10.	
**********	Polychlorinated biphenyls-- any chemical substance that is limited to the biphenyl molecule that has been chlorinated to varying degrees, or any combination of substances which contains such substances.	
**********	Radium compounds--	
**********	Radon compounds--	

	CATEGORY NAME AND CHEMICALS OR MIXTURES TO WHICH A CAS NUMBER HAS NOT BEEN ASSIGNED	RULE CODE
**********	Selenium compounds--	sr313
**********	Silver compounds--	sr313
**********	Thallium compounds--	sr313
**********	Thorium compounds--	sr110
**********	Uranium compounds--	sr110
**********	Zinc compounds--	sr313

RULE CODE	NAME OF RULE	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FR CITATION	FR CITATION	FR PUBLISH DATE	EFFECTIVE DATE	REPORTING DEADLINE DATE	SUNSET DATE	NOTES
a1	PBB-TRIS				45 FR 70728	10/24/80	11/24/80	12/24/80	05/01/85	Polybrominated biphenyls portion.
a2	PBB-TRIS				45 FR 70728	10/24/80	11/24/80	12/24/80	05/01/85	Tris (2,3-dibromopropyl) phosphate portion.
a3	Asbestos	763			47 FR 33198	07/30/82	08/30/82	11/28/82	08/03/87	Asbestos manufacturers reporting.
a4	CT	704.45			49 FR 11181	03/26/84	05/25/84	06/24/84		Chlorinated terphenyls.
a5	CN	704.43			49 FR 33649	08/24/84	10/08/84	11/06/84		Chlorinated naphthalenes.
a6	HEX-BCH	704.102			50 FR 47534	11/19/85	01/02/86	03/03/86		1,2,3,4,7,7-Hexachloronorbornadiene; or report no later than 30 days from management decision to produce.
a7	MBOCA	704.175			51 FR 13220	04/18/86	06/02/86	07/02/86		4,4'-Methylenebis(2-chloroaniline); or report no later than 30 days from management decision to produce.
a8	P-TBBA, P-TBT & P-TB B	704.33			51 FR 17336	05/12/86	06/25/86	08/23/86		p-tert-Butylbenzoic acid (P-TBBA), p-tert-Butyltoluene (P-TBT) & p-tert-Butylbenzaldehyde (P-TBB); or report no later than 30 days from management decision to produce.
a9	HFPO	704.104			52 FR 41296	10/27/87	12/10/87	02/08/88		Hexafluoropropylene oxide or Oxirane, trifluoro(trifluoromethyl)- ; or report no later than 30 days from management decision to manufacture, import, or process.
a10	11-AA	704.25			52 FR 19860	05/28/87	07/13/87	08/10/87		11-Aminoundecanoic acid; or report no later than 30 days from management decision to manufacture, import or process.
a11	Anthraquinone	704.30			52 FR 21018	06/04/87	07/20/87			9,10-Anthraquinone; report within 60 days of completion of every corporate fiscal year during which they manufacture or import 9,10-Anthraquinone after 07/20/87.
a12	EDTMPA and its salts	704.95			53 FR 41335	10/21/88	12/05/88	01/03/89		Phosphonic acid, [1,2-ethanediylbis[nitrilobis(methylene)]] tetrakis- (EDTMPA); or report within 30 days of making certain management decisions.
					53 FR 46745	11/10/88				Correction.

RULE CODE	NAME OF RULE	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FR CITATION	FR CITATION	FR PUBLISH DATE	EFFECTIVE DATE	REPORTING DEADLINE DATE	SUNSET DATE	NOTES
c1	Chlorendic acid/Chlorendic anhydride				52 FR 48321	12/21/87		02/04/88		Bicyclo[2.2.1]hept-5-ene-2,3-dicarboxylic acid, 1,4,5,6,7,7 hexachloro- (Chlorendic acid) & 4,7-Methanoisobenzofuran-1,3-dione, 4,5,6,7,8,8-hexachloro-3a,4,7,7a-tetrahydro- (Chlorendic anhydride); request for records and reports regarding significant adverse reactions.
c2	Tri(Alkyl/Alkoxy) Phosphates/Diisocyanat				53 FR 1408	01/19/88		03/04/88		Request for records and reports regarding significant adverse reactions.

RULE CODE	NAME OF RULE	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FR CITATION	FR CITATION	FR PUBLISH DATE	EFFECTIVE DATE	REPORTING DEADLINE DATE	SUNSET DATE	NOTES
d1	8(d)	716.120			47 FR 38791	09/02/82	10/04/82	12/03/82	10/04/92	1st-5th and 7th ITC & Asbestos.
d2	8(d) AMEND	716.120			47 FR 54624	12/03/82	01/03/83	03/04/83	01/03/93	7th & 11th ITC
d3	8(d) AMEND	716.120			48 FR 13178	03/30/83	04/29/83	06/28/83	04/29/93	6th - 10th ITC
d4	8(d) AMEND	716.120			48 FR 24366	06/01/83	07/01/83	08/30/83	07/01/93	12th ITC
d5	8(d) AMEND	716.120			49 FR 1696	01/13/84	02/13/84	04/14/84	02/13/94	10th (1 mixture) & 11th (4 rec.) ITC
d6	8(d) AMEND	716.120			49 FR 30188	07/27/84	09/10/84	11/09/84	09/19/94	Methylpyridine & Maleic anhydride.
d7	8(d) AMEND	716.120			48 FR 55686	12/14/83	01/13/84	03/14/84	01/13/94	13th ITC
d8	8(d) AMEND	716.120			49 FR 22286	05/29/84	06/28/84	08/27/84	06/28/94	14th ITC
d9	8(d) AMEND	716.120			50 FR 11697	03/25/85	05/08/85	07/07/85	05/08/95	14th ITC (1 rec.)
d10	8(d) AMEND	716.120			49 FR 46741	11/28/84	12/28/84	02/26/85	12/28/94	15th ITC
d11	8(d) AMEND	716.120			50 FR 18861	05/03/85	06/03/85	08/02/85	06/03/95	Urea-formaldehyde resins-see also 50 FR 46295
d12	8(d) AMEND	716.120			50 FR 20909	05/21/85	06/20/85	08/19/85	06/20/85	16th ITC
d13	8(d) AMEND	716.120			49 FR 1696	01/13/84	02/13/84	04/14/84	02/13/94	C (9) fraction mixture
d14	8(d) AMEND	716.120			50 FR 47538	11/19/85	12/19/85	02/18/86	12/19/95	17th ITC
d15	8(d) AMEND	716.120			50 FR 52923	12/27/86	02/10/86	04/11/86	02/10/96	Vinyl acetate
d16	8(d) AMEND	716.120			51 FR 2890	01/22/86	03/07/86	05/08/86	03/07/96	33 Chemicals for OSWER Land Disposal Restriction standards; non-TSCA inventory substances.
d17	8(d) AMEND	716.120			51 FR 17336	05/12/86	06/25/86	08/23/86	06/25/96	p-tert-Butylbenzoic acid (P-TBBA), p-tert-Butyltoluene (P-TBT), and p-tert-Butylbenzaldehyde (P-TBB).

RULE CODE	NAME OF RULE	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FR CITATION	FR CITATION	FR PUBLISH DATE	EFFECTIVE DATE	REPORTING DEADLINE	SUNSET DATE	NOTES
d18	8(d) AMEND	716.120			51 FR 18323	05/19/86	06/18/86	08/17/86	06/18/96	18th ITC
d19	8(d) AMEND	716.120			51 FR 41328	11/14/86	12/15/86	02/13/87	12/15/96	19th ITC
d20	8(d) AMEND	716.120			52 FR 16022	05/01/87	06/01/87	08/31/87	06/01/97	OTS/OSW/OW/CPSC - 102 substances.
d21	8(d) AMEND	716.120			52 FR 19027	05/20/87	06/19/87	08/18/87	06/19/97	20th ITC
d22	8(d) AMEND	716.120			52 FR 44826	11/20/87	12/21/87	02/19/88	12/21/97	21st ITC
					52 FR 47990	12/17/87				Correction.
		716.35			53 FR 46746	11/18/88				Correction.
d23	8(d) AMEND	716.120			53 FR 18211	05/20/88	06/20/88	08/19/88	06/20/98	22nd ITC
d24	8(d) AMEND	716.120			53 FR 46279	11/16/88	12/16/88	02/14/89	12/16/98	23RD ITC
					54 FR 4109	01/27/89				Correction.
d25	8(d) AMEND	716.120			54 FR 8484	02/28/89	04/13/89	06/13/89	04/13/99	Pesticide inerts; includes 29 chemical substances.
					54 FR 11478	03/20/89				Correction.
d26	8(d) AMEND	716.120			54 FR 31248	07/27/89	08/28/89			24th ITC; removes CAS No. 25550-98-5 from 17th ITC (p13 & d14); no new chemicals added.
d27	8(d) AMEND	716.120			54 FR 51131	12/12/89	01/11/90		01/11/00	25th ITC; includes 12 chemical substances.
d28	8(d) AMEND	716.120			55 FR 6012	02/21/90				Substitutes for Chlorofluorocarbons (CFCs). Includes: CAS No. 75-88-7, CAS No. 306-83-2, CAS No. 354-25-6, CAS N 354-33-6, CAS No. 811-97-2, CAS No. 1649-08-7, and CAS No. 1717-00-6.
			04/09/90	55 FR 13164						Correction; proposed rule. Corrects TSCA chemical substan inventory name, trivial name, and CAS number for HCFC-124. In the preamble & codified text, the third entry -- CAS No 354-25-6 -- should be deleted & CAS No. 2873-89-0, common name, TSCA chemical substance inventory name should be add

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FR CITATION	FINAL RULE FR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
e1	12(b) Amendment	707	07/12/89	54 FR 29526				Export notification; reporting & recordkeeping.

RULE CODE	NAME OF RULE	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FR CITATION	FR CITATION	FR PUBLISH DATE	EFFECTIVE DATE	REPORTING DEADLINE DATE	SUNSET DATE	NOTES
f1	MDA	Notice			48 FR 19078	04/27/83				Benzenamine, 4,4'-methylenebis- or 4,4'-Methylenedianiline; initiation of review.
					48 FR 42898	09/20/83				Initiation of Regulatory Action; Advanced Notice of Proposed Rulemaking (ANPR)
f2	Formaldehyde	Notice			49 FR 21898	05/23/84				Determination of significant risk.
					49 FR 21870	05/23/84				Determination of significant risk; (ANPR).
		Notice			48 FR 52507	11/18/83				Reconsideration; solicitation of comment.
f3	1,3-Butadiene	Notice			49 FR 845	01/05/84				Initiation of Accelerated Review.
					49 FR 20524					Initiation of Regulatory Action; (ANPR).
f4	Methylene chloride	Notice			50 FR 20126	05/14/85				Initiation of Accelerated Review.

RULE CODE	NAME OF RULE	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FR CITATION	FR CITATION	FR PUBLISH DATE	EFFECTIVE DATE	REPORTING DEADLINE DATE	NOTES
m1	CAIR	704.225			53 FR 51698	12/22/88	02/06/89		See Federal Register notice for various reporting dates; includes 19 chemical substances.
					54 FR 6918	02/15/89			Extension of notification and reporting deadlines.
					54 FR 14324	04/10/89	04/10/89		Notice of Temporary Administrative Relief.
					54 FR 25398	06/14/89	06/14/89		Technical Amendment; addition of Trade Names.
					54 FR 30632	07/21/89			Correction.
					54 FR 30211	07/19/89			Request for additional comments on the final rule.
					54 FR 35495	08/28/89	08/28/89		Correction.
					54 FR 31680	08/01/89			Correction.
					54 FR 5197	02/01/89			Correction.

RULE CODE	NAME OF RULE	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FR CITATION	FR CITATION	FR PUBLISH DATE	EFFECTIVE DATE	REPORTING DEADLINE DATE	NOTES
p1	PAIR	712.30(d)			47 FR 26992	06/22/82	07/22/82	11/19/82	1st - 5th & 10th ITC
p2	PAIR AMEND	712.30(e)			47 FR 26992	06/22/82	07/22/82	11/19/82	1st - 3rd ITC (3 cat.)
p3	PAIR AMEND	712.30(f)			48 FR 22694	05/19/83	06/20/83	08/17/83	6th - 9th ITC
p4	PAIR AMEND	712.30(h)			48 FR 28443	06/22/83	07/22/83	09/20/83	12th ITC
p5	PAIR AMEND	712.30(j)			48 FR 55685	12/14/83	01/13/84	03/13/84	13TH ITC
p6	PAIR AMEND	712.30(k)			49 FR 22284	05/29/84	06/28/84	08/27/84	14th ITC
p7	PAIR AMEND	712.30(g)			49 FR 25856	06/25/84	08/08/84	10/08/84	11th ITC
p8	PAIR AMEND	712.30(i)			49 FR 25859	06/25/84	08/08/84	10/08/84	Mesityl oxide
p9	PAIR AMEND	712.30(m)			49 FR 46739	11/28/84	12/28/84	02/26/85	15th ITC
p10	PAIR AMEND	712.30(l)			50 FR 11695	03/25/85	05/08/85	07/08/85	14th ITC (1 rec.)
p11	PAIR AMEND	712.30(n)			50 FR 18661	05/03/85	06/03/85	08/01/85	Urea-formaldehyde resins
p12	PAIR AMEND	712.30(o)			50 FR 20909	05/21/85	06/20/85	08/19/85	16th ITC
p13	PAIR AMEND	712.30(p)			50 FR 47538	11/19/85	12/19/85	02/18/86	17th ITC
p14	PAIR AMEND	712.30(q)			51 FR 18323	05/19/86	06/18/86	08/18/86	18th ITC
p15	PAIR AMEND	712.30(t)			51 FR 41328	11/14/86	12/15/86	02/12/87	19th ITC
p16	PAIR AMEND	712.30(u)			52 FR 19027	05/20/87	06/19/87	08/18/87	20th ITC
p17	PAIR AMEND	712.30(v)			52 FR 44826	11/20/87	12/21/87	02/18/88	21st ITC
p18	PAIR AMEND	712.30(w)			53 FR 10387	03/31/88	05/16/88	07/13/88	Outreach PAIR - OAOPS.

RULE CODE	NAME OF RULE	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FR CITATION	FR CITATION	FR PUBLISH DATE	EFFECTIVE DATE	REPORTING DEADLINE DATE	NOTES
p19	PAIR AMEND	712.30(w)			53 FR 18211	05/20/88	06/20/88	08/18/88	22nd ITC
p20	PAIR AMEND	712.30(w)			53 FR 46279 54 FR 4109	11/16/88 01/27/89	12/16/88	02/14/89	23rd ITC. Correction.
p21	PAIR AMEND	712.30(w)			54 FR 8484 54 FR 11478	02/28/89 03/20/89	04/13/89	06/13/89	Pesticide inerts; includes 29 chemical substances. Correction.
p22	PAIR AMEND	712.30(w)			54 FR 31248	07/27/89	08/28/89		24th ITC; removes CAS No. 25550-98-5 from 17th ITC (p13 & d14); no new chemicals added.
p23	PAIR AMEND	712.30(w)			54 FR 51131	12/12/89	01/11/90	03/12/90	25th ITC; includes 13 chemical substances.

RULE CODE	NAME OF RULE	FINAL RULE FR CITATION	FINAL RULE FR DATE	EFFECTIVE DATE	NOTES
r1	8 (d) Removal	50 FR 39677	09/30/85	01/13/86	Removal of seven substances from the model 8(d) rule.
		*51 FR 1233	01/09/86	01/13/86	Revision to the decision to remove hexachlorocyclopentadiene from the model 8(d) rule.
r2	Biennial review 8(d) report period term.	53 FR 38642	09/30/88	12/29/88	The reporting periods for 15 substances listed in 40 CFR 716.120(a) will be terminated 12/29/88. This is represented by the rule code r2. The reporting periods for certain individual members of the category "Phenylenediamine" will be terminated 12/29/88. This is represented by the rule code r2. However, for all other members in the "Phenylenediamine" category, the original sunset date will remain in effect. The reporting period for five categories listed in 40 CFR 716.120(c)--Alkyl epoxides, Alkyltin compounds, Chlorinated Naphthalenes, Ethyltoluenes and Halogenated Alkyl Epoxides--will be terminated 12/29/88. This is represented by the rule code r2. Certain substances within these categories have been transferred to the individual listing in 40 CFR 716.120(a) and their original sunset dates remain in effect.
		53 FR 45656	11/10/88		Correction.
		53 FR 49966	12/12/88		Correction.
		54 FR 617	01/09/89		Correction.

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FR CITATION	FINAL RULE FR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
s1	HEX-BCH	721.1150	02/22/85	50 FR 7351	50 FR 47534	11/19/85	01/02/86	Hexachlorononorbornadiene or 1,2,3,4,7,7-Hexachlorononorbornadiene; use other than as an intermediate in the production of isodrin or endrin.
s2	HMPA	721.1200	10/10/84	49 FR 39703	51 FR 9450	03/19/86	05/02/86	Hexamethylphosphoramide; any use.
s3	Urethane	721.2550	10/10/84	49 FR 39703	51 FR 9450	03/19/86	05/02/86	Any use.
s4	PCE	721.1475	03/24/86	51 FR 10024	51 FR 32077	09/09/86	10/23/86	Pentachloroethane; any use.
s5	PBBs	721.600	07/07/86	51 FR 24555	52 FR 2699	01/26/87	03/11/87	Polybrominated biphenyls - includes 8 chemical substances; any use.
s6	TRIS	721.2200	07/07/86	51 FR 24555	52 FR 2699	01/26/87	03/11/87	Tris(2,3-dibromopropyl) phosphate; any use.
s7	MBK	721.1300	07/07/86	51 FR 24551	52 FR 11822	04/13/87	05/27/87	Methyl n-butyl ketone; any use.
s8	11-AA	721.350	07/22/86	51 FR 26273	52 FR 19860	05/28/87	06/13/87	11-Aminoundecanoic acid; any use other than as...(i) an intermediate in the manufacturing of polymers in an enclose process when it is expected that the 11-AA will be fully polymerized during the manufacturing process, or (ii) a cosponent in photoprocessing solutions.
s9	HFPO	721.1175	01/02/87	52 FR 107	52 FR 41296	10/27/87	12/10/87	Hexafluoropropylene oxide or Oxirane, trifluoro(trifluoromethyl)-; any use other than as an intermediate in the manufacture of fluorinated substances in an enclosed process.
	EBH	721.950			52 FR 41296	10/27/87	12/10/87	Epibromohydrin or Oxirane, (bromoethyl)-; any use.
	TCBO	721.975			52 FR 41296	10/27/87	12/10/87	Trichlorobutylene oxide or Oxirane, (2,2,2-trichloroethyl)- any use.
s10	UNUSED RULE CODE	NONE		NONE	NONE			NOTE: This is an unused RULE CODE.
s11	UNUSED RULE CODE	NONE		NONE	NONE			NOTE: This is an unused RULE CODE.

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FR CITATION	FINAL RULE FR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
s12	82-400	721.1750	02/17/83	48 FR 7142	49 FR 35011	09/05/84	10/19/84	Potassium N,N-bis(hydroxyethyl) cocoamine oxide phosphate Potassium N,N-bis(hydroxyethyl) tallowamine oxide phosphat use in a consumer product at concentrations greater than five per-ent by weight; 5(e).
	82-409							
s13	80-289	721.1250	08/24/83	48 FR 38502	49 FR 46373	11/26/84	02/08/85	Isopropylamine, distillation residues & Ethylamine, distillation residues -- use in metalworking fluids; non-5(e).
	80-290							
s14	83-105	721.550	08/30/83	48 FR 39245	49 FR 43058	10/26/84	01/18/85	1,2-Benzenediamine, 4-ethoxy, sulfate -- manufacture, import, or processing in powder or dry solid form; non-5(e
s15	83-23	721.1875	01/03/84	49 FR 99	49 FR 50396	12/28/84	03/12/85	Substituted methylpyridine (P-83-24, P-83-49 & P-83-272) manufacture or processing without PPE where dermal contact inhalation may occur & notify; Substituted 2-phenoxypyridi (P-83-23 & P-83-75) -- manufacture or processing without PPE where dermal contact may occur & notification; 5(e).
	83-24							
	83-49							
	83-75							
	83-272							
s16	82-326		02/06/84	49 FR 4390				Non-5(e).
s17	83-237		02/06/84	49 FR 4390				5(e) Consent Order.
s18	83-330		02/06/84	49 FR 4390				Non-5(e). It appears that the correct PMN No. is P-83-33(not P-82-330, as previously seen in CORR.
s19	82-684	721.2100	01/03/84	49 FR 91	49 FR 42928	10/25/84	01/07/85	Derivative of tetrachloroethylene -- manufacture or processing without PPE where dermal contact/inhalation ma occur; manufacture or processing without requiring contai /formulation containing substance to be packaged to preve leakage and labeled to handle only with PPE; 5(e).

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FR CITATION	FINAL RULE FR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
s20	83-255	721.800	01/03/84	49 FR 82	49 FR 43061	10/26/84	01/18/85	Dicarboxylic acid monoester -- any manufacture in US for commercial purposes; failure to require PPE use where dermal contact may occur; distribution in commerce without affixing warning label to container; 5(e).
s21	83-370		01/13/84	49 FR 1753				5(e) Consent Order.
s22	83-394	721.520	12/29/83	48 FR 57440	49 FR 43649	10/31/84	01/14/85	Substituted polyglycidyl benzenamine -- (i) use in spray applications & (ii) manufacturing or processing without: requiring PPE use, notification of toxicological effects, and affixing warning label to each container; 5(e).
s23	81-69		12/27/84	49 FR 50209				Non-5(e).
s24	81-125		12/27/84	49 FR 50209				
s25	81 906 81 908 81 909 83-910		09/28/84	49 FR 38303				5(e) Consent Order.
s26	83-769		09/28/84	49 FR 38310				5(e) Consent Order.
s27	83-1023		09/20/84	49 FR 36880				5(e) Consent Order.
s28	82-438	721.575	01/02/85	50 FR 127	51 FR 16684	05/06/86	07/21/86	Benzoic acid, 3,3'-methylenebis(6-amino-di-2-propenyl) ester -- (i) any use other than the use described in PMN No. P-82-438 & (ii) any manner or method of manufacturing or processing for use described in PMN No. P-82-438 different than manner/method described in PMN No. P-82-438; non-5(e).
s29	83-817		10/25/84	49 FR 42960				Non-5(e).
s30	83-818		10/25/84	49 FR 42960				Non-5(e).

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FR CITATION	FINAL RULE FR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
a31	83-822	721.400	12/07/84	49 FR 47874	50 FR 34463	08/26/85	11/08/85	Substituted diamine anisole -- (i) use other than as an intermediate & (ii) manufacture, import, or processing for use as an intermediate without providing protective glove and requiring packages to be labeled for use/handled only with impervious gloves; 5(e).
a32	84-27		12/24/84					5(e) Consent Order.
a33	84-176		03/27/85					
a34	84-180 84-181 84-182 84-183 84-184		03/27/85	50 FR 12046				5(e) Consent Order.
a35	84-105 84-106 84-107		03/21/85	50 FR 11384				5(e) Consent Order.
a36	84-417		03/21/85	50 FR 11391				5(e) Consent Order.
a37	83-1085		08/26/85	50 FR 34500				5(e) Consent Order.
a38	84-341 84-342 84-343 84-344		04/04/86	51 FR 11591				5(e) Consent Order.
a39	84-274		08/26/85	50 FR 34505				5(e) Consent Order.
a40	84-1042		03/24/86	51 FR 10027				5(e) Consent Order.
a41	84-7		01/13/86	51 FR 1396				

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FR CITATION	FINAL RULE FR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
42	84-660 84-704		03/18/86	51 FR 9221				5(e) Consent Order.
43	84-1054 84-1056		06/11/86	51 FR 21190				Non-5(e).
44	86-83		07/24/86	51 FR 26557				5(e) Consent Order.
45	86-542		03/25/87	52 FR 9508				5(e) Consent Order.
46	CBE	721.648	09/04/87	52 FR 33606	53 FR 2842	02/02/88	03/17/88	1-Chloro-2-bromoethane; any use.
47	1-Decanamine, N-decyl-N-methyl-N-oxide		12/08/87	52 FR 46496				Use in laundry or dishwashing detergents.
48	Diphenyl-2,4,6-trimethylbenzoyl phosphin		02/02/88	53 FR 2857				Any manner or method of manufacture associated with any use within the U.S., import in dust or powder form associated with any use within the U.S., or use other than in solution with Styrene.
49	4-COI, 4-COI hydrochloride & 6-COI	721.462	09/16/88	53 FR 36079	54 FR 12445	03/27/89	05/10/89	Benzenamine, 4-chloro-2-methyl- (4-COI), Benzenamine, 4-chloro-2-methyl-, hydrochloride (4-COI hydrochloride), and Benzenamine, 2-chloro-6-methyl- (6-COI); any use.
			09/30/88	53 FR 38411				Correction; proposed rule.
					54 FR 17707	04/25/89	04/25/89	Correction; final rule.
50	PEB	721.1515	11/22/88	53 FR 47228	54 FR 18284	04/28/89	06/12/89	Pentabromoethylbenzene; any use.
51	86-1322		12/28/88	53 FR 52443	54 FR 38381	09/18/89	12/01/89	Mixture of 1,3-Benzenediamine, 2 (or 4)-methyl-4,6 (or 2,6) bis(methylthio); 5(e) Consent Order.
52	85-929; 1,3-Benzenediamine, 4-(1,1-Dimet	721.555	05/31/89	54 FR 23232	55 FR 20792	05/21/90	08/03/90	1,3-Benzenediamine, 4-(1,1-dimethyl)-ar-methyl. TSCA 5(a) consent order. Significant new uses and recordkeeping requirements for manufacturers, importers, or processors: use other than for applications where it will be completely reacted; disposal of the substance other than by

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FR CITATION	FINAL RULE FR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
								incineration or landfill; any manner or method of manufacture, import, or processing without establishing a program whereby: (1) persons exposed dermally and by inhalation wear personal protective equipment, (2) ... are informed of hazards and required personal protective equipment, (3) containers are labeled, and (4) exceeding a specified production limit prior to completion of certain tests; and maintain records for 5 years after the date of their creation by persons who manufacture, import, or process, including small businesses.
s53	85-433		09/12/86	54 FR 32495				1-Propanol, 3-mercapto-; 5(e) Consent Order.
s54	2,4-Pentanedione		09/27/89 10/16/89	54 FR 39568 54 FR 42439				Use in consumer products. Correction.
s55	Substitutes for Chlorofluorocarbons	721.760	02/21/90	55 FR 6012				Any use other than as an intermediate for: Ethane, 2-chloro-1,1,1-trifluoro- (CAS No. 75-88-7). Any use for: Ethane, 1,2-dichloro-1,1-difluoro- (CAS No. 1649-08-7).
s56	Expedited SNUR Rule-15CA Section 5(e)(2)	721			54 FR 31308	07/27/89	/ /	Expedited procedures & standard significant new use designations established in amendments in 40 CFR Part 721 for promulgating Direct Final SNURs.
s57	P-89-448	721.288		NONE	55 FR 17376	04/24/90	06/25/90	First rule issued using expedited procedures and standard significant new use designations (See CORR Rule Code s56 for more information). Alkanepolyol phosphate ester (generic name). Significant new uses are: industrial, commercial, consumer activities.
	P-89-650	721.1082		NONE	55 FR 17376	04/24/90	06/25/90	Substituted ethylene diamine, methyl sulfate quaternized (generic name). Significant new uses are: industrial, commercial, & consumer activities.
	P-89-653	721.266		NONE	55 FR 17376	04/24/90	06/25/90	Adipic acid, polymer with 1,4-Cyclohexane-dimethanol, diproylene glycol, alkanepolyol, substituted alkanolamine and carbomonocyclic dicarboxylic acid (generic name). Significant new uses are: industrial, commercial, & consu activities. (06/30/90)

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FR CITATION	FINAL RULE FR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
	P-89-703	721.295		NONE	55 FR 17376	04/24/90	06/25/90	Reaction products of secondary alkyl amines with a substituted benzenesulfonic acid and sulfuric acid (generic name). Significant new uses are: industrial, commercial, & consumer activities.
	P-89-755	721.295		NONE	55 FR 17376	04/24/90	06/25/90	Reaction products of secondary alkyl amines with a substituted benzenesulfonc acid and sulfuric acid (generic name). Significant new uses are: industrial, commercial, & consumer activities.
	P-89-756	721.295		NONE	55 FR 17376	04/24/90	06/25/90	Reaction products of secondary alkyl amines with a substituted benzenesulfonic acid and sulfuric acid (generic name). Significant new uses are: industrial, commercial, & consumer activities.
s58	Certain Aromatic Ether Diamine	721.785	05/30/90	55 FR 21887				Chemicals covered include: P-85-335, P-85-336, P-85-337, a P-86-1153. Significant new uses include: P-85-335 -- the manufacture, import, or processing of a specified annual volume, which is confidential, for any use; P-85-336 and P-85-337 -- any use; and P-86-1153 -- manufacture, import, or processing of a specified annual volume, which is confidential, for any use.
s59	Significant New Uses of Certai n Chemical	721		NONE	55 FR 26092	06/26/90	08/27/90	Direct Final Rule for several chemical substances, which were the subject of Pre-Manufacture Notices (PMNs) and TSC section 5(e) consent orders.
	P-86-1489	721.296		NONE	55 FR 26092	06/26/90	08/27/90	Alkyliphenoxypolyethoxyamine (generic name). Significant n uses are: hazard communication program & release to water.
	P-84-591	721.445		NONE	55 FR 26092	06/26/90	08/27/90	Sodium salt of an alkylated, sulfonated aromatic (generic name). Significant new uses are: industrial, commercial, & consumer activities
	P-84-954	721.450		NONE	55 FR 26092	06/26/90	08/27/90	Substituted aromatic (generic name). Significant new uses are: protection in the workplace; hazard communication program; industrial, commercial, & consumer activities; an release to water.
	P-84-824	721.523		NONE	55 FR 26092	06/26/90	08/27/90	Brominated aromatic compound (generic name). Significant new uses are: protection in the workplace; hazard communication program; industrial, commercial & consumer activities; and release to water.

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FR CITATION	FINAL RULE FR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
	P-84-913	721.612		NONE	55 FR 26092	06/26/90	08/27/90	N,N'-Bis(2-(2-(3-alkyl)thiazoline)vinyl)-1,4-phenylenediamine methyl sulfate double salt (generic name). Significant new uses are: protection in the workplace; hazard communication program; industrial, commercial & consumer activities.
	P-89-770	721.770		NONE	55 FR 26092	06/26/90	08/27/90	Coconut oil, reaction products with tetrahydroxy branched alkane esters of trisubstituted benzenepropanoic acid (generic name). Significant new uses are: industrial, commercial, & consumer activities.
	P-87-502	721.783		NONE	55 FR 26092	06/26/90	08/27/90	Dialkenylamide (generic name). Significant new uses are: protection in the workplace; hazard communication program; industrial, commercial, & consumer activities; and disposal
	P-89-506	721.792		NONE	55 FR 26092	06/26/90	08/27/90	Alkylated diarylamine, sulfurized (generic name). Significant new uses are: industrial, commercial, & consum activities.
	P-86-562	721.976		NONE	55 FR 26092	06/26/90	08/27/90	Perfluoroalkyl epoxide (generic name). Significant new use are: protection in the workplace; hazard communication program; industrial, commercial, & consumer activities; disposal; and release to water.
	P-89-279	721.1060		NONE	55 FR 26092	06/26/90	08/27/90	Formaldehyde, polymer with bisphenol A and substituted phenol (generic name). Significant new uses are: industrial commercial, & consumer activities.
	P-84-963	721.1483		NONE	55 FR 26092	06/26/90	08/27/90	6-Nitro-2(3H)-benzoxazolone. Significant new uses are: protection in the workplace; hazard communication program; industrial, commercial, & consumer activities; and release to water.
	P-85-730	721.1585		NONE	55 FR 26092	06/26/90	08/27/90	Substituted phosphate ester (generic name). Significant ne uses are: protection in the workplace; hazard communicatio program; industrial, commercial & consumer activities; and release to water.
	P-88-1658	721.1630		NONE	55 FR 26092	06/26/90	08/27/90	Polymer of alkanepolyol and polyalkylpolyisocyanatocarbomonocycle, acetone oxime-block (generic name). Significant new uses are: industrial, commercial, and consumer activities.
	P-88-854	721.1634		NONE	55 FR 26092	06/26/90	08/27/90	Polymer of alkenoic acid, substituted alkylacrylate sodium salt (generic name). Significant new uses are: industrial, commercial, & consumer activities.

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FR CITATION	FINAL RULE FR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
	P-89-292	721.1890		NONE	55 FR 26092	06/26/90	08/27/90	Carboxy alkyl silyl salt (generic name). Significant new uses are: industrial, commercial, & consumer activities.
	P-89-596	721.2070		NONE	55 FR 26092	06/26/90	08/27/90	Alkylene glycol terphthalate and substituted benzoate este (generic name). Significant new uses are: industrial, commercial & consumer activities.
	P-86-500	721.2132		NONE	55 FR 26092	06/26/90	08/27/90	Tetraglycidalamines (generic name). Significant new uses are: protection in the workplace; hazard communication program; industrial, commercial, & consumer activities; disposal; and release to water.
	P-86-502	721.2132		NONE	55 FR 26092	06/26/90	08/27/90	Tetraglycidalamines (generic name). Significant new uses are: protection in the workplace; hazard communication program; industrial, commercial, & consumer activities; disposal; and release to water.
	P-85-932	721.2192		NONE	55 FR 26092	06/26/90	08/27/90	Disubstituted alkyl triazines (generic name). Significant new uses are: protection in the workplace; hazard communication program; industrial, commercial, & consumer activities; and release to water.
	P-85-933	721.2192		NONE	55 FR 26092	06/26/90	08/27/90	Disubstituted alkyl triazines (generic name). Significant new uses are: protection in the workplace; hazard communication program; industrial, commercial, & consumer activities; and release to water.
	P-84-482	721.2480		NONE	55 FR 26092	06/26/90	08/27/90	Urea, condensate with poly[oxy(methyl-1,2-ethanediyl)]-alpha-(2-aminomethylethyl)-omu-(2-aminoethylethoxy) (generi name). Significant new uses are: industrial, commercial, consumer activities.
	P-89-303	721.2490		NONE	55 FR 26092	06/26/90	08/27/90	Urea, (hexahydro-6-methyl-2-oxopyrimidinyl)-. Significant new uses are: industrial, commercial, & consumer activitie
	P-84-1007	721.2585		NONE	55 FR 26092	06/26/90	08/27/90	3-Alkyl-2-(2-anilino)vinylthiazolinium salt (generic Significant new uses are: protection in the workplace; hazard communication program; industrial, commercial, & consumer activities.
s60	Significant New Uses of Certai n Chemical	721		NONE	55 FR 26102	06/26/90	08/27/90	Direct final Rule for several chemical substances, which were the subject of Pre-Manufacture Notices (PMNs) and TSC section 5(e) consent orders.

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FR CITATION	FINAL RULE FR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
		721		NONE	55 FR 26102	06/26/90	08/27/90	Direct Final Rule for several chemical substances, which were the subject of Pre-Manufacture Notices (PMNs) and TSCA section 5(a) consent orders.
	P-86-1043	721.291		NONE	55 FR 26102	06/26/90	08/27/90	Monosubstituted alkoxyaminotrazines (generic name). Significant new uses are: protection in the workplace; hazard communication program; industrial, commercial, & consumer activities; disposal; and release to water.
	P-86-1044	721.291		NONE	55 FR 26102	06/26/90	08/27/90	Monosubstituted alkoxyaminotrazines (generic name). Significant new uses are: protection in the workplace; hazard communication program; industrial, commercial, & consumer activities; disposal; & release to water.
	P-86-1252	721.617		NONE	55 FR 26102	06/26/90	08/27/90	Boric acid, alkyl and substituted alkyl esters (generic name). Significant new uses are: protection in the workplace; hazard communication program; industrial, commercial, & consumer activities; disposal; & release to water.
	P-86-501	721.782		NONE	55 FR 26102	06/26/90	08/27/90	Aromatic diamines (generic name). Significant new uses ar protection in the workplace; hazard communication program; industrial, commercial, & consumer activities; disposal; & release to water.
	P-86-503	721.782		NONE	55 FR 26102	06/26/90	08/27/90	Aromatic diamines (generic name). Significant new uses ar protection in the workplace; hazard communication program; industrial, commercial, & consumer activities; disposal; & release to water.
	P-86-628	721.818		NONE	55 FR 26102	06/26/90	08/27/90	Dimer acids, polymer with polyalkylene glycol, bisphenol A diglycidyl ether, and alkylenepolyols polyglycidyl ethers (generic name). Significant new uses are: protection in t workplace; hazard communication program; industrial, commercial, & consumer activities; & disposal.
	P-86-1079	721.853		NONE	55 FR 26102	06/26/90	08/27/90	Alkylated diphenyl oxide (generic name). Significant new uses are: protection in the workplace; hazard communicatio program; industrial, commercial, & consumer activities; & release to water.
	P-85-368	721.1078		NONE	55 FR 26102	06/26/90	08/27/90	Haloalkyl substituted cyclic ethers. Significant new uses are: protection in the workplace; hazard communication program; industrial, commercial, & consumer activities; & disposal.

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FR CITATION	FINAL RULE FR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
	P-85-369	721.1078		NONE	55 FR 26102	06/26/90	08/27/90	Heteroalkyl substituted cyclic ethers. Significant new uses are: protection in the workplace; hazard communication program; industrial, commercial, & consumer activities; & disposal.
	P-85-367	721.1078		NONE	55 FR 26102	06/26/90	08/27/90	Heteroalkyl substituted cyclic ether. Significant new uses are: protection in the workplace; hazard communication program; industrial, commercial, & consumer activities; & disposal.
	P-85-1331	721.1460		NONE	55 FR 26102	06/26/90	08/27/90	Naphthalene, 1,2,3,4-tetrahydro(1-phenylethyl). Significant new uses are: hazard communication program; industrial, commercial, & consumer activities; disposal; & release to water.
	P-87-1265	721.1465		NONE	55 FR 26102	06/26/90	08/27/90	2-Naphthalenecarboxamide-N-aryl-3-hydroxy-4-arylazo (generic name). Significant new uses are: protection in the workplace; hazard communication program; & industrial, commercial, & consumer activities.
	P-87-304	721.1488		NONE	55 FR 26102	06/26/90	08/27/90	Nitrothiophenecarboxylic acid, ethyl ester, bis[[[[(substituted)]amino]alkylphenyl]azo] (generic name). Significant new uses are: industrial, commercial, & consumer activities.
	P-85-605	721.1542		NONE	55 FR 26102	06/26/90	08/27/90	Trisubstituted phenol (generic name). Significant new uses are: protection in the workplace; hazard communication program; & industrial, commercial, & consumer activities.
	P-85-680	721.1560		NONE	55 FR 26102	06/26/90	08/27/90	1,1-Dimethylpropyl peroxyester (generic name). Significant new uses are: protection in the workplace; hazard communication program; industrial, commercial, & consumer activities; & disposal.
	P-86-1493	721.1565		NONE	55 FR 26102	06/26/90	08/27/90	Substituted alkyl peroxyhexene carboxylate (mixed isomers) (generic name). Significant new uses are: protection in the workplace; hazard communication program; industrial, commercial, & consumer activities; disposal; & release to water.
	P-84-820	721.1608		NONE	55 FR 26102	06/26/90	08/27/90	Phosphonium salt (generic name). Significant new uses are: protection in the workplace; hazard communication program; & industrial, commercial, & consumer activities.

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FR CITATION	FINAL RULE FR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
	P-88-63	721.2180		NONE	55 FR 26102	06/26/90	08/27/90	Substituted thiazine hydrazine salt (generic name). Significant new uses are: protection in the workplace; hazard communication program; industrial, commercial, & consumer activities; & disposal.
	P-87-1456	721.2500		NONE	55 FR 26102	06/26/90	08/27/90	Polyamine ureaformaldehyde condensate. Significant new uses are: release to water.

RULE CODE	NAME OF RULE OR PNN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FR CITATION	FINAL RULE FR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
ar110	List of hazardous substances u				52 FR 12866	04/17/87		First list of 100 hazardous substances.
	nder 104(i				52 FR 38340	09/15/87		Notice of Availability - Toxicological Profiles (Priority Group 1).
					53 FR 51192	12/20/88		Notice of Availability - Toxicological Profiles (Priority Group 2).
					53 FR 41280	10/20/88		Second list of 100 hazardous substances.
					53 FR 48614	12/01/88		Correction.
					54 FR 14037	04/06/89		* Notice of Availability - final versions of Toxicological Profiles (for 5 substances).
					54 FR 14395	04/11/89		Extension of comment period for draft Toxicological Profiles.
					54 FR 26417	06/23/89		* Notice of Availability - final versions of Toxicological Profiles (for 5 Substances).
	NOTE FOR ar110	ar110 NOTE		ar110 NOTE	ar110 NOTE			These citations refer to the list of hazardous substances under section 104(i) of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or Superfund), as amended by SARA section 110.

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FR CITATION	FINAL RULE FR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
sr313	List of toxic chemicals under		02/04/87	52 FR 3479				Statement of Policy and Guidance regarding petitions.
	313 of the		03/25/87	52 FR 9538				Technical amendment to add categories.
			07/20/87	52 FR 27226				* Proposed removal of Butyl phthalate.
			02/19/88	53 FR 5005	53 FR 23108	06/20/88	06/20/88	* Removal of Titanium dioxide.
			06/04/87	52 FR 21152	53 FR 4500	02/16/87		Toxic Chemical Release Reporting; Community Right-To-Know.
					53 FR 12748	04/18/88		Correction.
			04/12/88	53 FR 12035	53 FR 39476	10/07/88	10/07/88	* Removal of Acid Blue 9.
			06/20/88	53 FR 23128	54 FR 12912	03/29/89	03/29/89	* Removal of Melamine.
			12/09/88	53 FR 49688	54 FR 51298	12/14/89	12/14/89	Proposed deletion of Sodium hydroxide (solution) from 40 CFR section 372.65; deletion decision finalized and Sodium hydroxide (solution) removed from 40 CFR section 372.65(a) & CAS No. 1310-73-2 removed from 40 CFR section 372.65(b). NOTE: CAS No. entry also removed from CERR CAS No. list.
			02/17/89	54 FR 7217	54 FR 25850	06/20/89	06/20/89	* Removal of Sodium sulfate (solution).
		372	04/21/89	54 FR 16138	54 FR 49948	12/01/89	12/01/89	** Proposed addition of certain chemicals; addition of Diethylamine (CAS No. 109-89-7) is pending until further analysis of a 1986 NIOSH study (Lynch et al.) is completed.
	Aluminum oxide; Toxic Chemical	372.65	04/24/89	54 FR 16376	55 FR 5220	02/14/90	02/14/90	* Proposed removal of Aluminum oxide. Final rule - deletes non-fibrous forms of Aluminum oxide -- CAS No. 1344-28-1 -- from the list of toxic chemicals. Fibrous forms of Aluminum oxide will remain listed, and release reporting will continue to be required for fibrous forms.
	List of toxic chemicals under		05/15/89	54 FR 20866				* Proposed exemption for CAS Nos. 147-14-8, 1328-53-6, and 14302-13-7 from reporting requirements under category "Copper compounds."
	NOTE FOR sr313	sr313 NOTE		sr313 NOTE	sr313 NOTE			These citations refer to the list of toxic chemicals under section 313 of the Emergency Planning and Community Right-to-Know Act (EPCRA or SARA Title III).
		372			54 FR 42962	10/19/89	10/11/89	Denial of petition to delist Cadmium sulfide (CdS) and Cadmium selenide (CdSe); denial based on weight of evidence determination. NOTE: Effective Date of this denial petition is 10/11/89, which is the Statutory Deadline for EPA's response.
					54 FR 45891	10/31/89	10/31/89	Correction; Cadmium Sulfide and Cadmium Selenide.

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FR CITATION	FINAL RULE FR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
		372			54 FR 46424	11/03/89	11/03/89	Denial of petition to delist Decabromodiphenyl ether (DBDPE based on weight of evidence of developmental and chronic toxicological effects in humans.
	Change of Address Notice for S	350.16			55 FR 420	01/05/90	01/01/90	Technical amendment; final rule. New address is: Title III Reporting Center Environmental Protection Agency P.O. Box 223779 Washington, DC 20026-3779
	Chrome Antimony Titanium Buff	372			55 FR 650	01/08/90	12/26/89	Denial of petition to exempt Chrome Antimony Titanium Buff Rutile (CATBR) from reporting under categories "chromium compounds" and "antimony compounds." Denial based on determination that CATBR is a potential carcinogen and on evidence of carcinogenicity (chrom./cert. chrom. compounds)
	Barium Sulfate; Toxic Chemical	372.65	02/12/90	55 FR 4879				Proposed rule - to grant petitions to exempt barium sulfate from the reporting requirements under the category "barium compounds."
	Antimony Tris(iso-Octyl Mercap	372			55 FR 5030	02/13/90	03/03/90	Denial of petition to delete Antimony tris(iso-octyl mercaptoacetate) -- aka: AIOM (CAS No. 27288-44-4) -- from the list of toxic chemicals. Human health concerns based on antimony and antimony compounds. Concerns include: carcinogenicity, and developmental and reproductive effects
	Terephthalic Acid; Toxic Chemi	372.65	02/15/90	55 FR 5472				Proposed rule - to grant petition to remove Terephthalic acid from the list of toxic substances. Cas No. 100-21-0 would be removed.
	Zinc Borate Hydrate; Toxic Che	372			55 FR 10254	03/20/90	03/10/90	Denial of petition to delete Zinc borate hydrate (ZB-2335) from the list of toxic substances. Based on evidence that the chemical can be reasonably anticipated to: be toxic to aquatic organisms and cause developmental and reproductive effects in humans. Cas No. 12513-27-8 is ZB-2335.
	Ozone Depleting Chemicals; Tox	372	03/21/90	55 FR 10473				# Notice of receipt of petition to add seven ozone depleting chemicals to the list of toxic substances. Specific CAS Nos. would include: 75-69-4, 75-71-8, 76-14-2, 76-15-3, 421-01-2, 75-63-8, and 124-73-2.
	[illegible] Sulfate (Solution); T	372	03/30/90	55 FR 12163				Proposed rule - to delete Ammonium sulfate (solution) from the list of toxic chemicals because releases can be more effectively covered by the ammonia listing. CAS No. entry 7783-20-2 would also be removed, if finalized.

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FR CITATION	FINAL RULE FR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
	Change of Address Notice; Corr			NONE	55 FR 19264	05/09/90	05/09/90	Corrects change of address notice published in the Federal Register on 01/05/90 (55 FR 420). P.O. Box number 223779 was incorrect; correct P.O. Box is 23779.
	Sulfuric Acid; Toxic Chemical	372			55 FR 24637	06/18/90	06/11/90	Denial of petition to delete Sulfuric acid from the list of toxic chemicals. Denial is based on the conclusion that sulfuric acid is reasonably anticipated to cause human chronic health effects. Two petitions were filed on 12/12/8 & 03/07/90. NOTE: Effective Date is statutory deadline fo EPA's response to the petition.
	Phosphoric Acid; Toxic Chemica	372	06/25/90	55 FR 25876				Notice issuing the results of a technical review and evaluation of a petition to delete *Phosphoric Acid (PA)*. Also, EPA is requesting public comment on the development o a phosphate category under section 313, which would includ *PA*, as well as other sources of phosphate. *PA, because o* its corrosive properties, can cause moderate acute toxicit in humans; but, not anticipated to cause chronic toxicity humans. PA can reasonably be anticipated to cause environmental toxicity and contributes to phosphate loadin *Petition was withdrawn 06/01/90.*

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FR CITATION	FINAL RULE FR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
t1	TCEA	799.4400	06/05/81	46 FR 30300	49 FR 39810	10/10/84	11/23/84	1,1,1-Trichloroethane; developmental toxicity & environmental effects.
			08/07/85	50 FR 31895	50 FR 51683	12/19/85	02/03/86	Phase II rule.
		799.5000			54 FR 34991	08/23/89	08/23/89	Testing Consent Order - mutagenicity & neurotoxicity.
t2	Ethyl toluenes, Trimethylbenzenes & C9s	799.2175	05/23/83	48 FR 23088	50 FR 20662	05/17/85	07/01/85	Neurotoxicity, mutagenicity, developmental toxicity, reproductive effects & oncogenicity (unless certain mutagenicity test results are negative).
			03/27/86	51 FR 10557	52 FR 2522	01/23/87	03/09/87	Phase II rule.
					54 FR 27352	06/29/89	06/29/89	Technical amendment.
t3	DETA	799.1575	04/29/82	47 FR 18386	50 FR 21398	05/23/85	07/08/85	Diethylenetriamine; oral subchronic, dermal absorption, chemical fate & mutagenicity.
		799.1575	06/28/89	54 FR 27189	55 FR 3407	02/01/90	03/19/90	Proposed rule - extension of deadline & recision of dermal absorption testing. Final rule - recision of dermal absorption testing and extension of deadline for submissio of final report on chemical fate testing.
			04/10/86	51 FR 12344	52 FR 3230	02/03/87	03/19/87	Phase II rule.
		799.1575	05/23/85	50 FR 21413	55 FR 17769	04/27/90	04/19/90	Oncogenicity testing; proposed rule. Withdrawal of propos rule because chemical is not mutagenic.
					54 FR 27352	06/29/89	06/29/89	Technical amendment.
t4	Biphenyl	799.925	05/23/83	49 FR 23080	50 FR 37182	09/12/85	10/28/85	Environmental effects & chemical fate.
			07/15/86	51 FR 25577	52 FR 20710	06/03/87	07/17/87	Phase II rule.
					54 FR 27352	06/29/89	06/29/89	Technical amendment.
t5	Propylene oxide	799,3450	01/04/84	49 FR 430	50 FR 48762	11/27/85	01/10/86	Developmental toxicity.
			11/27/85	50 FR 48803	52 FR 35706	09/23/87	11/06/87	Testing standards & reporting requirements.
t6	Mesityl oxide (MO)	799.2500	07/05/83	48 FR 31812	50 FR 51857	12/20/85	02/03/86	Subchronic inhalation, mutagenicity & oncogenicity (if mutagenicity results are positive).
					52 FR 10752	04/03/87		Clarification of final rule.
			12/20/85	50 FR 51888	52 FR 19088	05/20/87	07/06/87	Test standards & reporting requirements.
t7	Hydroquinone	799.2200	01/04/84	49 FR 438	50 FR 53145	12/30/85	02/12/86	Toxicokinetics, central nervous system, reproductive effec & teratogenic effects.

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FR CITATION	FINAL RULE FR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
			12/30/85	50 FR 53160	50 FR 19865	05/28/87	06/13/87	Test standards & reporting requirements.
					54 FR 27352	06/29/89	06/29/89	Technical amendment.
t8	Certain Chlorinated Benzenes	799.1052	01/13/84	49 FR 1780	51 FR 11728	04/07/86	05/21/86	Dichlorobenzenes; environmental effects & chemical fate.
		799.1053	04/07/86	51 FR 11756	52 FR 24460	07/01/87	08/14/87	Trichlorobenzenes; Phase II rule.
t9	Cresols	799.1250	07/11/83	48 FR 31812	51 FR 15771	04/28/86	06/11/86	Mutagenicity, developmental toxicity & reproductive effec
			04/28/86	51 FR 15803	52 FR 19082	05/20/87	07/06/87	Phase II rule.
					54 FR 27352	06/29/89	06/29/89	Technical amendment.
t10	Certain Chlorinated Benzenes	799.1051	07/18/80	45 FR 48524	51 FR 24657	07/08/86	08/21/86	Monochlorobenzenes; reproductive effects.
		799.1052						Dichlorobenzenes; reproductive effects.
		799.1053						Trichlorobenzenes; oncogenicity.
		799.1054						1,2,4,5-Tetrachlorobenzene; developmental toxicity.
			12/28/84	49 FR 50408				Withdrawal of certain portions of proposed rule.
			11/27/85	50 FR 48806				Revision of proposed rule to reflect TSCA test guidelines
		799.1052			52 FR 10377	04/01/87	04/01/87	Dichlorobenzenes; modification of reporting deadlines.
		799.1054			52 FR 26477	07/15/87	07/15/87	1,2,4,5-Tetrachlorobenzene; modification of test substanc purity requirement.
		799.1054			54 FR 27352	06/29/89	06/29/89	1,2,4,5-Tetrachlorobenzene; technical amendment.
		799.1054			52 FR 10377	04/01/87	04/01/87	1,2,4,5-Tetrachlorobenzene; modification of reporting deadlines.
t11	1,2-Dichloropropane				54 FR 27352	06/29/89	06/29/89	Technical amendment.
		799.1550	01/06/84	49 FR 899	51 FR 32079	09/09/86	10/23/86	Neurotoxicity, mutagenicity, reproductive effects, developmental toxicity, acute toxicity & chronic toxicity
			09/09/86	51 FR 32107	52 FR 37138	10/05/87	11/18/87	Pharmacokinetics testing standards.
t12	Bisphenol A	799.940	05/17/85	50 FR 20691	51 FR 33047	09/18/86	11/03/86	Subchronic inhalation.
t13	2-Ethylhexanoic acid	799.1650	05/17/85	50 FR 20678	51 FR 40318	11/06/86		Subchronic toxicity, developmental toxicity & pharmacokinetics.
					52 FR 24157	06/29/87	06/29/87	Technical modification.
					52 FR 32240	08/26/87		Correction.

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FR CITATION	FINAL RULE FR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
t14	Cyclohexane		05/20/87	52 FR 19096				Subchronic toxicity, oncogenicity, reproductive toxicity, developmental toxicity, neurotoxicity, dermal absorption & dermal sensitization.
			07/27/87	52 FR 28023				Proposed rule; extension of comment period.
			06/07/89	54 FR 24360				Reopening of comment period.
t15	Anthraquinone	799.500	11/06/85	50 FR 46090	52 FR 21018	06/04/87	07/20/87	Water solubility, bioconcentration, acute toxicity to aquatic organisms, biodegradation & chronic toxicity to aquatic organisms (if triggered).
					52 FR 32990	09/01/87		Correction.
					54 FR 27352	06/29/89	06/29/89	Technical amendment.
t16	Benzyl butyl phthalate		09/06/85	50 FR 36446				Environmental fate & effects.
			10/29/87	52 FR 41593	Withdrawal			Withdrawal of proposed rule.
t17	Chloromethane		07/18/80	45 FR 48524				Health effects.
			05/07/85	50 FR 19213	Withdrawal			Withdrawal of proposed rule.
t18	Cumene	799.1285	11/06/85	50 FR 46104	53 FR 28195	07/27/88	09/09/88	Health effects, environmental effects & chemical fate.
t19	Diethylene glycol butyl ether/ acetate	799.1560	08/06/86	51 FR 27880	53 FR 5932	02/26/88	04/11/88	Diethylene glycol butyl ether (DGBE) & Diethylene glycol butyl ether acetate (DGBA); subchronic toxicity for DGBE & dermal absorption for DGBA.
			05/31/89	54 FR 13202				Proposed modification to final rule.
					54 FR 27352	06/29/89	06/29/89	Technical amendment.
		795.225			54 FR 41832	10/12/89	11/27/89	Revising the dose occlusion requirements for dermal pharmacokinetics testing for DGBE and DGBA.
		799.1560			54 FR 41832	10/12/89	11/27/89	Modifying the submission of progress and final pharmacokinetics test reports to EPA.
t20	1,1-Dichloroethylene		08/12/86	51 FR 28840				Dermal & oncogenicity bioassay.
t21	Dichloromethane		06/05/81	46 FR 30300				Health & environmental effects.
			06/19/84	49 FR 25009	Withdrawal			Withdrawal of proposed rule.

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FR CITATION	FINAL RULE FR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
t22	2-Ethylhexanol	799.1645	12/19/86	51 FR 45487	52 FR 28698	08/03/87	09/16/87	Oncogenicity bioassay.
t23	Fluoroalkenes	799.1700	11/06/85	50 FR 46133	52 FR 21516	06/08/87	07/22/87	Health effects.
					52 FR 26982	07/17/87		Correction of final rule; insertion of inadvertently omitted page.
					52 FR 43762	11/16/87		Technical amendment to final rule.
					54 FR 27352	06/29/89	06/29/89	Technical amendment.
		799.1700	12/23/88	53 FR 51847	55 FR 12639	04/05/90	05/21/90	Amendment to the requirement for the Mouse Visible Specific Locus Test (MVSL) to allow either the MVSL or the Mouse Biochemical Specific Locus Test (MBSL).
t24	Hexafluoropropylene oxide	799.2150	12/30/83	48 FR 57686				HFPO; carcinogenicity, mutagenicity & reproductive effects.
			10/14/88	53 FR 40264				Termination of rulemaking.
t25	2-Mercaptobenzothiazole	799.2475	11/06/85	50 FR 46121	53 FR 34514	09/07/88	10/21/88	Persistence & mobility, chronic aquatic toxicity, pharmacokinetics, developmental toxicity, reproductive toxicity, neurotoxicity & chromosomal aberrations.
					53 FR 37393	09/26/88		Final rule; correction.
t26	Commercial Hexane & Methylcyclopentane	799.2155	05/15/86	51 FR 17854	53 FR 3382	02/05/85	03/21/88	Commercial Hexane - health effects; * Methylcyclopentane - termination of rulemaking.
			07/21/86	51 FR 26170				Proposed rule; extension of comment period.
			05/27/88	53 FR 19315	53 FR 38952	10/04/88	11/17/88	Definition of test substance & effective date.
		795 & 799	11/09/88	53 FR 45289	55 FR 627	01/08/90	02/21/90	Proposed rule; proposed pharmacokinetics test requirements and revision of proposed test guidelines. Final rule; 40 CFR 795.232 - Inhalation and dermal pharmacokinetics of commercial hexane and 40 CFR 799.2155 - Commercial hexane. This rule amends final test rule - 53 FR 3382 (02/05/88).
			12/09/88	53 FR 49822				Correction.
		799.2155	12/23/88	53 FR 51847	55 FR 12639	04/05/90	05/21/90	Amendment to the requirement for the Mouse Visible Specific Locus Test (MVSL) to allow use of either the MVSL or the Mouse Biochemical Specific Locus Test (MBSL).
t27	Nitrobenzene		06/05/81	46 FR 30300				Health & environmental effects.
			06/19/84	49 FR 25013	Withdrawal			Withdrawal of proposed rule.

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FR CITATION	FINAL RULE FR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
t28	Octamethylcyclotetrasiloxane		10/30/85	50 FR 45123				Chemical fate & environmental effects.
		799.5000			54 FR 818	01/10/89	01/10/89	Consent Order - chemical fate and environmental effects.
					54 FR 3183	01/23/89		Correction.
t29	Oleylamine	799.3175	11/19/84	49 FR 45610	52 FR 31962	08/24/87	10/07/87	Mutagenicity & developmental toxicity (if triggered as an oncogen and mutagen).
					52 FR 37246	10/05/87		Correction.
			08/24/87	52 FR 31970	53 FR 48542	12/01/88	01/17/89	Phase II rule.
		799.3175	12/23/88	53 FR 51867	55 FR 12639	04/05/90	05/21/90	Amendment to the requirement for the Mouse Visible Specifi Locus Test (MVSL) to allow the use of either the MVSL or t Mouse Biochemical Specific Locus Test (MBSL).
t30	Pentabromoethylbenzene		11/13/85	50 FR 46785				Chemical fate & environmental effects.
			11/22/88	53 FR 47228	Withdrawal			Withdrawal of proposed rule.
t31	Polyhalogenated dibenzo-p-dioxins/furans	766.25	12/19/85	50 FR 51794	52 FR 21412	06/05/87	07/06/87	Testing for presence of certain chlorinated & brominated dioxins & furans; * CAS Nos. 96-75-7 & 96-82-6 - withdrawn in final rule.
			10/23/86	51 FR 37612				Amendment to proposed rule.
t32	Quinone		01/04/84	49 FR 456				Carcinogenicity, environmental effects & chemical fate.
			12/30/85	50 FR 53165	Withdrawal			Withdrawal of proposed rule.
t33	Tetrabromobisphenol A	799.4000	05/15/86	51 FR 17872	52 FR 25219	07/06/87	08/19/87	Chemical fate and environmental effects.
					54 FR 27352	06/29/89	06/29/89	Technical amendment.
t34	Triethylene glycol monomethyl ether	799.4440	05/15/86	51 FR 17883	54 FR 13472	04/03/89	05/17/89	TGME; developmental toxicity & neurotoxicity.
			12/09/88	53 FR 49822				Correction.
					54 FR 13470	04/03/89	04/03/89	Testing Consent Order - health effects.
t35	Solid Waste Chemicals	799.5055	05/29/87	52 FR 20336	53 FR 22300	06/15/88	07/29/88	Health effects and/or chemical fate; * Withdrawn from final rule without recommended testing at this time; ** Withdrawn from final rule with recommended testing.

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FR CITATION	FINAL RULE FR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
			08/07/87	52 FR 29395				Proposed rule; extension of comment period.
			08/12/87	52 FR 29990				Proposed rule; corrections.
			01/14/88	53 FR 911				Proposed rule; reopening of comment period.
					53 FR 48645	12/02/88	12/02/88	*** Removal of Phthalic anhydride (CAS No. 85-44-9) from testing requirements.
		799.5055			54 FR 49760	12/01/89	12/01/89	Technical amendment; CORRECT CAS number for hazardous waste constituent -- Trichloromethanethiol -- is 75-70-7, NOT CAS No. 594-42-3.
t36	Unsubstituted Phenylenediamine	799.3300	01/06/86	51 FR 472	54 FR 49285	11/30/89	01/16/90	Manufacturers & processors of o-PDA (CAS No. 95-54-5), m-PD (CAS No. 108-45-2) p-PDA (CAS No. 106-50-3) and sulfate salts: m-PDA.(H)2 S(O)4 (CAS No. 541-70-8)/p-PDA.(H)2 S(O)4 (CAS No. 16245-77-5) = Neurotoxicity, Chemical fate, Aquati toxicity; H/P of m-PDA & its sulfate salt = Mutagenicity.
			01/14/88	53 FR 913				Proposed rule; reopening of comment period.
		799.3300	12/23/88	53 FR 51847	55 FR 12639	04/05/90	05/21/90	Amendment to the requirement for the Mouse Visible Specific Locus Test (MVSL) to allow test sponsors to use either the MVSL or the Mouse Biochemical Specific Locus Test (MBSL).
t37	DCBTF	799.5000			52 FR 23547	06/23/87	06/23/87	3,4-Dichlorobenzotrifluoride; Testing Consent Order - chemical fate & environmental effects.
					52 FR 32990	09/01/87		Correction.
t38	DTBP		06/25/87	52 FR 23862				2,6-Di-tert-butyl phenol; chemical fate & environmental effects.
t39	Tributyl phosphate	799.4360	11/12/87	52 FR 43347	54 FR 33400	08/16/89	09/27/89	Chemical fate, health effects & environmental effects.
					54 FR 49844	12/01/89	12/01/89	Correction; final rule.
	Tributyl Phosphate; Final Test	795.228		NONE	55 FR 25392	06/21/90	06/21/90	Correction; final rule.
t40	Isopropanol	795 & 799	03/16/88	53 FR 8638	54 FR 43252	10/23/89	12/04/89	40 CFR 795.231 - Pharmacokinetics of Isopropanol and 40 CFR 799.2325 - Isopropanol. Testing includes: subchronic toxicity, reproductive toxicity, developmental toxicity, neurotoxicity, developmental neurotoxicity, mutagenicity, oncogenicity, and pharmacokinetics.

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FR CITATION	FINAL RULE FR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
			04/18/88	53 FR 12748				Correction; proposed rule.
		799.2325	12/23/88	53 FR 51847	55 FR 12639	04/05/90	05/21/90	Amendment to the requirement for the House Visible Specific Locus Test (HVSL) to allow use of either the HVSL or the House Biochemical Specific Locus Test (HBSL).
t41	Methyl tert-butyl ether	799.5000			53 FR 10391	03/31/88	03/31/88	Testing Consent Order - health effects.
t42	Aniline & seven Substituted Anilines	799.5000			53 FR 31804	08/19/88	08/19/88	Testing Consent Order - health & environmental effects.
					53 FR 37393	09/26/88		Testing Consent Order - correction.
					53 FR 49966	12/12/88		Testing Consent Order - correction.
t43	Methyl ethyl ketoxime	799.2700	09/15/88	53 FR 35838	54 FR 37799	09/13/89	10/27/89	MEKO; health effects.
					54 FR 49844	12/01/89	12/01/89	Correction.
t44	Alkyl phthalates	799.5000			54 FR 618	01/09/89	01/09/89	Testing Consent Order - chemical fate & environmental effects.
					54 FR 3183	01/23/89		Correction.
					54 FR 4109	01/27/89		Correction.
	Final Rule; Technical Amendmen	799.5000			55 FR 3058	01/30/90	01/30/90	Removes incorrect description of one of test mixtures -- Di(heptyl, nonyl, undecyl) phthalate (mixed isomers) -- CAS No. 68515-42-4. Changes title to: "Testing Consent Orders for Substances and Mixtures with Chemical Abstract Service Registry Numbers." CAS No. 68515-42-4 now removed from CORI
		799.5025			55 FR 3058	01/30/90	01/30/90	Establishes new section for mixtures subject to testing consent orders. Adds correct description to be tested: CAS No. 68515-44-6, CAS No. 68515-45-7, CAS No. 111381-89-6, CAS No. 3648-20-2, CAS No. 111381-90-9, and CAS No. 111381-91-0 Test mixture: Di(heptyl, nonyl, undecyl) phthalate (D711P)
t45	Diisodecyl phenyl phosphite	799.5000			54 FR 8112	02/24/89	02/24/89	Testing Consent Order - neurotoxicity.
t46	1,6-Hexamethylene diisocyanate		05/17/89	54 FR 21240				Health effects.
			06/02/89	54 FR 23739				Correction.
			08/10/89	54 FR 32829				Extension of comment period.

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FR CITATION	FINAL RULE FR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
t47	Crotonaldehyde	799.5000			54 FR 47082	11/09/89	11/09/89	Testing Consent Order for Crotonaldehyde (2-Butenal) - CAS No. 4170-30-3; perform certain Chemical fate and Environmental effects tests.
t48	C. I. Disperse Blue 79:1	799.5000			54 FR 48102	11/21/89	11/21/89	Testing Consent Order for C. I. Disperse Blue 79:1 (DB-79: - CAS No. 3618-72-2); perform certain Health and Environmental effects tests.
t49	4-Nonylphenol, Branched	799.5000	02/06/89	54 FR 6170	55 FR 5991	02/21/90	02/21/90	Testing Consent Order for 4-Nonylphenol, branched - CAS No 84852-15-3* (* = CAS does not consider this number to represent a unique chemical substance). Certain chemical fate and environmental effects tests will be performed. Chemical mostly comprised of para-branched C9 alkylphenols
t50	Technical Amendments to Test R ules.....	799			55 FR 7322	03/01/90	03/01/90	EPA has approved by letter certain modifications to test standards and schedules. These modifications cover the period from October 1, 1988 to September 30, 1989. Variou CAS numbers covered by final rules and testing consent orders appear in this rule.
t51	N-Methylpyrrolidone	799.2900	03/28/90	55 FR 11398				Proposed rule - to require manufacturers and processors to test for oncogenicity, mutagenicity, developmental toxicit reproductive toxicity, neurotoxicity, subchronic toxicity, and pharmacokinetics. Specific CAS No. is 872-50-4. Concer use as substitute for Methylene chloride in paint stripper
t52	House Visible Specific Locus T est Requir	798.5195	12/23/88	53 FR 51847	55 FR 12639	04/05/90	05/21/90	Allows test sponsors to choose either the HVSL or the Hous Biochemical Specific Locus Test (HBSL). Also, promulgates test guideline for HBSL; specifies reporting requirement o 51 months for test completion; and specifies specimen retention requirements.
		799	12/23/88	53 FR 51847	55 FR 12639	04/05/90	05/21/90	Changes in HVSL requirements effect final test rules for: Fluoroalkenes, Oleylamine (Phase I & Phase II), Commercial Hexane, Unsubstituted Phenylenediamines, & Isopropanol; an proposed test rule for: Triethylene glycol monomethyl, monoethyl, & monobutyl ethers.

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FR CITATION	FINAL RULE FR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
t53	Testing Consent Agreements & T est Rules	790	05/17/89	54 FR 21237	55 FR 18881	05/07/90	06/21/90	Eliminates requirement that certain manufacturers file letters of intent to test or exemption applications unless no other manufacturer submits a letter of intent to test. Modifies requirement to submit study plans at least 45 day prior to initiation of testing by eliminating requirement unless it is specified in a particular test rule or testir consent order. See also Notice of final rulemaking on dat reimbursement (48 FR 31786; 07/11/83) & Notice of interim final rule on single-phase test rule development and exemption procedures (50 FR 20652; 05/17/85).
t54	Office of Drinking Water Chemi cals	795.257	05/24/90	55 FR 21393				Require manufacturers and processors to test five substan for oral 14-day repeated dose and oral 90-day subchronic toxicity studies. Also, proposes a new testing guideline for 14-day repeated dose oral toxicity study. Chemicals include: Chloroethane (CAS No. 75-00-3); 1,1-Dichloroethar (CAS No. 75-34-3); 1,1,2,2-Tetrachloroethane (CAS No. 79-34-5); n-Propylbenzene (CAS No. 103-65-1); and 1,3,5-Trimethylbenzene (CAS No. 108-67-8).
		799.5075	05/24/90	55 FR 21393				

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FR CITATION	FINAL RULE FR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
a1	PCBs *	761	06/07/78	43 FR 24802	44 FR 31542	05/31/79	06/02/79	Certain prohibitions.
			04/22/82	47 FR 17426	47 FR 37342	08/25/82	09/24/82	Use in electrical equipment.
			06/08/82	47 FR 24976	47 FR 46980	10/21/82	11/22/82	Closed & controlled waste manufacturing process.
			12/01/83	48 FR 55079	49 FR 28173	07/10/84	10/01/84	Inadvertently generated.
			10/11/84	49 FR 39966	50 FR 29170	07/17/85	08/16/85	Use in electrical transformers.
					52 FR 10688	04/02/87	05/04/87	Spill clean-up policy.
					53 FR 40882	10/19/88	10/19/88	Spill clean-up policy; amendments & clarifications.
			07/08/87	52 FR 25838	53 FR 24206	06/27/88	07/27/88	Exclusions, exemptions & use authorizations.
			09/04/87	52 FR 33680				Exclusions, exemptions & use authorizations; corrections.
					53 FR 29114	08/02/88		Exclusions, exemptions & use authorizations; corrections.
		761.80	08/24/88	53 FR 32326	55 FR 21023	05/22/90	07/05/90	Manufacturing, processing, and distribution in commerce exemptions; proposed rule. Response to petitions; final rule.
			08/21/87	52 FR 31738	53 FR 27322	07/19/88	09/01/88	PCBs in electrical transformers.
			09/18/87	52 FR 35350				PCBs in electrical transformers; correction.
					53 FR 33897	09/01/88		Correction.
					53 FR 21641	06/09/88	06/09/88	Incorporation of test methods.
					53 FR 25049	07/01/88		Incorporated of test methods; correction.
		761	09/26/88	53 FR 37436	54 FR 52716	12/21/89	02/05/90	Notification and Manifesting for PCB Waste Activities; fin rule effects 40 CFR sections 761.3, 761.65, Subparts J & K
	PCBs *		11/09/88	53 FR 45288				Notification & Manifesting for PCB Waste Activities; extension of public comment period.
		761.80	09/12/89	54 FR 37698	55 FR 21023	05/22/90	07/05/90	Reopen comment period until 10/12/89 for manufacturing, processing, distribution in commerce exemptions; proposed exemption amendment. Response to petitions; final rule.
					54 FR 28419	07/06/89	07/06/89	Correction; PCBs in electrical transformers.
	NOTE FOR PCBs	NOTE FOR a1		NOTE FOR a1	NOTE FOR a1			* This is not a complete list of Federal Register referenc for PCBs. For purposes of compliance, you should consul Title 40 - Code of Federal Regulations.
	Correction; Notification & Man	761.65			55 FR 695	01/08/90	01/08/90	Correction; Polychlorinated Biphenyls; Notification and Manifesting for PCB Waste Activities Final Rule published 12/21/89 (54 FR 52716). Change 40 CFR 761.65(d)(1), on pag 52746, in first column, by removing "[insert date 224 days after date of...]" each time and insert "August 2, 1990."
	PCBs; Wet Weight/Dry Weight Cl	761.1	04/06/90	55 FR 12866				Proposed amendment which would add the phrase "on a dry weight basis" to 40 CFR 761.1(b). This phrase was omitted inadvertently from the final rule published on 07/10/84 (49 FR 28172).

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FR CITATION	FINAL RULE FR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
	Notice of Availability PCB Pen	761	09/10/80	45 FR 59776	55 FR 13955	04/13/90	04/09/90	Interim guidance was proposed on 03/10/80. Interim guida was published on 09/10/80. This revised policy will prov for penalties in administrative civil actions. Penalties are determined two stages: (1) determination of a "gravit based penalty" (GBP) and (2) adjustments to the GBP.
	PCBs Notification & Manifestin	761		NONE	55 FR 26204	06/27/90	06/27/90	Correction; final rule. Corrects technical errors in 54 FR 52716 (12/21/89). Corrections cover 40 CFR 761.3; 761.65; 761.180; & 761.215.
x2	CFCs *	762	05/13/77	42 FR 24542	45 FR 11318	03/17/78	11/15/78	Prohibition of use.
	NOTE FOR CFCs	NOTE FOR x2		NOTE FOR x2	NOTE FOR x2			* This is not a complete list of Federal Register referen for CFCs. For purposes of compliance, you should consu Title 40 - Code of Federal Regulations.
x3	Triethanolamine salt/Tricarbox ylic acid	747.200	01/23/84	49 FR 2772				Metalworking fluids; immediately effective.
x4	Triethanolamine salt/Substitu. org. acid	747.195	06/14/84	49 FR 24668				Metalworking fluids; immediately effective.
x5	Mixed Mono & Diamides of an Or ganic Acid	747.115	09/20/84	49 FR 36855				Metalworking fluids; immediately effective.
x6	Asbestos *	763	09/17/80	45 FR 61966	47 FR 23360	05/27/82	06/28/82	Asbestos in schools.
			07/12/85	50 FR 28530	51 FR 15722	04/25/86	06/09/86	Worker protection; immediately effective.
					52 FR 5618	02/25/87	03/27/87	Worker protection; incorporation of new OSHA regulations.
					53 FR 1021	02/15/88	02/15/88	Technical amendment.
			01/29/86	51 FR 3738	54 FR 29460	07/12/89		Ban/phase-down.
			04/30/87	52 FR 15833	52 FR 41826	10/20/87	12/14/87	Asbestos-containing materials in schools.
					54 FR 37531	09/11/89		Correction; ban/phase-down.
	NOTE FOR Asbestos	NOTE FOR x6		NOTE FOR x6	NOTE FOR x6			* This is not a complete list of Federal Register referen for Asbestos. For purposes of compliance, you should consult Title 40 - Code of Federal Regulations.
		763			54 FR 46897	11/08/89	11/08/89	Technical amendment; Asbestos: Manufacture, Importation, Processing, and Distribution in Commerce Prohibitions Fin Rule published as 54 FR 29460 (07/12/89).

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FR CITATION	FINAL RULE FR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
	Asbestos; Publication of Ident				55 FR 5144	02/13/90		Summaries of information submitted by manufacturers and processors of certain asbestos products in accordance with the Asbestos Information Act of 1988.
	Correction; Asbestos; Publicat			NONE	55 FR 20522	05/17/90	05/09/90	Correction notice for Asbestos; Publication of identifying information. Corrects summaries of information submitted manufacturers and processors of certain asbestos products.
x7	Tetrachlorodibenzo-p-dioxin	766	03/11/80	40 FR 15547	45 FR 32677	05/19/80	05/12/80	TCDD; disposal of waste containing TCDD; immediately effective.
					49 FR 44997	11/14/84	12/14/84	Change of administrative authority; transfer to EPA Office of Solid Waste.
x8	Hexavalent Chromium/Comfort Co ol. Towers	749.68	03/29/88	53 FR 10206	55 FR 221	01/03/90	02/20/90	Prohibition of Hexavalent Chromium Chemicals in Comfort Cooling Towers. Prohibition of distribution in commerce effective on 02/20/90. Prohibition of commercial use is effective on 05/18/90. Labeling, recordkeeping, and reporting requirements exist.

CHEMICALS ON REPORTING RULES DATABASE (CORR)

October 31, 1991 UPDATE

U.S. Environmental Protection Agency
Office of Pesticides and Toxic Substances
Office of Toxic Substances

Compiled by the
Existing Chemical Assessment Division
Chemical Screening Branch (TS-778)

The Chemicals on Reporting Rules Database (CORR) report contains information on chemicals that have been the subject of proposed or final regulations issued by the Office of Toxic Substances in the Federal Register (FR).

This CORR document contains two tables and a rule code list. The first table contains the Chemical Abstract Service (CAS) Registry Numbers that are referenced in the final list. Following the CAS number table, there is table of Premanufacture Notice (PMN) substances. Both of these tables are cross-referenced to the rule code list, which cites Federal Register publication information. The rule code section provides: FR citations, the Code of Federal Regulations (CFR) citation (when available), dates relevant to the FR citations, and other information contained in the FR citation relevant to the action.

All of the information that was published in the 4/30/91 update of CORR is included in this report. This document is an amendment to the 06/30/90 CORR Database Report and it covers the rulemaking period from July 1, 1990 to October 31, 1991. Therefore, to complete your copy of CORR, only the 6/30/90 original edition and the 10/31/91 amendment (this document) are required.

IMPORTANT NOTICE:

This document is intended to be an information resource. Since it may contain errors, omissions, etc., **this document SHOULD NOT be used in lieu of FR documents or the CFR for purposes of compliance.** Please report any errors or omissions to Tess Bateman at (202) 260-3416.

Copies of the 6/30/90 and 10/31/91 CORR Database Reports are available from the TSCA Hotline at (202) 554-1404, or you may request copies through the following address:

U.S. Environmental Protection Agency
OPTS/OTS/Environmental Assistance Division
Mail Code: TS-799
401 M Street, SW
Washington, D.C. 20460

.OTE: You can also fax your request for the CORR Database Reports or other TSCA publications to (202) 554-5603.

Rule codes are a letter and number combination. Rule codes beginning with the following letters are used throughout this document, and correspond to the specified action:

a = TSCA section 8(a) chemical specific rules (proposed and final rules)

c = TSCA section 8(c) requests for records and reports regarding significant adverse reactions

d = TSCA section 8(d) rules requiring the submission of unpublished health and safety studies (proposed and final rules)

e = TSCA section 12(b) export notification rules (proposed and final rules)

f = TSCA section 4(f) required actions

m = TSCA section 8(a) Comprehensive Assessment Information Rules (CAIR) (proposed and final rules)

p = TSCA section 8(a) Preliminary Assessment Information Rules (PAIR) (proposed and final rules)

r = Substances subject to reporting period terminations under the TSCA section 8(d) rule

s = TSCA section 5(a) Significant New Use Rule

sr11O = List of hazardous substances under §104(i) of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or Superfund) as amended by SARA §110

sr313 = List of toxic chemicals under §313 of the Emergency Planning and Community Right-to-Know Act (EPCRA or SARA Title III)

t = TSCA section 4 test rules and consent orders (proposed and final rules)

x = TSCA section 6 risk management rules (proposed and final rules)

For more information on the Agency for Toxic Substances and Disease Registry listing, ranking and toxicological profiles contact Dave Brooks at (202) 260-1501. Send your written request to U.S. EPA, 401 M. Street, SW, TS-796, Attn: Dave Brooks, Washington, DC 20460.

CHEMICALS ON REPORTING RULES (CORR) DATABASE

CHEMICAL ABSTRACT SERVICE (CAS) REGISTRY NUMBERS & CHEMICAL NAMES

CAS NUMBER	CHEMICAL NAME	RULE CODE
57-10-3	Hexadecanoic acid	t56
60-29-7	Diethyl ether	t57
67-63-0	Isopropanol (aka 2-Propanol)	t58, t55 - see also CORR listings 6/30/90 (t40, P15, d19, sr313, t52)
67-64-1	Acetone	t57 - see also CORR listings 6/30/90 (sr110, sr313)
71-36-3	1-Butanol (aka n-Butyl alcohol)	t57 - see also CORR listings 6/30/90 (sr313)
71-55-6	1,1,1-Trichloroethane (aka Methyl chloroform)	t55 - see also CORR listings 6/30/90 (sr110, P1, d1, t1, sr313)
74-97-5	Bromochloromethane	P24, t56 - see also CORR listings 6/30/90 (sr110, d20)
75-02-5	Vinyl fluoride	t58
75-15-0	Carbon disulfide	t56 - see also CORR listings 6/30/90 (sr110, sr313)
75-63-8	Bromotrifluoromethane (Halon-1301)	sr313 - see also CORR listings 6/30/90 (sr313)
75-69-4	Trichlorofluoromethane (CFC-11)	sr313 - see also CORR listings 6/30/90 (s4110, sr313)
75-71-8	Dichlorodifluoromethane (CFC-12)	sr313 - see also CORR listings 6/30/90 (sr110, sr313)
75-88-7	Ethane, 2-chloro-1,1,1-trifluoro- (HCFC-133a)	s55, d28 - see also CORR listings 6/30/90 (s55, d28)
76-14-2	Dichlorotetrafluoroethane (CFC-114)	sr313 - see also CORR listings 6/30/90 (sr313)
76-15-3	(mono)Chloropentafluoroethane (CFC-115)	sr313 - see also CORR listings 6/30/90 (sr313)
78-40-0	Triethyl phosphate (aka Phosphoric acid, triethyl ester)	d29, P24 - see also CORR listings 6/30/90 (C2)
78-42-2	Tris(2-ethylhexyl)phosphate (aka Phosphoric acid tris(2-ethylhexyl) ester)	d29, P24 - see also CORR listings 6/30/90 (C2)
78-51-3	Tris(2-butoxyethyl) phosphate (aka Ethanol, 2-butoxy-, phosphate (3:1))	d29, P24 - see also CORR listings 6/30/90 (C2)
78-83-1	Isobutyl alcohol (aka 1-Propanol, 2-methyl-)	t57 - see also CORR listings 6/30/90 (d16)
79-10-7	Acrylic Acid	t62
79-31-2	2-Methylpropanoic acid	t56

(10/31/91)

CHEMICALS ON REPORTING RULES (CORR) DATABASE

CHEMICAL ABSTRACT SERVICE (CAS) REGISTRY NUMBERS & CHEMICAL NAMES

CAS NUMBER	CHEMICAL NAME	RULE CODE
79-94-7	Tetrabromobisphenol-A	x7
87-10-5	3,4',5-Tribromosalicylanilide	P24, d29 - see also CORR listings 6/30/90 (t31)
87-83-2	2,3,4,5,6-Pentabromotoluene	d29, P24
87-84-3	1,2,3,4,5-Pentabromo-6-chlorocyclohexane	P24, d29
91-97-4	4,4'-Diisocyanate-3,3'-dimethylbiphenol	P24 - see also CORR listings 6/30/90 (C2, d20)
95-51-2	2-Chloroaniline	t58
95-54-5	o-Phenylenediamine (aka 1,2-Benzenediamine; o-diaminobenzene; O-PDA)	t58, t55 - see also CORR listings 6/30/90 (t36, P1, d3, t52)
95-63-6	Benzene, 1,2,4-trimethyl	r3 - see also CORR (p1, d3, sr313)
95-80-7	2,4-Toluenediamine (aka 1,3-benzenediamine, 4-methyl)	t56 - see also CORR listings 6/30/90 (P3, d3, sr313)
96-13-9	2,3-Dibromopropanol	P24, d29
96-29-7	Methyl ethyl ketoxime (aka MEKO; 2-butanone, oxinic)	t55 - see also CORR listings 6/30/90 (P15, d19, t43)
96-37-7	Methylcyclopentane	t55 - see also CORR listings 6/30/90 (t26, P12, d12, t50, t52)
98-82-8	Cumene	t58
100-21-0	Terephthalic acid	t56, sr313 - see also CORR listings 6/30/90 (sr313)
100-28-7	p-Nitrophenyl isocyanate	P24, d29
101-68-8	4,4'-Diphenylmethane diisocyanate	P24 - see also CORR listings 6/30/90 (C2, d28, sr313)
102-36-3	3,4-Dichlorophenyl isocyanate	P24, d29
103-71-9	Phenyl isocyanate (aka, Benzene, isocyanato-)	P24, d29 - see also CORR listings 6/30/90 (P1)
104-12-1	p-Chlorophenyl isocyanate	P24, d29
104-49-4	p-Phenylene diisocyanate (aka Benzene, 1,4-diisocyanato-)	P24 - see also CORR listings 6/30/90 (C2, d20)
104-76-7	2-Ethylhexanol	t56 - see also CORR listings 6/30/90 (t22, d20)
106-50-3	p-Phenylenediamine (aka p-diaminobenzene; p-PDA; 1,4-benzene diamine)	t58, t55 - see also CORR listings 6/30/90 (t36, P1, d1, sr313, t52)
107-13-1	Acrylonitrile	t56 - see also CORR listings 6/30/90 (sr110, sr313)
107-66-4	Dibutyl phosphate	P24, d29

(10/31/91)

CHEMICALS ON REPORTING RULES (CORR) DATABASE

CHEMICAL ABSTRACT SERVICE (CAS) REGISTRY NUMBERS & CHEMICAL NAMES

CAS NUMBER	CHEMICAL NAME	RULE CODE
108-10-1	Methyl isobutyl ketone (aka 2-Pentanone, 4-methyl-)	t57 - see also CORR listings 6/30/90 (sr110, P1, d1, sr313)
108-39-4	Meta-cresols (aka Phenol, 3-methyl-)	t55 - see also CORR listings 6/30/90 (P1, d1, sr313)
108-45-2	m-Phenylenediamine (aka m-Diaminobenzene; m-PDA; 1,3-benzene diamine)	t58, t55 - see also CORR listings 6/30/90 (t36, P1, d3, t52)
108-67-8	Benzene, 1,3,5-trimethyl-	r3 - see also CORR listing 6/30/90 (d5, p7, t54)
108-90-7	Monochlorobenzene (aka 1,2,3-Trichlorobenzene)	t55 - see also CORR listings 6/30/90 (sr110, P1, d1, t10, sr313, t50)
109-90-0	Ethyl isocyanate	d29, P24
109-99-9	Tetrahydrofuran	t57 - see also CORR listings 6/30/90 (sr110)
110-54-3	n-Hexane	t55 - see also CORR listings 6/30/90 (sr110, t50, t52)
110-78-1	n-Propyl isocyanate	P24, d29
110-80-5	2-Ethoxyethanol	t57 - see also CORR listings 6/30/90 (sr313)
111-11-5	Methyl ester octanoic acid	t56
111-36-4	n-Butyl isocyanate	P24, d29
111-40-0	Diethylenetriamine	t58
111-63-19-5	Decabromodiphenyloxide	x7
111-91-1	Bis(2-chloroethoxy)methane	t58
112-50-5	Triethylene glycol monomethyl ether	t58
112-96-9	Octadecyl isocyanate	d29, P24
118-79-6	2,4,6-tribromophenol	x7
120-80-9	o-Hydroxyphenol (aka Catechol)	t56 - see also CORR listings 6/30/90 (sr313)
120-82-1	1,2,4-Trichlorobenzene	t55 - see also CORR listings 6/30/90 (sr110, P1, d1, t8, t10, sr313)
123-30-8	p-Aminophenol	t56
123-61-5	1,3-Diisocyanatobenzene	P24 - see also CORR listings 6/30/90 (C2, d20)
123-86-4	n-Butyl acetate	t57
124-73-2	Dibromotetrafluoroethane (Halon-2402)	sr313 - see also CORR listings 6/30/90 (sr313)
126-71-6	Triisobutyl phosphate (aka Phosphoric acid, tris (2-methylpropyl) ester)	d29, P24 - see also CORR listings 6/30/90 (sr313)

(10/31/9

CHEMICALS ON REPORTING RULES (CORR) DATABASE

CHEMICAL ABSTRACT SERVICE (CAS) REGISTRY NUMBERS & CHEMICAL NAMES

CAS NUMBER	CHEMICAL NAME	RULE CODE
126-73-8	Tributyl phosphate (aka Phosphoric acid, tributyl ester)	t58, P24, t55, d29 - see also CORR listings 6/30/90 (C2, t39, P14, d18)
141-78-6	Ethyl acetate	t57
141-79-7	Mesityl oxide	t6 - see also CORR listings 6/30/90 (P8, d1, t6)
142-84-7	1-Propanamine, N-propyl	r3 - see also CORR listing 6/30/90 (d16)
143-33-9	Sodium cyanide	d29, P24
149-30-4	2-Mercaptobenzothiazole (aka 2(3H-)benzotriazole ethione)	t55 - see also CORR listings 6/30/90 (C25, P9, d10, t50)
149-57-5	2-Ethylhexanoic acid	t55 - see also CORR listings 6/30/90 (P6, d8, t13)
298-07-7	Di(2-ethylhexyl) phosphate	d29, P24
306-83-2	Ethane, 2,2-dichloro-1,1,1-trifluoro- (HCFC 123)	d28 - see also CORR listings 6/30/90 (d28)
329-01-1	(alpha; alpha; alpha-Trifluoro-m-tolyl) isocyanate	d29, P24
353-59-3	Bromochlorodifluoromethane	sr313
354-33-6	Ethane, pentafluoro- (HFC 125)	d28 - see also CORR listings 6/30/90 (d28)
421-01-2	Bromochlorodifluoromethane (Halon-1211)	sr313 - see also CORR listings 6/30/90 (sr313)
526-73-8	Benzene, 1,2,3-trimethyl	r3 - see also CORR listing 6/30/90 (d5, p7)
556-67-2	Octamethylcyclotetrasiloxane	t58
585-07-9	t-Butyl methacrylate (2-Propenoic acid-2-methyl-1,1-dimethylethyl ester)	s61
593-60-2	Vinylbromide (aka Ethene, bromo-)	P24, d29 - see also CORR listings 6/30/90 (P1, sr313)
611-14-3	Benzene, 1-ethyl-2-methyl-	r3 - see also CORR listing 6/30/90 (r2, d3)
614-68-6	1-Isocyanato-2-methylbenzene	P24, d29
615-58-7	2,4-Dibromophenol	P24, d29 - see also CORR listings 6/30/90 (t31)
620-14-4	Benzene, 1-ethyl-3-methyl-	r3 - see also CORR listing 6/30/90 (d3)
622-58-2	1-Isocyanato-4-methylbenzene	d29, P24
622-96-8	Benzene, 1-ethyl-4-methyl-	r3 - see also CORR listing 6/30/90 (d3)
624-83-9	Methyl isocyanate	P24, d29 - see also CORR listings 6/30/90 (sr313)

CHEMICALS ON REPORTING RULES (CORR) DATABASE

CHEMICAL ABSTRACT SERVICE (CAS) REGISTRY NUMBERS & CHEMICAL NAMES

CAS NUMBER	CHEMICAL NAME	RULE CODE
628-63-7	n-Amyl acetate	t57
811-97-2	Ethane, 1,1,1,2-tetrafluoro (HFC-124a)	d28 - see also CORR listings 6/30/90 (d28)
812-00-0	Monomethyl phosphate	d29, P24
1070-03-7	Mono(2-ethylhexyl) phosphate 70	P24, d29
1163-19-5	Decabromodiphenyl ether (DBDPE)	t59, x7
1476-23-9	3-Isocyanato-1-propene	d29, P24
1498-51-7	Ethyl dichlorophosphate	d29, P24
1511-62-2	Methane, bromodifluoro-	s71
1623-15-0	Monobutyl phosphate	P24, d29
1623-24-1	Mono(isopropyl) phosphate	P24, d29
1649-08-7	Ethane, 1,2-dichloro-1,1-difluoro- (HCFC-132b)	s55, d28 - see also CORR listings 6/30/90 (d28, s55)
1717-00-6	Ethane, 1,1-dichloro-1-fluoro (HCFC-141b)	s70, d28 - see also CORR listings 6/30/90 (d28)
2421-27-4	2-Propenoic acid, 2-hydroxybutyl ester	s61
2422-91-5	1,1',1''-Methylidynetris (4-isocyanato benzene)	P24, d29
2493-02-9	1-Bromo-4-isocyanatobenzene	d29, P24
2837-89-0	Ethane, 2-chloro-1,1,1,2-tetrafluoro-	s71
2873-89-0	Ethane, 2-chloro-1,1,1,2-tetrafluoro- (HCFC-124)	d28 - see also CORR listings 6/30/90 (d28)
2909-38-8	1-Chloro-3-isocyanatobenzene	d29, P24
2949-22-6	Ethyl isocyanato acetate	P24, d29
2958-09-0	Monooctadecyl phosphate	d29, P24
3173-53-3	Cyclohexyl isocyanate	P24, d29
3194-55-6	Hexabromocyclododecane (HBCD)	t59
3618-72-2	C.I. Disperse Blue 79:1	t58
3900-04-7	Monohexyl phosphate	P24, d29
3991-73-9	Monooctyl phosphate	P24, d29
4035-89-6	Tris(isocyanatohexyl) biuret	P24, d29
4098-71-9	Isophorone diisocyanate (aka Cyclohexane, 5-isocyanato-1-(isocyanatomethyl) 1,3,3-trimethyl)	P24 - see also CORR listings 6/30/90 (C2, d20)
4151-51-3	Tris(4-isocyanatophenyl) thiophosphate	P24, d29
4162-45-2	Ethoxylated tetrabromobisphenol A	x7, d29, P24 - see also CORR listings 6/30/90 (t31)
5124-30-1	1,1'-Methylenebis (4-isocyanatocyclohexane)	P24 - see also CORR listings 6/30/90 (C2, d20)

(10/31/91)

CHEMICALS ON REPORTING RULES (CORR) DATABASE

CHEMICAL ABSTRACT SERVICE (CAS) REGISTRY NUMBERS & CHEMICAL NAMES

CAS NUMBER	CHEMICAL NAME	RULE CODE
5384-21-4	Phenol,4,4'-methylenebis(2,6-dimethyl)	s63
5873-54-1	1-Isocyanato-2-((4-isocyanatophenyl) methyl) benzene	P24 - see also CORR listings 6/30/90 (C2, d20)
7057-92-3	Didodecyl phosphate	d29, P24
7332-46-9	2-(2-Butoxyethoxy)ethanol phosphate (3:1)	d29, P24 - see also CORR listings 6/30/90 (C2)
7664-39-3	Hydrogen Fluoride	sr110
7782-41-4	Fluorine	sr110
10031-75-1	Diphenylmethylene diisocyanate	d29, P24
12510-42-8	Erionite fiber	s69
12645-31-7	2-Ethylhexyl phosphate	P24, d29
12751-23-4	Dodecyl phosphate	d29, P24
14302-13-7	C.I. Pigment Green 36	sr313
15646-96-5	1,6-Diisocyanato-2,4,4-trimethylhexane	P24
16086-31-4	Oxirane, 2,2'-(1,6-hexandiylbis(oxy-methylene))bis-	s71
16938-22-0	1,6-Diisocyanato-2,2,4-trimethylhexane	P24 - see also CORR listings 6/30/90 (C2, d20)
25327-89-3	Tetrabromobisphenol A, bis(allyl) ether	x7, d29, P24 - see also CORR listings 6/30/90 (t31)
25550-14-5	Benzene, ethylmethyl-	r3 - see also CORR listing 6/30/90 (p1, d5)
25551-13-7	Benzene, trimethyl-	r3 - see also CORR listing 6/30/90 (d5, p7)
25854-16-4	Bis(isocyanatomethyl) benzene	P24, d29
26447-40-5	1,1'-Methylenebis-(isocyanatobenzene)	P24 - see also CORR listings 6/30/90 (C2, d20)
26603-40-7	1,3,5-Tris(3-isocyanatomethylphenyl) 1,3,5-triazine-2,4,6 (1H, 3H, 5H)-trione	P24, d29
26747-90-0	Toluene diisocyanate dimer	d29, P24
27193-86-8	Dodecylphenol	t56
27215-10-7	Diisooctyl phosphate	d29, P24
28178-42-9	2,6-Diisopropylphenyl isocyanate (aka Benzene, 2-isocyanato-1,3-bis (1-methylethyl)-)	d29, P24
28556-81-2	Benzene, 2-isocyanato-1,3-dimethyl- (aka 2-isocyanato-1,3-dimethylbenzene)	P24, d29
29091-20-1	Benzenamine, 3-chloro-2,6-dinitro-N,N-dipropyl-4-(trifluoromethyl)	s67
29305-12-2	1,3,5-Triazine-2,4,6-triamine, hydrobromide	s65
30554-72-4	Tetrabromodichlorocyclohexane	P24, d29
30554-73-5	Tribromotrichlorocyclohexane	d29, P24

(10/31/9

CHEMICALS ON REPORTING RULES (CORR) DATABASE

CHEMICAL ABSTRACT SERVICE (CAS) REGISTRY NUMBERS & CHEMICAL NAMES

CAS NUMBER	CHEMICAL NAME	RULE CODE
30674-80-7	2-Isocyanatoethyl methacrylate	d29, P24
32534-81-9	Pentabromodiphenyl ether (PBDE)	t59, x7
32536-52-0	Octabromodiphenyl ether (OBDPE)	t59, x7
34893-92-0	3,5-Dichlorophenyl isocyanate	P24, d29
36483-57-5	Tribromoneopentyl alcohol	P24, d29
37853-59-1	1,2-Bis(tribromophenoxy)-ethane	x7, t59
4126-45-2	Tetrabromodisphenol-A-bisethoxylate	t58
52277-33-5	Poly(oxy-1,4-butanediyl),a-(1-oxo-2-propenyl)-w-[1-oxo-2-propenyl)oxy]	s61
52495-71-3	Poly(oxy-1,2-ethanediyl),a-hydro-3-(oxiranyl-methoxyl)-, ether with 2-ethyl-2-(hydroxymethyl)-1,3-propanediol (3:1)	s71
54140-64-6	Poly(oxy-1,2-ethandiyl,a,a'-[(1-methylethylidene) di-4,1-[phenylene]bis[3-(oxiranylmethoxy)-	s71
54849-38-6	Monomethyltin tris(isooctyl mercaptoacetate) acetic acid, 2,2',2''-[(methylstannylidyne)tris(thio)]tris triisooctyl ester	r3 - see also CORR listing 6/30/90 (r2, p7, d2)
55205-38-7	Tetrabromobisphenol A diacrylate	d29, P24 - see also CORR listings 6/30/90 (t31)
60857-97-8	Methyl oxirane	s61
64630-63-3	2-Propenoic acid, 7-oxabicyclo[4.1.0]hept-3-ylmethyl ester	s66
64742-95-6	Solvent naphtha (petroleum) light aromatic	r3
65992-66-7	N,N,N',N'-tetrakis(oxiranylmethyl)-1,3-cyclohexane dimethamine	s67
66733-21-9	Erionite fiber	s69
68239-06-5	2-Heptyl-3,4-bis(9-isocyanatononyl)-1-pentylcyclohexane	P24, d29
68955-41-9	Alkanes, C_{10-18}, bromo chloro	d29, P24
69882-11-7	2,4-(or 2,6)-Dibromophenol, homopolymer	d29, P24
70693-06-0	C9 aromatic hydrocarbon fraction	t55
73597-26-9	Isophorone diisocyanate hydroxyethylmethacrylate adduct	d29, P24
79637-74-4	2-Propenoic acid, octahydro-4,7-methano-1H-indenyl ester	s71
82428-30-6	2-Propenoic acid, 2-methyl-,7-oxabicyclo[4.1.0] hept-3-ylmethyl ester	s66
84852-15-3	4-Nonylphenol branched	t58
85095-61-0	Hydrazinecarboxamide,N,N'-(methylenedi-4,1-phenylene)bis [2,2-dimethyl-	s66
87320-05-6	2-Propenoic acid, [2-[1,1-dimethyl-2[(1-oxo-2-propenyl) oxyethyl]-5-ethyl-1,3-dioxan-5yl] methyl ester	s67
88497-56-7	Benzene, ethenyl-, homopolymer, brominated	P24, d29
90884-29-0	Phenol,4,4'-(oxybis(2,1-ethanediylthio)bis	s65

(10/31/91)

CHEMICALS ON REPORTING RULES (CORR) DATABASE

CHEMICAL ABSTRACT SERVICE (CAS) REGISTRY NUMBERS & CHEMICAL NAMES

CAS NUMBER	CHEMICAL NAME	RULE CODE
93589-69-6	Phenol,4,4'-[methylenebis(oxy-2,1-ethandiylthio)]bis-	s63
96478-09-0	2-Propenoic acid, 2-methyl-,2-[-3-(2H-benzotriazol-2-yl)-4-hydroxyphenyl] ethyl ester	s71
96915-49-0	2-Oxepanone, homopolymer, ester with 3-hydroxy-2,2-dimethylpropanoic acid (2:1), di-2-propenoate	s67
96915-50-3	2-Oxepanone, homopolymer, 2-propenoate, [tetrahydro-2-furanyl] methyl ester	s67
96915-52-5	2-Oxepanone, homopolymer, 2-propenoate, ester with 2,2'-[oxybis(methylene)bis[2-hydroxymethyl]-1,3-propanediol	s67
104503-68-6	3,6,9,12,15,18,21-Heptaoxatetratriacontanoic acid, sodium salt	s71
105658-30-8	Ethanol, 2-amino-, compound with N-hydroxy-N-nitroso benzenamine (1:1)	s67
106158-22-9	Poly(oxy-1,2-ethanediyl),.a.-hydro-.o.hydroxy-, ether with 2-ethyl-2-(hydroxymethyl)-1,3-propanediol (3:1) di-2-propenoate methyl ether	s71
128504-11-2	Poly(oxy-1,2-ethanediyl),a-(1-oxo-2-propenyl)-o-hydroxy-, C_{10-16}-alkyl ethers	s61
129733-59-1	Phosphoric acid, C_{6-12}-alkyl esters, compound with 2-(dibutylamino) ethanol	s71

(10/31/91)

CHEMICALS ON REPORTING RULES (CORR) DATABASE

PREMANUFACTURE NOTICE (PMN) NUMBERS & CHEMICAL NAMES

PMN NUMBER	CHEMICAL NAME	RULE CODE
83-237	Halogenated alkyl pyridine (aka Substituted methyl pyridine)	s64 - see also CORR listings 6/30/90 (s17)
83-370	8-Acetyle-3-dodecyl-7,7,9,9-tetramethyl-1,3,8-triazspiro [4.5] decane-2,4-dione	s21 - see also CORR listings 6/30/90 (s21)
83-603	Substituted nitrile (generic)	s63
83-769	Substituted bromothiophene (generic)	s71, s67 - see also CORR listings 6/30/90 (s26)
83-817	[(Dinitrophenyl)azo]-[2,4-diamino-5-methoxybenzene] derivatives (generic)	s71, s67 - see also CORR listings 6/30/90 (s29)
83-818	[(Dinitrophenol)azo]-[2,4-diamino-5-methoxybenzene] derivatives (generic)	s71, s67 - see also CORR listings 6/30/90 (s30)
83-906	Brominated arylalkyl ether (generic)	s71, s67 - see also CORR listings 6/30/90 (s25)
83-908	Ethylated aminophenol (generic)	s71, s67 - see also CORR listings 6/30/90 (s25)
83-909	Aminophenol (generic)	s71, s67 - see also CORR listings 6/30/90 (s25)
83-910	Amino ether (generic) (aka aniline ether)	s71, s67 - see also CORR listings 6/30/90 (s25)
83-1023	Phosphine dialkylphenyl (generic)	s71, s67 - see also CORR listings 6/30/90 (s27)
83-1085	Halogenated-N-(2-propenyl)-N-(substituted phenyl) acetamide (generic)	s71, s67 - see also CORR listings 6/30/90 (s37)
83-1157	Substituted oxirane (generic)	s66
83-1162	Halogenated alkyl pyridine	s64
83-1163	Halogenated pyridine	s64
83-1222	Substituted alkyl halide (generic)	s66
83-1227	Perhalo alkoxy ether (generic)	s66
84-7	N,N,N',N'-tetrakis(oxiranylmethyl)-1,3-cyclohexane dimethanamine	s71, s67 - see also CORR listings 6/30/90 (s41)
84-27	Poly carboxylate ester (aka Alkyl glycol ether acrylic acid derivative)	s61 - see also CORR listings 6/30/90 (s32)
84-176	Alkanetriol dimethacrylate, substituted (generic)	s71, s67 - see also CORR listings 6/30/90 (s33)
84-180	Polyalkylene glycol monomethacrylate, substituted	s71, s67 - see also CORR listings 6/30/90 (s34)
84-181	Polyalkyl alkanediol monoacrylate, substituted	s71, s67 - see also CORR listings 6/30/90 (s34)
84-182	Alkanetriol polyalkylene glycol ester acrylate substituted	s67 - see also CORR listings 6/30/90 (s34)
84-183	Polyalkyl glycol monomethacrylate, substituted	s71, s67 - see also CORR listings 6/30/90 (s34)

CHEMICALS ON REPORTING RULES (CORR) DATABASE

PREMANUFACTURE NOTICE (PMN) NUMBERS & CHEMICAL NAMES

PMN NUMBER	CHEMICAL NAME	RULE CODE
84-184	Polyalkyl alkanediol monomethacrylate, substituted	s71, s67 - see also CORR listings 6/30/90 (s34)
84-274	Poly(oxy-1,4-butanediyl), α-(1-oxo-2-propenyl)-ω-[(1-oxo-2-propenyl)oxy]	s61 - see also CORR listings 6/30/90 (s39)
84-341	2-Oxepanone, homopolymer, ester with 3-hydroxy-2,2-dimethylpropanoic acid (2:1), di-2-propenoate	s71, s67 - see also CORR listings 6/30/90 (s38)
84-342	2-Oxepanone, homopolymer, 2-propenoate, (tetrahydro-2-furanyl) methyl ester,	s71, s67 - see also CORR listings 6/30/90 (s38)
84-343	2-Oxepanone, homopolymer, 2-propenoate, ester with 2,2'-[oxybis(methylene)]bis(2-hydroxymethyl)-1,3-propanediol	s71, s67 - see also CORR listings 6/30/90 (s38)
84-344	2-Propenoic acid, [2-[1,1-dimethyl-2-[(1-oxo-2-propenyl) oxy]ethyl]-5-ethyl-1,3-dioxan-5-yl] methyl ester	s71, s67 - see also CORR listings 6/30/90 (s38)
84-358	Unsaturated organic compound (generic)	s65
84-393	2-Chloro-N-methyl-N-substituted acetamide (generic)	s62
84-417	Methylphenol, bis(substituted) alkyl (generic)	s71, s67 - see also CORR listings 6/30/90 (s36)
84-491	Substituted aliphatic acid halide (generic)	s62
84-492	Substituted hydroxylamine (generic)	s66
84-527	Unsaturated amino alkyl ester salt (generic)	s63
84-537	Unsaturated amino ester salt (generic)	s63
84-713	Alkoxylated alkane polyol, polyacrylate ester (generic)	s61
84-814	Polysubstituted polyol (generic)	s61
84-860	Disubstituted nitrobenzene (generic)	s62
84-938	Polymer of hydroxyethyl acrylate and polyisocyanate (generic)	s65
84-951	Substituted aminobenzoic acid ester (generic)	s62
84-968	Alkyl ester (generic)	s62
84-1042	Carbamodithioic acid, methyl-, compound with methanamine (1:1)	s67 - see also CORR listings 6/30/90 (s40)
84-1167	Substituted bis(hydroxyalkane) polymer with epichlorohydrin acrylate (generic) (aka epoxy resin (generic))	s71, s65
84-1219	Substituted pyridine (generic)	s64
85-36	Substituted pyridine (generic)	s64
85-118	Polyurethane (generic)	s65
85-216	Halogenated pyridine (generic)	s64
85-236	Substituted pyridine (generic)	s64
85-296	Amine acrylate monomer (generic)	s61
85-298	Amine acrylate monomer (generic)	s61
85-301	Urethane acrylate	s61
85-415	Monoacrylate (generic)	s65

(10/31/91)

CHEMICALS ON REPORTING RULES (CORR) DATABASE

PREMANUFACTURE NOTICE (PMN) NUMBERS & CHEMICAL NAMES

PMN NUMBER	CHEMICAL NAME	RULE CODE
85-527	Vinyl epoxy ester (generic)	s65
85-535	Halogenated pyridine (generic)	s64
85-536	Halogenated pyridine (generic)	s64
85-544	2-Propenoic acid, 2-methyl,7,7,9-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane, 1,16-diyl ester	s65
85-545	2-Propenoic acid, 3-(dimethylamino)-2,2-dimethylpropyl ester	s65
85-546	2-Propenoic acid, 2-methyl-,3,3,5-trimethyl cyclohexyl ester	s65
85-547	2-Propenoic acid,3,3,5-trimethylcyclohexyl ester	s65
85-703	2-Propenol, 1-amino-, reaction products with melamine, polymer with 5-isocyanato-1-(isocyanatomethyl)-1,3,3-trimethylcyclohexane, 2-hydroxyethyl acrylate-blocked	s71, s67
85-706	Substituted pyridine	s64
85-718	Di(alkanepolyol) ether, polyacrylate (generic)	s71
85-1013	Aliphatic diurethane acrylate ester (generic)	s61
85-1034	Nickel acrylate complex (generic)	s65
85-1169	Acid modified acrylated epoxide (generic)	s61
85-1170	Acid modified acrylated epoxide (generic)	s61
85-1180	tert-Amyl peroxy alkylene ester (generic)	s62
85-1184	Substituted pyridine (generic)	s64
85-1370	Alkyl (heterocyclicyl) phenylazoheteromonocyclic polyene (generic)	s62
86-66	Substituted triazine isocyanurate (generic)	s62
86-83	Benzenamine, 3-chloro-2,6-dinitro-N,N-dipropyl-4-(trifluoromethyl)-	s71, s67 - see also CORR listings 6/30/90 (s44)
86-136	Alkyl (heterocyclicyl) phenylazoheteromonocyclic polyene, ((alkylimidazolyl)methyl) derivative (generic)	s62
86-164	Polymer (generic)	s65
86-334	Aromatic amine compound (generic)	s65
86-335	Aromatic nitro compound (generic)	s65
86-346	Substituted acrylated alkoxylated aliphatic polyol (generic)	s61
86-387	Modified acrylic ester (generic)	s62
86-501	Aromatic diamines (generic)	s60 - see also CORR listings 6/30/90 (s60)
86-503	Aromatic diamines (generic)	s60 - see also CORR listings 6/30/90 (s60)
86-542	Ethanol, 2-amino-, compound with N-hydroxy-N-nitrosobenzenamine (1:1)	s71, s67 - see also CORR listings 6/30/90 (s45)
86-554	Poly(oxy-1,2-ethanediyl),α-(1-oxo-2-propenyl)-ω-hydroxy, C_{10-14}-alkyl ethers	s61

CHEMICALS ON REPORTING RULES (CORR) DATABASE

PREMANUFACTURE NOTICE (PMN) NUMBERS & CHEMICAL NAMES

PMN NUMBER	CHEMICAL NAME	RULE CODE
86-588	Poly (oxy-1,2-ethanediyl) a (2-methyl-1-oxo-2-propenyl)-w-hydroxy-, C_{10-16}-alkyl ethers	s61
86-650	Methacrylic ester (generic)	s65
86-832	Reaction product of hydroxyethyl acrylate and methyl oxirane	s61
86-838	Halogenated substituted pyridine (generic)	s64
86-1088	Substituted hydroxyalkyl alkenoate, [[[[[(1-oxo-2-propenyl)oxy]alkoxy]carbonyl]amino]substituted] aminocarbonyl]oxy- (generic)	s71
86-1098	Halonitrobenzoic acid, substituted (generic)	s62
86-1263	Phosphoric acid,1,2-ethanediyl tetrakis(2-chloro-1-methylethyl) ester	s63
86-1492	Alkyl peroxy-2-ethyl hexanoate (generic)	s66
86-1634	Substituted dialkyl oxazolone (generic)	s63
86-1692	Benzene, substituted alkyl acrylate derivative (generic)	s63
86-1739	Substituted benzenedicarboxylic acid, (polyalkyl acrylate) derivative (generic)	s65
86-1771	Alkylbisoxyalkyl (substituted-1,1-dimethylethylphenyl) benzotriazole (generic)	s62
87-90	Methylenebistrisubstituted aniline (generic)	s63
87-147	2-(2-Hydroxy-3-tert-butyl-5-methylbenzyl)-4-methyl-6-tert-butylphenyl methacrylate	s65
87-723	Metalated alkylphenol copolymer (generic)	s62
87-739	Polymer of styrene, substituted alkyl methacrylates, 2-ethylhexyl acrylate, methacrylic acid and substituted bis(benzene) (generic)	s65
87-794	Acrylamide polymer with substituted alkylacrylamide salt (generic)	s63
87-930	2-Propenoic acid, 2-hydroxybutyl ester	s61
87-931	2-Propenoic acid, 1-(hydroxymethyl) propyl ester	s61
87-1192	Hydrazinecarboxamide, N,N'-1,6-hexanediylbis[2,2-dimethyl-	s70
87-1337	Disulfonic acid resin amine salt of a benzidine derivative (generic)	s63
87-1760	Phenol,4,4'-[methylenebis(oxy-2,1-ethanediylthio)]bis-	s63
88-217	Epoxidized polybutene	s63
88-270	Nitrophenoxyalkanoic acid substituted thiazine hydrazide (generic)	s62
88-436	Poly(substituted triazinyl) piperazine (generic)	s62
88-522	Hydrazinecarboxamide,N,N'-[methylenedi-4,1-phenylene]bis [2,2-dimethyl-	s66
88-701	Reaction product of a monoalkyl succinic anhydride with a co-hydroxy methacrylate (generic)	s61

CHEMICALS ON REPORTING RULES (CORR) DATABASE

PREMANUFACTURE NOTICE (PMN) NUMBERS & CHEMICAL NAMES

PMN NUMBER	CHEMICAL NAME	RULE CODE
88-831	Phenol,4,4'-(9H-fluoren-9-ylidene)bis,	s62
88-837	Diglycidyl ether of disubstituted carbopolycycle (generic)	s62
88-864	Phenol,4,4'-methylenebis(2,6-dimethyl)	s63
88-972	3,3',5,5'-Tetramethylbiphenyl-4,4'-diol	s63
88-1211	Poly(oxy-1,2-ethanediyl).a.-hydro-.w.-hydroxyl-, ether with 2-ethyl-2-(hydroxymethyl)-1,3-propanediol (3:1) di-2-propenoate, methyl ether	s71
88-1271	Substituted halogenated pyridinol, alkali salt	s64
88-1272	Substituted halogenated pyridinol, alkali salt	s64
88-1273	Substituted halogenated pyridinol (generic)	s64
88-1274	Substituted halogenated pyridinol (generic)	s64
88-1303	Ethane, 1,1-dichloro-1-fluoro-	s70
88-1460	2,5-Dimercapto-1,3,4-thiadiazole, alkyl polycarboxylate (generic)	s63
88-1540	Polymer of maleic anhydride benzenedicarboxylic acid and disubstituted alkylamine (generic)	s63
88-1616	Polymer of substituted alkylphenol formaldehyde and phthalic anhydride, acrylate (generic)	s63
88-1617	Terpenes and terpenoids, limonene fraction, polymer with substituted carbopolycycles (generic)	s63
88-1690	Monomethoxy neopentyl glycol propoxylate monoacrylate (generic)	s71
88-1691	Polyalkylene glycol alkyl ether acrylate (generic)	s71
88-1753	Bis(substituted)carbomonocyclic, azocarbomonocyclicol (generic)	s63
88-1763	Ethane, 2-chloro-1,1,1,2-tetrafluoro-	s71
88-1889	Fatty acid, amine salt (generic)	s63
88-1898	7-Oxabicyclo[4.1.0]heptane, 3-ethenyl, homopolymer ether with 2-ethyl-2-(hydroxymethyl)-1,3-propanediol (3:1) epoxidized	s65
88-2177	Ethane, 1,1-dichloro-1-fluoro-	s70
88-2179	Oxirane, 2,2'-(1,6-hexanediylbis(oxymethylene))bis	s71
88-2180	Poly[oxy(methyl-1,2-ethanediyl)[a,a'-(2,2-dimethyl-1,3-propanediyl)bis[3-(oxirane-methoxyl)-	s71
88-2181	Poly[oxy-1,2-ethanediyl,a,a'-[(1-methylethylidene)di-4,1-phenylene]bis[3-(oxiranylmethoxyl)-	s71
88-2188	Poly(oxy-1,2-ethanediyl),a-hydro-3-(oxiranyl-methoxy)-, ether with 2-ethyl-2-(hydroxymethyl)-1,3-propanediol (3:1)	s71
88-2380	Bisphenol A, epichlorohydrin, methylenebis (substituted carbomonocycle), polyalkylene glycol, alkanol, methacrylate polymer (generic)	s61
88-2463	Trimethylolpropane fatty acid diacrylate (generic)	s61

CHEMICALS ON REPORTING RULES (CORR) DATABASE

PREMANUFACTURE NOTICE (PMN) NUMBERS & CHEMICAL NAMES

PMN NUMBER	CHEMICAL NAME	RULE CODE
88-2470	Alkyl alkenoate, azobis- (generic)	s66
88-2540	Nitrate polyether polyol (generic)	s62
88-2566	Substituted oxide-alkylene polymer, methacrylate (generic)	s61
88-2582	2-Oxepanone, polymer with 4,4'-(1-methyethylidene) bisphenol and 2,2-[(1-methylethylidene)]bis(4,1-phenyleneoxymethylene)] bisoxrane, graft	s63
89-30	2-Propenoic acid, 2-methyl-, 7-oxabicyclo[4.1.0] hept-3-yl methyl ester	s66
89-31	2-Propenoic acid, 7-oxabicyclo[4.1.0] hept-3-ylmethyl ester	s66
89-73	Polymer of alkyl carbomonocycle diisocyanate with alkanepolyol polyacrylate (generic)	s61
89-77	Alkylidcarboxylic acids, polymers with alkanepolyol and TDI, alkanol blocked, acrylate (generic)	s61
89-336	Alanine, N-(2-carboxyethyl)-N-alkyl, salt (generic)	s70
89-396	Sulphur-bridged substituted phenols (generic)	s62
89-422	2-Propenoic acid, 2-methyl-, 1-1-dimethylethyl ester (aka t-Butyl methacrylate)	s61
89-423	Polyalkylpolysilazane, bis(substituted acrylate) (generic)	s61
89-424	Carbamic acid (trialkyloxysilylalkyl)-substituted acrylate ester (generic)	s61
89-448	Alkane polyol phosphate ester (generic)	s57 - see also CORR listings 6/30/90 (s57)
89-483	Polyalkylenepolyol alkylamine (generic)	s63
89-507	Hydroxyalkyl methacrylate, alkyl ester (generic)	s61
89-539	Oxirane, 2,2'-(1,6-hexanediylbis(oxy-methylene))bis	s71
89-576	Metal salt of inorganic oxyacid	s63
89-577	Metal salt of complex inorganic oxyacid	s63
89-626	Alkylenebis (substituted carbomonocycle), epichlorohydrin, disubstituted heteromonocycle, acrylate polymer (generic)	s71
89-632	1,3-Propanediamine,N,N'-1,2-ethanediylbis-polymer with 2,4,6-trichloro-1,3,5-triazine, reaction products with N-butyl-2,2,6,6-tetramethyl-4-1 piperidinamine	s63
89-651	Phenol,4,4'-(oxybis(2,1-ethanediylthio)bis-	s65
89-672	Alkanoic acid, butanediol and cyclohexanealkanol polymer (generic)	s62
89-676	Distillates (petroleum), C(3-6), polymers with styrene and mixed terpenes (generic)	s62
89-694	Alkanoic acid, trisubstituted phenylalkyl disubstituted phenyl ester	s61
89-697	Alkenoic acid, trisubstituted-benzyl-disubstituted-phenyl ester (generic)	s61

(10/31/91)

CHEMICALS ON REPORTING RULES (CORR) DATABASE

PREMANUFACTURE NOTICE (PMN) NUMBERS & CHEMICAL NAMES

PMN NUMBER	CHEMICAL NAME	RULE CODE
89-708	Sulfurized alkylphenols (generic)	s65
89-711	Benzene,1,2-dimethyl-, polypropene derivatives, sulfonated, potassium salts (generic)	s70
89-726	Polymer of adipic acid, alkanepolyol, alkylidiiso cyanatocarbomonocycle, hydroxyalkyl acrylate ester	s65
89-749	Methylene bis(4-isocyanatobenzene), polymer with polycaprolactone triol and alkoxylated alkanepolyol hydroxyalkyl methacrylate ester (generic)	s61
89-750	Bisphenol A, epichlorohydrin, polyalkylenepolyol and polyisocyanate derivative (generic)	s66
89-760	Reaction product of alkanediol and epichlorohydrin (generic)	s66
89-769	Resorcinol, formaldehyde, substituted carbomonocycle resin (generic)	s65
89-776	Substituted benzenesulfonic acid, alkali metal salt (generic)	s70
89-810	Polymer of polyethylenepolyamine and alkanediol diglycidyl ether (generic)	s66
89-836	Phosphorylated oxoheteromonocycle polyoxyethylene alkyl ether (generic)	s62
89-837	Phosphorylated caprolactone alkyloxoheteromonocycle and polyalkylene polyol alkyl ether (generic)	s62
89-844	1,3,5-Triazine-2,4,6-triamine, hydrobromide	s65
89-906	Silane, (1,1-dimethylethoxy)dimethoxy (2-methyl-propyl)-	s66
89-946	Caprolactone, polymer with hexamethylene diisocyanate, hydroxyalkyl acrylate ester, reaction products with substituted alkanoic acid and metal heteromonocycle (generic)	s61
89-998	Polyaromatic urethane (generic)	s66
89-1036	Aliphatic polyglycidyl ester (generic)	s65
89-1062	Amide of polyamine and organic acid (generic)	s65
89-1072	Oxyalkanepolyol polyacrylate (generic)	s71
89-1081	Reaction product of alkyl carboxylic acids, alkane polyols, alkyl acrylate, and isophorone diisocyanate (generic)	s71
89-1093	Methane, bromodifluoro-	s71
89-1104	Polymer of substituted phenol, formaldehyde, epichlorohydrin, and disubstituted benzene (generic)	s71
89-1133	2-Propenoic acid [octahydro-4,7-methano-1H-indene-1,5(1,6 or 2,5)-diyl]bis(methylene) ester	s71
90-113	Toluene sulfonamide bisphenol A epoxy adduct (generic)	s70
90-212	Ethane, 1,1-dichloro-1-fluoro-	s70
90-244	Polymer of bisphenol A diglycidal ether, substituted alkenes, and butadiene (generic)	s70

CHEMICALS ON REPORTING RULES (CORR) DATABASE

PREMANUFACTURE NOTICE (PMN) NUMBERS & CHEMICAL NAMES

PMN NUMBER	CHEMICAL NAME	RULE CODE
90-245	Polymer of bisphenol A diglycidal ether, substituted alkenes, and butadiene (generic)	s70
90-274	Dialkylamino alkenoate, metal salt (generic)	s70
90-299	Halogenated acrylonitrile (generic)	s70
90-333	2-Propenoic acid, 2-methyl-,2-[-3-(2H-benzotriazol-2-yl)-4-hydroxyphenol]ethyl ester	s71
90-335	2-Substituted benzotriazole (generic)	s71
90-384	Phosphoric acid, C_{6-12}-alkyl esters, compound with 2-(dibutylamino) ethanol	s71
90-440	Substituted carbocheterocyclic butane tetracarboxylate (generic)	s71
90-456	Alkylbenzene sulfonate, amine salt (generic)	s71
90-481	Alkyl polyethylene glycol phosphate, potassium salt (generic)	s70
90-489	3,6,9,12,15,18,21-Heptaoxatetratriacontanoic acid sodium salt	s71
90-549	Benzoate ester (generic)	s70
90-583	Reaction product of alkylphenol, tetraalkyl titanate and tin complex (generic)	s70
90-584	Caprolactone modified acrylate monomer (generic)	s71
90-587	Polyfluorosulfonic acid salt (generic)	s70
90-643	Bisalkylated fatty alkyl amine oxide (generic)	s71
90-667	Formaldehyde, polymer with (chloromethyl) oxirane,4,4'-(1-methyl ethylidene) bis[2,6-dibromophenol] and phenol, 2-methyl-2-propenoate	s71
90-668	2-Propenenitrile, polymer with 1,3-butadiene, 3-carboxy-1-cyano-1-methylpropyl-terminated, polymers with epichlorohydrin, formaldehyde, 4,4'-(1-methylethylidene) bis[2,6-dibromophenol] and phenol, 2-methyl-2-propenoate	s71
90-1285	2-Propenoic acid, octahydro-4,7-methano-1H-indenyl ester	s71
90-1393	2-Propenenitrile, polymer with 1,3-butadiene, 3-carboxy-1-cyano-1-methylpropyl-terminated, polymers with bisphenol A, epichlorohydrin and 4,4'-(1-methylethylidene) bis[2,6-dibromophenol], dimethacrylate	s71

CHEMICALS O TING RULES (CORR) DATABASE

RULE CODE, CODE OF FEDERAL REGULATION), AND FEDERAL REGISTER (FR) INFORMATION

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	REPORTING DEADLINE DATE	SUNSET DATE	NOTES
d28	Certain Chemical Substances, Significant New Use Rule and Addition to Health and Safety Data Reporting Rule	716			55 FR 35628	8/31/90			10/15/90	EPA is adding seven potential CFC substitutes to the Health and Safety Data Reporting Rule (40 CFR Part 716) and for two of these substances, EPA is promulgating a SNUR.
d28	2-Chloro-1,1,1-trifluoroethane (HCFC-133a)	716.120			55 FR 35628	8/31/90			10/15/90	Ethane, 2-chloro-1,1,1-trifluoro (CAS No. 75-88-7).
d28	2,2-Dichloro-1,1,1-trifluoroethane (HCFC-123)	716.120			55 FR 35628	8/31/90			10/15/90	Ethane, 2,2-dichloro-1,1,1-trifluoro- (CAS No. 306-83-2).
d28	Pentafluoroethane (HFC-125)	716.120			55 FR 35628	8/31/90			10/15/90	Ethane, pentafluoro- (CAS No. 354-33-6).
d28	1,1,1,2-Tetrafluoroethane (HFC-134a)	716.120			55 FR 35628	8/31/90			10/15/90	Ethane, 1,1,1,2-tetrafluoro- (CAS No. 811-97-2).
d28	1,2-Dichloro-1,1-difluoroethane (HCFC-132b)	716.120			55 FR 35628	8/31/90			10/15/90	Ethane, 1,2-dichloro-1,1-difluoro- (CAS No. 1649-08-7).
d28	1,1-Dichloro-1-fluoroethane (HCFC-141b)	716.120			55 FR 35628	8/31/90			10/15/90	Ethane, 1,1-dichloro-1-fluoro- (CAS No. 1717-00-6).
d28	2-Chloro-1,1,1,2-tetrafluoroethane (HCFC-124)	716.120			55 FR 35628	8/31/90			10/15/90	Ethane, 2-chloro-1,1,1,2-tetrafluoro- (CAS No. 2873-89-0).
d28	Certain Chemical Substances Significant New Use Rule and Addition to Health and Safety Data Reporting Rule	716			55 FR 39774	9/28/90	10/15/90			Correction: A table on pages 35631 and 35632 of 55 FR was corrected to reflect effective dates of rule and sunset provisions for chemicals added to the Health and Safety Data Reporting Rule.
d28		716.120			55 FR 39774	9/28/90	10/15/90		10/15/00	Ethane, 2-chloro-1,1,1-trifluoro- (CAS No. 75-88-7)
d28		716.120			55 FR 39774	9/28/90	10/15/90		10/15/00	Ethane, 2,2-dichloro-1,1,1-trifluoro- (CAS No. 306-83-2)
d28		716.120			55 FR 39774	9/28/90	10/15/90		10/15/00	Ethane, pentafluoro- (CAS No. 354-33-6)

CHEMICALS ON REPORTING RULES (CORR) DATABASE

RULE CODE, CODE OF FEDERAL REGULATION (CFR), AND FEDERAL REGISTER (FR) INFORMATION

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	REPORTING DEADLINE DATE	SUNSET DATE	NOTES
d28		716.120			55 FR 39774	9/28/90	10/15/90		10/15/00	Ethane, 1,2-dichloro-1,1-difluoro (CAS No. 1649-08-7)
d28		716.120			55 FR 39774	9/28/90	10/15/90		10/15/00	Ethane, 1,1,1,2-tetrafluoro (CAS No. 811-97-2)
d28		716.120			55 FR 39774	9/28/90	10/15/90		10/15/00	Ethane, 1,1-dichloro-1-fluoro- (CAS No. 1717-00-6)
d28		716.120			55 FR 39774	9/28/90	10/15/90		10/15/00	Ethane, 2-chloro-1,1,1,2-tetrafluoro- (CAS No. 2873-89-0)

RULE CODE	NAME OF RULE	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	REPORTING DEADLINE DATE	SUNSET DATE	NOTES
d29	Preliminary Assessment Information and Health and Safety Data Reporting: Addition of Chemicals	716.120			55 FR 39780	9-28-90	10-29-90		10-29-00	Final Rule: Add substance and categories to two model information-gathering rules; TSCA Section 8(a) PAIR and TSCA Section 8(d) Health and Safety Data Reporting. Specifies substances and listed mixtures subject to rule.
d29	Sodium cyanide	716.120			55 FR 39780	9-28-90	10-29-90		10-29-00	Sodium cyanide (CAS No. 143-33-9)
d29	Isocyanates	716.120			55 FR 39780	9-28-90	10-29-90		10-29-00	p-Nitrophenyl isocyanate (CAS No. 100-28-7)
d29	Isocyanates	716.120			55 FR 39780	9-28-90	10-29-90		10-29-00	3,4-Dichlorophenyl isocyanate (CAS No. 102-36-3)
d29	Isocyanates	716.120			55 FR 39780	9-28-90	10-29-90		10-29-00	Phenyl isocyanate (CAS No. 103-71-9)
d29	Isocyanates	716.120			55 FR 39780	9-28-90	10-29-90		10-29-00	p-Chlorophenyl isocyanate (CAS No. 104-12-1)
d29	Isocyanates	716.120			55 FR 39780	9-28-90	10-29-90		10-29-00	Ethyl isocyanate (CAS No. 109-90-0)
d29	Isocyanates	716.120			55 FR 39780	9-28-90	10-29-90		10-29-00	n-Propyl isocyanate (CAS No. 110-78-1)
d29	Isocyanates	716.120			55 FR 39780	9-28-90	10-29-90		10-29-00	n-Butyl isocyanate (CAS No. 111-36-4)
d29	Isocyanates	716.120			55 FR 39780	9-28-90	10-29-90		10-29-00	Octadecyl isocyanate (CAS No. 112-96-9)
d29	Isocyanates	716.120			55 FR 39780	9-28-90	10-29-90		10-29-00	(alpha, alpha, alpha-Trifluoro-m-tolyl) isocyanate (CAS No. 329-01-1)

CHEMICALS ON REPORTING RULES (CORR) DATABASE

RULE CODE, CODE OF FEDERAL REGULATION (CFR), AND FEDERAL REGISTER (FR) INFORMATION

RULE CODE	NAME OF RULE	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	REPORTING DEADLINE DATE	SUNSET DATE	NOTES
d29	Isocyanates	716.120			55 FR 39780	9-28-90	10-29-90		10-29-00	1-Isocyanato-2-methylbenzene (CAS No. 614-68-6)
d29	Isocyanates	716.120			55 FR 39780	9-28-90	10-29-90		10-29-00	1-Isocyanato-4-methylbenzene (CAS No. 622-58-2)
d29	Isocyanates	716.120			55 FR 39780	9-28-90	10-29-90		10-29-00	Methyl isocyanate (CAS No. 624-83-9)
d29	Isocyanates	716.120			55 FR 39780	9-28-90	10-29-90		10-29-00	3-Isocyanato-1-propene (CAS No. 1476-23-9)
d29	Isocyanates	716.120			55 FR 39780	9-28-90	10-29-90		10-29-00	1-Bromo-4-isocyanatobenzene (CAS No. 2493-02-9)
d29	Isocyanates	716.120			55 FR 39780	9-28-90	10-29-90		10-29-00	1-Chloro-3-isocyanatobenzene (CAS No. 2909-38-8)
d29	Isocyanates	716.120			55 FR 39780	9-28-90	10-29-90		10-29-00	Ethyl isocyanatoacetate (CAS No. 2949-22-6)
d29	Isocyanates	716.120			55 FR 39780	9-28-90	10-29-90		10-29-00	Cyclohexyl isocyanate (CAS No. 3173-53-3)
d29	Isocyanates	716.120			55 FR 39780	9-28-90	10-29-90		10-29-00	Tris(isocyanatohexyl)biuret (CAS No. 4035-89-6)
d29	Isocyanates	716.120			55 FR 39780	9-28-90	10-29-90		10-29-00	Tris(4-isocyanatophenyl) thiophosphate (CAS No. 4151-51-3)
d29	Isocyanates	716.120			55 FR 39780	9-28-90	10-29-90		10-29-00	1,1',1''-Methylidynetris(4-isocyanato-benzene) (CAS No. 2422-91-5)
d29	Isocyanates	716.120			55 FR 39780	9-28-90	10-29-90		10-29-00	Diphenylmethylene diisocyanate (CAS No. 10031-75-1)
d29	Isocyanates	716.120			55 FR 39780	9-28-90	10-29-90		10-29-00	Bis(isocyanatomethyl) benzene (CAS No. 25854-16-4)
d29	Isocyanates	716.120			55 FR 39780	9-28-90	10-29-90		10-29-00	1,3,5-Tris(3-isocyanatomethylphenyl) 1,3,5-triazine-2,4,6 (1H, 3H, 5H)-trione (CAS No. 26603-40-7)
d29	Isocyanates	716.120			55 FR 39780	9-28-90	10-29-90		10-29-00	2,6-Diisopropylphenyl isocyanate (CAS No. 28178-42-9)

CHEMICALS (TING RULES (CORR) DATABASE

RULE CODE, CODE OF FEDERAL REGULATION), AND FEDERAL REGISTER (FR) INFORMATION

RULE CODE	NAME OF RULE	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	REPORTING DEADLINE DATE	SUNSET DATE	NOTES
d29	Isocyanates	716.120			55 FR 39780	9-28-90	10-29-90		10-29-00	Toluene diisocyanate dimer (CAS No. 26747-90-0)
d29	Isocyanates	716.120			55 FR 39780	9-28-90	10-29-90		10-29-00	2-Isocyanato-1,3-dimethylbenzene (CAS No. 28556-81-2)
d29	Isocyanates	716.120			55 FR 39780	9-28-90	10-29-90		10-29-00	2-Isocyanatoethyl methacrylate (CAS No. 30674-80-7)
d29	Isocyanates	716.120			55 FR 39780	9-28-90	10-29-90		10-29-00	3,5-Dichlorophenyl isocyanate (CAS No. 34893-92-0)
d29	Isocyanates	716.120			55 FR 39780	9-28-90	10-29-90		10-29-00	2-Heptyl-3,4-bis(9-isocyanatononyl)-1-pentylcyclohexane (CAS No. 68239-06-5)
d29	Isocyanates	716.120			55 FR 39780	9-28-90	10-29-90		10-29-00	Isophorone diisocyanate, hydroxyethylmethacrylate adduct (CAS No. 73597-26-9)
d29	Brominated Flame Retardants	716.120			55 FR 39780	9-28-90	10-29-90		10-29-00	3,4',5-Tribromosalicylanilide (CAS No. 87-10-5)
d29	Brominated Flame Retardants	716.120			55 FR 39780	9-28-90	10-29-90		10-29-00	2,3,4,5,6-Pentabromotoluene (CAS No. 87-83-2)
d29	Brominated Flame Retardants	716.120			55 FR 39780	9-28-90	10-29-90		10-29-00	1,2,3,4,5-Pentabromo-6-chlorocyclohexane (CAS No. 87-84-3)
d29	Brominated Flame Retardants	716.120			55 FR 39780	9-28-90	10-29-90		10-29-00	2,3-Dibromopropanol (CAS No. 96-13-9)
d29	Brominated Flame Retardants	716.120			55 FR 39780	9-28-90	10-29-90		10-29-00	Vinylbromide (CAS No. 593-60-2)
d29	Brominated Flame Retardants	716.120			55 FR 39780	9-28-90	10-29-90		10-29-00	2,4-Dibromophenol (CAS No. 615-58-7)
d29	Brominated Flame Retardants	716.120			55 FR 39780	9-28-90	10-29-90		10-29-00	Ethoxylated tetrabromobisphenol A (CAS No. 4162-45-2)
d29	Brominated Flame Retardants	716.120			55 FR 39780	9-28-90	10-29-90		10-29-00	Tetrabromobisphenol A, bis(allyl ether) (CAS No. 25327-89-4)
d29	Brominated Flame Retardants	716.120			55 FR 39780	9-28-90	10-29-90		10-29-00	Tetrabromodichlorocyclohexane (CAS No. 30554-72-4)

CHEMICALS ON REPORTING RULES (CORR) DATABASE

RULE CODE, CODE OF FEDERAL REGULATION (CFR), AND FEDERAL REGISTER (FR) INFORMATION

RULE CODE	NAME OF RULE	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	REPORTING DEADLINE DATE	SUNSET DATE	NOTES
d29	Brominated Flame Retardants	716.120			55 FR 39780	9-28-90	10-29-90		10-29-00	Tribromoneopentyl alcohol (CAS No. 36483-57-5)
d29	Brominated Flame Retardants	716.120			55 FR 39780	9-28-90	10-29-90		10-29-00	Tetrabromobisphenol A diacrylate (CAS No. 55205-38-7)
d29	Brominated Flame Retardants	716.120			55 FR 39780	9-28-90	10-29-90		10-29-00	Alkanes, C10-18, bromo chloro (CAS No. 68955-41-9)
d29	Brominated Flame Retardants	716.120			55 FR 39780	9-28-90	10-29-90		10-29-00	Tribromotrichlorocyclohexane (CAS No. 30554-73-5)
d29	Brominated Flame Retardants	716.120			55 FR 39780	9-28-90	10-29-90		10-29-00	2,4-(or 2,6)-Dibromophenol, homopolymer (CAS No. 69882-11-7)
d29	Brominated Flame Retardants	716.120			55 FR 39780	9-28-90	10-29-90		10-29-00	Benzene, ethenyl-, homopolymer, brominated (CAS No. 88497-56-7)
d29	Alkyl Phosphates	716.120			55 FR 39780	9-28-90	10-29-90		10-29-00	Triethyl phosphate (CAS No. 78-40-0)
d29	Alkyl Phosphates	716.120			55 FR 39780	9-28-90	10-29-90		10-29-00	Tris(2-ethylhexyl)phosphate (CAS No. 78-42-2)
d29	Alkyl Phosphates	716.120			55 FR 39780	9-28-90	10-29-90		10-29-00	Dibutyl phosphate (CAS No. 107-66-4)
d29	Alkyl Phosphates	716.120			55 FR 39780	9-28-90	10-29-90		10-29-00	Triisobutyl phosphate (CAS No. 126-71-6)
d29	Alkyl Phosphates	716.120			55 FR 39780	9-28-90	10-29-90		10-29-00	Tributyl phosphate (CAS No. 126-73-8)
d29	Alkyl Phosphates	716.120			55 FR 39780	9-28-90	10-29-90		10-29-00	Di(2-ethylhexyl)phosphate (CAS No. 298-07-7)
d29	Alkyl Phosphates	716.120			55 FR 39780	9-28-90	10-29-90		10-29-00	Monomethyl phosphate (CAS No. 812-00-0)
d29	Alkyl Phosphates	716.120			55 FR 39780	9-28-90	10-29-90		10-29-00	Tris(2-butoxyethyl)phosphate (CAS No. 78-51-3)
d29	Alkyl Phosphates	716.120			55 FR 39780	9-28-90	10-29-90		10-29-00	Mono(2-ethylhexyl)phosphate 70 (CAS No. 1070-03-7)
d29	Alkyl Phosphates	716.120			55 FR 39780	9-28-90	10-29-90		10-29-00	Ethyl dichlorophosphate (CAS No. 1498-51-7)

CHEMICALS ON ING RULES (CORR) DATABASE

RULE CODE, CODE OF FEDERAL REGU...), AND FEDERAL REGISTER (FR) INFORMATION

RULE CODE	NAME OF RULE	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	REPORTING DEADLINE DATE	SUNSET DATE	NOTES
d29	Alkyl Phosphates	716.120			55 FR 39780	9-28-90	10-29-90		10-29-00	Monobutyl phosphate (CAS No. 1623-15-0)
d29	Alkyl Phosphates	716.120			55 FR 39780	9-28-90	10-29-90		10-29-00	Mono(isopropyl) phosphate (CAS No. 1623-24-1)
d29	Alkyl Phosphates	716.120			55 FR 39780	9-28-90	10-29-90		10-29-00	Monooctadecyl phosphate (CAS No. 2958-09-0)
d29	Alkyl Phosphates	716.120			55 FR 39780	9-28-90	10-29-90		10-29-00	Monohexyl phosphate (CAS No. 3900-04-7)
d29	Alkyl Phosphates	716.120			55 FR 39780	9-28-90	10-29-90		10-29-00	Monooctyl phosphate (CAS No. 3991-73-9)
d29	Alkyl Phosphates	716.120			55 FR 39780	9-28-90	10-29-90		10-29-00	Didodecyl phosphate (CAS No. 7057-92-3)
d29	Alkyl Phosphates	716.120			55 FR 39780	9-28-90	10-29-90		10-29-00	2-(2-Butoxyethoxy)ethanol phosphate (3:1) (CAS No. 7332-46-9)
d29	Alkyl Phosphates	716.120			55 FR 39780	9-28-90	10-29-90		10-29-00	2-Ethylhexyl phosphate (CAS No. 12645-31-7)
d29	Alkyl Phosphates	716.120			55 FR 39780	9-28-90	10-29-90		10-29-00	Dodecyl phosphate (CAS No. 12751-23-4)
d29	Alkyl Phosphates	716.120			55 FR 39780	9-28-90	10-29-90		10-29-00	Diisooctyl phosphate (CAS No. 27215-10-7)

CHEMICALS ON REPORTING RULES (CORR) DATABASE

RULE CODE, CODE OF FEDERAL REGULATION (CFR), AND FEDERAL REGISTER (FR) INFORMATION

RULE CODE	NAME OF RULE	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	REPORTING DEADLINE DATE	SUNSET DATE	NOTES
d30	Preliminary Assessment Information and Health and Safety Data Reporting; Addition of Chemicals	716.120			56 FR 42688	8-29-91	9-30-91	11-27-91	9-30-00	The Interagency Testing Committee (ITC) in its Twenty-seventh Report to EPA revised the Toxic Substances Control Act (TSCA) Section 4(e) Priority List by designating two chemical substances that were previously in the "recommended with intent-to-designate" category and by adding one chemical substance and four categories of chemical substances. EPA is adding the substance and the four categories to two model information-gathering rules: the Toxic Substances Control Act(TSCA) section 8(a) Preliminary Assessment Information Rule (PAIR) and the TSCA section 8(d) Health and Safety Data Reporting Rule.
d30	Preliminary Assessment Information and Health and Safety Data Reporting; Addition of Chemicals; Technical Amendment	716.120			56 FR 59146	9-27-91	9-30-91			This notice corrects an error in a final rule published in the Federal Register of August 29, 1991, concerning six chemicals which were inadvertently included for reporting among the chemicals added to the IRIS category for: In § 716.120(d) the following chemicals under the IRIS category are removed: acrylic acid (CAS. No 79-10-7), acetophenone (CAS No. 98-86-2), N,N-dimethylaniline (CAS No. 121-69-7), ethyl acetate (CAS No. 141-78-6), 2,6-dimethylphenol (CAS No. 576-26-1), and under the category Sulphones, the substance Bisphenol A is revised to read Bisphenol S.

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
f4	Informational Notice on the Interagency Chlorinated Solvents Project, Notice.				56 FR 24811	5/31/91		This notice is provided to update the activities of the Chlorinated Solvents Project. The Chlorinated Solvents Project was initiated in 1985 by EPA in response to concerns with the use of methylene chloride (DCM, CAS No. 75-09-2), and expanded to include four Federal agencies investigating six major chlorinated solvents in four high-use categories. DCM, its focus expanded to include the following solvent chemicals deemed possible substitutes for DCM: trichloroethylene (TCE, CAS No. 79-01-6); perchloroethylene (tetrachloroethylene, PCE, CAS No. 127-18-4); 1,1,1-trichloroethane (methyl chloroform, TCA, CAS No. 71-55-6); carbon tetrachloride (CAS No. 56-23-5); and 1,1,2-trichloro-1,2,2-trifluoroethane (CFC-113, CAS No. 76-13-1).

CHEMICALS ON REPORTING RULES (CORR) A AND I

RULE CODE, CODE OF FEDERAL REGULATION (CFR), AND FEDERAL REGISTER (FR) CITATIONS

RULE CODE	NAME OF RULE	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FR CITATION	FINAL RULE FR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	REPORTING DEADLINE DATE	NOTES
P24	Preliminary Assessment Information and Health and Safety Data Reporting: Addition of Chemicals	712			55 FR 39780	9-28-90	10-29-90	12-27-90	Final Rule: Adds one substance and three categories of substances (with 76 individual substances identified) to the PAIR; specifies chemicals and reporting periods.
P24	Sodium Cyanide	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	Sodium cyanide (CAS No. 143-33-9)
P24	Isocyanates	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	4,4'-Diisocyanate-3,3'-dimethylbiphenol (CAS No. 91-97-4)
P24	Isocyanates	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	p-Nitrophenyl isocyanate (CAS No. 100-28-7)
P24	Isocyanates	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	4,4'-Diphenylmethane diisocyanate (CAS No. 101-68-8)
P24	Isocyanates	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	3,4-Dichlorophenyl isocyanate (CAS No. 102-36-3)
P24	Isocyanates	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	Phenyl isocyanate (CAS No. 103-71-9)
P24	Isocyanates	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	p-Chlorophenyl isocyanate (CAS No. 104-12-1)
P24	Isocyanates	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	p-Phenylene diisocyanate (CAS No. 104-49-4)
P24	Isocyanates	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	Ethyl isocyanate (CAS No. 109-90-0)
P24	Isocyanates	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	n-Propyl isocyanate (CAS No. 110-78-1)
P24	Isocyanates	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	n-Butyl isocyanate (CAS No. 111-36-4)
P24	Isocyanates	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	Octadecyl isocyanate (CAS No. 112-96-9)
P24	Isocyanates	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	1,3-Diisocyanatobenzene (CAS No. 123-61-5)

CHEMICALS C 'ING RULES (CORR) DATABASE

RULE CODE, CODE OF FEDERAL REG...), AND FEDERAL REGISTER (FR) INFORMATION

RULE CODE	NAME OF RULE	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	REPORTING DEADLINE DATE	NOTES
P24	Isocyanates	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	(alpha, alpha, alpha-Trifluoro-m-tolyl) isocyanate (CAS No. 329-01-1)
P24	Isocyanates	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	1-Isocyanato-2-methylbenzene (CAS No. 614-68-6)
P24	Isocyanates	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	1-Isocyanato-4-methylbenzene (CAS No. 622-58-2)
P24	Isocyanates	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	Methyl isocyanate (CAS No. 624-83-9)
P24	Isocyanates	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	3-Isocyanato-1-propene (CAS No. 1476-23-9)
P24	Isocyanates	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	1,1',1''-Methylidynetris (4-isocyanatobenzene) (CAS No. 2422-91-5)
P24	Isocyanates	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	1-Bromo-4-isocyanatobenzene (CAS No. 2493-02-9)
P24	Isocyanates	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	1-Chloro-3-isocyanatobenzene (CAS No. 2909-38-8)
P24	Isocyanates	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	Ethyl isocyanatoacetate (CAS No. 2949-22-6)
P24	Isocyanates	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	Cyclohexyl isocyanate (CAS No. 3173-53-3)
P24	Isocyanates	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	Tris(isocyanatohexyl) biuret (CAS No. 4035-89-6)
P24	Isocyanates	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	Isophorone diisocyanate (CAS No. 4098-71-9)
P24	Isocyanates	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	Tris(4-isocyanatophenyl) thiophosphate (CAS No. 4151-51-3)
P24	Isocyanates	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	1,1'-Methylenebis(4-isocyanatocyclohexane) (CAS No. 5124-30-1)
P24	Isocyanates	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	1-Isocyanato-2-((4-isocyanatophenyl)methyl)-benzene (CAS No. 5873-54-1)

CHEMICALS ON REPORTING RULES (CORR) DATABASE

RULE CODE, CODE OF FEDERAL REGULATION (CFR), AND FEDERAL REGISTER (FR) INFORMATION

RULE CODE	NAME OF RULE	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	REPORTING DEADLINE DATE	NOTES
P24	Isocyanates	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	Diphenylmethylene diisocyanate (CAS No. 10031-75-1)
P24	Isocyanates	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	1,6-Diisocyanato-2,4,4-trimethylhexane (CAS No. 15646-96-5)
P24	Isocyanates	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	1,6-Diisocyanato-2,2,4-trimethylhexane (CAS No. 16938-22-0)
P24	Isocyanates	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	Bis(isocyanatomethyl) benzene (CAS No. 25854-16-4)
P24	Isocyanates	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	1,1'-Methylenebis-(isocyanatobenzene) (CAS No. 26447-40-5)
P24	Isocyanates	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	1,3,5-Tris(3-isocyanatomethylphenyl) 1,3,5-triazine-2,4,6 (1H, 3H, 5H)-trione (CAS No. 26603-40-7)
P24	Isocyanates	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	Toluene diisocyanate dimer (CAS No. 26747-90-0)
P24	Isocyanates	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	2,6-Diisopropylphenyl isocyanate (aka Benzene, 2-isocyanato-1,3-bis (1-methylethyl)-) (CAS No. 28178-42-9)
P24	Isocyanates	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	Benzene, 2-isocyanato-1,3-dimethyl- (CAS No. 28556-81-2)
P24	Isocyanates	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	2-Isocyanatoethyl methacrylate (CAS No. 30674-80-7)
P24	Isocyanates	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	3,5-Dichlorophenyl isocyanate (CAS No. 34893-92-0)
P24	Isocyanates	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	2-Heptyl-3,4-bis(9-isocyanatononyl)-1-pentylcyclohexane (CAS No. 68239-06-5)
P24	Isocyanates	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	Isophorone diisocyanate hydroxyethylmethacrylate adduct (CAS No. 73597-26-9)
P24	Brominated Flame Retardants	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	Bromochloromethane (CAS No. 74-97-5)

CHEMICALS C ING RULES (CORR) DATABASE

RULE CODE, CODE OF FEDERAL REGULATION), AND FEDERAL REGISTER (FR) INFORMATION

RULE CODE	NAME OF RULE	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	REPORTING DEADLINE DATE	NOTES
P24	Brominated Flame Retardants	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	3,4',5-Tribromosalicylanilide (CAS No. 87-10-5)
P24	Brominated Flame Retardants	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	2,3,4,5,6-Pentabromotoluene (CAS No. 87-83-2)
P24	Brominated Flame Retardants	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	1,2,3,4,5-Pentabromo-6-chlorocyclohexane (CAS No. 87-84-3)
P24	Brominated Flame Retardants	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	2,3-Dibromopropanol (CAS No. 96-13-9)
P24	Brominated Flame Retardants	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	Vinylbromide (CAS No. 593-60-2)
P24	Brominated Flame Retardants	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	2,4-Dibromophenol (CAS No. 615-58-7)
P24	Brominated Flame Retardants	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	Ethoxylated tetrabromobisphenol A (CAS No. 4162-45-2)
P24	Brominated Flame Retardants	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	Tetrabromobisphenol A, bis(allyl ether) (CAS No. 25327-89-3)
P24	Brominated Flame Retardants	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	Tetrabromodichlorocyclohexane (CAS No. 30554-72-4)
P24	Brominated Flame Retardants	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	Tribromotrichlorocyclohexane (CAS No. 30554-73-5)
P24	Brominated Flame Retardants	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	Tribromoneopentyl alcohol (CAS No. 36483-57-5)
P24	Brominated Flame Retardants	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	Tetrabromobisphenol A diacrylate (CAS No. 55205-38-7)
P24	Brominated Flame Retardants	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	Alkanes, C_{10-18}, bromo chloro (CAS No. 68955-41-9)
P24	Brominated Flame Retardants	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	2,4- (or 2,6-) Dibromophenol, homopolymer (CAS No. 69882-11-7)
P24	Brominated Flame Retardants	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	Benzene, ethenyl-,homopolymer, brominated (CAS No. 88497-56-7)
P24	Alkyl Phosphates	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	Triethyl phosphate (CAS No. 78-40-0)

CHEMICALS ON REPORTING RULES (CORR) DATABASE

RULE CODE, CODE OF FEDERAL REGULATION (CFR), AND FEDERAL REGISTER (FR) INFORMATION

RULE CODE	NAME OF RULE	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	REPORTING DEADLINE DATE	NOTES
P24	Alkyl Phosphates	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	Tris(2-ethylhexyl) phosphate (CAS No. 78-42-2)
P24	Alkyl Phosphates	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	Tris(2-butoxyethyl) phosphate (CAS No. 78-51-3)
P24	Alkyl Phosphates	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	Dibutyl phosphate (CAS No. 107-66-4)
P24	Alkyl Phosphates	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	Triisobutyl phosphate (CAS No. 126-71-6)
P24	Alkyl Phosphates	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	Tributyl phosphate (CAS No. 126-73-8)
P24	Alkyl Phosphates	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	Di(2-ethylhexyl) phosphate (CAS No. 298-07-7)
P24	Alkyl Phosphates	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	Monomethyl phosphate (CAS No. 812-00-0)
P24	Alkyl Phosphates	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	Mono(2-ethylhexyl) phosphate 70 (CAS No. 1070-03-7)
P24	Alkyl Phosphates	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	Ethyl dichlorophosphate (CAS No. 1498-51-7)
P24	Alkyl Phosphates	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	Monobutyl phosphate (CAS No. 1623-15-0)
P24	Alkyl Phosphates	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	Mono(isopropyl) phosphate (CAS No. 1623-24-1)
P24	Alkyl Phosphates	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	Monooctadecyl phosphate (CAS No. 2958-09-0)
P24	Alkyl Phosphates	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	Monohexyl phosphate (CAS No. 3900-04-7)
P24	Alkyl Phosphates	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	Monooctyl phosphate (CAS No. 3991-73-9)
P24	Alkyl Phosphates	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	Didodecyl phosphate (CAS No. 7057-92-3)
P24	Alkyl Phosphates	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	2-(2-Butoxyethoxy)ethanol phosphate (3:1) (CAS No. 7332-46-9)

CHEMICALS ON ING RULES (CORR) DATABASE

RULE CODE, CODE OF FEDERAL REGULATION), AND FEDERAL REGISTER (FR) INFORMATION

RULE CODE	NAME OF RULE	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	REPORTING DEADLINE DATE	NOTES
P24	Alkyl Phosphates	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	2-Ethylhexyl phosphate (CAS No. 12645-31-7)
P24	Alkyl Phosphates	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	Dodecyl phosphate (CAS No. 12751-23-4)
P24	Alkyl Phosphates	712.30			55 FR 39780	9-28-90	10-29-90	12-27-90	Diisooctyl phosphate (CAS No. 27215-10-7)

CHEMICALS ON REPORTING RULES (CORR) DATABASE

RULE CODE, CODE OF FEDERAL REGULATION (CFR), AND FEDERAL REGISTER (FR) INFORMATION

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	REPORTING DEADLINE DATE	NOTES
P2S	Preliminary Assessment Information and Health and Safety Data Reporting; Addition of Chemicals	712.30			56 FR 42688	8/29/91	9/30/91	11-27-91	The Interagency Testing Committee (ITC) in its Twenty-seventh Report to EPA revised the Toxic Substances Control Act (TSCA) Section 4(e) Priority List by designating two chemical substances that were previously in the "recommended with intent-to-designate" category and by adding one chemical substance and four categories of chemical substances. EPA is adding the substance and the four categories to two model information-gathering rules: the Toxic Substances Control Act (TSCA) section 8(a) Preliminary Assessment Information Rule (PAIR) and the TSCA section 8(d) Health and Safety Data Reporting Rule.
P2S	Preliminary Assessment Information and Health and Safety Data Reporting; Addition of Chemicals; Technical Amendment	712.30			56 FR 49146	9/27/91	9/30/91		This notice corrects an error in a final rule published in the Federal Register of August 29, 1991, concerning six chemicals which were inadvertently included for reporting among the chemicals added to the IRIS category for: In § 712.30(x) the following chemicals under the IRIS category are removed: acrylic acid (CAS No. 79-10-7), acetophenone (CAS No. 98-86-2), phenol (CAS No. 108-95-2), N,N-dimethylaniline (CAS No. 121-69-7), ethyl acetate (CAS No. 141-78-6) 2,6-dimethylphenol (CAS No. 576-26-1), and under the category Sulphones, the substance Bisphenol A is revised to read Bisphenol S.

RULE CODE	NAME OF RULE	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	REPORTING DEADLINE DATE	SUNSET DATE	NOTES
r3	1-Propanamine, N-propyl	716.120 (a)			55 FR 36638	9/6/90	3/7/86		12/5/90	Termination of reporting periods for 1-propanamine, N-propyl (CAS No. 142-84-7). This action redesignates aromatic C_9 from a mixture to a substance, making a technical amendment.
r3	Aromatic C_9 Fraction From Petroleum Refining	716.120 (b)			55 FR 36638	9/6/90	12/5/90			Removal of §716.120(b) entire mixture entry for aromatic C_9 fraction from petroleum refining and reserving paragraph (b) -- (also refers to CORR Rule Code d5). CAS Nos. affected 95-63-6 (benzene, 1,2,4-trimethyl), 108-67-8 (benzene, 1,3,5-trimethyl-), 526-73-8 (benzene, 1,2,3-trimethyl-), 611-14-3 (benzene, 1-ethyl-2-methyl-), 620-14-4 (benzene, 1-ethyl-3-methyl-), 622-96-8 (benzene, 1-ethyl-4-methyl), 25550-14-5 (benzene, ethylmethyl-), 25551-13-7 (benzene, trimethyl-).
r3	Solvent Naphtha (Petroleum) Light Aromatic	716.120 (a)			55 FR 36638	9/6/90	2/13/84		2/13/94	Addition of Solvent naphtha (petroleum) light aromatic (CAS No. 64742-95-6) to §716.120(a) (see also CORR 6/30/90).
r3	Correction of Last Chemical Substance Under Alkyltin Compounds	716.120 (c)			55 FR 36638	9/6/90	12/5/90			Correct name is monomethyltin tris(isooctyl)mercaptoacetate aka: acetic acid, 2,2',2"-[(methylstannylidyne)tris (thio)]tris-, triisooctyl ester (CAS No. 54841-38-6).

CHEMICALS ON REPORTING RULES (CORR) DATABASE

RULE CODE, CODE OF FEDERAL REGULATION (CFR), AND FEDERAL REGISTER (FR) INFORMATION

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
s21	8-Acetyl-3-dodecyl-7,7,9,9-tetramethyl-1,3,8-triazaspiro,[4.5] decane-2,4-diene; Withdrawal of Proposed Significant New Use Rule	721.260			56 FR 8171	2/27/91	2/27/91	SNUR was withdrawn based on test data submitted under terms of the Consent Order. Effective date of revocation of Section 5(e) Consent Order was 8/30/85.
s21	P-83-370	721.260			56 FR 8171	2/27/91	2/27/91	8-Acetyl-3-dodecyl-7,7,9,9-tetramethyl-1,3,8-triazaspiro [4.5] decane-2,4-diene (PMN No. 83-370).

CHEMICALS C TING RULES (CORR) DATABASE

RULE CODE, CODE OF FEDERAL REGULATION), AND FEDERAL REGISTER (FR) INFORMATION

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
a55	Certain Chemical Substances, Significant New Use Rule	721			55 FR 35628	8-31-90		EPA is promulgating a SNUR for two potential CFC substitutes.
a55	2-Chloro-1,1,1-trifluoroethane (HCFC-133a)	721.760			55 FR 35628	8-31-90		Ethane, 2-chloro-1,1,1-trifluoro- (CAS No. 75-88-7).
a55	1,2-Dichloro-1,1-difluoroethane (HCFC-132b)	721.760			55 FR 35628	8-31-90		Ethane, 1,2-dichloro-1,1-difluoro- (CAS No. 1649-08-7).

CHEMICALS ON REPORTING RULES (CORR) DATABASE

RULE CODE, CODE OF FEDERAL REGULATION (CFR), AND FEDERAL REGISTER (FR) INFORMATION

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
s57	Alkane Polyol Phosphate Ester; Revocation of a Significant New Use Rule	721.288	2/27/91	56 FR 8172	56 FR 43877	9-5-91	11-4-91	EPA is revoking the significant new use rule (SNUR) at 40 CFR 721.288 that was promulgated under section 5(a)(2) of the Toxic Substances Control Act (TSCA) for the above chemical substance based on receipt of new data.
s57	P-89-448	721.288	2/27/91	56 FR 8172	56 FR 43877	9-5-91	11-4-91	Alkane polyol phosphate ester (generic).

CHEMICALS ON ING RULES (CORR) DATABASE

RULE CODE, CODE OF FEDERAL REGULATION ., AND FEDERAL REGISTER (FR) INFORMATION

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PRO-POSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFEC-TIVE DATE	NOTES
s58	Certain Aromatic Ether Diamines Extension of Comment Period	721	07/09/90	55 FR 28063			07/09/90	On July 9, 1990, EPA extended the comment period for the proposed SNUR on certain aromatic ether diamines published in 55 FR 21887, May 30, 1990. Comments on the rule were due 7/30/90 (55 FR 26063).

CHEMICALS ON REPORTING RULES (CORR) DATABASE

RULE CODE, CODE OF FEDERAL REGULATION (CFR), AND FEDERAL REGISTER (FR) INFORMATION

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
s59	Carboxy Alkyl Silyl Salt and Formaldehyde, Polymer with Bisphenol A and substituted Phenol; Proposed Revocation of Significant New Use Rules	721	8/29/91	56 FR 42714				EPA is proposing to revoke significant new use rules (SNURs) for two chemical substances based on receipt of new data. The data indicate that for purposes of TSCA section 5, further regulation under section 5 of TSCA is not warranted at this time. Written comments must be submitted to EPA by September 30, 1991.
s59	P-89-279	721.1060	8/29/91	56 FR 42714				Polymer with Bisphenol A and substituted Phenol
s59	P-89-292	721.1890	8/29/91	56 FR 42714				Carboxy Alkyl Silyl Salt

CHEMICALS (TING RULES (CORR) DATABASE

RULE CODE, CODE OF FEDERAL RE), AND FEDERAL REGISTER (FR) INFORMATION

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PRO-POSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFEC-TIVE DATE	NOTES
s60	Aromatic Diamines; Withdrawal of Significant New Use Rule	721.782			56 FR 12851	3/28/91	5/28/91	EPA is withdrawing SNUR for PMN No. P-86-501 (aromatic diamines generic name); it will propose a SNUR for the specific substance with a 30-day comment period in 56 FR, March 28, 1991.
s60	Aromatic Diamines Proposed Significant New Use Rule	721	3-28-91	56 FR 12880				EPA is proposing significant new use rule (SNUR) under Section 5(a)(2) of the Toxic Substances Control Act (TSCA).
s60	P-86-501	721.782	3-28-91	56 FR 12880				Aromatic diamines (generic name). Significant new uses affect protection in the workplace; hazard communication program; industrial, commercial, and consumer activities; disposal; and release to water.
s60	P-86-503	721.782	3-28-91	56 FR 12880				Aromatic diamines (generic name). Significant new uses affect protection in the workplace; hazard communication program; industrial, commercial, and consumer activities; disposal; and release to water.
s60	Aromatic Diamines; Extension of Comment Period for Proposed Significant New Use Rule	721	7/25/91	56 FR 34047				EPA is extending the comment period for a proposed significant new use rule (SNUR) for two aromatic diamines P-86-501 and P-86-503. Written comments must be submitted to EPA by August 26, 1991

CHEMICALS ON REPORTING RULES (CORR) DATABASE

RULE CODE, CODE OF FEDERAL REGULATION (CFR), AND FEDERAL REGISTER (FR) INFORMATION

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
s61	Proposed Significant New Uses of Chemical Substances	721 Subpart B	7-2-90	55 FR 27257	55 FR 45994	10-31-90	12-31-90	This rule also amends standard language regarding the hazard communication program (§§271.21, 271.72).
s61	P-84-27	721.1710	7-2-90	55 FR 27257	55 FR 45994	10-31-90	12-31-90	Polyol carboxylate ester (generic name). Significant uses affect protection in workplace; hazard communication program; industrial, commercial and consumer activities; disposal.
s61	P-87-930	721.1810	7-2-90	55 FR 27257	55 FR 45994	10-31-90	12-31-90	2-Propenoic acid, 2-hydroxybutyl ester (CAS No. 2421-27-4). Significant new uses affect protection in the workplace; hazard communication program; industrial, commercial and consumer activities; disposal.
s61	P-87-931	721.1814	7-2-90	55 FR 27257	55 FR 45994	10-31-90	12-31-90	2-Propenoic acid, 1-(hydroxymethyl) propyl ester. Significant new uses affect protection in workplace; hazard communication program; industrial, commercial and consumer activities; disposal.
s61	P-88-701	721.1282	7-2-90	55 FR 27257	55 FR 45994	10-31-90	12-31-90	Reaction product of a monoalkyl succinic anhydride with a co-hydroxy methacrylate (generic). Significant new uses affect protection in workplace; hazard communication program; industrial, commercial and consumer activities.
s61	P-88-2380	721.607	7-2-90	55 FR 27257	55 FR 45994	10-31-90	12-31-90	Bisphenol A, epichlorohydrin, methylenebis (substituted carbomonocycle), polyalkylene glycol, alkanol, methacrylate polymer (generic). Significant new uses affect protection in workplace; hazard communication program; industrial, commercial and consumer activities.
s61	P-88-2463	721.1045	7-2-90	55 FR 27257	55 FR 45994	10-31-90	12-31-90	Trimethylolpropane fatty acid diacrylate (generic). Significant new uses affect protection in workplace; hazard communication program; industrial, commercial and consumer activities.
s61	P-88-2566	721.1290	7-2-90	55 FR 27257	55 FR 45994	10-31-90	12-31-90	Substituted oxide-alkylene polymer, methacrylate (generic). Significant new uses affect protection in workplace; hazard communication program; industrial, commercial and consumer activities.

CHEMICALS C ING RULES (CORR) DATABASE

RULE CODE, CODE OF FEDERAL REGULATION , AND FEDERAL REGISTER (FR) INFORMATION

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PRO-POSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFEC-TIVE DATE	NOTES
s61	P-89-73	721.1612	7-2-90	55 FR 27257	55 FR 45994	10-31-90	12-31-90	Polymer of alkyl carbomonocycle diisocyanate with alkanepolyol polyacrylates (generic). Significant new uses affect protection in workplace; hazard communication program; industrial, commercial and consumer activities.
s61	P-89-77	721.275	7-2-90	55 FR 27257	55 FR 45994	10-31-90	12-31-90	Alkyldicarboxylic acids, polymers with alkanepolyol and TDI, alkanol blocked, acrylate (generic). Significant new uses affect protection in workplace; hazard communication program; industrial, commercial and consumer activities.
s61	P-89-422	721.1818	7-2-90	55 FR 27257	55 FR 45994	10-31-90	12-31-90	2-Propenoic acid, 2-methyl-1,1-dimethylethyl ester. Significant new uses affect protection in workplace; hazard communication program; industrial, commercial and consumer activities.
s61	P-89-423	721.1617	7-2-90	55 FR 27257	55 FR 45994	10-31-90	12-31-90	Polyalkylpolysilazane, bis (substituted acrylate) (generic). Significant new uses affect protection in workplace; hazard communication program; industrial, commercial and consumer activities.
s61	P-89-424	721.767	7-2-90	55 FR 27257	55 FR 45994	10-31-90	12-31-90	Carbamic acid (trialkyloxysilylalkyl)-substituted acrylate ester (generic). Significant new uses affect protection in workplace; hazard communication program; industrial, commercial and consumer activities.
s61	P-89-507	721.1285	7-2-90	55 FR 27257	55 FR 45994	10-31-90	12-31-90	Hydroxyalkyl methacrylate, alkyl ester (generic). Significant new uses affect protection in workplace; hazard communication program; industrial, commercial and consumer activities.
s61	P-89-694	721.290	7-2-90	55 FR 27257	55 FR 45994	10-31-90	12-31-90	Alkenoic acid, trisubstituted phenylalkyl disubstituted phenyl ester. Significant new uses affect protection in workplace; hazard communication program; industrial, commercial and consumer activities.
s61	P-89-697	721.289	7-2-90	55 FR 27257	55 FR 45994	10-31-90	12-31-90	Alkenoic acid, trisubstituted benzyl-disubstituted phenyl ester (generic). Significant new uses affect protection in workplace; hazard communication program; industrial, commercial and consumer activities.

CHEMICALS ON REPORTING RULES (CORR) DATABASE

RULE CODE, CODE OF FEDERAL REGULATION (CFR), AND FEDERAL REGISTER (FR) INFORMATION

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PRO-POSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFEC-TIVE DATE	NOTES
s61	P-89-749	721.1390	7-2-90	55 FR 27257	55 FR 45994	10-31-90	12-31-90	Methylene bis(4-isocyanatobenzene), polymer with polycaprolactone triol and alkoxylated alkanepolyol, hydroxyalkyl methacrylate ester (generic). Significant new uses affect protection in workplace; hazard communication program; industrial, commercial and consumer activities.
s61	P-89-946	721.759	7-2-90	55 FR 27257	55 FR 45994	10-31-90	12-31-90	Caprolactone, polymer with hexamethylene diisocyanate, hydroxyalkyl acrylate ester, reaction products with substituted alkanoic acid and metal heteromonocycle (generic). Significant new uses affect protection in workplace; hazard communication program; industrial, commercial and consumer activities.
s61	P-86-832	721.1500	7-2-90	55 FR 27257	55 FR 45994	10-31-90	12-31-90	Reaction product of hydroxyethyl acrylate and methyl oxirane (CAS No. 60857-97-8). Significant new uses affect protection in workplace; hazard communication program; industrial, commercial and consumer activities; disposal.
s61	P-84-274	721.1700	7-2-90	55 FR 27257	55 FR 45994	10-31-90	12-31-90	Poly(oxy-1,4-butanediyl), a-(1-oxo-2-propenyl)-o-[(1-oxo-2-propenyl)oxy]- (CAS No. 52277-33-5). Significant new uses affect protection in workplace; hazard communication program; industrial, commercial and consumer activities; disposal.
s61	P-84-713	721.1715	7-2-90	55 FR 27257	55 FR 45994	10-31-90	12-31-90	Alkoxylated alkane polyol, polyacrylate ester (generic). Significant new uses affect protection in workplace; hazard communication program; industrial, commercial and consumer activities; disposal.
s61	P-84-814	721.1725	7-2-90	55 FR 27257	55 FR 45994	10-31-90	12-31-90	Polysubstituted polyol (generic). Significant new uses affect protection in workplace; hazard communication program; industrial, commercial and consumer activities; disposal.
s61	P-85-296 P-85-298	721.278	7-2-90	55 FR 27257	55 FR 45994	10-31-90	12-31-90	Amino acrylate monomer (generic). Significant new uses affect protection in workplace; hazard communication program; industrial, commercial and consumer activities; disposal.

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PRO-POSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFEC-TIVE DATE	NOTES
s61	P-85-301	721.2555	7-2-90	55 FR 27257	55 FR 45994	10-31-90	12-31-90	Urethane acrylate (generic). Significant new uses affect protection in workplace; hazard communication program; industrial, commercial and consumer activities; disposal.
s61	P-85-1013	721.273	7-2-90	55 FR 27257	55 FR 45994	10-31-90	12-31-90	Aliphatic diurethane acrylate ester (generic). Significant new uses affect protection in workplace; hazard communication program; industrial, commercial and consumer activities; disposal.
s61	P-85-1169 P-85-1170	721.960	7-2-90	55 FR 27257	55 FR 45994	10-31-90	12-31-90	Acid modified acrylated epoxide (generic). Significant new uses affect protection in workplace; hazard communication program; industrial, commercial and consumer activities; disposal.
s61	P-86-346	721.1740	7-2-90	55 FR 27257	55 FR 45994	10-31-90	12-31-90	Substituted acrylated alkoxylated aliphatic polyol (generic). Significant new uses affect protection in workplace; hazard communication program; industrial, commercial and consumer activities; disposal.
s61	P-86-354	721.1780	7-2-90	55 FR 27257	55 FR 45994	10-31-90	12-31-90	Poly(oxy-1,2-ethanediyl), a-[1-oxo-2-propenyl)-a-hydroxy-, C_{10-16}-alkyl ethers (CAS No. 128504-11-2). Significant new uses affect protection in workplace; hazard communication program; industrial, commercial and consumer activities; disposal.
s61	P-86-588	721.1778	7-2-90	55 FR 27257	55 FR 45994	10-31-90	12-31-90	Poly(oxy-1,2-ethanediyl), a-(2-methyl-1-oxo-2-propenyl)-a-hydroxy-, C_{10-16} alkyl ethers. Significant new uses affect protection in workplace; hazard communication program; industrial, commercial and consumer activities; disposal.

CHEMICALS ON REPORTING RULES (CORR) DATABASE

RULE CODE, CODE OF FEDERAL REGULATION (CFR), AND FEDERAL REGISTER (FR) INFORMATION

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
s62	Significant New Uses of Certain Chemical Substances (SNUR)	721			55 FR 32406	8-9-90	10-9-90	This SNUR will require certain persons to notify EPA at least 90 days before commencing manufacturing or processing activities designated by this SNUR as a significant new use.
s62	P-84-393	721.224			55 FR 32406	8-9-90	10-9-90	2-Chloro-N-methyl-N-substituted acetamide (generic). Significant new uses affect protection in workplace; hazard communication program; industrial, commercial and consumer activities.
s62	2-Chloro-N-methyl-N-substituted Acetamide and Mixed Alkylphenol Formaldehyde Polymer, Metal Salt; Proposed Modification of Significant New Use Rules, Proposed Rule	721.224	5/23/91	56 FR 23667				EPA is proposing to modify significant new use rules (SNURs) promulgated under section 5(a)(2) of the Toxic Substances Control Act (TSCA) for two chemical substances based on receipt of additional data. The data indicate that the original terms of the SNURs for these substances should be modified.
s62	P-84-491	721.263			55 FR 32406	8-9-90	10-9-90	Substituted aliphatic acid halide (generic). Significant new uses affect protection in workplace; hazard communication program; industrial, commercial and consumer activities; disposal.
s62	P-84-860	721.1477			55 FR 32406	8-9-90	10-9-90	Disubstituted nitrobenzene (generic). Significant new uses affect protection in workplace; hazard communication program; industrial, commercial and consumer activities; disposal.
s62	P-84-951	721.979			55 FR 32406	8-9-90	10-9-90	Substituted aminobenzoic acid ester (generic). Significant new uses affect protection in workplace; hazard communication program; industrial, commercial and consumer activities; disposal.
s62	P-84-968	721.978			55 FR 32406	8-9-90	10-9-90	Alkyl ester (generic). Significant new uses affect protection in workplace; hazard communication program; industrial, commercial and consumer activities; release to water.
s62	P-85-1180	721.377			55 FR 32406	8-9-90	10-9-90	tert-Amyl peroxy alkylene ester (generic). Significant new uses affect protection in workplace; hazard communication program; industrial, commercial and consumer activities; disposal; release to water.

CHEMICALS ON NG RULES (CORR) DATABASE

RULE CODE, CODE OF FEDERAL REGULATION), AND FEDERAL REGISTER (FR) INFORMATION

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
s62	P-85-1370	721.1760			55 FR 32406	8-9-90	10-9-90	Alkyl (heterocyclicyl) phenylazohetero monocyclic polyone (generic). Significant new uses affect protection in workplace; hazard communication program; industrial, commercial and consumer activities; disposal; release to water.
s62	P-86-66	721.2194			55 FR 32406	8-9-90	10-9-90	Substituted triazine isocyanurate (generic). Significant new uses affect protection in workplace; hazard communication program; industrial, commercial and consumer activities; disposal.
s62	P-86-136	721.1763			55 FR 32406	8-9-90	10-9-90	Alkyl (heterocyclicyl) phenylazohetero monocyclic polyone, ((alkylimidazolyl) methyl) derivative (generic). Significant new uses affect protection in workplace; hazard communication program; industrial, commercial and consumer activities; disposal.
s62	P-86-387	721.977			55 FR 32406	8-9-90	10-9-90	Modified acrylic ester (generic). Significant new uses affect protection in workplace; hazard communication program; industrial, commercial and consumer activities; disposal.
s62	P-86-1098	721.1478			55 FR 32406	8-9-90	10-9-90	Halonitrobenzoic acid, substituted (generic). Significant new uses affect protection in workplace; hazard communication program; industrial, commercial and consumer activities; disposal.
s62	P-86-1771	721.580			55 FR 32406	8-9-90	10-9-90	Alkylbisoxyalkyl (substituted-1,1-dimethylethylphenyl) benzotriazole (generic). Significant new uses affect protection in workplace; hazard communication program; industrial, commercial and consumer activities.
s62	P-87-723	721.1272			55 FR 32406	8-9-90	10-9-90	Metalated alkylphenol copolymer (generic). Significant new uses affect hazard communication program; industrial, commercial and consumer activities; disposal; release to water.
s62	2-Chloro-N-methyl-N-substituted Acetamide and Mixed Alkylphenol Formaldehyde Polymer, Metal Salt; Proposed Modification of Significant New Use Rules, Proposed Rule	721.1272	5/23/91	56 FR 23667				EPA is proposing to modify significant new use rules (SNURs) promulgated under section 5(a)(2) of the Toxic Substances Control Act (TSCA) for two chemical substances based on receipt of additional data. The data indicate that the original terms of the SNURs for these substances should be modified.

CHEMICALS ON REPORTING RULES (CORR) DATABASE

RULE CODE, CODE OF FEDERAL REGULATION (CFR), AND FEDERAL REGISTER (FR) INFORMATION

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
s62	P-88-270	721.1232			55 FR 32406	8-9-90	10-9-90	Nitrophenoxyalkanoic acid substituted thiazino hydrazide (generic). Significant new uses affect protection in workplace; hazard communication program; industrial, commercial and consumer activities; disposal.
s62	P-88-436	721.2196			55 FR 32406	8-9-90	10-9-90	Poly(substituted triazinyl) piperazine (generic). Significant new uses affect hazard communication program; industrial, commercial and consumer activities.
s62	P-88-831	721.1536			55 FR 32406	8-9-90	10-9-90	Phenol,4,4'-(9H-fluoren-9-ylidene)bis. Significant new uses affect protection in workplace; hazard communication program; industrial, commercial and consumer activities.
s62	P-88-837	721.1030			55 FR 32406	8-9-90	10-9-90	Diglycidyl ether of disubstituted carbopolycycle (generic). Significant new uses affect protection in workplace; hazard communication program; industrial, commercial and consumer activities.
s62	P-88-2540	721.1712			55 FR 32406	8-9-90	10-9-90	Nitrate polyether polyol (generic). Significant new uses affect hazard communication program; industrial, commercial and consumer activities.
s62	P-89-396	721.1544			55 FR 32406	8-9-90	10-9-90	Sulphur-bridged substituted phenols (generic). Significant new uses affect protection in workplace; hazard communication program; industrial, commercial and consumer activities.
s62	P-89-672	721.1632			55 FR 32406	8-9-90	10-9-90	Alkanoic acid, butanediol and cyclohexanealkanol polymer (generic). Significant new uses affect protection in workplace; hazard communication program; industrial, commercial and consumer activities.
s62	P-89-676	721.880			55 FR 32406	8-9-90	10-9-90	Distillates (petroleum), C(3-6), polymers with styrene and mixed terpenes (generic). Significant new uses affect protection in workplace; hazard communication program; industrial, commercial and consumer activities.

CHEMICALS C TING RULES (CORR) DATABASE

RULE CODE, CODE OF FEDERAL REG), AND FEDERAL REGISTER (FR) INFORMATION

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PRO-POSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFEC-TIVE DATE	NOTES
e62	P-89-836	721.1033			55 FR 32406	8-9-90	10-9-90	Phosphorylated oxoheteromonocycle polyoxyethylene alkyl ether (generic). Significant new uses affect protection in workplace; hazard communication program; industrial, commercial and consumer activities.
e62	P-89-837	721.740			55 FR 32406	8-9-90	10-9-90	Phosphorylated caprolactone alkyloxoheteromono-cycle and polyalkylene polyol alkyl ether (generic). Significant new uses affect protection in workplace; hazard communication program; industrial, commercial and consumer activities.

CHEMICALS ON REPORTING RULES (CORR) DATABASE

RULE CODE, CODE OF FEDERAL REGULATION (CFR), AND FEDERAL REGISTER (FR) INFORMATION

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
s63	Significant New Use Rules of Certain Chemicals (SNUR)	721			55 FR 33296	8-15-90	10-15-90	This SNUR will require certain persons to notify EPA at least 90 days before commencing manufacturing or processing activities designated by this SNUR as a significant new use.
s63	P-83-603	721.1475			55 FR 33296	8-15-90	10-15-90	Substituted nitrile (generic). Significant new uses effect protection in the workplace, hazard communication program, industrial, commercial, and consumer activities, and release to water.
s63		721.1475			55 FR 52275	12-21-90	12-21-90	Section 721.1475(a)(2)(ii) is amended by correcting the reference "(g)(4)(i)" to read "(g)(4)(i)."
s63	P-84-527	721.983			55 FR 33296	8-15-90	10-15-90	Unsaturated amino alkyl ester salt (generic). Significant new uses effect protection in the workplace, hazard communication program, industrial, commercial, and consumer activities.
s63	P-84-537	721.980			55 FR 33296	8-15-90	10-15-90	Unsaturated amino ester salt (generic). Significant new uses effect protection in the workplace, hazard communication program, industrial, commercial, and consumer activities.
s63	P-86-1263	721.1611			55 FR 33296	8-15-90	10-15-90	Phosphoric acid, 1,2-ethanediyl tetrakis(2-chloro-1-methylethyl) ester. Significant new uses effect protection in the workplace, hazard communication program, industrial, commercial, and consumer activities, and disposal.
s63	P-86-1634	721.1491			55 FR 33296	8-15-90	10-15-90	Substituted dialkyl oxazolene (generic). Significant new uses effect protection in the workplace, hazard communication program, industrial, commercial, and consumer activities, and disposal.
s63	P-86-1692	721.467			55 FR 33296	8-15-90	10-15-90	Benzene, substituted alkyl acrylate derivative (generic). Significant new uses effect protection in the workplace, hazard communication program, industrial, commercial, and consumer activities, and disposal.

CHEMICALS ON [illegible]MG RULES (CORR) DATABASE

RULE CODE, CODE OF FEDERAL REGULATION), AND FEDERAL REGISTER (FR) INFORMATION

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
s63	P-87-90	721.1395			55 FR 33296	8-15-90	10-15-90	Methylenebistrisubstituted aniline (generic). Significant new uses affect protection in the workplace, hazard communication program, industrial, commercial, and consumer activities, and disposal.
s63	P-87-796	721.266			55 FR 33296	8-15-90	10-15-90	Acrylamide polymer with substituted alkylacrylamide salt (generic). Significant new uses affect industry, commercial, and consumer activities.
s63	P-87-1337	721.567			55 FR 33296	8-15-90	10-15-90	Disulfonic acid rosin amine salt of a benzidine derivative (generic). Significant new uses affect industrial, commercial, and consumer activities.
s63	P-87-1760	721.1540			55 FR 33296	8-15-90	10-15-90	Phenol, 4,4'-[methylenebis(oxy-2,1-ethanediylthio)]bis- (CAS No. 93589-69-6). Significant new uses affect hazard communication program and release to water.
s63	P-88-217	721.1621			55 FR 33296	8-15-90	10-15-90	Epoxidized polybutene. Significant new uses affect industrial, commercial, and consumer activities.
s63	P-88-864	721.1537			55 FR 33296	8-15-90	10-15-90	Phenol,4,4'-methylenebis(2,6-dimethyl) (CAS No. 5384-21-4). Significant new uses affect protection in the workplace, hazard communication program, industrial, commercial, and consumer activities, and release to water.
s63	P-88-972	721.2155			55 FR 33296	8-15-90	10-15-90	3,3',5,5'-Tetramethylbiphenyl-4,4'-diol. Significant new uses affect protection in the workplace, hazard communication program, industrial, commercial, and consumer activities, and disposal.
s63	P-88-1460	721.821			55 FR 33296	8-15-90	10-15-90	2,5-Dimercapto-1,3,4-thiadiazole, alkyl polycarboxylate (generic). Significant new uses affect industrial, commercial, and consumer activities.
s63	P-88-1540	721.1645			55 FR 33296	8-15-90	10-15-90	Polymer of maleic anhydride, benzenedicarboxylic acid and disubstituted alkylamine (generic). Significant new uses affect industrial, commercial, and consumer activities.

CHEMICALS ON REPORTING RULES (CORR) DATABASE

RULE CODE, CODE OF FEDERAL REGULATION (CFR), AND FEDERAL REGISTER (FR) INFORMATION

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PRO-POSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFEC-TIVE DATE	NOTES
s63	P-88-1616	721.1638			55 FR 33296	8-15-90	10-15-90	Polymer of substituted alkylphenol formaldehyde and phthalic anhydride, acrylate (generic). Significant new uses affect protection in the workplace, hazard communication program, industrial, commercial, and consumer activities.
s63	P-88-1617	721.2075			55 FR 33296	8-15-90	10-15-90	Terpenes and terpenoids, limonene fraction, polymer with substituted carbopolycycles (generic). Significant new uses affect industrial, commercial, and consumer activities.
s63	P-88-1753	721.766			55 FR 33296	8-15-90	10-15-90	Bis(substituted)carbomonocyclic, azocarbomonocyclicol (generic). Significant new uses affect hazard communication program, industrial, commercial, and consumer activities, and disposal.
s63	P-88-1889	721.1040			55 FR 33296	8-15-90	10-15-90	Fatty acid, amine salt (generic). Significant new uses affect hazard communication program, industrial, commercial, and consumer activities, and release to water.
s63	P-88-2582	721.1495			55 FR 33296	8-15-90	10-15-90	2-Oxepanone, polymer with 4,4'-(1-methylethylidene) bisphenol and 2,2,-[(1-methylethylidene)bis(4,1-phenyleneoxymethylene)]bisoxirane, graft. Significant new uses affect protection in the workplace, hazard communication program, industrial, commercial, and consumer activities.
s63	P-89-483	721.1616			55 FR 33296	8-15-90	10-15-90	Polyalkylenepolyol alkylamine (generic). Significant new uses affect protection in the workplace, hazard communication program, industrial, commercial, and consumer activities.
s63	P-89-576	712.1265			55 FR 33296	8-15-90	10-15-90	Metal salt of complex inorganic oxyacid. Significant new uses affect industrial, commercial, and consumer activities.
s63	P-89-577	712.1265			55 FR 33296	8-15-90	10-15-90	Metal salt of complex inorganic oxyacid. Significant new uses affect industrial, commercial, and consumer activities.

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
s63	P-89-632	721.1795			55 FR 33296	8-15-90	10-15-90	1,3-Propanediamine,N,N'-1,2-ethanediylbis-polymer with 2,4,6-trichloro-1,3,5-triazine, reaction products with N-butyl-2,2,6,6-tetramethyl-4-piperidinamine. Significant new uses affect protection in the workplace, hazard communication program, industrial, commercial, and consumer activities, and release to water.
s63	Significant New Uses of Certain Chemical Substances Correction	721			55 FR 52275	12-21-90	12-21-90	Correction of two cross-references which were inadvertently stated in the August 15, 1990 Federal Register (55 FR 33296).
s63		721.1616			55 FR 52275	12-21-90	12-21-90	Section 721.1616(a)(2)(ii) is amended by correcting the reference "(g)(i)(ix)" to read "(g)(1)(ix)."
s63	Technical Amendment to Significant New Use Rule P-87-794	721.264			55 FR 52276	12-21-90	12-21-90	Final Rule; Technical Amendment. Document (FR DOC 90-19185) published in the August 15, 1990 Federal Register (55 FR 33296) inadvertently assigned § 721.266 to acrylamide, polymer with substituted alkylacrylamide salt (P-87-794). This substance is being redesignated as § 721.264.
s63	Polymer of Maleic Anhydride, Benzenedicarboxylic Acid and Disubstituted Alkylamine, Proposed Revocation of a Significant New Use Rule	721	2/27/91	56 FR 8173				EPA is proposing to revoke a SNUR for a chemical substance because of additional toxicity data received indicating that the substance will not present an unreasonable risk of injury to human health.
s63	Polymer of Maleic Anhydride, Benzenedicarboxylic Acid and Disubstituted Alkylamine; Revocation of a Significant New Use Rule P-88-1540	721.1645	2/27/91	56 FR 8173	56 FR 43877	9/5/91	11/4/91	EPA is revoking the significant new use rule (SNUR) at 40 CFR 721.1645.
s63	Significant New Use Rule; Correction P-83-603	721.1475			56 FR 29903	7/1/91	7/1/91	For substituted nitrile in § 721.1475. Inadvertently the redesignation of § 721.1475 was omitted from FR Doc. 90-19185. This document corrects that omission.

CHEMICALS ON REPORTING RULES (CORR) DATABASE

RULE CODE, CODE OF FEDERAL REGULATION (CFR), AND FEDERAL REGISTER (FR) INFORMATION

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PRO-POSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFEC-TIVE DATE	NOTES
s64	Significant New Use of Certain Chemical Substances - Final Rule	721	9-28-90	55 FR 39882	56 FR 23766	5-23-91	7-22-91	EPA has promulgated this SNUR to require certain persons to notify EPA at least 90 days before commencing manufacturing or processing activity designated by this SNUR as a significant new use.
s64	P-83-237	721.1858	9-28-90	55 FR 39882	56 FR 23766	5-23-91	7-22-91	Halogenated alkyl pyridine (generic name). Significant new uses effect protection in the workplace, hazard communication program, disposal, and release to water.
s64	P-83-1162	721.1858	9-28-90	55 FR 39882	56 FR 23766	5-23-91	7-22-91	Halogenated alkyl pyridine (generic name). Significant new uses effect protection in the workplace, hazard communication program, disposal, and release to water.
s64	P-83-1163	721.1835	9-28-90	55 FR 39882	56 FR 23766	5-23-91	7-22-91	Halogenated pyridine (generic name). Significant new uses effect protection in the workplace, hazard communication program, disposal, and release to water.
s64	P-84-1219	721.1845	9-28-90	55 FR 39882	56 FR 23766	5-23-91	7-22-91	Substituted pyridine (generic name). Significant new uses effect protection in the workplace, hazard communication program, disposal, and release to water.
s64	P-85-36	721.1845	9-28-90	55 FR 39882	56 FR 23766	5-23-91	7-22-91	Substituted pyridine (generic name). Significant new uses effect protection in the workplace, hazard communication program, disposal, and release to water.
s64	P-85-216	721.1835	9-28-90	55 FR 39882	56 FR 23766	5-23-91	7-22-91	Halogenated pyridine (generic name). Significant new uses effect protection in the workplace, hazard communication program, disposal, and release to water.
s64	P-85-236	721.1845	9-28-90	55 FR 39882	56 FR 23766	5-23-91	7-22-91	Substituted pyridine (generic name). Significant new uses effect protection in the workplace, hazard communication program, disposal, and release to water.

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
s64	P-85-535	721.1835	9-28-90	55 FR 39882	56 FR 23766	5-23-91	7-22-91	Halogenated pyridine (generic name). Significant new uses affect protection in the workplace, hazard communication program, disposal, and release to water.
s64	P-85-536	721.1835	9-28-90	55 FR 39882	56 FR 23766	5-23-91	7-22-91	Halogenated pyridine (generic name). Significant new uses affect protection in the workplace, hazard communication program, disposal, and release to water.
s64	P-85-706	721.1845	9-28-90	55 FR 39882	56 FR 23766	5-23-91	7-22-91	Substituted pyridine (generic name). Significant new uses affect protection in the workplace, hazard communication program, disposal, and release to water.
s64	P-85-1184	721.1845	9-28-90	55 FR 39882	56 FR 23766	5-23-91	7-22-91	Substituted pyridine (generic name). Significant new uses affect protection in the workplace, hazard communication program, disposal, and release to water.
s64	P-86-838	721.1840	9-28-90	55 FR 39882	56 FR 23766	5-23-91	7-22-91	Halogenated substituted pyridine (generic name). Significant new uses affect protection in the workplace, hazard communication program, disposal, and release to water.
s64	P-88-1271	721.1886	9-28-90	55 FR 39882	56 FR 23766	5-23-91	7-22-91	Substituted halogenated pyridinol, alkali salt (generic name). Significant new uses affect protection in the workplace, hazard communication program, disposal, and release to water.
s64	P-88-1272	721.1886	9-28-90	55 FR 39882	56 FR 23766	5-23-91	7-22-91	Substituted halogenated pyridinol, alkali salt (generic name). /Significant new uses affect protection in the workplace, hazard communication program, disposal, and release to water.
s64	P-88-1273	721.1883	9-28-90	55 FR 39882	56 FR 23766	5-23-91	7-22-91	Substituted halogenated pyridinol (generic name). Significant new uses affect protection in the workplace, hazard communication program, disposal, and release to water.
s64	P-88-1274	721.1880	9-28-90	55 FR 39882	56 FR 23766	5-23-91	7-22-91	Disubstituted halogenated pyridinol (generic name). Significant new uses affect protection in the workplace, hazard communication program, disposal, and release to water.

CHEMICALS ON REPORTING RULES (CORR) DATABASE

RULE CODE, CODE OF FEDERAL REGULATION (CFR), AND FEDERAL REGISTER (FR) INFORMATION

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
s65	Significant New Uses of Chemical Substances	721			55 FR 39892	9-28-90	11-27-90	This SNUR will require certain persons to notify EPA at least 90 days before commencing manufacturing or processing activity designated by this SNUR as a significant new use.
s65	P-84-358	721.1489			55 FR 39892	9-28-90	11-27-90	Unsaturated organic compound (generic name). Significant new uses affect protection in the workplace; hazard communication program; industrial, commercial, and consumer activities; and disposal.
s65	P-84-938	721.1641			55 FR 39892	9-28-90	11-27-90	Polymer of hydroxyethyl acrylate and polyisocyanate (generic name). Significant new uses affect protection in the workplace; hazard communication program; industrial, commercial, and consumer activities; and disposal.
s65	P-84-1167	721.1887			55 FR 39892	9-28-90	11-27-90	Epoxy resin (generic name). Significant new uses affect protection in the workplace; hazard communication program; and industrial, commercial, and consumer activities.
s65	P-85-118	721.1790			55 FR 39892	9-28-90	11-27-90	Polyurethane (generic name). Significant new uses affect protection in the workplace; hazard communication program; industrial, commercial, and consumer activities; and disposal.
s65	P-85-415	721.1454			55 FR 39892	9-28-90	11-27-90	Monoacrylate (generic name). Significant new uses affect protection in the workplace; hazard communication program; industrial, commercial, and consumer activities; and disposal.
s65	P-85-527	721.1005			55 FR 39892	9-28-90	11-27-90	Vinyl epoxy ester (generic name). Significant new uses affect protection in the workplace; hazard communication program; industrial, commercial, and consumer activities; and disposal.

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
a65	P-85-544	721.1828			55 FR 39892	9-28-90	11-27-90	2-Propenoic acid, 2-methyl-,7,7,9-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane, 1,16-diyl ester. Significant new uses affect protection in the workplace; hazard communication program; industrial, commercial, and consumer activities; and disposal.
a65	P-85-545	721.1805			55 FR 39892	9-28-90	11-27-90	2-Propenoic acid, 3-(dimethylamino)-2,2-dimethylpropyl ester. Significant new uses affect protection in the workplace; hazard communication program; industrial, commercial, and consumer activities; and disposal.
a65	P-85-546	721.1824			55 FR 39892	9-28-90	11-27-90	2-Propenoic acid, 2-methyl-, 3,3,5-trimethyl cyclohexyl ester. Significant new uses affect protection in the workplace; hazard communication program; industrial, commercial, and consumer activities; and disposal.
a65	P-85-547	721.1816			55 FR 39892	9-28-90	11-27-90	2-Propenoic acid, 3,3,5-trimethylcyclohexyl ester. Significant new uses affect protection in the workplace; hazard communication program; industrial, commercial, and consumer activities; and disposal.
a65	P-85-1034	721.1470			55 FR 39892	9-28-90	11-27-90	Nickel acrylate complex (generic name). Significant new uses affect protection in the workplace; hazard communication program; industrial, commercial, and consumer activities; and disposal.
a65	P-86-164	721.1622			55 FR 39892	9-28-90	11-27-90	Polymer (generic name). Significant new uses affect protection in the workplace; hazard communication program; industrial, commercial, and consumer activities; and disposal.
a65	P-86-334	721.435			55 FR 39892	9-28-90	11-27-90	Aromatic amine compound (generic name). Significant new uses affect protection in the workplace; hazard communication program; industrial, commercial, and consumer activities; and disposal.
a65	P-86-335	721.440			55 FR 39892	9-28-90	11-27-90	Aromatic nitro compound (generic name). Significant new uses affect protection in the workplace; hazard communication program; and industrial, commercial, and consumer activities.

CHEMICALS ON REPORTING RULES (CORR) DATABASE

RULE CODE, CODE OF FEDERAL REGULATION (CFR), AND FEDERAL REGISTER (FR) INFORMATION

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PRO-POSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFEC-TIVE DATE	NOTES
a65	P-86-650	721.990			55 FR 39892	9-28-90	11-27-90	Methacrylic ester (generic name). Significant new uses affect protection in the workplace; hazard communication program; industrial, commercial, and consumer activities; and disposal.
a65	P-86-1739	721.564			55 FR 39892	9-28-90	11-27-90	Substituted benzenedicarboxylic acid, poly(alkyl acrylate) derivative (generic name). Significant new uses affect protection in the workplace; hazard communication program; industrial, commercial, and consumer activities; and disposal.
a65	P-87-147	721.1287			55 FR 39892	9-28-90	11-27-90	2-(2-Hydroxy-3-tert-butyl-5-methylbenzyl)-4-methyl-6-tert-butylphenyl methacrylate. Significant new uses affect protection in the workplace; hazard communication program; industrial, commercial, and consumer activities; and disposal.
a65	P-87-739	721.1648			55 FR 39892	9-28-90	9-28-90	Polymer of styrene, substituted alkyl methacrylates, 2-ethylhexyl acrylate, methacrylic acid and substituted bis(benzene) (generic name). Significant new uses affect protection in the workplace; hazard communication program; industrial, commercial, and consumer activities; disposal; and release to water.
a65	P-88-1898	721.1490			55 FR 39892	9-28-90	11-27-90	7-Oxabicyclo[4.1.0]heptane,3-ethenyl, homopolymer ether with 2-ethyl-2-(hydroxymethyl)-1,3-propanediol (3:1) epoxidized. Significant new uses affect protection in the workplace; hazard communication program; industrial, commercial, and consumer activities; and disposal.
a65	P-89-651	721.1538			55 FR 39892	9-28-90	11-27-90	Phenol, 4,4'-(oxybis(2,1-ethanediylthio)bis-, (CAS No. 90884-29-0). Significant new uses affect protection in the workplace; hazard communication program; and industrial, commercial, and consumer activities.
a65	P-89-708	721.1541			55 FR 39892	9-28-90	11-27-90	Sulfurized alkylphenols (generic name). Significant new uses affect hazard communication program; and industrial, commercial, and consumer activities.

RULE CODE	NAME OF RULE OR PHN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
sr110	Availability of Draft Toxicological Profiles				56 FR 52036	10/17/91		This notice announces the availability of 20 updated draft toxicological profiles prepared by ATSDR for review and comment.
sr110	The Revised Priority List of Hazardous Substances That Will Be the Subject of Toxicological Profiles				56 FR 52166	10/17/91		CERCLA as amended by SARA establishes certain requirements for ATSDR and EPA with regard to hazardous substances which are most commonly found at facilities on the CERCLA National Priorities List (NPL). This notice provides a revised priority list of 275 hazardous substances based on the most comprehensive information currently available for substances found at NPL sites.
sr110	Identification of Priority Data Needs for 38 Priority Hazardous Substances				56 FR 52178	10/17/91		This notice announces the initiation of the ATSDR Substance-Specific Applied Research Program as mandated by CERCLA by announcing for public comment the priority data needs for 38 hazardous substances.

								designated i
s66	P-83-1157	721.1504			55 FR 46766	11-6-90	1-7-91	Substituted oxirane (generic name). Significant new uses affect protection in the workplace; hazard communication program; and industrial, commercial, and consumer activities.
s66	P-83-1222	721.1125			55 FR 46766	11-6-90	1-7-91	Substituted alkyl halide (generic name). Significant new uses affect protection in the workplace; hazard communication program; and industrial, commercial, and consumer activities.
s66	P-83-1227	721.1032			55 FR 46766	11-6-90	1-7-91	Perhalo alkoxy ether (generic name). Significant new uses affect protection in the workplace; hazard communication program; and industrial, commercial, and consumer activities.
s66	P-84-492	721.1243			55 FR 46766	11-6-90	1-7-91	Substituted hydroxylamine (generic). Significant new uses affect protection in the workplace; hazard communication program; industrial, commercial, and consumer activities; and release to water.
s66	P-86-1492	721.1208			55 FR 46766	11-6-90	1-7-91	Alkyl peroxy-2-ethyl hexanoate (generic name). Significant new uses affect protection in the workplace; hazard communication program; industrial, commercial, and consumer activities; disposal; and release to water.
s66	P-88-522	721.1235			55 FR 46766	11-6-90	1-7-91	Hydrazinecarboxamide,N,N'-(methylenedi-4,1-phenylene)bis(2,2-dimethyl- (CAS No. 85095-61-0). Significant new uses affect protection in the workplace; hazard communication program; industrial, commercial, and consumer activities; and release to water.

CHEMICALS C TING RULES (CORR) DATABASE

RULE CODE, CODE OF FEDERAL REGULATION), AND FEDERAL REGISTER (FR) INFORMATION

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
er313	Community Right-to-Know Reporting Requirements	350, 355, 370, 372			55 FR 30632	7-26-90	8-27-90	EPA is promulgating final reporting thresholds under Sections 311 and 312 at the current levels, 10,000 pounds for non-EHS hazardous chemicals that must be reported, and 500 pounds or the TPQ, whichever is lower for EHS's.

CHEMICALS ON REPORTING RULES (CORR) DATABASE

RULE CODE, CODE OF FEDERAL REGULATION (CFR), AND FEDERAL REGISTER (FR) INFORMATION

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
s67	Reproposal of Significant New Uses of Certain Chemical Substances	721	11-9-90	55 FR 47286				This proposed SNUR would require certain persons to notify EPA at least 90 days before commencing any activity designated herein as a significant new use.
s67	P-83-817	721.850	11-9-90	55 FR 47286				[(Dinitrophenyl)azo]-[2,4-diamino-5-methoxybenzene] derivatives (generic name). Significant new uses affect industrial, commercial, and consumer activities.
s67	P-83-818	721.850	11-9-90	55 FR 47286				[(Dinitrophenyl)azo]-[2,4-diamino-5-methoxybenzene] derivatives (generic name). Significant new uses affect industrial, commercial, and consumer activities.
s67	P-83-769	721.660	11-9-90	55 FR 47286				Substituted bromothiophene (generic name). Significant new uses affect protection in the workplace and hazard communication program.
s67	P-83-906	721.1029	11-9-90	55 FR 47286				Brominated arylalkyl ether (generic name). Significant new uses affect protection in the workplace and hazard communication program.
s67	P-83-908	721.315	11-9-90	55 FR 47286				Ethylated aminophenol (generic name). Significant new uses affect protection in the workplace and hazard communication program.
s67	P-83-909	721.305	11-9-90	55 FR 47286				Aminophenol (generic name). Significant new uses affect protection in the workplace and hazard communication program.
s67	P-83-910	721.425	11-9-90	55 FR 47286				Aniline ether (generic name). Significant new uses affect protection in the workplace and hazard communication program.
s67	P-83-1023	721.1600	11-9-90	55 FR 47286				Phosphine, dialkylphenyl (generic name). Significant new uses affect protection in the workplace; hazard communication program; disposal; and release to water.

CHEMICALS ON ING RULES (CORR) DATABASE

RULE CODE, CODE OF FEDERAL REGULATION), AND FEDERAL REGISTER (FR) INFORMATION

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
sr313	Delisting of Terephthalic Acid	372.65			55 FR 50687	12-10-90	1-9-91	Final Rule: Terephthalic acid (TA), (CAS No. 100-21-0), delisted from list of toxic chemicals under Section 313 of EPCRA. Proposed rule of 02/15/90 (55 FR 5472).

CHEMICALS ON REPORTING RULES (CORR) DATABASE

RULE CODE, CODE OF FEDERAL REGULATION (CFR), AND FEDERAL REGISTER (FR) INFORMATION

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
s67	P-84-341	721.285	11-9-90	55 FR 47286				2-Oxepanone, homopolymer, ester with 3-hydroxy-2,2-dimethylpropanoic acid (2:1), di-2-propenoate, (CAS No. 96915-49-0). Significant new uses affect protection in the workplace; industrial, commercial, and consumer activities; hazard communication program; and disposal.
s67	P-84-342	721.285	11-9-90	55 FR 47286				2-Oxepanone, homopolymer, 2-propenoate, [tetrahydro-2-furanyl] methyl ester, (CAS No. 96915-50-3). Significant new uses affect protection in the workplace; industrial, commercial, and consumer activities; hazard communication program; and disposal.
s67	P-84-343	721.285	11-9-90	55 FR 47286				2-Oxepanone, homopolymer, 2-propenoate, ester with 2,2'-[oxybis(methylene)bis[2-hydroxymethyl]-1,3-propanediol, (CAS No. 96915-52-5). Significant new uses affect protection in the workplace; industrial, commercial, and consumer activities; hazard communication program; and disposal.
s67	P-84-344	721.285	11-9-90	55 FR 47286				2-Propenoic acid, [2-[1,1-dimethyl-2[(1-oxo-2-propenyl) oxyethyl]-5-ethyl-1,3-dioxan-5-yl] methyl ester, (CAS No. 87320-05-6). Significant new uses affect protection in the workplace; industrial, commercial, and consumer activities; hazard communication program; and disposal.
s67	P-84-417	721.1425	11-9-90	55 FR 47286				Methylphenol, bis(substituted) alkyl (generic name). Significant new uses affect protection in the workplace; industrial, commercial, and consumer activities; and hazard communication program.
s67	P-84-1042	721.1375	11-9-90	55 FR 47286				Carbamodithioic acid, methyl-, compound with methanamine (1:1). Significant new uses affect protection in the workplace; industrial, commercial, and consumer activities; hazard communication program; and disposal.
s67	P-85-703	721.285	11-9-90	55 FR 47286				2-Propanol, 1-amino-, reaction products with melamine, polymer with 5-isocyanato-1-(isocyanatomethyl)-1,3,3-trimethylcyclohexane, 2-hydroxy ethyl acrylate-blocked. Significant new uses affect protection in the workplace; industrial, commercial, and consumer activities; hazard c nication program; and disposal.

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
sr313	Zinc Sulfide; Denial of Petition	372			55 FR 31342	8-1-90	7-24-90	Denial of petition to exempt zinc sulfide from reporting under EPCRA. Denial based on evidence that zinc ion can become available from zinc sulfide through several mechanisms and that zinc ion can reasonably be anticipated to be toxic to aquatic organisms, and can reasonably be anticipated to cause adverse developmental effects in humans. Statutory deadline for EPA's response was 07/28/90.

CHEMICALS ON REPORTING RULES (CORR) DATABASE

RULE CODE, CODE OF FEDERAL REGULATION (CFR), AND FEDERAL REGISTER (FR) INFORMATION

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
s68	Alkali Metal Nitrites; Proposed Significant New Use Rule	721	1/24/91	56 FR 2733				EPA is proposing this SNUR addressing alkali metal nitrites for use in metalworking fluids containing amines. This SNUR would require persons who intend to manufacture, import, or process these substances to notify EPA 90 days before such activities.
s68		721.1402	1/24/91	56 FR 2733				Alkali metal nitrites for use in metalworking fluids containing amines.

RULE CODE	NAME OF RULE OR PRN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
sr313	Barium Sulfate; Toxic Chemical Release Reporting; Community Right-To-Know. Withdrawal of Proposed Rule.	372.65	2-12-90	55 FR 4879				EPA is withdrawing its proposed rule granting two petitions to exempt barium sulfate from the reporting requirements under the category "barium compounds" of the list of toxic chemicals under section 313 of the Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA). The withdrawal of the proposal is based on EPA's review of the availability of barium ion from barium sulfate and the potential for barium ion to induce toxicity.

CHEMICALS ON REPORTING RULES (CORR) DATABASE

RULE CODE, CODE OF FEDERAL REGULATION (CFR), AND FEDERAL REGISTER (FR) INFORMATION

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
s70	Significant New Uses of Certain Chemical Substances; Final Rule	721			56 FR 15784	4-17-91	6-17-91	This SNUR will require persons to notify EPA at least 90 days before commencing any activity designated by this SNUR as a significant new use.
s70	P-87-1192	721.1234			56 FR 15784	4-17-91	6-17-91	Hydrazinecarboxamide,N,N'-1,6-hexanediylbis(2,2-dimethyl-. Significant new uses effect hazard communication program; industrial, commercial, and consumer activities; release to water; and protection in the workplace.
s70	P-88-1303	721.1007			56 FR 15784	4-17-91	6-17-91	Ethane,1,1-dichloro-1-fluoro-. (CAS No. 1717-00-6) Significant new uses effect hazard communication program and industrial, commercial, and consumer activities.
s70	P-88-2177	721.1007			56 FR 15784	4-17-91	6-17-91	Ethane,1,1-dichloro-1-fluoro-. (CAS No. 1717 00 6) Significant new uses effect hazard communication program and industrial, commercial, and consumer activities.
s70	P-90-212	721.1007			56 FR 15784	4-17-91	6-17-91	Ethane,1,1-dichloro-1-fluoro-. (CAS No. 1717-00-6) Significant new uses effect hazard communication program and industrial, commercial, and consumer activities.
s70	P-89-336	721.270			56 FR 15784	4-17-91	6-17-91	Alanine,N-(2-carboxyethyl)-N-alkyl, salt (generic name). Significant new uses effect hazard communication program; industrial, commercial, and consumer activities; and release to water.
s70	P-89-711	721.464			56 FR 15784	4-17-91	6-17-91	Benzene,1,2-dimethyl-, polypropene derivatives, sulfonated, potassium salts (generic name). Significant new uses effect hazard communication program; industrial, commercial, and consumer activities; and release to water.
s70	P-89-776	721.566			56 FR 15784	4-17-91	6-17-91	Substituted benzenesulfonic acid, alkali metal salt (generic name). Significant new uses effect hazard communication program and industrial, commercial, and consumer activities.
s70	P-90-113	721.611			56 FR 15784	4-17-91	6-17-91	Toluene sulfonamide bisphenol A epoxy adduct (generic). Significant new uses effect hazard communication program and industrial, commercial, and consumer activities.

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
sr313	Sulfuric Acid; Toxic Chemical Release Reporting; Community Right-To-Know	372.65	7/26/91	56 FR 34156				EPA is granting a petition to modify the listing for sulfuric acid on the list of toxic chemicals subject to section 313 of the Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA). Specifically, EPA is proposing to delete nonaerosol forms of sulfuric acid from the list of toxic chemicals subject to section 313. The proposal to delete non-aerosol forms of sulfuric acid is based on EPA's review of the available data on health and environmental effects of sulfuric acid. EPA has concluded that these forms of sulfuric acid cannot reasonably be anticipated to cause adverse effects to human health or the environment under normal exposure scenarios. Written comments must be submitted on or before September 24, 1991.

CHEMICALS ON REPORTING RULES (CORR) DATABASE

RULE CODE, CODE OF FEDERAL REGULATION (CFR), AND FEDERAL REGISTER (FR) INFORMATION

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
s71	Significant New Uses of Certain Chemical Substances (SNUR); Final Rule	721			56 FR 19228	4-25-91	6-24-91	This SNUR requires certain persons to notify EPA at least 90 days before commencing any manufacturing or processing activity designated by this SNUR as a significant new use.
s71	P-84-1167	721.956			56 FR 19228	4-25-91	6-24-91	Substituted bis(hydroxyalkane) polymer with epichlorohydrin, acrylate (generic). Significant new uses are: protection in the workplace; hazard communication program; and industrial, commercial, and consumer activities.
s71	P-85-718	721.1028			56 FR 19228	4-25-91	6-24-91	Di(alkanepolyol) ether, polyacrylate (generic). Significant new uses are: protection in the workplace; hazard communication program; and industrial, commercial, and consumer activities.
s71	P-86-1088	721.1237			56 FR 19228	4-25-91	6-24-91	Substituted hydroxyalkyl alkenoate, [[[[[(1-oxo-2-propenyl)oxy]alkoxy]carbonyamino]substituted] aminocarbonyl]oxy- (generic). Significant new uses are: protection in the workplace; hazard communication program; and industrial, commercial, and consumer activities.
s71	P-88-1211	721.1702			56 FR 19228	4-25-91	6-24-91	Poly(oxy-1,2-ethanediyl),.a.-hydro-.o.-hydroxyl-, ether with 2-ethyl-2-(hydroxymethyl)-1,3-propanediol (3:1) di-2-propenoate, methyl ether (CAS No. 106158-22-9). Significant new uses are: protection in the workplace; hazard communication program; and industrial, commercial, and consumer activities.
s71	P-88-1690	721.1456			56 FR 19228	4-25-91	6-24-91	Nonamethoxy neopentyl glycol propoxylate monoacrylate (generic). Significant new uses are: protection in the workplace; hazard communication program; and industrial, commercial, and consumer activities.

RULE CODE	NAME OF RULE OR PRN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
sr313	Notice Regarding Revisions to Toxic Chemical Release Inventory Reporting Forms under Section 313 of the Emergency Planning and Community Right-to Know Act of 1986	372			56 FR 48795	9/26/91	11/30/91	This notice informs the public of EPA's administering of the data management aspects of the Toxic Release Inventory (TRI) program. First, interested parties are given notice that the Agency must receive voluntary revisions to Toxic Chemical Release Inventory Reporting Forms (Form R or report) from facilities on or before November 30th, in order for the revisions to be included in the initial annual release of TRI.

CHEMICALS ON REPORTING RULES (CORR) DATABASE

RULE CODE, CODE OF FEDERAL REGULATION (CFR), AND FEDERAL REGISTER (FR) INFORMATION

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
s71	P-88-2180	721.1704			56 FR 19228	4-25-91	6-24-91	Poly(oxy(methyl-1,2-ethanediyl))a a'-(2,2-dimethyl-1,3-propanediyl)bis[o-(oxiranylmethoxy)-. Significant new uses are: protection in the workplace; hazard communication program; industrial, commercial, and consumer activities; disposal; and release to water.
s71	P-88-2181	721.1706			56 FR 19228	4-25-91	6-24-91	Poly(oxy-1,2-ethanediyl,a,a'-[(1-methylethylidene)di-4,1-phenylene]bis[o-(oxiranylmethoxy)- (CAS No. 54140-64-6). Significant new uses are: protection in the workplace; hazard communication program; industrial, commercial, and consumer activities; disposal; and release to water.
s71	P-88-2188	721.1708			56 FR 19228	4-25-91	6-24-91	Poly(oxy-1,2-ethanediyl),a-hydro-o-(oxiranyl-methoxy)-,ether with 2-ethyl-2-(hydroxymethyl)-1,3-propanediol (3:1) (CAS No. 52495-71-3). Significant new uses are: protection in the workplace; hazard communication program; industrial, commercial, and consumer activities; disposal; and release to water.
s71	P-89-626	721.1143			56 FR 19228	4-25-91	6-24-91	Alkylenebis (substituted carbomonocycle), epichlorohydrin, disubstituted heteromonocycle, acrylate polymer (generic). Significant new uses are: protection in the workplace; hazard communication program; and industrial, commercial, and consumer activities.
s71	P-89-1072	721.1614			56 FR 19228	4-25-91	6-24-91	Oxyalkanepolyol polyacrylate (generic). Significant new uses are: protection in the workplace; hazard communication program; and industrial, commercial, and consumer activities.
s71	P-89-1081	721.1247			56 FR 19228	4-25-91	6-24-91	Reaction product of alkyl carboxylic acids, alkane polyols, alkyl acrylate, and isophorone diisocyanate (generic). Significant new uses are: protection in the workplace; hazard communication program; and industrial, commercial, and consumer activities.
s71	P-89-1093	721.1296			56 FR 19228	4-25-91	6-24-91	Methane, bromodifluoro- (CAS No. 1511-62-2). Significant new uses are: hazard communication program; and industrial, commercial, and consumer activities.

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
t14	Reopening of Comment Period For Proposed Test Rules; Office of Drinking Water Chemicals: Cyclohexane; 1,6-Hexamethylene Diisocyanate; and N-methylpyrrolidone	799	7-15-91	56 FR 32292				EPA is reopening the comment period for the proposed test rules on cyclohexane for 60 days to permit further comment on the findings made for these chemicals under TSCA section 4(a)(1)(B)(i), in light of the proposed policy articulated elsewhere in today's Federal Register for making legal findings under TSCA section 4(a)(1)(B)(i). Submit written comments on or before September 13, 1991.

CHEMICALS ON REPORTING RULES (CORR) DATABASE

RULE CODE, CODE OF FEDERAL REGULATION (CFR), AND FEDERAL REGISTER (FR) INFORMATION

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
s71	P-90-584	721.756			56 FR 19228	4-25-91	6-24-91	E-caprolactone modified 2-hydroxyethyl acrylate monomer (generic). Significant new uses are: protection in the workplace; hazard communication program; and industrial, commercial, and consumer activities.
s71	P-90-584	721.756			56 FR 29902	7-1-91	7-1-91	EPA is issuing this document to correct certain paragraph citations and cross-references that were inadvertently incorrect in several Federal Register documents.
s71	P-90-643	721.1497			56 FR 19228	4-25-91	6-24-91	Bisalkylated fatty alkyl amine oxide (generic). Significant new use is: release to water.
s71	P-90-667	721.1066			56 FR 19228	4-25-91	6-24-91	Formaldehyde, polymer with (chloromethyl) oxirane,4,4'-(1-methyl ethylidene) bis[2,6-dibromophenol] and phenol, 2-methyl-2-propenoate. Significant new uses are: protection in the workplace; hazard communication program; and industrial, commercial, and consumer activities.
s71	P-90-668	721.1798			56 FR 19228	4-25-91	6-24-91	2-Propenenitrile, polymer with 1,3-butadiene, 3-carboxy-1-cyano-1-methylpropyl-terminated, polymers with epichlorohydrin, formaldehyde, 4,4'-(1-methylethylidene)bis[2,6-dibromophenol] and phenol, 2-methyl-2-propenoate. Significant new uses are: protection in the workplace; hazard communication program; and industrial, commercial, and consumer activities.
s71	P-90-1285	721.1832			56 FR 19228	4-25-91	6-24-91	2-Propenoic acid, octahydro-4,7-methano-1H-indenyl ester (CAS No. 79637-74-4). Significant new uses are: protection in the workplace; hazard communication program; industrial, commercial, and consumer activities; and disposal.
s71	P-90-1393	721.1797			56 FR 19228	4-25-91	6-24-91	2-Propenenitrile, polymer with 1,3-butadiene, 3-carboxy-1-cyano-1-methylpropyl-terminated, polymers with bisphenol A, epichlorohydrin and 4,4'-(1-methylethylidene) bis[2,6-dibromophenol], dimethacrylate. Significant new uses are: protection in the workplace; hazard communication program; and industrial, commercial, and consumer activities.

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
t51	Reopening of Comment Period For Proposed Test Rules; Office of Drinking Water Chemicals: Cyclohexane; 1,6-Hexamethylene Diisocyanate; and N-methylpyrrolidone	799	7-15-91	56 FR 32292				EPA is reopening the comment period for the proposed test rules on N-methylpyrrolidone for 60 days to permit further comment on the findings made for this chemical under TSCA section 4(a)(1)(B)(i), in light of the proposed policy articulated elsewhere in today's Federal Register for making legal findings under TSCA section 4(a)(1)(B)(i). Submit written comments on or before September 13, 1991.

CHEMICALS ON REPORTING RULES (CORR) DATABASE

RULE CODE, CODE OF FEDERAL REGULATION (CFR), AND FEDERAL REGISTER (FR) INFORMATION

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
s73	Significant New Uses of Certain Chemical Substances, Final Rule	721			56 FR 40204	8/13/91	10/15/91	EPA requires certain persons who intend to manufacture, import, or process these substances for a significant new use to notify EPA at least 90 days before commencing the manufacturing or processing of the substance for a use designated by this SNUR as a significant new use.
s73	P-88-894	721.466			56 FR 40204	8/13/91		The chemical substance identified as benzene, (1-methylethyl) (2-phenylethyl)-, (CAS No. 77851-17-3) is subject to reporting under this section for the significant new uses The significant new uses are: Protection in the workplace. Hazard communication program. Industrial, commercial, and consumer activities. Disposal.
s73	P-90-1366	721.490			56 FR 40204	8/13/91	10/15/91	The chemical substance identified as benzenediazonium, 4-(dimethylamino)-, salt with 2-hydroxy-5-sulfobenzoic acid (CAS No. 124737-31-1) is subject to reporting under this section for the significant new uses. Protection in the workplace. Hazard communication program. Industrial, commercial and consumer activities. Release to water.
s73	P-90-1357	721.1100			56 FR 40204	8/13/91	10/15/91	The chemical substance identified generically as glycol monobenzoate is subject to reporting under this section for the significant new uses. Hazard communication program. Industrial, commercial, and consumer activities.
s73	P-90-1565	721.1105			56 FR 40204	8/13/91	10/15/91	The chemical substance identified as glycols, polyethylene-,3- sulfo-2-hydroxypropyl-p-(1,1,3,3-tetramethyl butyl)phenyl ether, sodium salt is subject to reporting under this section for the significant new uses. Hazard communication program. Industrial, commercial, and consumer activities.
s73	P-90-142	721.1140			56 FR 40204	8/13/91	10/15/91	The chemical substance identified generically as tris(disubstituted alkyl) heterocycle is subject to reporting under this section for the significant new uses. Protection in the workplace. Hazard communication program. Industrial, commercial, and consumer activities.

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PRO-POSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFEC-TIVE DATE	NOTES
t55	Conditional Exemptions from TSCA Section 4 Test Rules	790.80			55 FR 50879	12/11/90	12/11/90	Notice: EPA is granting conditional exemptions from TSCA Section 4 test rule requirements to certain manufacturers of chemicals substances subject to these rules.
t55		799.2175			55 FR 50879	12/11/90	12/11/90	C9 aromatic hydrocarbon fraction (CAS No. 70693-06-0)
t55		799.2155			55 FR 50879	12/11/90	12/11/90	Methylcyclopentane (CAS No. 96-37-7)
t55		799.2155			55 FR 50879	12/11/90	12/11/90	n-Hexane (CAS No. 110-54-3)
t55		799.1650			55 FR 50879	12/11/90	12/11/90	2-Ethylhexanoic acid (CAS No. 149-57-5)
t55		799.2325			55 FR 50879	12/11/90	12/11/90	Isopropanol (CAS No. 67-63-0)
t55		799.1250			55 FR 50879	12/11/90	12/11/90	Meta-cresols (CAS No. 108-39-4)
t55		799.2700			55 FR 50879	12/11/90	12/11/90	Methyl ethyl ketoxime (CAS No. 96-29-7)
t55		799.2475			55 FR 50879	12/11/90	12/11/90	2-Mercaptobenzothiazole (CAS No. 149-30-4)
t55		799.1051			55 FR 50879	12/11/90	12/11/90	Monochlorobenzene (CAS No. 108-90-7)
t55		799.1053			55 FR 50879	12/11/90	12/11/90	1,2,4-Trichlorobenzene (CAS No. 120-82-1)
t55		799.4400			55 FR 50879	12/11/90	12/11/90	1,1,1-Trichloroethane (CAS No. 71-55-6)
t55		799.4360			55 FR 50879	12/11/90	12/11/90	Tributyl phosphate (CAS No. 126-73-8)
t55		799.3300			55 FR 50879	12/11/90	12/11/90	m-Phenylenediamine (CAS No. 108-45-2)

CHEMICALS ON REPORTING RULES (CORR) DATABASE

RULE CODE, CODE OF FEDERAL REGULATION (CFR), AND FEDERAL REGISTER (FR) INFORMATION

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFEC-TIVE DATE	NOTES
s72	P-84-181	721.285	3-27-85	50 FR 12046	56 FR 25986	6-5-91	8-5-91	The proposed CFR cite has been redesignated.
s72	P-84-182	721.285	3-27-85	50 FR 12046	56 FR 25986	6-5-91	8-5-91	The proposed CFR cite has been redesignated.
s72	P-84-183	721.285	3-27-85	50 FR 12046	56 FR 25986	6-5-91	8-5-91	The proposed CFR cite has been redesignated.
s72	P-84-184	721.285	3-27-85	51 FR 11591	56 FR 25986	6-5-91	8-5-91	The proposed CFR cite has been redesignated.
s72	P-84-341	721.285	4-4-86	51 FR 11591	56 FR 25986	6-5-91	8-5-91	The proposed CFR cite has been redesignated
s72	P-84-342	721.285	4-4-86	51 FR 11591	56 FR 25986	6-5-91	8-5-91	The proposed CFR cite has been redesignated.
s72	P-84-343	721.285	4-4-86	51 FR 11591	56 FR 25986	6-5-91	8-5-91	The proposed CFR cite has been redesignated.
s72	P-84-344	721.285	4-4-86	51 FR 11591	56 FR 25986	6-5-91	8-5-91	The proposed CFR cite has been redesignated.
s72	P-84-417	721.1425	3-21-85	50 FR 11391	56 FR 25986	6-5-91	8-5-91	The proposed CFR cite has been redesignated.
s72	P-84-1042	721.1375	3-24-86	51 FR 10027	56 FR 25986	6-5-91	8-5-91	The proposed CFR cite has been redesignated.
s72	P-85-703	721.285	6-23-86	51 FR 22831	56 FR 25986	6-5-91	8-5-91	The proposed CFR cite has been redesignated.
s72	P-86-83	721.460	7-24-86	52 FR 26557	56 FR 25986	6-5-91	8-5-91	The proposed CFR cite has been redesignated.
s72	P-86-542	721.1025	3-25-87	52 FR 26557	56 FR 25986	6-5-91	8-5-91	The proposed CFR cite has been redesignated.

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PRO-POSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUB-LISH DATE	EFFEC-TIVE DATE	NOTES
t56	Multi-substance Testing for Developmental and Reproductive Toxicity and Neurotoxicity	799.5050	3-4-91	56 FR 9092				EPA is proposing a test rule under TSCA Section 4 to obtain developmental and/or reproductive toxicity data for the 12 substances designated in this rule.
t56		799.5050	3-4-91	56 FR 9092				Acrylonitrile (CAS No. 107-13-1)
t56		799.5050	3-4-91	56 FR 9092				p-Aminophenol (CAS No. 123-30-8)
t56		799.5050	3-4-91	56 FR 9092				Bromochloromethane (CAS No. 74-97-5)
t56		799.5050	3-4-91	56 FR 9092				Carbon disulfide (CAS No. 75-15-0)
t56		799.5050	3-4-91	56 FR 9092				Dodecylphenol (CAS No. 27193-86-8)
t56		799.5050	3-4-91	56 FR 9092				2-Ethylhexanol (CAS No. 104-76-7)
t56		799.5050	3-4-91	56 FR 9092				Hexadecanoic acid (CAS No. 57-10-3)
t56		799.5050	3-4-91	56 FR 9092				o-Hydroxyphenol (CAS No. 120-80-9)
t56		799.5050	3-4-91	56 FR 9092				2-Methylpropanoic acid (CAS No. 79-31-2)
t56		799.5050	3-4-91	56 FR 9092				Methyl ester octanoic acid (CAS No. 111-11-5)
t56		799.5050	3-4-91	56 FR 9092				Terephthalic acid (CAS No. 100-21-0)
t56		799.5050	3-4-91	56 FR 9092				2,4-Toluenediamine (CAS No. 95-80-7)

CHEMICALS ON REPORTING RULES (CORR) DATABASE

RULE CODE, CODE OF FEDERAL REGULATION (CFR), AND FEDERAL REGISTER (FR) INFORMATION

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
s73	P-91-11	721.1643			56 FR 40204	8/13/91	10/15/91	The chemical substance identified generically as polymer of isophorone diisocyanate, trimethylolpropane, polyalkylenepolyol, disubstituted alkanes and hydroxyethyl acrylate is subject to reporting under this section for the significant new uses. Protection in the workplace. Hazard communication program. Industrial, commercial, and consumer activities.
s73	P-86-1602	721.1796			56 FR 40204	8/13/91	10/15/91	The chemical substance identified as 2-propenamide, N-[3-dimethylamino)propyl]-(PMN P-86-1602) is subject to reporting under this section for the significant new uses. Protection in the workplace. Hazard communication program. Industrial, commercial, and consumer activities. Release to water.
s73	P-88-0083	721.1896			56 FR 40204	8/13/91	10/15/91	The chemical substance identified generically as bis(2,2,6,6-tetramethyl piperidinyl) ester of cycloalkyl spiroketal is subject to reporting under this section for the significant new uses. Protection in the workplace. Hazard communication program. Industrial, commercial, and consumer activities.
s73	P-91-100	721.1898			56 FR 40204	8/13/91	10/15/91	The chemical substance identified as an a-olefin sulfonate, potassium salt is subject to reporting under this section for the significant new uses. Release to water.
s73	P-90-0226	721.2184			56 FR 40204	8/13/91	10/15/91	The chemical substance identified as titanate [$Ti_6O_{13}(2-)$], dipotassium (CAS No. 12056-51-8) is subject to reporting under this section for the significant new uses. Hazard communication program. Industrial, commercial, and consumer activities.
s73	P-87-1553	721.2198			56 FR 40204	8/13/91	10/15/91	The chemical substance identified generically as a substituted triphenylmethane is subject to reporting under this section for the significant new uses. Industrial, commercial, and consumer activities.

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
t58	Technical Amendments to Test Rules and Consent Orders. Final Rule.	799			56 FR 23228	5/21/91	5/21/91	Pursuant to 40 CFR 790.55 and 790.68, EPA has approved by letter certain modifications to test standards and schedules for chemical testing programs under section 4 of the Toxic Substances Control Act (TSCA). Because these modifications do not significantly alter the scope of a test or significantly change the schedule for its completion, EPA approved these requests without seeking notice and comment. EPA issued an interim final rule published in the Federal Register of September 1, 1989 (54 FR 36311).

CHEMICALS ON REPORTING RULES (CORR) DATABASE

RULE CODE, CODE OF FEDERAL REGULATION (CFR), AND FEDERAL REGISTER (FR) INFORMATION

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
sr110	Notice of the First Priority List of Hazardous Substances That Will Be the Subject of Toxicological Profiles				52 FR 12866	4/17/87		SARA amends CERCLA or Superfund by establishing certain requirements for EPA and the Agency for Toxic Substances and Disease Registry (ATSDR) of DHHS with regard to hazardous substances which are most commonly found at facilities on the CERCLA National Priorities List (NPL). This notice contains that priority list of 100 substances, and provides a brief summary of the methodology used to assemble the list.
sr110	Hazardous Substances Priority List, Toxicological Profiles; Second List				53 FR 41280	10/20/88		CERCLA as amended by SARA establishes certain requirements for EPA and ATSDR of DHHS with regard to hazardous substances which are most commonly found at facilities on the CERCLA National Priorities List (NPL). This notice contains the revised priority list containing an additional 100 substances, and provides a brief summary of the procedure used to assemble the list.
sr110	The Third List of Hazardous Substances That Will Be the Subject of Toxicological Profiles				54 FR 43615	10/26/89		CERCLA as amended by SARA establishes certain requirements for ATSDR (of HHS) and EPA with regard to hazardous substances which are most commonly found at facilities on the CERCLA National Priorities List (NPL). This notice contains the required list of 25 additional substances and provides a summary of the procedure used to assemble the list.
sr110	Fourth List of Hazardous Substances That Will Be the Subject of Toxicological Profiles				55 FR 42067	10/17/90	10/17/90	This notice contains the required list of 25 additional substances and provides a summary of the procedure used to generate this list.

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
t59	Brominated Flame Retardants (group 1); Proposed Rule; Extension of Public Comment Period	795,798, 799	9-3-91	56 FR 43574				EPA is extending the written comment period for the brominated flame retardants (group 1) proposed rule published in the Federal Register on June 25, 1991. EPA is also announcing a public meeting to discuss the proposed rule to be held on November 20, 1991. Written comments should be submitted on or before October 10, 1991.

CHEMICALS ON REPORTING RULES (CORR) DATABASE

RULE CODE, CODE OF FEDERAL REGULATION (CFR), AND FEDERAL REGISTER (FR) INFORMATION

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PRO-POSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFEC-TIVE DATE	NOTES
sr110	Availability of Final Toxicological Profiles				56 FR 29308	6/26/91		In notice document 91-14176 beginning on page 27261, in the issue of Thursday, June 13, 1991, make the following correction: On Page 27262, in the second column of the table, in the sixth line from the bottom, "PB/91/18180448/AS" should read "PB/91/180448/AS".
sr110	Intent To Revise the Priority List of Hazardous Substances That Will Be the Subject of Toxicological Profiles. Request for Public Comment on the Revised Methodology for Generating the Priority List of Hazardous Substances.		6/27/91	56 FR 29485				This notice provides notification that the algorithm used to generate the priority list of hazardous substances is being reevaluated and revised to include more current and comprehensive information in the ranking process. With this notice, ATSDR and EPA solicit public comment on this revised approach for evaluating and ranking hazardous substances found at NPL sites. Comments concerning this notice must be received by July 18 1991.
sr110	Availability of Draft Toxicological Profile for Fluorides		9/12/91	56 FR 46436				This notice announces the availability of the Draft Toxicological Profile for Fluorides prepared by ATSDR for review and comment. This profile is to be included in the fourth set of 30 draft toxicological documents which profile the 36 hazardous substances that were announced in the Federal Register on October 16, 1990 (55 FR 41881). Comments must be received on or before December 16, 1991.

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
t61	Metabolism and Pharmacokinetic Test Guideline	798	7-17-91	56 FR 32537				EPA is issuing a proposed rule to establish a test guideline for generating metabolism and pharmacokinetic data (40 CFR part 798). This proposed rule is a joint guideline to harmonize the pharmacokinetics testing guidelines of the Office of Toxic Substances (OTS) and the Office of Pesticide Programs (OPP). This guideline was previously proposed in the Federal Register of September 15, 1988 (53 FR 35847). Today EPA is reproposing the PK and metabolism test guideline to provide notice of the harmonization effort and to allow for additional comments. Persons who commented on the initial proposed rule (53 FR 35847, Sept. 15, 1988) should bear in mind that this proposed test guideline differs considerably from the September 1988 version.

CHEMICALS ON REPORTING RULES (CORR) DATABASE

RULE CODE, CODE OF FEDERAL REGULATION (CFR), AND FEDERAL REGISTER (FR) INFORMATION

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
er313	Final Rule Addition of Ozone Depleting Chemicals to EPCRA "	372.65			55 FR 31594	8-3-90	8-3-90	Seven chemicals added to list of toxic chemicals subject to reporting under Section 313 of the Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA). Proposed rule of 03/21/90 (55 FR 10472).
er313		372.65			55 FR 31594	8-3-90	8-3-90	Trichlorofluoromethane (CFC-11) (CAS No. 75-69-4)
er313		372.65			55 FR 31594	8-3-90	8-3-90	Dichlorodifluoromethane (CFC-12) (CAS No. 75-71-8)
er313		372.65			55 FR 31594	8-3-90	8-3-90	Dichlorotetrafluoroethane (CFC-114) (CAS No. 76-14-2)
er313		372.65			55 FR 31594	8-3-90	8-3-90	(mono)Chloropentafluoroethane (CFC-115) (CAS No. 76-15-3)
er313		372.65			55 FR 31594	8-3-90	8-3-90	Bromochlorodifluoromethane (Halon-1211) (CAS No. 421-01-2)
er313		372.65			55 FR 31594	8-3-90	8-3-90	Bromotrifluoromethane (Halon-1301) (CAS No. 75-63-8)
er313		372.65			55 FR 31594	8-3-90	8-3-90	Dibromotetrafluoroethane (Halon-2402) (CAS No. 124-73-2)
er313	Ozone Depleting Chemicals; Technical Amendment	372.65			55 FR 35434	8-30-90	8-30-90	This notice corrects the CAS number for the chemical substance bromochlorodifluoromethane to 353-59-8 which was published in the final rule.

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
t63	Testing Consent Order for 4-vinylcyclohexene. Final Rule.	799.5000	12-12-89	56 FR 5114	56 FR 47912	9-23-91	9-23-91	This final rule announces that EPA has signed an enforceable Testing Consent Order for 4-vinylcyclohexene (4-VCH, butadiene dimer, CAS No. 100-40-3), with nine manufacturers, who have agreed to perform subchronic effects, mutagenicity, pharmacokinetics, and aqueous volatilization rate testing on 4-VCH.

CHEMICALS ON REPORTING RULES (CORR) DATABASE

RULE CODE, CODE OF FEDERAL REGULATION (CFR), AND FEDERAL REGISTER (FR) INFORMATION

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
sr313	Extremely Hazardous Substance/List	355	8-27-90	55 FR 35012				Advanced Notice of Proposed Rulemaking to develop specific criteria to be used to add chemicals to the extremely hazardous substance (EHS) list under Section 302 of the Title III of SARA.

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PRO-POSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFEC-TIVE DATE	NOTES
x1	Receipt of Application to Operate a Commercial Polychlorinated Biphenyl (PCB) Storage Facility. Notice of Receipt of Applications.	761.65(d)	6/10/91	56 FR 26673				EPA has received approximately 100 applications from applicants requesting approval to operate a commercial PCB storage facility. These applications are being submitted and reviewed under the authority of section 6(e) of the Toxic Substances Control Act (TSCA). EPA is notifying interested persons of these applications and requesting comments on the qualifications of the applicants and their principals and key employees to engage in PCB commercial storage activities. Comments must be received by July 10, 1991.
x1	Disposal of Polychlorinated Biphenyls. Advanced notice of proposed rulemaking.	761.60	6/10/91	56 FR 26738				EPA is providing advance notice of proposed rulemaking (ANPRM) for the disposal of certain classes of PCBs and PCB Items and certain other areas of the PCB regulations under the Toxic Substances Control Act (TSCA). EPA is considering amending its TSCA PCB disposal regulations (40 CFR 761.60) to address (1) alternative disposal methods to those currently permitted which do not pose an unreasonable risk of injury to human health and the environment, (2) classes of PCBs and PCB Items not contemplated by the disposal regulations, and (3) regulatory requirements for existing classes of PCBs and PCB Items. Written comments on the ANPRM or other issues raised by this notice must be submitted on or before August 9, 1991.
x1	Disposal of Polychlorinated Biphenyls; Availability of Draft Guidance.	761.60	6/10/91	56 FR 26745				EPA is announcing the availability of draft proposed guidance regarding alternative disposal methods which may be used for certain nonliquid polychlorinated biphenyls (PCBs) under site-specific conditions. Written comments on the proposed guidelines should be submitted on or before August 9, 1991.

CHEMICALS ON REPORTING RULES (CORR) DATABASE

RULE CODE, CODE OF FEDERAL REGULATION (CFR), AND FEDERAL REGISTER (FR) INFORMATION

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
sr313	Toxic Chemical Release Reporting, Community Right-to-Know; Sunset Provisions	372.30	1/11/91	56 FR 1154	56 FR 29183	6/26/91	6/26/91	EPA is issuing a final regulation pertaining to the "sunset" provision of 40 CFR 372.30(e), the rule that implements section 313 of the Emergency Planning and Community Right-to-Know Act. This final rule retains range reporting with only minor modifications.

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
x7	Dibenzo-para-dioxins/Dibenzofurans in Bleached Wood Pulp and Paper Products; Referral for Action				55 FR 53047	12/26/90	12/29/90	EPA/TSCA Section 9(a) referral to FDA for action needed to protect public health and the environment from use of food contact papers contaminated with chlorinated dibenzo-para-dioxins and chlorinated dibenzofurans.
x7	Proposed Regulation of Land Application of Sludge from Pulp and Paper Mills Using Chlorine and Chlorine Derivative Bleaching Processes. Proposed rule.	744	5/10/91	56 FR 21802				This proposed rule would regulate the use, disposal, and distribution in commerce of process wastewater treatment sludges intended for land application from pulp and paper mills employing chlorine or chlorine derivative-based bleaching processes (hereafter referred to as "paper mill sludge" or "sludge"). This rule is proposed under the authority of section 6(e) of the Toxic Substances Control Act (TSCA) to prevent unreasonable risks to wildlife and humans presented by exposure to 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD) and 2,3,7,8-tetrachlorodibenzofuran (TCDF) present in paper mill sludge. Written comments in triplicate must be received on or before August 8, 1991.
x7	Proposed Land Application of Sludge from Pulp and Paper Mills Using Chlorine Derivative Bleaching Processes; Correction. Proposed rule, correction.	744	6/13/91	56 FR 27222				EPA issued a proposed rule on land application of sludge from pulp and paper mills using chlorine derivative bleaching processes in the Federal Register of May 10, 1991 (51 FR 21802). The paragraph estimating the public burden for information collection was inadvertently omitted. This document corrects that omission.
x7	Technical Amendments to Test Rules and Consent Orders. Final Rule.	766			56 FR 23228	5/21/91	5/21/91	Pursuant to 40 CFR 790.55 and 790.68, EPA has approved by letter certain modifications to test standards and schedules for chemical testing programs under section 4 of the Toxic Substances Control Act (TSCA). Because these modifications do not significantly alter the scope of a test or significantly change the schedule for its completion, EPA approved these requests without seeking notice and comment. EPA issued an interim final rule published in the Federal Register of September 1, 1989 (54 FR 36311).

CHEMICALS ON REPORTING RULES (CORR) DATABASE

RULE CODE, CODE OF FEDERAL REGULATION (CFR), AND FEDERAL REGISTER (FR) INFORMATION

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
er313	Copper Phthalocyanine Pigments; Toxic Chemical Release Reporting; Community Right-to-Know. Final Rule.	372.65	5/15/89	54 FR 20866	56 FR 23650	5/23/91	6/24/91	EPA is promulgating a rule to delete Pigment Blue 15, Pigment Green 7, and Pigment Green 36 from reporting requirements under the category "copper compounds" from the list toxic chemicals under section 313 of the Emergency Planning and Community Right-to-Know-Act.

RULE CODE	NAME OF RULE OR PAN #	40 CFR CITATION	PRO-POSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFEC-TIVE DATE	NOTES
x9	Notice of Open Meeting of the Negotiated Rulemaking Advisory Committee; Lead Acid Battery Recycling Rule		8/28/91	56 FR 42572				As required by section 9(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), we are giving notice of the final meeting of the Advisory Committee to negotiate a rule to recycle lead acid batteries. The purpose of the meeting is to discuss recent data generated by EPA and to further determine whether the committee should continue work towards reaching a consensus on a rule to promote recycling of lead acid batteries. The meeting will be held on September 17, 1991.

CHEMICALS ON REPORTING RULES (CORR) DATABASE

RULE CODE, CODE OF FEDERAL REGULATION (CFR), AND FEDERAL REGISTER (FR) INFORMATION

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
sr313	Statement of Policy and Guidance for Petitions under Section 313 of the Emergency Planning and Community Right-to-Know Act of 1986. Notice.	372			56 FR 23703	5-23-91	5-23-91	This document outlines EPA's policy concerning the provision for petitions to delist individual members of the metal compound categories reportable under section 313 of the Emergency Planning and Community Right-to-Know Act of 1986. This FR notice also provides guidance regarding the appropriate support documentation that will be necessary to allow the Agency to make decisions on such petitions.

APPENDIX 8

PREMANUFACTURE NOTICE (PMN)

CHEMICALS ON REPORTING RULES (CORR) DATABASE

RULE CODE, CODE OF FEDERAL REGULATION (CFR), AND FEDERAL REGISTER (FR) INFORMATION

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FR CITATION	FINAL RULE FR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
sr313	Toxic Chemical Release Reporting; Pollution Prevention Information	372	9/25/91	56 FR 48475				EPA is proposing to add several data elements to the current Toxic Chemical Release Inventory (TRI) reporting requirements. This proposed rule would incorporate into existing regulations the source reduction and recycling information specified in the PPA that all facilities subject to reporting under section 313 must provide beginning in the 1991 reporting (calendar) year. Comments must be submitted on or before November 12, 1991.

U.S. ENVIRONMENTAL PROTECTION AGENCY INSTRUCTIONS MANUAL FOR PREMANUFACTURE NOTIFICATION OF NEW CHEMICAL SUBSTANCES

PA-7710-25(I)(January 1991) OFFICE OF TOXIC SUBSTANCES Washington, D C. 20460

The U S Environmental Protection Agency (EPA) has prepared this manual to assist you in submitting a premanufacture notice under section 5 of the Toxic Substances Control Act (TSCA) The manual provides instructions on submitting a premanufacture notice, asserting confidentiality claims completing the notice form, and submitting test data and optional information Before consulting this manual, you should read the Premanufacture Notice Requirements and Review Procedures (Premanufacture Notification Rule)(40 CFR 720)

TABLE OF CONTENTS

I. INSTRUCTIONS FOR COMPLETING THE PREMANUFACTURE NOTICE FORM Page

A. General Instructions . . . 1
B. Confidentiality . . . 1
C. Optional Information . . . 2
D. Test Data and Other Data . . . 2
E. Type of Notice . . . 3
F Certification . . . 3
G. Completing the Parts of the Notice Form . . . 4

Part I General Information . . . 4
Section A - Submitter Indentification . . . 4
Section B - Chemical Identity Information . . . 4
Section C - Production, Import, and Use Information . . . 8

Part II Human Exposure and Environmental Release . . . 10
Section A - Industrial Sites Controlled by the Submitter . . . 10
Section B - Industrial Sites Contolled by Others . . . 12
Pollution Prevention and Recycling Information (Optional) . . . 13
Part III List of Attachments . . . 13

SUPPLEMENTARY INFORMATION . . . 14

A. Who Must Submit a Premanufacture Notice . . . 14

B. Substances Which Must be Reported . . . 14
1. General . . . 14
2. Bona fide request for a TSCA Inventory search . . . 14

C. Substances Excluded from Notification . . . 14
1. General . . . 14
2. Research and development exemption . . . 14
3. Test marketing exemptions . . . 15
4. Section 5(h)(4) exemptions (Low Volume, Polymer) . . . 15

D. When to Submit a Notice . . . 16

E. Consolidated Notice . . . 16

F. Submission of Information by Others . . . 16
1. Submission by an agent . . . 16
2. Joint submissions . . . 16

G. Consultation with EPA Concerning the Premanufacture Notice . . . 16
1. Before notice submission . . . 16
2. During notice review . . . 17

H. Notice of Commencement of Manufacture . . . 17

I. Recordkeeping . . . 17

Appendix A - Examples of Test Data . . . 19

Printed on Recycled Paper

CHEMICALS ON REPORTING RULES (CORR) DATABASE

RULE CODE, CODE OF FEDERAL REGULATION (CFR), AND FEDERAL REGISTER (FR) INFORMATION

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
t6	Mesityl Oxide; Testing Consent Agreement Development	799.5000	10-2-90	55 FR 40234	56 FR 43878	9-5-91	9-5-91	This rule announces that EPA has signed an enforceable testing consent order with four of the manufacturers of mesityl oxide.
t6	Revocation of Mesityl Oxide Final Rule	799.2500	9-5-91	56 FR 43897				This document announces EPA's proposal to revoke the Mesityl Oxide Final Test Rule at 40 CFR 799.2500. EPA is proposing to revoke this rule because four of the manufacturers of MO have agreed to enter into a consent order with EPA to perform certain health effects tests.

I. INSTRUCTIONS FOR COMPLETING THE PREMANUFACTURE NOTICE FORM

A. General Instructions

Complete the premanufacture notice (PMN) form using a typewriter or by printing legibly in black ink. Information which is not submitted on a photocopy of the form available from EPA (e.g., an electronically generated form created by utilizing commercial form-making software) must be in a format pre-approved by the Agency. Approval can be obtained by contacting the Office of Toxic Substances (OTS) Document Control Officer (DCO) (TS-790), whose address appears on page 1 of the form.

All information must be in English. Provide all information requested on the notice form to the extent that you know or can reasonably ascertain it. If you do not know or cannot reasonably ascertain the information, enter "NK" (for not known or not reasonably ascertainable). You may attach continuation sheets to any subsection or item on the form. Mark (X) the appropriate box on the notice form if you attach continuation sheets.

The use of the term "manufacture" in this manual includes both manufacture and import. Importers must fully comply with the information requirements outlined in the Premanufacture Notification Rule. However, importers are not required to submit any data which relates solely to exposure to humans or the environment outside the United States under §720.50(d)(3) of the Rule. Importers must submit non-exposure data such as data on health effects (including epidemiological studies), ecological effects, physical and chemical properties, or environmental fate characteristics and exposure information (on sites under their control within the United States).

You may photocopy the notice form, sections of the form, or this manual as frequently as you need.

Send your completed notice to the OTS DCO (TS-790), whose address appears on page 1 of the form.

A user fee must be remitted for Section 5 notices in accordance with 40 CFR 700.45. You must create a personal alpha-numeric identification number to identify and link your notice with the remittance fee. This six digit number must be placed on the first page of the form in the boxes that have been provided. This number must also be placed on your fee remittance which is sent to: EPA, HQ Accounting Operations Branch (PM-226), P.O. 360399M, Pittsburgh, PA. 15251-6399, Attn. TSCA User Fee. Once the check has been processed and certified under 40 CFR 700.45(e), a listing of the TS User Identification Number is sent to EPA Headquarters. EPA Headquarters then verifies that the appropriate remittance with a TS identification number corresponds to a user fee identification number on a PMN and further processing of the notice commences. However, if a problem arises in the payment procedure, (i.e., insufficient funds, improper usage of the TS identification number), then the Section 5 notice will be given incomplete notice status in accordance with 40 CFR 720.65(c). The EPA will inform the submitter in writing if this action is taken. If a notice is declared incomplete for these or other reasons as described at 40 CFR 720.65(c), any fee remitted will be held by the Agency for thirty days to allow for resubmission of a complete notice, unless otherwise notified by a submitter that a notice will not be resubmitted.

B. Confidentiality

1. Asserting claims

You may assert a claim of confidentiality for any information submitted to EPA. To assert confidentiality claims for specific information on the form (e.g., submitter identity, chemical identity, or use information), mark (X) in the "Confidential" or Confidential Business Information (CBI) box on the form located to the right of the information. Also mark (X) the box at the bottom of page 1 of the form to indicate if any information in the notice was claimed as confidential in the form.

To assert confidentiality claims for information in attachments to the form, provide a complete copy of the attachment that clearly indicates (e.g., by circling or bracketing) the information you wish to claim as confidential. Bracket only the specific information you claim as confidential. For example, if you submit a study which contains a physical or chemical property, and it is only that property which you wish to claim as confidential, bracket only that property. Do not simply stamp "Confidential" on the page which contains that property.

If you claim the identity of the new chemical substance or its category of use as confidential, you must provide a generic description of this information, as indicated in the appropriate sections the form. Guidance on developing generic names is given in Section I. Part B(6) of this Manual (p.7).

To ensure that no confidential information is disclosed to the public, you must submit a second copy of the

CHEMICALS ON REPORTING RULES (CORR) DATABASE

RULE CODE, CODE OF FEDERAL REGULATION (CFR), AND FEDERAL REGISTER (FR) INFORMATION

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
t46	Reopening of Comment Period For Proposed Test Rules; Office of Drinking Water Chemicals: Cyclohexane; 1,6-Hexamethylene Diisocyanate; and N-methylpyrrolidone		7-15-91	56 FR 32292				EPA is reopening the comment period for the proposed test rules on hexamethylene diisocyanate for 60 days to permit further comment on the findings made for these chemicals under TSCA section 4(a)(1)(B)(i), in light of the proposed policy articulated elsewhere in today's Federal Register for making legal findings under TSCA section 4(a)(1)(B)(i). Submit written comments on or before September 13, 1991.

anticipated completion date If significant preliminary results or final results are obtained prior to the completion of the notice review period or any other additional information significant to the review of the notice becomes available to you, you must submit this information within 10 days of receipt, but no later than 5 days before the end of the review period If information becomes available during the last 5 days of the review period, you must immediately inform EPA by telephone. Examples of the types of test data you must submit are provided in Appendix A of this manual. In addition, a Physical and Chemical Properties Worksheet now appears on the last page of the form. For additional information on health and safety studies and on submitting test data, see §§720 3 and 720 50 of the Premanufacture Notification Rule. Attach test data to the notice form and reference it by page number in Part III, List of Attachments.

You are not required to submit any data previously submitted to EPA with no claims of confidentiality if you identify the office or person to whom you submitted the data, the date it was submitted, and, if appropriate, a standard literature citation. If you submitted the data with claims of confidentiality, you must resubmit the data with the notice and any claim of confidentiality under §720.80 of the Rule. You also are not required to submit data related solely to product efficacy. This exception does not apply to information required in the notice, test data, or other data.

E. Type of Notice (Page 1)

Please check the type of notice submitted. If this notice is for a consolidated PMN, the number of chemicals included in the notice should be entered on page one in the space provided. A separate PMN number is assigned to each chemical substance identified in a consolidated notice. Approval for a consolidated PMN notice must be obtained from the Prenotice Coordinator prior to submission. See Section II, Part E of this manual for further information on submitting a consolidated notice.

The Significant New Use Notice (SNUN) box should be marked for any notice that is submitted in accordance with a SNUR.

If the notice being submitted is for a polymer exemption application, the type of polymer exemption criteria met as specified at 40 CFR 723.250(e)(1) or e(2) must be checked. To meet the criteria for an e(1) polymer, the polymer must have a number average molecular weight greater than 1000. To meet the criteria for an e(2) polymer, or polyester polymer, the polymer must contain a minimum of two carboxylic acid ester linkages, at least one of which links internal subunits together and is manufactured solely from one or more of the reactants listed in the Table at 40 CFR 723.250(e)(2).

The Intermediate PMN box should be checked if this notice is for a chemical substance which is an intermediate used in the production of a final product for which a separate notice is submitted simultaneously. If an intermediate (or series of intermediates) is submitted with a final product PMN, a reduced fee of $1000 must be submitted for each intermediate PMN. The final product PMN is subject to the full fee of $2,500. In addition, the intermediate PMN must identify the final product. Separate user fee identification numbers must be generated for and appear on each notice, although, a single check may be remitted bearing all user fee identification numbers for an intermediate(s) and final product sequence. For further information on "Intermediate PMNs" see 40 CFR 700 43 and 700 45()(ii).

F. Certification (Page 2)

The official named in Part 1, Section A of the form, as the person submitting the notice, must sign the certification on page 2 of the notice form. This official is responsible for the truth and accuracy of each statement in the certification. If an agent assists you in preparing the notice, the agent must also sign the certification. All signatures must be original.

In addition, the submitter must check certain "user fee" certification statements as appropriate as required at 40 CFR 700. If a PMN is submitted, including Polymer Exemption application, consolidated PMN or SNUN, the company must pay the remittance fee identified in either 40 CFR 720.45(b)(1) (a small business concern that remits a fee of only $100) or 40 CFR 700.45(b)(2) (all others who must remit a fee of $2,500). A small business concern is one who's total annual sales taken together of all sites owned or controlled by the foreign or domestic parent company is below $40 million for the fiscal year preceding the date of the submission of the applicable section 5 notice (see 40 CFR 700.43).

If the new chemical substance is submitted as a polymer exemption application following the criteria at 40 CFR 723.250, additional certification statements must be made by checking the appropriate box for the user fee statement that applies and by checking the box that certifies that the new chemical substance meets the definition of a polymer, is not specifically excluded from the exemption and meets the conditions of the exemption

When using the PMN form (recommended, not required) to submit a Low Volume Exemption (LVE) application in accordance with 40 CFR 723.50, all three of the corresponding LVE certification statement boxes must be checked to acknowledge that you will manufacture under the terms of the exemption. There is no fee for a LVE

CHEMICALS ON REPORTING RULES (CORR) DATABASE

RULE CODE, CODE OF FEDERAL REGULATION (CFR), AND FEDERAL REGISTER (FR) INFORMATION

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PRO-POSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFEC-TIVE DATE	NOTES
t54	Reopening of Comment Period For Proposed Test Rules; Office of Drinking Water Chemicals: Cyclohexane; 1,6-Hexamethylene Diisocyanate; and N-methylpyrrolidone	799	7-15-91	56 FR 32292				EPA is reopening the comment period for the proposed test rules on the Office of Drinking Water Chemicals for 60 days to permit further comment on the findings made for these chemicals under TSCA section 4(a)(1)(B)(i), in light of the proposed policy articulated elsewhere in today's Federal Register for making legal findings under TSCA section 4(a)(1)(B)(i). Submit written comments on or before September 13, 1991.

Class 2 substance or a polymer. A **Class 1 chemical substance** is a substance whose composition, except for impurities, can be represented by a definite chemical structural diagram. Examples of such substances are 1,3-butadiene, benzene, and sodium chloride. A **Class 2 chemical substance** is a substance whose composition cannot be easily represented by a definite chemical structural diagram. Such substances are generally derived from natural sources or complex reactions. Their composition may be complex, difficult to characterize, and variable. Examples include chlorinated naphthalene, the glycerol monoester of hydrogenerated cottonseed oil acids, or a reaction product of specified reactants. A **polymer** is a substance composed of molecules characterized by the regular or irregular repetition of one or more types of identical monomeric units. In most cases, the number of monomeric units is quite large and not precisely known.

If the substance is clearly a Class 1 or 2 substance, then items a-d of Question 1 on Page 4 must be properly completed. If the substance meets the definition of a polymer, then items a-c of Question 2 on Page 5 must be addressed and answered appropriately. If an uncertainty revolves around the chemical substances identification as either a Class 2 substance (or, Class 1) or as a polymer, then both Questions 1 and 2 on Pages 4 and 5 should be completed in full or contact the Prenotice Coordinator for further assistance. If the variability of the composition of a reaction product is too complex to be described as distinct individual components, then reaction product nomenclature is employed. If however, components of a reaction product can be readily identified and will always be present in the reaction product, then the components should be specifically identified and may be listed individually on the TSCA inventory. All reaction products may be reported as Class 2 substances.

1. Class 1 or Class 2 chemical substances

a. Mark (X) the appropriate class.

b. Enter the specific chemical name of the new chemical substance.

For a Class 1 substance, the name must be a clear description of a unique substance. In describing the chemical substance, the EPA prefers Chemical Abstracts Service (CAS) chemical nomenclature be used for identification purposes. There is a separate box in question one, item c on page 4 for entry of the CAS number. The Agency encourages submitters to have contact with CAS prior to submission in order to obtain concise chemical identity information. Use standard rules of chemical nomenclature, such as from CAS or, although not preferred, the International Union of Pure and Applied Chemistry (IUPAC) to identify the new substance. Identify the positions of attachment of chemical groups or of unsaturation, if any, by using locants. The chemical name should contain all of the information known about the details of the structure and should permit the drawing of an unambiguous chemical structural diagram.

The chemical name of a Class 2 substance must describe the chemical substance as completely as possible. In some cases, the name may be similar to the names used to describe Class 1 compounds, but it should indicate the substance's multiple components. For example, the name polychlorinated biphenyl indicates a composition that has multiple components varying both in the number and the placement of the substituent chlorine atoms. In other cases, the best possible name may only identify the substance as a reaction product of specified reactants, for example, the anhydrosorbitol monoester of hydrogenated castor oil acids.

c. Provide a molecular formula that gives the identity and number of atoms of each element contained in the molecule. For example, C_6H_6 is the molecular formula for benzene. When the substance is not molecular or when the exact number of atoms in the molecule is indefinite, such as sodium chloride, which is an infinite crystal, give the relative numbers of each element's atoms. Also enter the CAS Registry Number (if one has been assigned to the substance).

d. For a Class 1 substance, provide a structural diagram. The diagram should clearly indicate the identity of the atoms and the nature of bonds joining the atoms. Any ionic charges or stereochemistry should be shown clearly. In the description of the nature of the reaction or process, as much specific detail as possible should be provided on the reaction conditions, (i.e. temperature, time, etc.) and on the relative amounts of reactants. All known stereochemical details should be provided. Carbon atoms in ring systems and their attached hydrogen atoms need not be explicitly shown. Where applicable, specify the proportions of isomers or tautomeric forms, degree of neutralization, etc.

For a Class 2 substance:

(1) List the immediate precursor substances by chemical name and CAS Registry Number (if known).

(2) For substances prepared by chemical reaction,

CHEMICALS ON REPORTING RULES (CORR) DATABASE

RULE CODE, CODE OF FEDERAL REGULATION (CFR), AND FEDERAL REGISTER (FR) INFORMATION

RULE CODE	NAME OF RULE OR PAIR #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
t55		799.3300			55 FR 50879	12/11/90	12/11/90	o-Phenylenediamine (CAS No. 95-54-5)
t55		799.3300			55 FR 50879	12/11/90	12/11/90	p-Phenylenediamine (CAS No. 106-50-3)

Column (5) - CBI claim.

Column (6) - Indicate the maximum weight percent of each reactant that may be present as a residual (unreacted material) in the polymer as manufactured for commercial purposes.

Column (7) - CBI claim.

Note that you must make separate confidentiality claims for reactant identity, composition information, and residual reactant information.

c. Provide a simple, representative structural diagram that illustrates what you know or can reasonably ascertain concerning the key structural features of the polymer molecules. For example, you could identify the linkages formed during polymerization, the functional groups present, the range and typical values for the number of repeating structural units, and the relative molar ratios of the precursors. Indicate if the repeating substructures are arranged in a nonrandom order such as in graft or block arrangements. For example:

$HO\text{-}R\text{-}O\text{-}(C\text{-}R'\text{-}C\text{-}O\text{-}R\text{-}O)_n\text{-}H$

$3 \leq n \leq 10$

where R may be either $-CH_2CH_2-$ or $-CH_2\underset{\displaystyle CH_3}{\underset{|}{CH}}-$

and R' may be either a benzene ring or $-(CH_2)_4-$

Approximate relative mole ratios of precursors:

diethyl terephthalate:	2.0
adipic acid	1.5
ethylene glycol	1.0
propylene glycol	3.0

3. **Impurities (Page 6)**

a. Identify each impurity you reasonably anticipate will be present in the substance as manufactured for commercial purposes. An impurity is any chemical substance that is unintentionally present in the new chemical substance. List all impurities (regardless of weight percent). If the substance contains some unidentified impurities, also enter "unidentified" in column (a). Do not include any substances that are mixed with the new substance after manufacture.

In addition to impurities, list in this section other chemical substances, such as solvents, inhibitors, etc., that also may be reasonably anticipated to be present in the chemical substance as manufactured for commercial purposes.

You should consider the following in identifying impurities:

(1) **Chemical and instrumental analyses** - often performed on the chemical substance during research and development to characterize the substance before it undergoes health effects or environmental effects testing, to optimize product performance, or to understand process chemistry and optimize output.

(2) **Manufacturing process chemistry** - including feedstocks, feedstock impurities, byproducts, and intermediates both from the major reaction pathway and from significant side reactions.

(3) **Quality control operations** - operations which determine the nature and level of impurities that may be present in the chemical substance.

Identify impurities as specifically as possible. You should give the following information:

(1) the specific chemical name; or

(2) a class or range of structures (e.g., C_6 - C_{18} fatty acid salts or polychlorinated cyclic and acyclic hydrocarbons in the range C_5 - C_{12}); or

(3) the source (e.g., pyrolysis products of cellulose or coal tar residues).

Include the CAS Registry Number if available.

b. Enter the maximum weight percent of each impurity in the new chemical substance in column (b). If the substance contains unidentified impurities, enter the total weight percent of unidentified impurities in column (b).

4. **Synonyms** - Enter common chemical names by which the new chemical substance may be identified in the scientific or technical literature, including the names or codes used to identify the new chemical in test data or other data which are attached to the notice.

5. **Trade identification** - Enter any trade name under which the new substance has been or will be marketed. Report all trade names or brand names, even if they are not registered.

6. **Generic chemical name** – If the new substance's identity is claimed as confidential, enter the generic chemical name that is only as generic as necessary to protect the confidential chemical identity. The generic

CHEMICALS ON REPORTING RULES (CORR) DATABASE

RULE CODE, CODE OF FEDERAL REGULATION (CFR), AND FEDERAL REGISTER (FR) INFORMATION

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
t57	Multi-substance Rule for the Testing of Neurotoxicity	799.5050	3-4-91	56 FR 9105				EPA is proposing a test rule under Section 4(a) of TSCA to obtain neurotoxicity data for 10 volatile substances that have substantial production, for which there is/may be substantial human exposure.
t57		799.5050	3-4-91	56 FR 9105				Acetone (CAS No. 67-64-1)
t57		799.5050	3-4-91	56 FR 9105				n-Amyl acetate (CAS No. 628-63-7)
t57		799.5050	3-4-91	56 FR 9105				1-Butanol (CAS No. 71-36-3)
t57		799.5050	3-4-91	56 FR 9105				n-Butyl acetate (CAS No. 123-86-4)
t57		799.5050	3-4-91	56 FR 9105				Diethyl ether (CAS No. 60-29-7)
t57		799.5050	3-4-91	56 FR 9105				2-Ethoxyethanol (CAS No. 110-80-5)
t57		799.5050	3-4-91	56 FR 9105				Ethyl acetate (CAS No. 141-78-6)
t57		799.5050	3-4-91	56 FR 9105				Isobutyl alcohol (CAS No. 78-83-1)
t57		799.5050	3-4-91	56 FR 9105				Methyl isobutyl ketone (CAS No. 108-10-1)
t57		799.5050	3-4-91	56 FR 9105				Tetrahydrofuran (CAS No. 109-99-9)

Column (7) CBI claim

Column (8) Mark (X) to indicate if the category of use is site-limited or whether the substance is intended for industrial, commercial, and/or consumer use, as defined below.

Site-limited - The substance will be used only on the contiguous property unit where it is manufactured and not intentionally distributed outside that site except for waste disposal. This includes all factories, storage places, and warehouses at the site. An example would be an intermediate which is further reacted on-site to produce a pesticide.

Consumer - The new chemical substance or products containing the substance will be used by private individuals in or around a residence, or during recreation, or for any other personal use or enjoyment, e g., automotive polish, dyed wearing apparel, household cleaners, etc. If a consumer use is identified, then the EPA requests the following information to be provided on an attached continuation sheet: a detailed description of the use of the new chemical substance expected in consumer products and any reactions that occur causing the substance to lose its identity in the consumer product.

Industrial - The new chemical substance or products containing the substance will be used at the site of other manufacturers or processors, e.g., textile dyeing, paint formulation, use of a curable resin to manufacture an article.

Commercial - The new chemical substance or products containing the substance will be used by a commercial enterprise providing a consumer service, e.g., use by commercial dry cleaning establishments, use by painting contractors, or use by roofers in commercial building construction.

Mark all boxes, as appropriate. For example, a surfactant in an automobile wax may have a consumer use in liquid wax, a commercial use in auto washes, and an industrial use by automobile manufacturers. Mark the binding option statement where applicable.

Note: You must make separate confidentiality claims for the description of the category of use, the percent of production devoted to each category, the percent in formulation, and category of use information.

The information in this section is used to evaluate potential exposure and release of the new substance. If you wish to provide any additional information which would assist in this analysis, it may be submitted as optional information.

c. **Generic use description** - For each category of use description which is claimed as confidential, provide a generic description of the category. Identify the category of use to which the generic description applies. The generic use should reveal the intended category of use of the maximum extent possible. For example, the specific use of a new substance as an antioxidant in a lubricant could be described generically as a lubricant additive; a fiber-reactive dye for nylon carpeting could be described generically as a dye for fibers. If such a generic description does not provide a sufficient indication of potential exposure, the description can also describe the degree of containment of the new chemical substance, as shown in the list below; however, a generic use description that solely describes the degree of containment such as "open, non-dispersive use" is not acceptable.

Degree of Containment

(a) destructive use	(e g., fuels, fuel additives chemical intermediates)
(b) contained use	(e.g., catalysts used in closed processes, certain photographic chemicals, capacitor fluids)
(c) open, non-dispersive use	(e.g., printing inks, textiles, dyes, plasticizers, adhesives, liquid paints, resins)
(d) dispersive use	(e.g., cutting fluids, fabric softeners, automobile tire rubber)
(e) highly dispersive use	(e g., pesticides, fertilizers, salt for de-icing, paint solvents, spray paints)
(f) other	(describe)

3. **Hazard information** - Include in the notice a copy or reasonable facsimile of any hazard warning statement, label, material safety data sheet (MSDS), or other information which will be provided to any person regarding protective equipment, engineering controls, or practices for the safe transport, use, or disposal of the new chemical substance. If hazard warning information is not yet prepared, describe the statement you intend to provide, if any. You are not required to develop hazard warning statements for this notice if you do not otherwise intend to do so. Identify copies of hazard warning statements or other hazard information that you attach in Part III, List of Attachments.

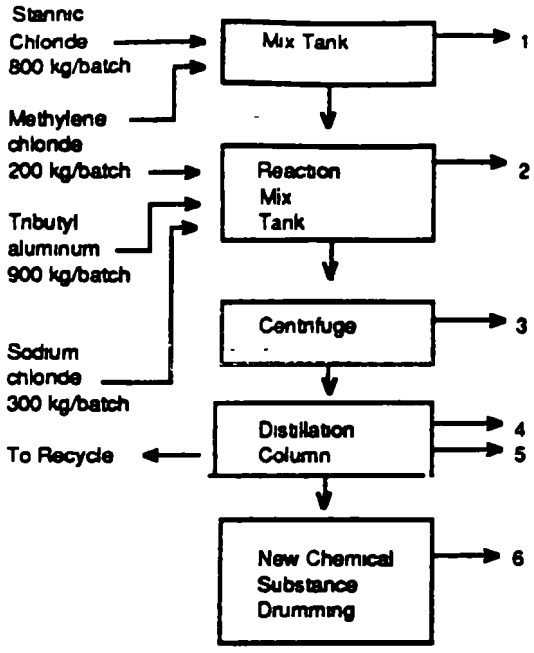
CHEMICALS ON REPORTING RULES (1988) (40 CFR)

RULE CODE, CODE OF FEDERAL REGULATION (CFR), AND FEDERAL REGISTER (FR) INFORMATION

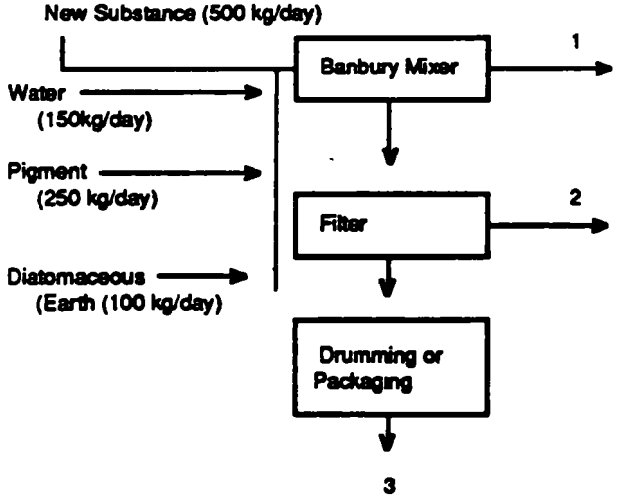
RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
t59	Brominated Flame Retardants (Group I); Proposed Test Rule	799,798, 795	6/25/91	56 FR 29140				EPA is issuing a proposed test rule under section 4(a) of the Toxic Substances Control Act (TSCA) in response to the Interagency Testing Committee (ITC) designation of the following five brominated flame retardants (BFRs) for health and environmental effects and chemical fate testing (1) pentabromodiphenyl ether (PBDPE; CAS. No. (32534-81-9), (2) octabromodiphenyl ether (OBDPE; CAS. No. 32536-52-0), (3) decabromodiphenyl ether (DBDPE; CAS No. 1163-19-5), (4) 1,2,bis(2,4,6-tribromophenoxy)ethane (BTBPE; CAS. No. 37853-59-1), and (5) hexabromocyclododecane (HBCD; CAS. No. 3194-55-6) EPA has concluded that: activities involving these BFRs may pose an unreasonable risk of injury to human health or the environment as suggested by certain preliminary data; existing data are inadequate to assess the risks to human health and the environment posed by exposure to these substances, and testing of each of the five BFRs is necessary to develop such data. Submit written comments on or before August 26, 1991.
t59		799.5110	6-25-91	56 FR 29140				Pentabromodiphenyl ether (PBDPE; CAS No. 32534-81-9) shall be tested in accordance with this section.
t59		799.5110	6-25-91	56 FR 29140				Octabromodiphenyl ether (OBDPE; CAS No. 32536-52-0) shall be tested in accordance with this section.
t59		799.5110	6-25-91	56 FR 29140				Decabromodiphenyl ether (DBDPE; CAS No. 1163-19-5) shall be tested in accordance with this section.
t59		799.5110	6-25-91	56 FR 29140				1,2-bis(2,4,6-tribromophenoxy)ethane (BTBPE; CAS No. 37953-59-1) shall be tested in accordance with this section.
t59		799.5110	6-25-91	56 FR 29140				Hexabromocyclododecane (HBCD; CAS No. 3194-55-6) shall be tested in accordance with this section.

For example, -

SAMPLE MANUFACTURING OPERATION



SAMPLE PROCESSING OPERATION



2. Occupational Exposure

Column (1) - Describe each specific activity in the operation during which workers may be exposed to the new chemical substance. Such activities may include charging reactor vessels, sampling for quality control, transferring materials from one work area to another, drumming, bulk loading, changing filters, and cleaning equipment, etc.. Activities must be described even if workers wear protective equipment. (Material Safety Data Sheets indicating recommended protective equipment should be submitted as part of Hazard Information in part I, section C, subsection 3 of the notice form.)

Column (2) - CBI claim for worker activity

Column (3) - Provide information on the specific types of protective equipment and engineering controls that will be employed to protect the worker from potential exposure to the new chemical substance, i.e., gloves, goggles, 21c respirator, 19c respirator, closed containment system, nitrogen blanket, etc.

Column (4) - Binding option for protective equipment and engineering controls.

Column (5) - Indicate the physical form of the new substance at the time of exposure, e.g., solid (crystals, granules, powder, dust), liquid (solution, paste, slurry, emulsion, mist, spray), gas (vapor, fume), wet press cake, even if workers wear protective equipment.

Column (6) - Binding option for physical forms.

Column (7) - CBI claim for physical form.

Column (8) - Estimate the maximum number of workers involved in each specific activity, based on the estimated maximum 12-month production volume.

Column (9) - CBI claim.

Column (10) - Enter the maximum duration that any one worker will engage in the activity in hours/day, e.g., 8 hours/day.

Column (11) - Enter the maximum duration that any one worker will engage in the activity in days/year, e.g., 200 days/year, based on the estimated maximum production volume.

Column (12) - CBI claim.

Note that you must make separate confidentiality claims for the description of worker activity, physical form of the new substance, number of workers exposed, and duration of exposure. (See 2, 7, 9, 12)

3. Environmental Release and Disposal

Column (1) - For each release point indicated in the process description (Part II, Section A, subsection 1d(3) of the notice form, enter the corresponding number.

Column (2) - Estimate the amount of new chemical (in kg/day for continuous operations or kg/batch for batch operations) that will be released from the release point directly into either (a) the environment or (b) into control technology (in kg/day or kg/batch). Base your estimate on the expected maximum twelve month production volume.

CHEMICALS ON REPORTING RULES (CORR) DATABASE

RULE CODE, CODE OF FEDERAL REGULATION (CFR), AND FEDERAL REGISTER (FR) INFORMATION

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
t60	TSCA Section 4(a)(1)(B) Proposed Statement of Policy		7-15-91	56 FR 32294				EPA is proposing standards and criteria it intends to use in interpreting its legal authority to make findings under the Toxic Substances Control Act (TSCA) section 4(e)(1)(B)(i) for determining substantial production, release to the environment in substantial quantities, and substantial or significant human exposure. Submit written comments on or before September 13, 1991.

(OPTIONAL) POLLUTION PREVENTION AND RECYCLING INFORMATION (Page 11)

This page requests optional information that will be used in the evaluation of the new chemical substance and a comparison of the relative risks and benefits of the substance as a substitute for substances currently on the market. PMN submitters are encouraged to report any and all relevant information not reported elsewhere which is believed to be important to a thorough regulatory decision.

Part III - LIST OF ATTACHMENTS (Page 12)

Attach any continuation sheets for sections of the form, test data and other data (including structure-activity information), and optional information after the last page of the form. Clearly identify the attachment and the section to which it relates, if appropriate. Number consecutively the pages of the attachments. Enter the inclusive page numbers of each attachment. Enter the total number of pages in the notice on page 1 of the form.

Mark (X) the "Confidential" box next to any attachment name you claim as confidential. Read part I, section C.1 on page 2 of this manual for guidance on how to claim any information in an attachment as confidential. You must include with the sanitized copy of the notice a sanitized version of any attachment in which you claim information as confidential.

A worksheet which assists EPA's review of the physical/chemical property information you submit is provided on the last page of the form. Providing physical/chemical property information in this format is optional. However, physical/chemical properties data in your possession or control must be submitted with your notice. If you submit this worksheet, identify it on the List of Attachments.

CHEMICALS ON REPORTING RULES (CORR) DATABASE

RULE CODE, CODE OF FEDERAL REGULATION (CFR), AND FEDERAL REGISTER (FR) INFORMATION

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PRO-POSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFEC-TIVE DATE	NOTES
t62	Testing Consent Agreement Development for Acrylic Acid; Solicitation for Interested Parties	790.22	8-20-91	56 FR 41353				This notice serves three purposes under these procedures. First it requests "interested persons" who wish to participate in testing negotiations for acrylic acid (CAS. No. 79-10-7) to identify themselves to EPA. Second, it announces a public meeting to initiate testing negotiations for this chemical. Third, it proposes a target schedule for implementation of the consent agreement process. Submit written notice to be designated an interested party on or before September 5, 1991.

development activities must be conducted under the supervision of a technically qualified individual. Persons who engage in R&D for, or obtain an R&D chemical from, a manufacturer must be notified of any risk to health which may be associated with the chemical. However, R&D conducted entirely in laboratories under prudent laboratory practices are exempted from the requirement for risk evaluation.

In accordance with 40 CFR 720.78, the following R&D records must be retained: information reviewed and evaluated to determine the need to make any notification of risk, documentation of the nature and method of risk notification, documentation of prudent lab practices used instead of risk notification and evaluation and, if an R&D substance is manufactured at greater than 100 kgs/yr, records regarding the chemical identity of the substance to the extent known, the production volume, and the disposition of the R&D chemical substance must also be retained.

Manufacturers and importers who distribute an R&D substance to other persons must provide those persons with written notification of known hazards and of the requirement that the substance be used solely for R&D. For additional information on R&D requirements see the New Chemical Information Bulletin: Exemptions for Research and Development and Test Marketing available from the Environmental Assistance Division (see Section II, Part G of this manual for addresses and telephone numbers).

3. **Test-marketing exemptions (TME)** - You may apply for an exemption from premanufacture notification if you plan to manufacture or import a new chemical substance for test-marketing. Test-marketing involves the distribution of a predetermined limited amount of a chemical substance, or of a mixture or article containing the chemical substance, to specified number of customers to explore market acceptability before general distribution.

To approve a test-marketing exemption application, the Agency must make an affirmative finding that the new chemical substance will not present an unreasonable risk to health or the environment during the test-marketing activities. Section 720.38 of the Rule identifies the type of information you should submit with a test-marketing exemption application. EPA must approve or deny the application within 45 days. If you do not provide sufficient information for EPA to make its determination within 45 days, the Agency will deny the request.

You should send applications for test-marketing exemptions to the OTS Document Control Officer (TS-790). You are not required but are encouraged to use the PMN form for a TME application.

4. **Section 5(h)(4) exemptions** - Under section 5(h)(4) of the Act, you may apply to EPA for an exemption from some or all premanufacture notification requirements. EPA may grant an exemption if it makes an affirmative finding that the manufacture, processing, distribution in commerce, use, or disposal of the new substance will not present an unreasonable risk to health or the environment. Unlike other exemptions, such as test marketing, EPA may only grant a section 5(h)(4) exemption by rule. In the rulemaking proceeding, the applicant should provide information sufficient to show that the chemical substance will not present an unreasonable risk to health or the environment. You should send applications for section 5(h)(4) exemptions to the OTS Document Control Officer (TS-790). The following 5(h)(4) exemptions have been promulgated:

a. **Low Volume Exemption (LVE)** - Requirements for a LVE application are found at 40 CFR 723.50. This exemption is available for substances manufactured in quantities of 1,000 kg or less per year. Only one exemption is available per substance regardless of potential manufacturers. Low volume substances are not added to the TSCA Inventory; however, a separate inventory of LVEs granted is maintained. The manufacturer must submit a low volume exemption (LVE) notice to EPA at least 21 days prior to manufacturing the substance. The notice must include the site of manufacture and proposed use of the new chemical substance which are legally binding upon the company. The manufacturer may also provide information on exposure controls. If provided, any controls specified in the notice are binding throughout the period of the exemption. EPA will grant the LVE if it determines that the substance will not present an unreasonable risk of injury.

Companies must submit a new exemption notice before they change the site of manufacture or application. Manufacturers (importers) must notify processors and industrial users that the substance can be used only for the uses specified in the exemption notice. Manufacturers must also notify processors and users of any exposure controls.

Under this exemption, submitters must maintain records for five years concerning the annual production volume of the new substance, documentation of information provided in the exemption notice, and compliance with the terms of this section. See Section II (I).

CHEMICALS ON REPORTING RULES (CORR) DATABASE

RULE CODE, CODE OF FEDERAL REGULATION (CFR), AND FEDERAL REGISTER (FR) INFORMATION

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
x1	Polychlorinated Biphenyls (PCBs) Manufacturing, Processing, and Distribution in Commerce, Stay of Interpretation.	761.20			55 FR 37714	9/13/90	7/3/90	This notice announces EPA's stay of an interpretation of 40 CFR 761.20(c)(1) which was included in the preamble to the PCB Manufacturing, Processing, and Distribution in Commerce Exemption Rule (55 FR 21023).
x1	Polychlorinated Biphenyls (PCBs) Manufacturing, Processing, and Distribution in Commerce	761.80			55 FR 38998	9-24-90	9-24-90	Technical Amendment. Adds paragraphs for class exemptions and automatic renewals to EPA's PCBs Exemption Rule (55 FR 21023) on May 22, 1990, which were inadvertently omitted in the codified section of that rule.
x1	Polychlorinated Biphenyls in Electrical Transformers; Correction of Final Rule	761.30			55 FR 45804	10/31/90	10/31/90	This action reinserts paragraphs (A), (B), and (C) inadvertently omitted from the final rule published July 19, 1988 (53 FR 27322).
x1	Polychlorinated Biphenyls; Criteria and Procedures for Terminating Storage and Disposal Approvals	22; 761	11/2/90	55 FR 46470				Proposed Rule: criteria and procedures for the suspension or revocation of PCB storage and disposal approvals under Section 6(e)(1) of TSCA.
x1	Polychlorinated Biphenyls (PCBs); Manufacturing, Processing, and Distribution in Commerce, Partial Rescission of Exemption Rule	761.20			55 FR 46790	11/7/90	8/29/90	This notice announces EPA's decision to rescind an interpretation of 40 CFR 761.20(c)(1) which was published in 55 FR 21023 in May 22, 1990. Regarding requiring of exemptions for entities such as EASA to buy and sell intact, non-leaking PCB or PCB-contaminated transformers.
x1	Polychlorinated Biphenyls in Electrical Transformers	761			55 FR 49043	11/26/90	2/25/91	Final Rule: amends Sections 6(e) of TSCA concerning enhanced electrical protection requirements for low volume radial transformers containing polychlorinated biphenyls (PCBs), and extends deadline for compliance.
x1	Polychlorinated Biphenyls (PCBs)	761.60	8-31-90	55 FR 35720				Receipt of application for nationwide approval to dispose of polychlorinated biphenyls (PCBs) using mobile solvent extraction/distillation systems. Comments to be received by October 1, 1990.

be directed to the Prenotice Coordinator Persons may contact the Prenotice Coordinator by telephone (202) 382-3745. Written inquiries may be sent to:

Prenotice Coordinator
Chemical Control Division
Office of Toxic Substances, TS-794
U.S. E.P.A.
401 M Street, S.W.
Washington, D.C. 20460

2. **During notice review** - The notice review period begins upon receipt of the notice by the OTS Document Control Officer if your notice is determined to be "complete". However, you will receive written notification if your notice is declared "incomplete" as described at 40 CFR 720.65. If your notice is complete, you will receive an acknowledgement letter telling you your notice number and the date of expiration of the review period. The inventory is searched to ensure that the substance for which the notice is submitted is not already included on the TSCA Chemical Substance Inventory. If your chemical substance is on the inventory, you will be notified that your substance is not subject to premanufacture notification, and therefore you are free to begin manufacture immediately. If the substance is not on the inventory, a Program Manager is assigned to coordinate the review of the notice and to be your official contact with the Agency throughout the review period. During the review period, the Program Manager may contact you for clarification of information you have provided in the notice or if the Agency identifies issues of concern. If you are not contacted prior to the expiration of the review period, you are free to commence manufacture of the substance identified in your notice after the review period has expired.

The Program Manager will also notify you before the review period expires if he/she will extend the review period under TSCA section 5(c) or if regulatory action is being considered on the new substance under TSCA section 5(e) or 5(f). 5(e) Consent Orders are typically issued with a follow-up SNUR subsequently promulgated. In addition, a Program Manager will contact you if the Agency plans to develop a non-5(e) SNUR (a case in which a 5(e) Consent Order does not precede the development of a SNUR) on the chemical substance identified in your notice.

H. Notice of Commencement (NOC) of Manufacture (or Import)

If EPA has not taken any action to regulate the new chemical substance during the review period, you may begin manufacturing the new chemical substance upon expiration of the review period. EPA requires that you notify the Agency by letter no later than 30 calendar days, after the first day of such manufacture or import.

Your notice of commencement of manufacture should be sent to the OTS Document Control Officer (TS-790). In your letter, you must provide the specific chemical identity of the substance, its premanufacture notice number, and the date when manufacture or import began. You must also substantiate a confidentiality claim for chemical identity in your letter if you want EPA to maintain the claim after you begin manufacture or import. See 40 CFR 720.85(b) for further information on substantiating confidentiality claims.

If you have submitted a NOC and you wish to be advised of the TSCA Chemical Substance Inventory name for the substance identified in the NOC and the Chemical Abstract Service (CAS) number (for non-confidentially listed substances) "or" Accession number (a 5 digit number generated to identify confidentially listed substances), you should send a separate letter to the OTS Document Control Officer (TS-790); Attention: Chemical Inventory Section.

I. Recordkeeping

Section 720.78 of the Premanufacture Notification Rule requires that you retain documentation of information in the premanufacture notice for five years from the date of commencement of manufacture. The records you must retain include (1) information supporting the information supplied on the notice form, (2) other data, as defined in § 720.50 (b) of the Rule, in your possession or control, (3) production volume for the first three years of production or import, and documentation of production volume, and (4) date of commencement of manufacture, and documentation of this date. For example, if you performed a market analysis to estimate maximum production volume as reported on the notice form, you would retain this analysis, even though production volume and market share may change. If you have performed a chemical analysis to determine what byproducts may result from operations at sites you control, you would retain that analysis. You are not required to develop information solely for recordkeeping purposes, but only to retain information you have obtained or developed in the course of completing your submission.

If you manufacture a new chemical substance under the exemption for substances manufactured solely for research and development, you must retain documentation of compliance with the exemption for five years from the final date of manufacture or import under the exemption. If you manufacture under a test-marketing exemption under TSCA, you must retain documentation of information in the application and documentation of your compliance with any restrictions imposed by EPA when it granted the application. You must retain this information for five years from the final date of manufacture or import under the exemption.

CHEMICALS ON REPORTING RULES (CORR) DATABASE

RULE CODE, CODE OF FEDERAL REGULATION (CFR), AND FEDERAL REGISTER (FR) INFORMATION

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
x6	Model Contractor Accreditation Plan; Intent to Revise the Plan, Notice	763			56 FR 13169	3/29/91		EPA announces its intent to revise the Model Accreditation Plan which was issued on April 30, 1987, pursuant to section 206 of the Asbestos Hazard Emergency Response Act (AHERA).

APPENDIX A

EXAMPLES OF TEST DATA

Following is a list of the types of test data which you must attach to the notice form if it is in your possession or control. This list is illustrative, not exhaustive.

Physical and Chemical Properties and Environmental Fate Data

Chromatograms
Spectra (ultraviolet, visible, infrared)
Density/relative density
Solubility in water
Melting temperature
Boiling/sublimation temperature
Softening point
Vapor pressure
Dissociation constant
Particle size distribution
Octanol/water partition coefficient
Henry's law constant
Volatilization from water
Volatilization from soil
pH
Flammability
Explodability
Adsorption/desorption characteristics
Photochemical degradation
Viscosity
Odor
Hydrolysis
Thermal analysis
Chemical analysis
Chemical oxidation
Chemical reduction
Biodegradation
Transformation to persistent or toxic products

Health Effects Data

Mutagenicity
Carcinogenicity
Teratogenicity
Neurotoxicity/ behavioral effects
Pharmacological effects
Mammalian absorption
Distribution
Metabolism and excretion
Cumulative, additive and synergistic effects
Acute, subchronic and chronic effects
Structure/activity relationships
Epidemiology
Reproductive effects
Clinical studies
Dermatoxicity
Phototoxicity
Irritation
Sensitization
Allergy
Skin staining

Environmental Effects Data

Microbial bioassay
Algal bioassay
Aquatic macrophyte bioassay
Seed germination and root elongation
Seedling growth inhibition
Plant uptake
Acute toxicity to invertebrates
Life cycle test on invertebrates
Acute toxicity to fish
Early life stage (fish)
Avian dietary/ reproduction
Bioaccumulation/ bioconcentration
Model ecosystem studies
Physical environment impairment effects
Flesh staining of aquatic organisms

CHEMICALS ON REPORTING RULES (CHEMR) [illegible]

RULE CODE, CODE OF FEDERAL REGULATION (CFR), AND FEDERAL REGISTER (FR) INFORMAT[illegible]

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
x7	Receipt of Requests for Exclusion From Testing From Three Chemical Companies. Notice of Receipt.	766	7/15/91	56 FR 32208				EPA requires that specified chemical substances be tested to determine if they are contaminated with halogenated dibenzo-p-dioxins (HDDs), or halogenated dibenzofurans (HDFs), and that results be reported to EPA. However, provisions are made for exclusion from these requirements if an appropriate application is submitted to EPA and is approved. Submit written comments on or before July 30, 1991.
x7	Proposed Regulation of Land Application of Sludge From Pulp and Paper Mills Using Chlorine and Chlorine Derivative Bleaching Processes. Proposed rule; extension of comment period and announcement of public hearing.	744	8/8/91	56 FR 37686				Notice is hereby given that the period for filing public comment on the proposed rule for Land Application of Sludge from Paper Mills Using Chlorine and Chlorine-Derivative Bleaching Processes is extended, and that an informal public hearing on the proposed rule will be held. Public comments must be received on or before September 17, 1991. The informal public hearing will begin on October 29, 1991.
x7	Proposed Regulation of Land Application of Sludge From Pulp and Paper Mills Using Chlorine and Chlorine Derivative Bleaching Processes. Proposed rule; notice of meeting.	744	9/20/91	56 FR 47717				Notice is hereby given that a peer review panel will meet to evaluate the risk assessments underlying the proposed regulation of land application of sludge from pulp and paper mills using chlorine and chlorine derivative bleaching processes. The peer review panel will meet on October 1 and 2, 1991.

Form Approved. O.M.B. No. 2070-0012. Approval Expires 1-31-94.

U. S. ENVIRONMENTAL PROTECTION AGENCY

EPA PREMANUFACTURE NOTICE

FOR NEW CHEMICAL SUBSTANCES

AGENCY USE ONLY

Date of receipt

When completed send this form to

DOCUMENT CONTROL OFFICER
OFFICE OF TOXIC SUBSTANCES, TS-790
U.S. E.P.A.
401 M STREET, SW
WASHINGTON, D.C. 20460

Enter the total number of pages in the Premanufacture Notice

Document control number

EPA case number

GENERAL INSTRUCTIONS

TS- ☐☐☐☐☐☐

- You must provide all information requested in this form to the extent that it is known to or reasonably ascertainable by you. Make reasonable estimates if you do not have actual data.
- Before you complete this form, you should read the "Instructions Manual for Premanufacture Notification" (Instructions Manual).
- If a user fee has been remitted for this notice (40 CFR 700.45), indicate in the TS boxes above the TS-user fee identification number you have generated. Remember, your user fee ID number must also appear on your corresponding fee remittance.

Part I – GENERAL INFORMATION

You must provide the chemical identity of the new chemical substance, even if you claim the identity as confidential. You may authorize another person to submit the identity for you, but your submission will not be complete and review will not begin until EPA receives this information. A letter of support from another person should reference your TS user fee identification number.

Part II – HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE

You may need additional copies of part II, sections A and B if there are several manufacture, processing, or use operations that you will describe in the notice. You should reproduce these sections as needed.

Part III – LIST OF ATTACHMENTS

You should attach additional sheets if you do not have enough space on the form to answer a question fully. Label each continuation sheet with the corresponding section heading. In part III, list these attachments, any test data or other data and any optional information that you include in the notice.

OPTIONAL INFORMATION

You may include in the notice any information that you want EPA to consider in evaluating the new substance. The Instructions Manual identifies categories of optional information that you may want EPA to review. On page 11 of this form, space has been provided for you to describe pollution prevention and recycling information you may have regarding the new substance.

Binding Options: In order to effectively implement risk management options, EPA may wish to exercise its authority under section 5(e) to make certain statements in your notice such as use, production volume, protective equipment and/or process description legally binding and enforceable. If you wish to initiate such discussions with the EPA, precisely describe those aspects in this notice deliberately designed to protect against unreasonable risk to human health or the environment and indicate your willingness to be bound to the appropriate statements by marking (X) in the boxes provided. Should the Agency wish to pursue this option, you will be contacted by an EPA staff person.

CONFIDENTIALITY CLAIMS

You may claim any information in this notice as confidential. To assert a claim on the form, mark (X) the confidential box next to the information that you claim as confidential. To assert a claim in an attachment, circle or bracket the information you claim as confidential. If you claim information in the notice as confidential, you must provide a sanitized version of the notice, including attachments, to EPA with your submission. For additional instructions on claiming information as confidential, read the Instructions Manual.

☐ Mark (X) if any information in this notice is claimed as confidential.

TEST DATA AND OTHER DATA

You are required to submit all test data in your possession or control and to provide a description of all other data known to or reasonably ascertainable by you if these data are related to the health and environmental effects of the manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance. Standard literature citations may be submitted for data in the open scientific literature. Complete test data (written in English), not summaries of data, must be submitted if they do not appear in the open literature. Following are examples of test data and other data. You should submit these data according to the requirements of §720.50 of the Premanufacture Notification Rule (40 CFR Part 720).

Test Data (See Appendix A of the Instructions Manual and the Physical and Chemical Properties Worksheet on the last page of this form for examples of data to be submitted).

- Environmental fate data ☐ Yes ☐ No
- Health effects data ☐ Yes ☐ No
- Environmental effects data ☐ Yes ☐ No
- Physical/Chemical Properties ☐ Yes ☐ No

Other data ☐ Yes ☐ No

- Risk assessments
- Structure/activity relationships
- Test data not in the possession or control of the submitter

TYPE OF NOTICE (Check Only One)

☐ PMN

☐ CONSOLIDATED PMN - # OF CHEMICALS _____
(Prenotice Communication # required, enter # on page 3)

☐ SNUN (Significant New Use Notice)

☐ INTERMEDIATE PMN - AS DEFINED AT 40 CFR 700.43

☐ TMEA (Test Marketing Exemption)

☐ LVE (Low Volume Exemption)

☐ POLYMER EXEMPTION - ☐ e(1) or ☐ e(2)

☐ OTHER EXEMPTION - SPECIFY

_____

CHEMICALS ON REPORTING RULES (CORR) DATABASE

RULE CODE, CODE OF FEDERAL REGULATION (CFR), AND FEDERAL REGISTER (FR) INFORMATION

RULE CODE	NAME OF RULE OR PMN #	40 CFR CITATION	PROPOSED RULE DATE	PROPOSED RULE FOR CITATION	FINAL RULE FOR CITATION	FINAL RULE PUBLISH DATE	EFFECTIVE DATE	NOTES
x10	Proposed Ban on Acrylamide and N-methylolacrylamide Grouts. Notice of proposed rulemaking.	764.125	10/2/91	56 FR 49863				This proposed rule would prohibit the manufacture, importation, distribution in commerce, and use of acrylamide grout; and would prohibit all uses of N-methylolacrylamide (NMA) grout, except its use for sewer line repair. Written requests to participate in the informal hearing must be received by December 2, 1991.

notice form, including attachments, which does not contain confidential information. This "sanitized" version will be placed in the public file. It must contain all non-confidential information, including health and safety studies. If you do not provide the sanitized copy with your submission, the submission will be incomplete and the review period will not begin. If you provide a subsequent amendment to your PMN or additional information/data, you must also provide a non-confidential version for the public file.

2. Substantiating claims

You are not required to provide substantiation of any confidentiality claim when you submit your notice. However, you must substantiate your claim of confidentiality for chemical identity at the time you submit a notice of commencement of manufacture, if you want EPA to maintain your confidentiality claim after you begin manufacture. To substantiate that claim, you must provide EPA with detailed answers to the questions which appear in the Premanufacture Notification Rule (§ 720.85(b)(3)(iv)). This substantiation must accompany your notice of commencement. You may be required to substantiate other confidentiality claims if EPA receives a Freedom of Information Act request on that information.

C. Optional Information

During the course of its review, the Agency will be considering whether the activities surrounding the manufacture, processing, use, and disposal of the substance identified in the notice may present an unreasonable risk of injury to human health or the environment. Control measures instituted by the submitter to reduce exposures and/or releases of the substance may have a direct bearing on the Agency's conclusions regarding risk. Therefore, you may wish to indicate your willingness to be bound to certain information you have submitted on this form which may be related to the issue of potential risk such as use, production volume, protective equipment, engineering controls, and/or process description. By providing this information, you would be indicating an interest in future negotiations if the Agency deems them necessary. In order to make your intentions known to EPA, mark (X) in the "Binding Option" box on the form located to the right of the appropriate information. The purpose of the binding option is to enable EPA (if necessary) to efficiently negotiate with the submitter the development of section 5(e) consent orders and promulgate Significant New Use Rules (SNURs) for those new chemical substances that the Agency determines may present an unreasonable risk if certain control actions are not implemented. This option is intended to reduce delays that routinely accompany the development of consent orders under the current process.

Should the Agency wish to discuss your intention, you will be contacted by a Program Manager and negotiations may ensue. Therefore, indicating a willingness to be bound by the terms of your notice does not by itself prohibit the submitter from deviating from the information (except chemical identity) reported in the form.

The Agency is interested in obtaining all information relevant to making the appropriate regulatory decision during the course of a (new) chemical review. It is important that EPA acquire information regarding any technological, risk reduction, or environmental benefits which may be possible if the new chemical being reported is introduced in commerce. Therefore, PMN submitters are encouraged to complete and provide the optional information on pollution prevention on page 11 of the form. For example, the EPA will consider any information on methods used to minimize potential risks associated with the new substance through source reduction or recycling. Some of the benefits for which information may be provided are a reduction in the volume manufactured, a reduction in the generation of waste materials, a reduction in exposure and/or environmental release or increased performance and/or operation efficiency of the new chemical substance in comparison to existing chemical substances used in similar applications. Recycling activities include reclamation of useful chemical components from wastes that would otherwise be released as air emissions, water discharges or land releases during manufacture, process or use. All descriptions may be quantitative or qualitative.

D. Test Data and Other Data

You are required to provide test data on the health and environmental effects of the new chemical substance, including data on physical/chemical properties, in your possession or control, and a description of any other health and environmental effects data on the substance known to or reasonably ascertainable by you. The Agency holds the position that data in the possession or control of either a parent company or an affiliated subsidiary located outside the U.S. are considered data that should be known to or reasonably ascertainable by a submitter. Data must be submitted in English. Standard literature citations may be submitted for data in the open scientific literature. Complete test data, not summaries of data, must be submitted if they do not appear in the open literature. Incomplete reports (e.g., from ongoing studies) are exempt from full reporting. However, you must describe the nature and objective of any incomplete study, report, or test, the name and address of any laboratory developing the data; progress to date; type of data collected; significant preliminary results; and an

Part I – GENERAL INFORMATION

Section A – SUBMITTER IDENTIFICATION

Mark (X) the "Confidential" box next to any subsection you claim as confidential.

Confidential

Person Submitting Notice (in U.S.)

Name of authorized official | Title

Company

Mailing address (number and street)

City, State, ZIP Code

b. Agent (if applicable)

Name of authorized official | Title

Company

Mailing address (number and street)

City, State, ZIP Code | Telephone: Area Code | Number

c. If you are submitting this notice as part of a joint submission, mark (X) this box. → ☐

Joint Submitter (if applicable)

Name of authorized official | Title

Company

Mailing address (number and street)

City, State, ZIP Code | Telephone: Area Code | Number

2. Technical Contact (in U.S.)

Name | Title

Company

Mailing address (number and street)

City, State, ZIP Code | Telephone: Area Code | Number

3. If you have had a prenotice communication (PC) concerning this notice and EPA assigned a PC Number to the notice, enter the number. →

Mark (X) if none → ☐

4. If you have submitted an exemption notice/application for the chemical substance covered by this notice, enter the exemption number assigned by EPA. If you have withdrawn a previously submitted PMN enter the PMN number. →

Mark (X) if none → ☐

5. If you have submitted a bona fide request for the chemical substance covered by this notice, enter the bona fide request number assigned by EPA. →

Mark (X) if none → ☐

Type of Notice – Mark (X)

1. ☐ Manufacture Only ☐ Binding Option Mark (x)

2. ☐ Import Only ☐ Binding Option Mark (x)

3. ☐ Both

G. Completing the Parts of the Notice Form

Part I – GENERAL INFORMATION

Section A - Submitter Identification (Page 3)

1a. Person submitting notice - Enter information on the official who signed the general certification.

b. Agent - Complete only if you authorize an agent to assist you in preparing this notice. The agent must also sign the certification as noted above.

If you mark (X) the "Confidential" box next to items a or b, all information in the item will be treated as confidential.

c. Mark (X) the box if your submission is a joint submission. Identify in Part I, Section A (1)(c) the name of the joint submitter who is authorized by the U.S. submitter to provide some of the information required in the notice. For additional information on joint submissions, see part II, section F of this Manual. A notice will not be considered complete until all information is received by the Agency. If information from multiple sources will not be sent together, use your TS-User Fee Number to link multiple notices.

Mark (X) the "Confidential" box next to item c if you wish this information to be treated as confidential.

If you authorize another person (e.g., a foreign manufacturer or supplier) to provide information, such as, confidentially held tradename chemical substance identification directly to EPA, indicate which information will be supplied by the other person. Identify that person by name, company, and address in a continuation sheet. That person's identity may be claimed as confidential. Such a letter in support of your notice should be provided by the other person on company letterhead. A notice will be considered incomplete until this information is provided. Whenever possible use your TS-User Identification Number to link this information.

2. Technical contact - Identify a person who can provide EPA with additional information on the new chemical substance during the notice review period. The technical contact identified should be located in the United States and be available to be reached by telephone during normal business hours. If you mark (X) the "Confidential" box next to this subsection, all information in it will be treated as confidential.

3. Provide any prenotice communication's number assigned to your prenotice inquiry. In addition, see Section II, Part E of this manual for further information on submission of a consolidated PMN that requires a prenotice consultation.

4. Provide the exemption number assigned for any previous exemption application submitted for the chemical substance covered by this notice. Also, provide any previously assigned PMN number, if any, for the chemical substance.

5. Self-explanatory.

6. Mark (X) to indicate whether you intend to manufacture or import the new chemical substance or both manufacture and import. Use the optional binding box to indicate your willingness to be bound to either import or domestic manufacture only.

Section B - Chemical Identity Information (Pages 4-6)

EPA must receive complete and unambiguous identification of the new chemical substance. If the substance is not adequately identified, the submission will not meet statutory requirements and the notice review period will not begin. If a principal importer does not know the specific identity of the new substance, the submitter must contact the foreign manufacturer or supplier and have the specific chemical identity information required in the PMN provided directly to EPA. In this way, foreign manufacturers can protect confidential business information. The same holds true for U.S. manufacturers reporting chemical substances using a generic or trade name to identify a component of the new chemical substance. The submitter of the new chemical substance must have the supplier provide chemical identity information directly to EPA before the notice can be considered complete. This information may be provided in a letter of support from the supplier or as a joint submission. A letter of support should be provided on the supplier's company letterhead. See Part II, Section F(2) of this manual on how and when to file a joint submission. Since a letter of support or a joint submission may be received separately by the Agency, an identification number such as a TS-user fee number or a Prenotice Communications number should be used to link a PMN with information from a supplier or foreign manufacturer. The identical identification number should appear on both pieces of correspondence submitted to EPA; otherwise there may be a delay in processing the PMN.

The type of chemical identity information required in the notice depends on whether the substance is a Class 1 or

Part I – GENERAL INFORMATION – Continued

Section B – CHEMICAL IDENTITY INFORMATION – Continued

Polymers (For a definition of polymer, see the Instructions Manual.)

Confi-dential

1. Indicate the number-average weight of the lowest molecular weight composition of the polymer you intend to manufacture. Indicate maximum weight percent of low molecular weight species (not including residual monomers, reactants, or solvents) below 500 and below 1,000 absolute molecular weight of that composition. Describe the methods of measurement or the bases for your estimates. GPC ☐ Other ☐ (Specify) _____

- lowest number average molecular weight:
- maximum weight % below 500 molecular weight:
- maximum weight % below 1000 molecular weight:

☐ Mark (X) this box if you attach a continuation sheet.

b. You must make separate confidentiality claims for monomer or other reactant identity, composition information, and residual information. Mark (X) the "Confidential" box next to any item you claim as confidential.
(1) – Provide the chemical name and CAS Registry Number of each monomer or other reactant used in the manufacture of the polymer.
(2) – Mark (X) this column if entry in column (1) is confidential.
(3) – Indicate the typical weight percent of each monomer or other reactant in the polymer.
(4) – Mark (X) the identity column if you want a monomer or other reactant used at two weight percent or less to be listed as part of the polymer description on the TSCA Chemical Substance Inventory.
(5) – Mark (X) this column if entries in columns (3) and (4) are confidential.
(6) – Indicate the maximum weight percent of each monomer or other reactant that may be present as a residual in the polymer as manufactured for commercial purposes.
(7) – Mark (X) this column if entry in column (6) is confidential.

Monomer or other reactant and CAS Registry Number (1)	Confi-dential (2)	Typical composition (3)	Identity Mark (X) (4)	Confi-dential (5)	Maximum residual (6)	Confi-dential (7)
		%			%	
		%			%	
		%			%	
		%			%	
		%			%	
		%			%	
		%			%	

☐ Mark (X) this box if you attach a continuation sheet.

c. Provide a representative structural diagram of the polymer, if possible.

☐ Mark (X) this box if you attach a continuation sheet.

describe the nature of the reaction or process. A description should appear in the form of a reaction scheme:

A + B ————————> C

The nature of the reaction must be described as specifically as possible (e.g., acetylation, alkaline hydrolysis, diazotization). For substances that have been produced without chemical reaction (e.g., by chemical extraction from a natural source), specify the source, the production process, and the nature of the product.

(3) If you intend to manufacture a Class 2 chemical substance within a limited range of possible compositions, report the range. For example, a manufacturer filing a notice for chlorinated naphthalene might specify a compositional range of 20-40 percent chlorine by weight. In determining the range, you may have to consider the reaction conditions, the catalyst, or the purification process that may be used to produce the substance, and other factors. You should provide the range of composition in weight percent for each specific component or class of components that you intend to manufacture for commercial purposes. Indicate the typical composition or any actual values for samples.

(4) Provide as complete a structural diagram as possible. The diagram should indicate the characteristic structure or variable compositional elements of the substance.

2. Polymers (Page 5)

a. Indicate the lowest number-average molecular weight of any composition of the polymer you intend to manufacture. Identify the method you used to make this determination (e.g., vapor pressure osmometry or other colligative property determinations, gel-permeation chromatography, light scattering, or various correlative techniques). If you have not determined number-average molecular weight by analytical methods, briefly explain the basis for your estimate. Indicate the maximum weight percent of low molecular weight species below 500 and below 1,000 absolute molecular weight. Include the weight of oligomeric reaction products (including molecules formed that are not polymer molecules) in your determination but do not include the weight of residual monomers or other reactants. Attach test data supporting your estimate. If you do not have actual test data, provide an estimate and describe the basis for the estimate.

b. Column (1) - Provide the chemical name and CAS Registry Number of each reactant used in the manufacture of the polymer, including those used at 2 weight percent or less. Reactants include monomers, free radical initiators, and cross-linking, chain transfer, and other reactive agents that are used intentionally to become chemically a part of the polymer composition. If prepolymer is used in the manufacture of the polymer, list the prepolymer in terms of its component reactants. Identify by bracketing or another method that the monomers are components of a prepolymer.

Column (2) - CBI claim.

Column (3) - For each reactant (including monomers), indicate its typical weight percent in the polymer. The weight percent of a reactant is the weight of the reactant charged to the reactor divided by the weight of the polymeric chemical manufactured (times 100). Thus, the weight percent of reactant A of a polymer manufactured from reactants A, B, and C is the weight of A charged to the reactor divided by the dry weight of the polymer A-B-C (times 100).

If you use a prepolymer in the manufacture of the polymer, you must determine the weight percent of its component reactants. For example, the weight percent of E used in the manufacture of a polymer from reactants A, B, and C and prepolymer D-E is the total weight of monomer E in the prepolymer D-E used divided by the weight of the polymer A-B-C-D-E manufactured (times 100). You must provide the identity and typical weight percent of each monomer and other reactant used in the manufacture of the polymer regardless of the weight percent at which it is used. If you will typically manufacture the polymer using a reactant in a range of weight composition, you may indicate the range of weight percent instead of the typical weight percent.

Column (4) - Reactants used at greater than 2 weight percent in the manufacture of the polymer are included as part of the description of the polymer listed on the TSCA Chemical Substance Inventory. However, you may choose whether or not to include reactants used at 2 weight percent or less in the inventory description of the polymer.

Mark (X) the identity column if you want a reactant present at 2 weight percent or less to be included in the description of the polymer which is added to the inventory.

Part I – GENERAL INFORMATION – Continued

Section C – PRODUCTION, IMPORT, AND USE INFORMATION

Mark (X) the "Confidential" box next to any item you claim as confidential.

1. Production volume – Estimate the maximum production volume during the first 12 months of production. Also estimate the maximum production volume for any consecutive 12-month period during the first three years of production.

Maximum first 12-month production (kg/yr)	Maximum 12-month production (kg/yr)	Confidential	Binding Option Mark (x)

2. Use Information – You must make separate confidentiality claims for the description of the category of use, the percent of production volume devoted to each category, the formulation of the new substance, and other use information. Mark (X) the "Confidential" box next to any item you claim as confidential.

a. (1) – Describe each intended category of use of the new chemical substance by function and application.
(2) – Mark (X) this column if entry in column (1) is confidential business information (CBI).
(3) – Indicate your willingness to have the information provided in column (1) binding.
(4) – Estimate the percent of total production for the first three years devoted to each category of use.
(5) – Mark (X) this column if entry in column (4) is confidential business information (CBI).
(6) – Estimate the percent of the new substance as formulated in mixtures, suspensions, emulsions, solutions, or gels as manufactured for commercial purposes at sites under your control associated with each category of use.
(7) – Mark (X) this column if entry in column (6) is confidential business information (CBI).
(8) – Mark (X) whether the use is site-limited, industrial, commercial and/or consumer. Mark more than one box if appropriate. Mark (X) to indicate your willingness to have the information provided in (8) binding.
(9) – Mark (X) this column if entry(ies) in column (8) is (are) confidential business information (CBI).

Category of use (1)	CBI (2)	Binding Option Mark (x) (3)	Production % (4)	CBI (5)	% in Formulation (6)	CBI (7)	Mark (X) appropriate column(s) (8)					CBI (9)
							Site-limited	Consumer*	Industrial	Commercial	Binding Option	
			%		%							
			%		%							
			%		%							
			%		%							
			%		%							

*If you have identified a "consumer" use, please provide on a continuation sheet a detailed description of the use(s) of this chemical substance in consumer products. In addition include estimates of the concentration of the new chemical substance as expected in consumer products and describe the chemical reactions by which this substance loses its identity in the consumer product.

☐ Mark (X) this box if you attach a continuation sheet.

b. Generic use description

If you claim any category of use description in subsection 2a as confidential, enter a generic description of that category. Read the Instructions Manual for examples of generic use descriptions.

☐ Mark (X) this box if you attach a continuation sheet.

3. Hazard Information – Include in the notice a copy of reasonable facsimile of any hazard warning statement, label, material safety data sheet, or other information which will be provided to any person who is reasonably likely to be exposed to this substance regarding protective equipment or practices for the safe handling, transport, use, or disposal of the new substance. List in part III hazard information you include.

Binding Option Mark (x)

☐ Mark (X) this box if you attach hazard information.

name should reveal the chemical identity of the substance to the maximum extent possible. Guidelines for developing a generic name are provided in Appendix B of the TSCA Chemical Substance Inventory, Volume 1. The generic name will be published in the FEDERAL REGISTER notice on the new substance. EPA will review the adequacy of the generic chemical name when the notice of commencement of manufacture of the substance is submitted. If the name seems more generic than necessary, EPA will contact you to develop an adequate name.

7. Byproducts - List the byproducts that you reasonably anticipate will result from the manufacture, processing, use, and disposal of the new chemical substance at sites you control. Identify the byproducts as specifically as possible by name and CAS Registry Number (if available). You should give the following information:

   (1) the specific chemical name; or

   (2) a class or range of structures (e.g., C_8 - C_{18} fatty acid salts or polychlorinated cyclic and acyclic hydrocarbons in the range C_5 - C_{12}); or

   (3) the source (e.g., pyrolysis products of cellulose or coal tar residues). If there are no byproducts, enter "None."

Section C - Production, Import, & Use Information (Pg. 7)

1. Production volume - Estimate the maximum production volume for the first 12 months of production. Also estimate the maximum production volume for any consecutive 12-month period during the first 3 years of manufacture. Provide your estimates in kilograms. Maximum production volume is the maximum amount of the new chemical substance you expect to produce over a one-year period (e.g., June 1990 through May 1991). Include in this total amounts produced by persons under contract to you. If part of the amount manufactured is for export, include this amount in your estimates. (You are not allowed to exclude amounts once the substance is no longer manufactured solely for export.)

2. Use information

   a. Column (1) Identify the intended category of use of the new chemical substance by describing its function and application.

      "Function" is related to the inherent physical and chemical properties of the substance (e.g., degreaser, catalyst, plasticizer, ultraviolet absorber). "Application" refers to the use of the substance in particular processes or products (e.g., a degreaser may be used for cleaning of fabricated metal parts).

      Following are some examples of how you should describe categories of use:
      - a disperse dye carrier for finishing polyester fibers
      - a cross-linking agent for epoxy-type coatings for metal surfaces
      - a flame retardant for surface application on cotton apparel, textile home furnishings, and exterior canvas products
      - a surfactant in automobile spray wax
      - a colorant for paper and other cellulosics
      - fiber-reactive dye for nylon carpeting and upholstery
      - an antioxidant in fuels oils and lubricants

      Column (2) CBI claim.

      Column (3) Binding option for category of use.

      Column (4) Estimate the percent of the total production volume that you anticipate will be manufactured for each category of use.

      Column (5) CBI claim.

      Column (6) Estimate the weight percent of the new chemical substance that will be contained in any formulated mixture, suspension, emulsion, solution, or gel associated with each category of use as manufactured for commercial purposes at sites under your control. Where the substance is distributed from your site neat, enter N/A (for not applicable).

      For example, a PMN substance will be used for several different uses, including a cross-linking agent where the substance is distributed neat and as a surfactant where the substance is present in the formulation at a weight percent of 4. Eighty percent of the production volume encompasses the first use and twenty percent of the production volume will be used for the second use.

Category of Use	CBI	Binding	Production Percent	CBI	Percent in Formulation	CBI
1. Cross-linking agent	X	80%	X		NA	
2. Surfactant in automobile spray wax	X	20%	X		4	

Part II – HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE – Continued

Section A – INDUSTRIAL SITES CONTROLLED BY THE SUBMITTER – Continued

Occupational Exposure – You must make separate confidentiality claims for the description of worker activity, physical form of the new chemical substance, number of workers exposed, and duration of activity. Mark (X) the "Confidential" box next to any item you claim as confidential.

(1) – Describe the activities in which workers may be exposed to the new chemical substance.
(2) – Mark (X) this column if entry in column (1) is confidential business information (CBI).
(3) – Describe any protective equipment and engineering controls used to protect workers.
(4) and (6) – Indicate you willingness to have the information provided in column (3) or (5) binding.
(5) – Indicate the physical form(s) of the new chemical substance at the time of exposure.
(7) – Mark (X) this column if entry in column (5) is confidential business information (CBI).
(8) – Estimate the maximum number of workers involved in each activity.
(9) – Mark (X) this column if entry in column (8) is confidential business information (CBI).
(10) and (11) – Estimate the maximum duration of the activity for any worker in hours per day and days per year.
(12) – Mark (X) this column if entries in columns (10) and (11) are confidential business information (CBI).

Worker activity (1)	CBI (2)	Protective Equipment/ Engineering Controls (3)	Binding Option Mark (x) (4)	Physical form(s) (5)	Binding Option Mark (x) (6)	CBI (7)	# of Workers Exposed (8)	CBI (9)	Maximum duration		CBI (12)
									Hrs/day (10)	Days/yr (11)	

☐ Mark (X) this box if you attach a continuation sheet.

3. **Environmental Release and Disposal** – You must make separate confidentiality claims for the release number and the amount of the new chemical substance released and other release and disposal information. Mark (X) the "Confidential" box next to each item you claim as confidential.

(1) – Enter the number of each release point identified in the process description, part II, section A, subsection 1d(3).
(2) – Estimate the amount of the new substance released (a) directly to the environment or (b) into control technology (in kg/day or kg/batch).
(3) – Mark (X) this column if entries in columns (1) and (2) are confidential business information (CBI).
(4) – Identify the media (air, land, or water) to which the new substance will be released from that release point.
(5) – a. Describe control technology, if any, and control efficiency that will be used to limit the release of the new substance to the environment. For releases disposed of on land, characterize the disposal method and state whether it is approved for disposal of RCRA hazardous waste. On a continuation sheet, for each site describe any additional disposal methods that will be used and whether the waste is subject to secondary or tertiary on-site treatment. b. Estimate the amount released to the environment after control technology (in kg/day).
(6) – Mark (X) this column if entries in columns (4) and (5) are confidential business information (CBI).
(7) – Identify the destination(s) of releases to water. Please supply NPDES (National Pollutant Discharge Elimination System) numbers for direct dischargers or NPDES numbers of the POTW (Publicly Owned Treatment Works). Mark (X) if the POTW name or NPDES # is confidential business information (CBI).

Release Number (1)	Amount of new substance released (2a)	(2b)	CBI (3)	Media of release (4)	Control technology and efficiency (5a)	Binding Mark (x)	(5b)	CBI (6)

) Mark (X) the estination(s) of leases to water.	☐ POTW provide name(s) below: _____	CBI	☐ Navigable waterway	☐ Other - Specify	NPDES #	CBI

☐ Mark (X) this box if you attach a continuation sheet.

OPTIONAL POLLUTION PREVENTION INFORMATION

To claim information in this section as confidential circle or bracket the specific information that you claim as confidential.

In this section you may provide information not reported elsewhere in this form regarding your efforts to reduce or minimize potential risks associated with activities surrounding manufacturing, processing, use and disposal of the PMN substance. Please include new information pertinent to pollution prevention, including source reduction, recycling activities and safer processes or products available due to the new chemical substance. Source reduction includes the reduction in the amount or toxicity of chemical wastes by technological modification, process and procedure modification, product reformulation, raw materials substitution, and/or inventory control. Recycling refers to the reclamation of useful chemical components from wastes that would otherwise be treated or released as air emissions or water discharges, or land disposal. Descriptions of pollution prevention, source reduction and recycling should emphasize potential risk reduction subsequent to compliance with existing regulatory requirements and can be either quantitative or qualitative. The EPA is interested in this information to assess overall net reductions in toxicity or environmental releases and exposures, not the shifting of risks to other environmental media or non-environmental areas (e.g., occupational or consumer exposure). In addition, information on the relative cost or performance characteristics of the PMN substance to potential alternatives may be provided. **All information provided in this section will be taken into consideration during the review of this substance.**

Describe the expected net benefits, such as (1) an overall reduction in risk to human health or the environment; (2) a reduction in the volume manufactured; (3) a reduction in the generation of waste materials through recycling, source reduction or other means; (4) a reduction in potential toxicity or human exposure and/or environmental release; (5) an increase in product performance, a decrease in the cost of production and/or improved operation efficiency of the new chemical substance in comparison to existing chemical substances used in similar applications; or (6) the extent to which the new chemical substance may be a substitute for an existing substance that poses a greater overall risk to human health or the environment.

☐ Mark (X) this box if you attach a continuation sheet.

PHYSICAL AND CHEMICAL PROPERTIES WORKSHEET

To assist EPA's review of physical and chemical properties data, please complete the following worksheet for data you provide and include it in the notice. Identify the property measured, the page of the notice on which the property appears, the value of the property, the units in which the property is measured (as necessary), and whether or not the property is claimed as confidential. You are not required to submit this worksheet; however, EPA strongly recommends that you do so, as it will simplify review and ensure that confidential information is properly protected. You should submit this worksheet as a supplement to your submission of test data. This worksheet is not a substitute for submission of test data.

Property (a)	Mark (X) if provided	Page number (b)	Value (c)	Confidential Mark (X) (d)
Vapor pressure @ Temperature _____ °C			Torr	
Density/relative density			g/cm3	
Solubility @ Temperature _____ °C Solvent _____			g/L	
Solubility in water @ Temperature _____ °C			°C	
Melting temperature			°C	
Boiling/sublimation temperature @ _____ torr pressure				
Spectra				
Dissociation constant				
Particle size distribution				
Octanol/water partition coefficient				
Henry's Law constant				
Volitalization from water				
Volitalization from soil				
pH @ concentration _____				
Flammability				
Explodability				
Adsorption/coefficient				
Other - Specify				

Column (7) CBI claim.

Column (8) Mark (X) to indicate if the category of use is site-limited or whether the substance is intended for industrial, commercial, and/or consumer use, as defined below.

Site-limited - The substance will be used only on the contiguous property unit where it is manufactured and not intentionally distributed outside that site except for waste disposal. This includes all factories, storage places, and warehouses at the site. An example would be an intermediate which is further reacted on-site to produce a pesticide.

Consumer - The new chemical substance or products containing the substance will be used by private individuals in or around a residence, or during recreation, or for any other personal use or enjoyment, e g., automotive polish, dyed wearing apparel, household cleaners, etc. If a consumer use is identified, then the EPA requests the following information to be provided on an attached continuation sheet: a detailed description of the use of the new chemical substance expected in consumer products and any reactions that occur causing the substance to lose its identity in the consumer product.

Industrial - The new chemical substance or products containing the substance will be used at the site of other manufacturers or processors, e.g., textile dyeing, paint formulation, use of a curable resin to manufacture an article.

Commercial - The new chemical substance or products containing the substance will be used by a commercial enterprise providing a consumer service, e.g., use by commercial dry cleaning establishments, use by painting contractors, or use by roofers in commercial building construction.

Mark all boxes, as appropriate. For example, a surfactant in an automobile wax may have a consumer use in liquid wax, a commercial use in auto washes, and an industrial use by automobile manufacturers. Mark the binding option statement where applicable.

Note: You must make separate confidentiality claims for the description of the category of use, the percent of production devoted to each category, the percent in formulation, and category of use information.

The information in this section is used to evaluate potential exposure and release of the new substance. If you wish to provide any additional information which would assist in this analysis, it may be submitted as optional information.

c. Generic use description - For each category of use description which is claimed as confidential, provide a generic description of the category. Identify the category of use to which the generic description applies. The generic use should reveal the intended category of use of the maximum extent possible. For example, the specific use of a new substance as an antioxidant in a lubricant could be described generically as a lubricant additive; a fiber-reactive dye for nylon carpeting could be described generically as a dye for fibers. If such a generic description does not provide a sufficient indication of potential exposure, the description can also describe the degree of containment of the new chemical substance, as shown in the list below; however, a generic use description that solely describes the degree of containment such as "open, non-dispersive use" is not acceptable.

Degree of Containment

(a) destructive use	(e.g., fuels, fuel additives chemical intermediates)
(b) contained use	(e.g., catalysts used in closed processes, certain photographic chemicals, capacitor fluids)
(c) open, non-dispersive use	(e.g., printing inks, textiles, dyes, plasticizers, adhesives, liquid paints, resins)
(d) dispersive use	(e.g., cutting fluids, fabric softeners, automobile tire rubber)
(e) highly dispersive use	(e.g., pesticides, fertilizers, salt for de-icing, paint solvents, spray paints)
(f) other	(describe)

3. Hazard information - Include in the notice a copy or reasonable facsimile of any hazard warning statement, label, material safety data sheet (MSDS), or other information which will be provided to any person regarding protective equipment, engineering controls, or practices for the safe transport, use, or disposal of the new chemical substance. If hazard warning information is not yet prepared, describe the statement you intend to provide, if any. You are not required to develop hazard warning statements for this notice if you do not otherwise intend to do so. Identify copies of hazard warning statements or other hazard information that you attach in Part III, List of Attachments.

Part II - HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE (Pages 8-10)

In sections A and B, you must provide information on manufacturing, processing, and use operations involving the new chemical substance or products containing the new substance. Preparing a chemical for an end use application typically involves several production steps, or operations, where potential human exposure and environmental release could occur. Use section A to provide information on operations that occur at industrial sites you control. Typically, this will involve manufacturing and processing operations. Use section B to describe operations that occur at industrial sites controlled by others. Typically, this will involve processing and end use applications, e.g., dyeing of nylon carpeting, paint spraying of automobiles.

For example, for a solvent used in automotive paint for automobile manufacture, there are solvent manufacture, paint manufacture, and industrial paint spraying operations. Paint manufacture may occur at a site you control or at a site you do not control. If paint manufacture occurs at a site you control, describe that operation in section A. If paint manufacture occurs at a site you do not control, describe that operation in section B. If processing or end use operations occur at industrial sites you control, they should be described in section A.

In most cases, you will have more specific information on sites you control than sites you do not control. If you do not have specific information on sites controlled by others, describe a typical operation involving the particular processing or end use application based on information available to you and on your experience with similar chemicals. Provide all information requested to the extent to which it is known to or reasonably ascertainable by you. Where EPA has available only limited information on worker exposure and environmental release, its evaluation will be based on reasonable worst case assumptions.

Note that if you are an importer, although you do not have to complete section A or B for operations outside the United States, you may still have to report information in these sections. If there are further industrial processing or use operations after import of the substance, you must describe these operations in section A or B as appropriate.

Section A - Industrial Sites Controlled by the Submitter

Complete a separate section A for each type of manufacturing, processing, or use operation involving the new chemical substance at sites you control. If the same operation is performed at more than one site, you are not required to complete a separate section A for each operation, but simply describe the typical operation common to these sites. However, if operations vary substantially among the different sites, you must provide a separate section A for each different type of operation.

1. Operation Description

   a. Identity - Identify the site which the section describes. If this section describes more than one site, provide additional site identities on a continuation sheet. Indicate the total number of sites at which the operation this section describes will occur. If you mark (X) the confidential box next to this item, all information in it will be treated as confidential.

   b. Type - Mark (X) the appropriate box.

   c. Amount and duration - Estimate the maximum amount of the new substance manufactured, processed, or used in the operation and the duration of the operation. Provide information per batch for batch operations and per day for continuous operations.

   d. Process description - Provide a diagram which describes the manufacturing, processing, or use operation involving the new chemical substance.

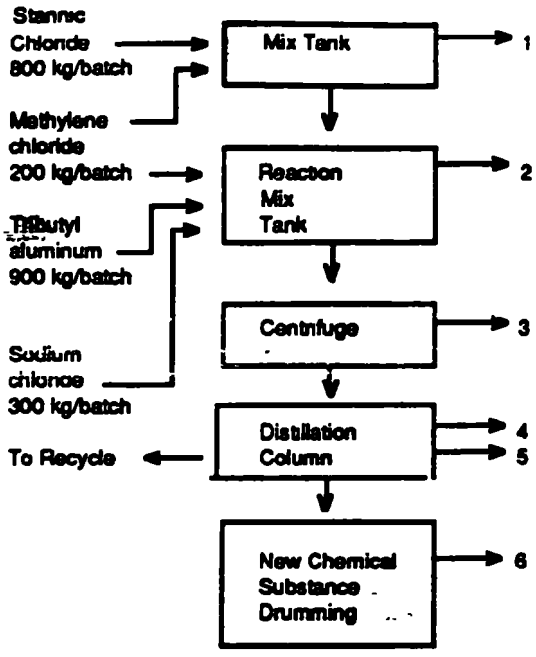
      (1) Identify the major unit operation steps and chemical conversions. "Unit operation" means a functional step in a manufacturing, processing, or use operation where substances undergo chemical changes and/or changes in location, temperature, pressure, physical state, or similar characteristics. Include steps in which the new substance is formulated into gels, mixtures, suspensions, solutions, etc.

      (2) Indicate in your diagram the entry point of all feedstocks (e.g., reactants, solvents, catalysts) used in the operation. Identify each feedstock and specify its approximate weight (by kg/day for continuous operations or kg/batch for batch operations).

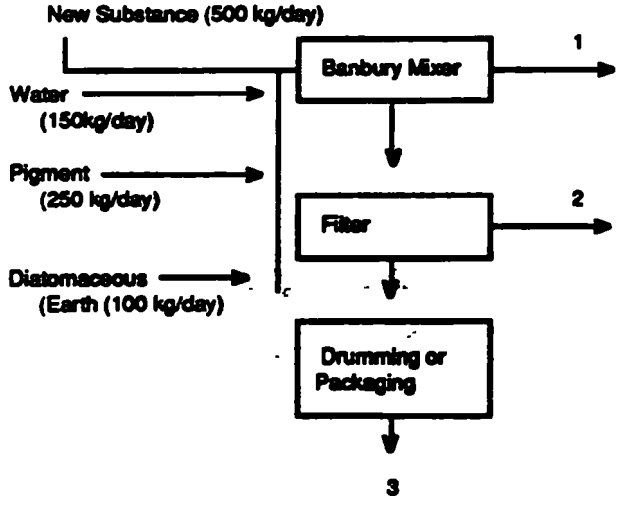
      (3) Number all points from which the new chemical substance and substances containing the new chemical substance will be released into air, land, or water. Do not include accidental releases or fugitive emissions. Mark the box if you wish to indicate your willingness to have your process description binding.

For example: -

SAMPLE MANUFACTURING OPERATION



SAMPLE PROCESSING OPERATION



2. Occupational Exposure

Column (1) - Describe each specific activity in the operation during which workers may be exposed to the new chemical substance. Such activities may include charging reactor vessels, sampling for quality control, transferring materials from one work area to another, drumming, bulk loading, changing filters, and cleaning equipment, etc.. Activities must be described even if workers wear protective equipment. (Material Safety Data Sheets indicating recommended protective equipment should be submitted as part of Hazard Information in part I, section C, subsection 3 of the notice form)

Column (2) - CBI claim for worker activity.

Column (3) - Provide information on the specific types of protective equipment and engineering controls that will be employed to protect the worker from potential exposure to the new chemical substance, i.e., gloves, goggles, 21c respirator, 19c respirator, closed containment system, nitrogen blanket, etc..

Column (4) - Binding option for protective equipment and engineering controls.

Column (5) - Indicate the physical form of the new substance at the time of exposure, e.g., solid (crystals, granules, powder, dust), liquid (solution, paste, slurry, emulsion, mist, spray), gas (vapor, fume), wet press cake, even if workers wear protective equipment.

Column (6) - Binding option for physical forms.

Column (7) - CBI claim for physical form.

Column (8) - Estimate the maximum number of workers involved in each specific activity, based on the estimated maximum 12-month production volume.

Column (9) - CBI claim.

Column (10) - Enter the maximum duration that any one worker will engage in the activity in hours/day, e.g., 8 hours/day.

Column (11) - Enter the maximum duration that any one worker will engage in the activity in days/year, e.g., 200 days/year, based on the estimated maximum production volume.

Column (12) - CBI claim.

Note that you must make separate confidentiality claims for the description of worker activity, physical form of the new substance, number of workers exposed, and duration of exposure. (See 2, 7, 9, 12).

3. Environmental Release and Disposal

Column (1) - For each release point indicated in the process description (Part II, Section A, subsection 1d(3) of the notice form, enter the corresponding number.

Column (2) - Estimate the amount of new chemical (in kg/day for continuous operations or kg/batch for batch operations) that will be released from the release point directly into either (a) the environment or (b) into control technology (in kg/day or kg/batch). Base your estimate on the expected maximum twelve month production volume.

Column (3) - CBI claim.

Column (4) - Enter the media (air, land, water) into which the release stream discharges (whether or not control technology is used).

Column (5) (a) For releases to the air and water, describe the type of technology used to control the release of the new chemical and the efficiency of the control technique. Examples of control technologies include carbon filter, scrubber and biological treatment (primary, secondary, etc.). Use the optional binding box to indicate your willingness to be bound to control technology described. (b) Enter the estimated amount released to the environment after control technology (in kg/day). Enter "none" if no control technology is used and the substance is released directly into the environment.

For disposal on land, describe the landfill site construction (including liners) and handling procedures. Describe landfill containers.

Column (6) - CBI claim.

Column (7) - Mark (X) the appropriate box and/or specify other destinations of water releases. (i.e., POTW (Publicly Owned Treatment Works), navigable waterway or specify other). Provide the name of the POTW receiving water releases and the NPDES (National Pollutant Discharge Elimination System) number for the POTW, navigable waterway or other direct discharger. This 9-digit number is assigned by EPA or the State under the authority of the Clean Water Act. When appropriate, contact your POTW to obtain their NPDES number.

Note that you must make separate confidentiality claims for the release number, amount of new chemical substance released, control technology disposal information, and the destination of the releases to water.

Section B - Industrial Sites Controlled by Others (Pg. 10)

Complete a separate Section B for each type of processing or use operation associated with each category of use specified in Part 1, Section C, subsection 2a at industrial sites you do not control. If the same operation is performed at more than one site, then describe the typical operation and enter the number of sites in the space provided.

Describe each typical processing or use operation to the maximum extent possible from information known to or reasonably ascertainable by you. Information may be provided as ranges or estimates.

1. Operation Description - Self-explanatory.

2. Worker Exposure/Environmental Release
   Column (1) - Provide the letter for each activity from the diagram above and complete columns 2-8 for each worker activity associated with the letter.

Column (2) - Estimate the maximum number of workers exposed to the new substance during the operation.

Column (3) - CBI claim.

Column (4) - Estimate the duration of exposure of the new chemical substance per worker in (a) hours per day and (b) days per year.

Column (5) - CBI claim.

Column (6) - Provide information on the protective equipment and engineering controls employed to safeguard the worker from potential exposure associated with the new chemical substance, i.e., gloves, goggles, respirators, etc..

Column (7) - Estimate the percent formulation of the new chemical substance in the product to which the worker is potentially exposed during the activity.

Column (8) - CBI claim.

Column (9) - Enter the number of release points in reference to the process diagram above and complete 9-13 for each release point identified.

Column (10) - Provide an estimate for the maximum amount of new chemical substance in kg per year that may be released to the workplace, air, water, or land under typical operating conditions. Provide this information for releases (a) directly to the environment or (b) into control technology to the environment in kg per day or kg per batch.

Column (11) - CBI claim.

Column (12) - Describe control technology which is used to limit the release of the new substance to the environment to the extent that the information is known to you.

Column (13) - CBI claim.

Column (14) - Identify all byproducts resulting from the reaction to the extent that the information is available to you.

Note that you must make separate confidentiality claims for the numbers of workers exposed, the duration of exposure, the percentage of the product in formulation, the amount of new substance released, and the control technology.

(OPTIONAL) POLLUTION PREVENTION AND RECYCLING INFORMATION (Page 11)

This page requests optional information that will be used in the evaluation of the new chemical substance and a comparison of the relative risks and benefits of the substance as a substitute for substances currently on the market. PMN submitters are encouraged to report any and all relevant information not reported elsewhere which is believed to be important to a thorough regulatory decision.

Part III - LIST OF ATTACHMENTS (Page 12)

Attach any continuation sheets for sections of the form, test data and other data (including structure-activity information), and optional information after the last page of the form. Clearly identify the attachment and the section to which it relates, if appropriate. Number consecutively the pages of the attachments. Enter the inclusive page numbers of each attachment. Enter the total number of pages in the notice on page 1 of the form.

Mark (X) the "Confidential" box next to any attachment name you claim as confidential. Read part I, section C.1 on page 2 of this manual for guidance on how to claim any information in an attachment as confidential. You must include with the sanitized copy of the notice a sanitized version of any attachment in which you claim information as confidential.

A worksheet which assists EPA's review of the physical/chemical property information you submit is provided on the last page of the form. Providing physical/chemical property information in this format is optional. However, physical/chemical properties data in your possession or control must be submitted with your notice. If you submit this worksheet, identify it on the List of Attachments.

II. SUPPLEMENTARY INFORMATION

A. Who Must Submit A Premanufacture Notice

If you intend to manufacture or import a new chemical substance for a commercial purpose, you must submit a premanufacture notice to EPA. You must submit a notice if you intend to import a new substance in bulk form or as part of a mixture, but not if you intend to import the substance only as part of an article.

Premanufacture notices for imported new chemical substances should be submitted by the principal importer. "Principal importer" is defined in §720.3(z) of the Premanufacture Notification Rule.

Generally, when you contract with another person to manufacture a new chemical substance, that person must submit the notice. However, if you request another person to manufacture a new chemical substance, and if you specify the identity and total amount of the substance to be manufactured and the basic technology and controls under which the substance will be produced, and if that person manufactures the substance exclusively for you, you must submit the notice. Information regarding human exposure and environmental release should be submitted in Part II, Section A, Industrial Sites Controlled by the Submitter. EPA recognizes that in this and similar instances, the other manufacturer may have information useful to the Agency's review of the new chemical. Therefore, EPA strongly encourages joint submission in these situations (see section E.2 below).

This manual does not discuss biotechnology submission information requirements for uses of microorganisms subject to the Toxic Substances Control Act (TSCA). For specific information on submitting notices for biotechnology products please contact the Program Development Branch (TS-794) (Biotechnology Program) of the Office of Toxic Substances.

For additional information on who must submit a notice, see §720.22 of the Rule or consult the Prenotice Coordinator.

B. Substances Which must Be Reported

1. **General** - You are responsible for determining whether a substance you intend to manufacture or import is a "new" chemical substance as defined by the Act and § 720.3 of the Rule. You must submit a premanufacture notice for any new chemical substance which is not on the TSCA inventory or otherwise excluded from notification, as discussed below.

2. **Bona fide request for a TSCA inventory search** - The specific identities of some chemical substances on the inventory are confidential and therefore do not appear on the inventory available to the public. Such substances are described by generic names in the Appendix to the inventory. If a substance you intend to manufacture or import is not on the published inventory but falls within one of the generic categories in the Appendix, you may request that EPA search the inventory's confidential file. EPA will search the confidential file only if you can demonstrate a bona fide intent to manufacture or import the substance. Section 720.25 of the Rule describes the procedure for demonstrating such a bona fide intent.

   After conducting its search, EPA will tell you if the substance is included on the inventory and therefore not subject to premanufacture notification or if you must submit a premanufacture notice.

C. Substances Excluded from Notification

1. **General** - Section 720.30 of the Rule excludes certain substances from premanufacture notification. These include mixtures, substances manufactured solely for use as pesticides, food, food additives, drugs, or cosmetics; tobacco and tobacco products; nuclear source materials; firearms and ammunition; impurities; byproducts which have no commercial use; non-isolated intermediates; new chemical substances manufactured solely for export; and substances as described in § 720.30(h)(3-7).

2. **Research and development (R&D) exemption** - R&D includes synthesis of new chemical substances or analysis, experimentation, or research on new or existing chemical substances, including product development activities. R&D may include tests of the physical, chemical, production, and performance characteristics of a substance.

   You do not have to submit a notice for a new substance manufactured or imported in small quantities solely for research and development as specified in § 720.36 of the Rule. "Small quantities" are those not greater than reasonably necessary for research and development purposes. The quantity which is reasonable may vary depending on the segments of the industry or the nature of the research and development activities. It is your responsibility to determine what is reasonable in your situation. You do not have to apply for this exemption. However, you must submit a premanufacture notice 90 days before you intend to manufacture the substance for a purpose other than research and development.

   To qualify for the exemption, your research and

development activities must be conducted under the supervision of a technically qualified individual. Persons who engage in R&D for, or obtain an R&D chemical from, a manufacturer must be notified of any risk to health which may be associated with the chemical. However, R&D conducted entirely in laboratories under prudent laboratory practices are exempted from the requirement for risk evaluation.

In accordance with 40 CFR 720.78, the following R&D records must be retained: information reviewed and evaluated to determine the need to make any notification of risk, documentation of the nature and method of risk notification, documentation of prudent lab practices used instead of risk notification and evaluation and, if an R&D substance is manufactured at greater than 100 kgs/yr, records regarding the chemical identity of the substance to the extent known, the production volume, and the disposition of the R&D chemical substance must also be retained.

Manufacturers and importers who distribute an R&D substance to other persons must provide those persons with written notification of known hazards and of the requirement that the substance be used solely for R&D. For additional information on R&D requirements see the New Chemical Information Bulletin: Exemptions for Research and Development and Test Marketing available from the Environmental Assistance Division (see Section II, Part G of this manual for addresses and telephone numbers).

3. **Test-marketing exemptions (TME)** - You may apply for an exemption from premanufacture notification if you plan to manufacture or import a new chemical substance for test-marketing. Test-marketing involves the distribution of a predetermined limited amount of a chemical substance, or of a mixture or article containing the chemical substance, to specified number of customers to explore market acceptability before general distribution.

To approve a test-marketing exemption application, the Agency must make an affirmative finding that the new chemical substance will not present an unreasonable risk to health or the environment during the test-marketing activities. Section 720.38 of the Rule identifies the type of information you should submit with a test-marketing exemption application. EPA must approve or deny the application within 45 days. If you do not provide sufficient information for EPA to make its determination within 45 days, the Agency will deny the request.

You should send applications for test-marketing exemptions to the OTS Document Control Officer (TS-790). You are not required but are encouraged to use the PMN form for a TME application.

4. **Section 5(h)(4) exemptions** - Under section 5(h)(4) of the Act, you may apply to EPA for an exemption from some or all premanufacture notification requirements. EPA may grant an exemption if it makes an affirmative finding that the manufacture, processing, distribution in commerce, use, or disposal of the new substance will not present an unreasonable risk to health or the environment. Unlike other exemptions, such as test marketing, EPA may only grant a section 5(h)(4) exemption by rule. In the rulemaking proceeding, the applicant should provide information sufficient to show that the chemical substance will not present an unreasonable risk to health or the environment. You should send applications for section 5(h)(4) exemptions to the OTS Document Control Officer (TS-790). The following 5(h)(4) exemptions have been promulgated:

a. **Low Volume Exemption (LVE)** - Requirements for a LVE application are found at 40 CFR 723.50. This exemption is available for substances manufactured in quantities of 1,000 kg or less per year. Only one exemption is available per substance regardless of potential manufacturers. Low volume substances are not added to the TSCA inventory; however, a separate inventory of LVEs granted is maintained. The manufacturer must submit a low volume exemption (LVE) notice to EPA at least 21 days prior to manufacturing the substance. The notice must include the site of manufacture and proposed use of the new chemical substance which are legally binding upon the company. The manufacturer may also provide information on exposure controls. If provided, any controls specified in the notice are binding throughout the period of the exemption. EPA will grant the LVE if it determines that the substance will not present an unreasonable risk of injury.

Companies must submit a new exemption notice before they change the site of manufacture or application. Manufacturers (importers) must notify processors and industrial users that the substance can be used only for the uses specified in the exemption notice. Manufacturers must also notify processors and users of any exposure controls.

Under this exemption, submitters must maintain records for five years concerning the annual production volume of the new substance, documentation of information provided in the exemption notice, and compliance with the terms of this section. See Section II (I).

b. Polymer Exemption - Requirements for a Polymer Exemption can be found at 40 CFR 723.250. This exemption is available for certain classes of polymers which are not chemically active or bioavailable. The manufacturer must submit a polymer exemption notice to EPA for a 21-day review. EPA will grant the exemption if it determines that the substance will not present an unreasonable risk of injury. Unlike the other exemptions, substances subject to Polymer Exemptions are added to the Inventory and a Notice of Commencement must be submitted when commercial production commences.

Manufacturers must specify residual amounts of monomers in a polymer and are bound to those quantities. If the residual levels exceed the specified limits, a manufacturer must either submit another exemption or a PMN. The simultaneous submission of a polymer exemption and a PMN is acceptable. However, separate notices and user fees must be submitted for each type of notice.

The polymer exemption also retains a five year recordkeeping requirement. See section II (I).

D. When to Submit a Notice

You must submit a premanufacture notice at least 90 days before you begin to manufacture or import a new chemical substance for a commercial purpose.

E. Consolidated Notices

If you are manufacturing two or more structurally similar new substances, you may contact the prenotice coordinator (see section G.1.b. below) to obtain approval to submit a single consolidated notice. A consolidated notice is suitable for chemical substances of similar structure with the same or similar uses and which share similar test data and other information. A consolidated notice must identify each new substance individually; you may not submit a consolidated notice for an open-ended category. A separate chemical identity page must be provided for each substance. A distinct Agency "PMN" number is assigned to each chemical. You may not submit a consolidated notice for a series of intermediates and a final product because they do not share common uses, test data, and other information. EPA encourages you to submit consolidated notices when appropriate. However, you may not submit a consolidated notice unless you have received prior approval from the prenotice coordinator. Remember to enter your prenotice communications number in Part I, Section A (3) (page 3) of the form.

F. Submission of Information by Others

1. Submission by an agent - You may designate an agent to submit a premanufacture notice for you. Both you and the agent must sign the certification on the form. You are responsible for ensuring that all information known or reasonably ascertainable by you and all test data in your possession or control are submitted to EPA. For information on submissions by agents, see § 720.40(e) of the Rule.

2. Joint submissions - You may also prepare and submit a premanufacture notice with another person. A joint submission may be useful where different persons have information required in the notice. For example, you may have information on the identity and the physical and chemical properties of the new substance and another person may know its manufacturing process and its intended use. A joint submission may also be useful when another person has information fundamental to the notice, but wishes to keep it confidential.

Each joint submitter must use a notice form and sign the certification on the form. Each person must also assert all confidentiality claims as described in § 720.80 of the Rule and Part I of this manual. However, you are not relieved of statutory notice requirements by arranging a joint submission. You are required to complete all mandatory sections of the form to the extent that you know or can reasonably ascertain the information, even if another person also submits information for a certain section. If you submit a joint notice, the review period will not begin until EPA has received all required parts of the notice. You should identify the joint submitter in your notice and identify the section(s) which the person is submitting. See § 720.40(e) for additional information on joint submissions.

G. Consultation with EPA Concerning the Premanufacture Notice

1. Before notice submission

a. General inquiries - General inquiries concerning the premanufacture notification program which are not related to a specific chemical or notice should be directed to the Environmental Assistance Division. Copies of the Rule, Instructions Manual, notice form, and other materials relating to the Rule are available from this office. (These materials are also available at EPA regional offices.) Persons may contact this office in Washington at 202-554-1404. Written inquiries may be sent to:

Director, Environmental Assistance Division
Office of Toxic Substances, TS-799
U.S. E.P.A.
401 M Street, S.W.
Washington, D.C. 20460

b. Specific inquiries - Specific inquiries concerning the Rule, confidentiality, joint submissions, consolidated notices, etc., should

be directed to the Prenotice Coordinator. Persons may contact the Prenotice Coordinator by telephone (202) 382-3745. Written inquiries may be sent to:

Prenotice Coordinator
Chemical Control Division
Office of Toxic Substances, TS-794
U.S. E.P.A.
401 M Street, S.W.
Washington, D.C. 20460

2. During notice review - The notice review period begins upon receipt of the notice by the OTS Document Control Officer if your notice is determined to be "complete". However, you will receive written notification if your notice is declared "incomplete" as described at 40 CFR 720.65. If your notice is complete, you will receive an acknowledgement letter telling you your notice number and the date of expiration of the review period. The inventory is searched to ensure that the substance for which the notice is submitted is not already included on the TSCA Chemical Substance Inventory. If your chemical substance is on the inventory, you will be notified that your substance is not subject to premanufacture notification, and therefore you are free to begin manufacture immediately. If the substance is not on the inventory, a Program Manager is assigned to coordinate the review of the notice and to be your official contact with the Agency throughout the review period. During the review period, the Program Manager may contact you for clarification of information you have provided in the notice or if the Agency identifies issues of concern. If you are not contacted prior to the expiration of the review period, you are free to commence manufacture of the substance identified in your notice after the review period has expired.

The Program Manager will also notify you before the review period expires if he/she will extend the review period under TSCA section 5(c) or if regulatory action is being considered on the new substance under TSCA section 5(e) or 5(f). 5(e) Consent Orders are typically issued with a follow-up SNUR subsequently promulgated. In addition, a Program Manager will contact you if the Agency plans to develop a non-5(e) SNUR (a case in which a 5(e) Consent Order does not precede the development of a SNUR) on the chemical substance identified in your notice.

H. Notice of Commencement (NOC) of Manufacture (or Import)

If EPA has not taken any action to regulate the new chemical substance during the review period, you may begin manufacturing the new chemical substance upon expiration of the review period. EPA requires that you notify the Agency by letter no later than 30 calendar days, after the first day of such manufacture or import.

Your notice of commencement of manufacture should be sent to the OTS Document Control Officer (TS-790). In your letter, you must provide the specific chemical identity of the substance, its premanufacture notice number, and the date when manufacture or import began. You must also substantiate a confidentiality claim for chemical identity in your letter if you want EPA to maintain the claim after you begin manufacture or import. See 40 CFR 720.85(b) for further information on substantiating confidentiality claims.

If you have submitted a NOC and you wish to be advised of the TSCA Chemical Substance Inventory name for the substance identified in the NOC and the Chemical Abstract Service (CAS) number (for non-confidentially listed substances) "or" Accession number (a 5 digit number generated to identify confidentially listed substances), you should send a separate letter to the OTS Document Control Officer (TS-790); Attention: Chemical Inventory Section.

I. Recordkeeping

Section 720.78 of the Premanufacture Notification Rule requires that you retain documentation of information in the premanufacture notice for five years from the date of commencement of manufacture. The records you must retain include (1) information supporting the information supplied on the notice form, (2) other data, as defined in § 720.50 (b) of the Rule, in your possession or control, (3) production volume for the first three years of production or import, and documentation of production volume, and (4) date of commencement of manufacture, and documentation of this date. For example, if you performed a market analysis to estimate maximum production volume as reported on the notice form, you would retain this analysis, even though production volume and market share may change. If you have performed a chemical analysis to determine what byproducts may result from operations at sites you control, you would retain that analysis. You are not required to develop information solely for recordkeeping purposes, but only to retain information you have obtained or developed in the course of completing your submission.

If you manufacture a new chemical substance under the exemption for substances manufactured solely for research and development, you must retain documentation of compliance with the exemption for five years from the final date of manufacture or import under the exemption. If you manufacture under a test-marketing exemption under TSCA, you must retain documentation of information in the application and documentation of your compliance with any restrictions imposed by EPA when it granted the application. You must retain this information for five years from the final date of manufacture or import under the exemption.

A manufacturer of a polymer under the terms of the polymer exemption at 40 CFR 723.250 must maintain records for five years from the date of commencement of manufacture for: the production volume for the first three years of manufacture, the date of commencement of manufacture, documentation of the information provided above, documentation of any other information provided in the notice such as, information that demonstrates that the new polymer is not specifically excluded from the exemption and the polymer meets the exemption criteria.

Each manufacturer of a new substance reported under the terms of a low volume exemption at 40 CFR 723.50 must maintain records of 1) the annual production volume of the new chemical substance under the exemption, and 2) documentation of information in the exemption notice in compliance with the terms of the exemption. Records must be retained for five years after date of their preparation.

APPENDIX A

EXAMPLES OF TEST DATA

Following is a list of the types of test data which you must attach to the notice form if it is in your possession or control. This list is illustrative, not exhaustive.

Physical and Chemical Properties and Environmental Fate Data

Chromatograms
Spectra (ultraviolet, visible, infrared)
Density/relative density
Solubility in water
Melting temperature
Boiling/sublimation temperature
Softening point
Vapor pressure
Dissociation constant
Particle size distribution
Octanol/water partition coefficient
Henry's law constant
Volatilization from water
Volatilization from soil
pH
Flammability
Explodability
Adsorption/desorption characteristics
Photochemical degradation
Viscosity
Odor
Hydrolysis
Thermal analysis
Chemical analysis
Chemical oxidation
Chemical reduction
Biodegradation
Transformation to persistent or toxic products

Health Effects Data

Mutagenicity
Carcinogenicity
Teratogenicity
Neurotoxicity/ behavioral effects
Pharmacological effects
Mammalian absorption
Distribution
Metabolism and excretion
Cumulative, additive and synergistic effects
Acute, subchronic and chronic effects
Structure/activity relationships
Epidemiology
Reproductive effects
Clinical studies
Dermatoxicity
Phototoxicity
Irritation
Sensitization
Allergy
Skin staining

Environmental Effects Data

Microbial bioassay
Algal bioassay
Aquatic macrophyte bioassay
Seed germination and root elongation
Seedling growth inhibition
Plant uptake
Acute toxicity to invertebrates
Life cycle test on invertebrates
Acute toxicity to fish
Early life stage (fish)
Avian dietary/ reproduction
Bioaccumulation/ bioconcentration
Model ecosystem studies.
Physical environment impairment effects
Flesh staining of aquatic organisms

Form Approved. O.M.B. No. 2070-0012. Approval Expires 1-31-94.

U. S. ENVIRONMENTAL PROTECTION AGENCY

PREMANUFACTURE NOTICE

FOR NEW CHEMICAL SUBSTANCES

AGENCY USE ONLY

Date of receipt

When completed send this [illegible] form to:

DOCUMENT CONTROL OFFICER
OFFICE OF TOXIC SUBSTANCES, TS-790
U.S. E.P.A.
401 M STREET, SW
WASHINGTON, D.C. 20460

Enter the total number of pages in the Premanufacture Notice

Document control number

EPA case number

TS- ☐☐☐☐☐☐

GENERAL INSTRUCTIONS

- You must provide all information requested in this form to the extent that it is known to or reasonably ascertainable by you. Make reasonable estimates if you do not have actual data.
- Before you complete this form, you should read the "Instructions Manual for Premanufacture Notification" (Instructions Manual).
- If a user fee has been remitted for this notice (40 CFR 700.45), indicate in the TS boxes above the TS-user fee identification number you have generated. Remember, your user fee ID number must also appear on your corresponding fee remittance.

Part I – GENERAL INFORMATION

You must provide the chemical identity of the new chemical substance, even if you claim the identity as confidential. You may authorize another person to submit the identity for you, but your submission will not be complete and review will not begin until EPA receives this information. A letter of support from another person should reference your TS user fee identification number.

Part II – HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE

You may need additional copies of part II, sections A and B if there are several manufacture, processing, or use operations that you will describe in the notice. You should reproduce these sections as needed.

Part III – LIST OF ATTACHMENTS

You should attach additional sheets if you do not have enough space on the form to answer a question fully. Label each continuation sheet with the corresponding section heading. In part III, list these attachments, any test data or other data and any optional information that you include in the notice.

OPTIONAL INFORMATION

You may include in the notice any information that you want EPA to consider in evaluating the new substance. The Instructions Manual identifies categories of optional information that you may want EPA to review. On page 11 of this form, space has been provided for you to describe pollution prevention and recycling information you may have regarding the new substance.

Binding Options: In order to effectively implement risk management options, EPA may wish to exercise its authority under section 5(e) to make certain statements in your notice such as use, production volume, protective equipment and/or process description legally binding and enforceable. If you wish to initiate such discussions with the EPA, precisely describe those aspects in this notice deliberately designed to protect against unreasonable risk to human health or the environment and indicate your willingness to be bound to the appropriate statements by marking (X) in the boxes provided. Should the Agency wish to pursue this option, you will be contacted by an EPA staff person.

CONFIDENTIALITY CLAIMS

You may claim any information in this notice as confidential. To assert a claim on the form, mark (X) the confidential box next to the information that you claim as confidential. To assert a claim in an attachment, circle or bracket the information you claim as confidential. If you claim information in the notice as confidential, you must provide a sanitized version of the notice, including attachments, to EPA with your submission. For additional instructions on claiming information as confidential, read the Instructions Manual.

☐ Mark (X) if any information in this notice is claimed as confidential.

TEST DATA AND OTHER DATA

You are required to submit all test data in your possession or control and to provide a description of all other data known to or reasonably ascertainable by you if these data are related to the health and environmental effects of the manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance. Standard literature citations may be submitted for data in the open scientific literature. Complete test data (written in English), not summaries of data, must be submitted if they do not appear in the open literature. Following are examples of test data and other data. You should submit these data according to the requirements of §720.50 of the Premanufacture Notification Rule (40 CFR Part 720).

Test Data (See Appendix A of the Instructions Manual and the Physical and Chemical Properties Worksheet on the last page of this form for examples of data to be submitted).

- Environmental fate data ☐ Yes ☐ No
- Health effects data ☐ Yes ☐ No
- Environmental effects data ☐ Yes ☐ No
- Physical/Chemical Properties ☐ Yes ☐ No

Other data ☐ Yes ☐ No
- Risk assessments
- Structure/activity relationships
- Test data not in the possession or control of the submitter

TYPE OF NOTICE (Check Only One)

☐ PMN

☐ CONSOLIDATED PMN - # OF CHEMICALS _____
(Premotice Communication # required, enter # on page 3)

☐ SNUN (Significant New Use Notice)

☐ INTERMEDIATE PMN - AS DEFINED AT 40 CFR 700.43

☐ TMEA (Test Marketing Exemption)

☐ LVE (Low Volume Exemption)

☐ POLYMER EXEMPTION - ☐ e(1) or ☐ e(2)

☐ OTHER EXEMPTION - SPECIFY

_____

Public reporting burden for this collection of information is estimated to average 110 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223; U.S. Environmental Protection Agency, 401 M. St., S.W.,, Washington, D.C. 20460; and to the Office Management and Budget, Paperwork Reduction Act (2070-0012), Washington, D.C. 20503.

CERTIFICATION

I certify that to the best of my knowledge and belief:

1. The company named in Part I, section A, subsection 1a of this notice form intends to manufacture or import for a commercial purpose, other than in small quantities solely for research and development, the substance identified in Part I, Section B.

2. All information provided in this notice is complete and truthful as of the date of submission.

3. I am submitting with this notice all test data in my possession or control and a description of all other data known to or reasonably ascertainable by me as required by §720.50 of the Premanufacture Notification Rule.

Additional Certification Statements:

If you are submitting a PMN, (including a polymer exemption notice in accordance with 40 CFR 723.250), Intermediate PMN, Consolidated PMN, or SNUN, check the following user fee certification statement that applies:

☐ The Company named in Part I, Section A has remitted the fee specified in 40 CFR 700.45 (b), or

☐ The Company named in Part I, Section A is a small business concern under 40 CFR 700.43 and has remitted a fee of $100 in accordance with 40 CFR 700.45 (b).

If you are submitting a **polymer exemption** notice in accordance with 40 CFR 723.250, check the following:

☐ The new chemical substance meets the definition of polymer, is not specifically excluded from the exemption, and meets the conditions of the exemption.

If you are submitting a **low volume exemption** application in accordance with 40 CFR 723.50, check the following certification statements:

☐ The manufacturer submitting this notice intends to manufacture or import the new chemical substance for commercial purposes, other than in small quantities solely for research and development, under the terms of 40 CFR 723.50.

☐ The manufacturer is familiar with the terms of this section and will comply with those terms; and

☐ The new chemical substance for which the notice is submitted meets all applicable exemption conditions.

The accuracy of the statements you make in this notice should reflect your best prediction of the anticipated facts regarding the chemical substance described herein. Any knowing and willful misinterpretation is subject to criminal penalty pursuant to 18 USC 1001.

Signature and title of Authorized Official (Original Signature Required)	Date	Confidential
Signature of agent - (if applicable)	**Date**	

Part I – GENERAL INFORMATION

Section A – SUBMITTER IDENTIFICATION

Mark (X) the "Confidential" box next to any subsection you claim as confidential.

Confidential

Person Submitting Notice (in U.S.)

Name of authorized official | Title

Company

Mailing address (number and street)

City, State, ZIP Code

b. Agent (if applicable)

Name of authorized official | Title

Company

Mailing address (number and street)

City, State, ZIP Code | Telephone: Area Code | Number

c. If you are submitting this notice as part of a joint submission, mark (X) this box. → ☐

Joint Submitter (if applicable)

Name of authorized official | Title

Company

Mailing address (number and street)

City, State, ZIP Code | Telephone: Area Code | Number

2. Technical Contact (in U.S.)

Name | Title

Company

Mailing address (number and street)

City, State, ZIP Code | Telephone: Area Code | Number

3. If you have had a prenotice communication (PC) concerning this notice and EPA assigned a PC Number to the notice, enter the number. →

Mark (X) if none → ☐

4. If you have submitted an exemption notice/application for the chemical substance covered by this notice, enter the exemption number assigned by EPA. If you have withdrawn a previously submitted PMN enter the PMN number. →

Mark (X) if none → ☐

5. If you have submitted a bona fide request for the chemical substance covered by this notice, enter the bona fide request number assigned by EPA. →

Mark (X) if none → ☐

Type of Notice – Mark (X)

1. ☐ Manufacture Only ☐ Binding Option Mark (x)

2. ☐ Import Only ☐ Binding Option Mark (x)

3. ☐ Both

Part I – GENERAL INFORMATION – Continued

Section B – CHEMICAL IDENTITY INFORMATION

Mark (X) the "Confidential" box next to any item you claim as confidential.

Complete either item 1 (Class 1 or 2 substances) or 2 (Polymers) as appropriate. Complete all other items.

If another person will submit chemical identity information for you (for either item 1 or 2), mark (X) the box at the right. → ☐ Identify the name, company, and address of that person in a continuation sheet.

Confi-dential

1. Class 1 or 2 chemical substances (for definitions of class 1 and class 2 substances, see the Instructions Manual)

a. Class of substance – Mark (X) 1 ☐ Class 1 or 2 ☐ Class 2

b. Chemical name (preferably CAS or IUPAC nomenclature)

c. Molecular formula and CAS Registry Number (if known)

CAS #

d. For a class 1 substance, provide a structural diagram. For a class 2 substance – (1) List the immediate precursor substances with their respective CAS Registry Numbers. (2) Describe the nature of the reaction or process. (3) Indicate the range of composition and the typical composition (where appropriate). (4) Provide a representative structural diagram (if possible).

☐ Mark (X) this box if you attach a continuation sheet.

Part I – GENERAL INFORMATION – Continued

Section B – CHEMICAL IDENTITY INFORMATION – Continued

Polymers (For a definition of polymer, see the Instructions Manual.)

Confi-dential

a. Indicate the number-average weight of the lowest molecular weight composition of the polymer you intend to manufacture. Indicate maximum weight percent of low molecular weight species (not including residual monomers, reactants, or solvents) below 500 and below 1,000 absolute molecular weight of that composition. Describe the methods of measurement or the bases for your estimates. GPC ☐ Other ☐ (Specify) _____

- lowest number average molecular weight:
- maximum weight % below 500 molecular weight:
- maximum weight % below 1000 molecular weight:

☐ Mark (X) this box if you attach a continuation sheet.

b. You must make separate confidentiality claims for monomer or other reactant identity, composition information, and residual information. Mark (X) the "Confidential" box next to any item you claim as confidential.
(1) – Provide the chemical name and CAS Registry Number of each monomer or other reactant used in the manufacture of the polymer.
(2) – Mark (X) this column if entry in column (1) is confidential.
(3) – Indicate the typical weight percent of each monomer or other reactant in the polymer.
(4) – Mark (X) the identity column if you want a monomer or other reactant used at two weight percent or less to be listed as part of the polymer description on the TSCA Chemical Substance Inventory.
(5) – Mark (X) this column if entries in columns (3) and (4) are confidential.
(6) – Indicate the maximum weight percent of each monomer or other reactant that may be present as a residual in the polymer as manufactured for commercial purposes.
(7) – Mark (X) this column if entry in column (6) is confidential.

Monomer or other reactant and CAS Registry Number (1)	Confi-dential (2)	Typical composition (3)	Identity Mark (X) (4)	Confi-dential (5)	Maximum residual (6)	Confi-dential (7)
		%			%	
		%			%	
		%			%	
		%			%	
		%			%	
		%			%	
		%			%	

☐ Mark (X) this box if you attach a continuation sheet.

c. Provide a representative structural diagram of the polymer, if possible.

☐ Mark (X) this box if you attach a continuation sheet.

Part I – GENERAL INFORMATION – Continued

Section B – CHEMICAL IDENTITY INFORMATION – Continued

3. Impurities
(a) – Identify each impurity that may be reasonably anticipated to be present in the chemical substance as manufactured for commercial purposes. Provide the CAS Registry Number if available. If there are unidentified impurities, enter "unidentified."
(b) – Estimate the maximum weight % of each impurity. If there are unidentified impurities, estimate their total weight %.

Impurity and CAS Registry Number (a)	Maximum percent (b)	Confidential
	%	
	%	
	%	
	%	
	%	
	%	
	%	

☐ Mark (X) this box if you attach a continuation sheet.

4. Synonyms – Enter any synonyms for the new chemical substance identified in subsection 1 or 2. Confidential

☐ Mark (X) this box if you attach a continuation sheet.

5. Trade identification – List trade names for the new chemical substance identified in subsection 1 or 2.

☐ Mark (X) this box if you attach a continuation sheet.

6. Generic chemical name – If you claim chemical identity is confidential, you must provide a generic chemical name for your substance that reveals the specific chemical identity of the new chemical substance to the maximum extent possible. Refer to the TSCA Chemical Substance Inventory, 1985 Addition, Appendix B for guidance on developing generic names.

☐ Mark (X) this box if you attach a continuation sheet.

7. Byproducts – Describe any byproducts resulting from the manufacture, processing, use, or disposal of the new chemical substance at sites you control. Provide the CAS Registry Number if available.

Byproduct (1)	CAS Registry Number (2)	Confidential

☐ Mark (X) this box if you attach a continuation sheet.

Part I – GENERAL INFORMATION – Continued

Section C – PRODUCTION, IMPORT, AND USE INFORMATION

Mark (X) the "Confidential" box next to any item you claim as confidential.

1. Production volume – Estimate the maximum production volume during the first 12 months of production. Also estimate the maximum production volume for any consecutive 12-month period during the first three years of production.

Maximum first 12-month production (kg/yr)	Maximum 12-month production (kg/yr)	Confidential	Binding Option Mark (x)

2. Use Information – You must make separate confidentiality claims for the description of the category of use, the percent of production volume devoted to each category, the formulation of the new substance, and other use information. Mark (X) the "Confidential" Box next to any item you claim as confidential.

a. (1) – Describe each intended category of use of the new chemical substance by function and application.
(2) – Mark (X) this column if entry in column (1) is confidential business information (CBI).
(3) – Indicate your willingness to have the information provided in column (1) binding.
(4) – Estimate the percent of total production for the first three years devoted to each category of use.
(5) – Mark (X) this column if entry in column (4) is confidential business information (CBI).
(6) – Estimate the percent of the new substance as formulated in mixtures, suspensions, emulsions, solutions, or gels as manufactured for commercial purposes at sites under your control associated with each category of use.
(7) – Mark (X) this column if entry in column (6) is confidential business information (CBI).
(8) – Mark (X) whether the use is site-limited, industrial, commercial and/or consumer. Mark more than one box if appropriate. Mark (X) to indicate your willingness to have the information provided in (8) binding.
(9) – Mark (X) this column if entry(ies) in column (8) is (are) confidential business information (CBI).

Category of use (1)	CBI (2)	Binding Option Mark (x) (3)	Production % (4)	CBI (5)	% in Formulation (6)	CBI (7)	Mark (X) appropriate column(s) (8) Site-limited	Consumer*	Industrial	Commercial	Binding Option	CBI (9)
			%		%							
			%		%							
			%		%							
			%		%							
			%		%							

*If you have identified a "consumer" use, please provide on a continuation sheet a detailed description of the use(s) of this chemical substance in consumer products. In addition include estimates of the concentration of the new chemical substance as expected in consumer products and describe the chemical reactions by which this substance loses its identity in the consumer product.

☐ Mark (X) this box if you attach a continuation sheet.

b. Generic use description — If you claim any category of use description in subsection 2a as confidential, enter a generic description of that category. Read the Instructions Manual for examples of generic use descriptions.

☐ Mark (X) this box if you attach a continuation sheet.

3. Hazard Information – Include in the notice a copy of reasonable facsimile of any hazard warning statement, label, material safety data sheet, or other information which will be provided to any person who is reasonably likely to be exposed to this substance regarding protective equipment or practices for the safe handling, transport, use, or disposal of the new substance. List in part III hazard information you include.

Binding Option Mark (x)

☐ Mark (X) this box if you attach hazard information.

Part II – HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE

Section A – INDUSTRIAL SITES CONTROLLED BY THE SUBMITTER

Complete section A for each type of manufacture, processing, or use operation involving the new chemical substance at industrial sites you control.

Mark (X) the "Confidential" box next to any item you claim as confidential.

1. Operation description

a. Identity – Enter the identity of the site at which the operation will occur.

Confidential

Name

Site address (number and street)

City, County, State, ZIP Code

If the same operation will occur at more than one site, enter the number of sites. Identify the additional sites on a continuation sheet. →

☐ Mark (X) this box if you attach a continuation sheet.

b. Type – Mark (X) ☐ Manufacturing ☐ Processing ☐ Use

c. Amount and Duration – Complete 1 or 2 as appropriate

1. Batch	Maximum kg/batch	Hours/batch	Batches/year
2. Continuous	Maximum kg/day	Hours/day	Days/year

d. Process description ☐ Mark (X) to indicate your willingness to have your process description binding.

(1) Diagram the major unit operation steps and chemical conversions.
(2) Provide the identity, the approximate weight (by kg/day or kg/batch), and entry point of all feedstocks (including reactants, solvents, and catalysts, etc.).
(3) Identify by number the points of release to the environment of the new chemical substance.

☐ Mark (X) this box if you attach a continuation sheet.

Part II – HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE – Continued

Section A – INDUSTRIAL SITES CONTROLLED BY THE SUBMITTER – Continued

Occupational Exposure – You must make separate confidentiality claims for the description of worker activity, physical form of the new chemical substance, number of workers exposed, and duration of activity. Mark (X) the "Confidential" box next to any item you claim as confidential.

(1) – Describe the activities in which workers may be exposed to the new chemical substance.
(2) – Mark (X) this column if entry in column (1) is confidential business information (CBI).
(3) – Describe any protective equipment and engineering controls used to protect workers.
(4) and (6) – Indicate you willingness to have the information provided in column (3) or (5) binding.
(5) – Indicate the physical form(s) of the new chemical substance at the time of exposure.
(7) – Mark (X) this column if entry in column (5) is confidential business information (CBI).
(8) – Estimate the maximum number of workers involved in each activity.
(9) – Mark (X) this column if entry in column (8) is confidential business information (CBI).
(10) and (11) – Estimate the maximum duration of the activity for any worker in hours per day and days per year.
(12) – Mark (X) this column if entries in columns (10) and (11) are confidential business information (CBI).

Worker activity (1)	CBI (2)	Protective Equipment/ Engineering Controls (3)	Binding Option Mark (x) (4)	Physical form(s) (5)	Binding Option Mark (x) (6)	CBI (7)	# of Workers Exposed (8)	CBI (9)	Maximum duration		CBI (12)
									Hrs/day (10)	Days/yr (11)	

☐ Mark (X) this box if you attach a continuation sheet.

3. **Environmental Release and Disposal** – You must make separate confidentiality claims for the release number and the amount of the new chemical substance released and other release and disposal information. Mark (X) the "Confidential" box next to each item you claim as confidential.

(1) – Enter the number of each release point identified in the process description, part II, section A, subsection 1d(3).
(2) – Estimate the amount of the new substance released (a) directly to the environment or (b) into control technology (in kg/day or kg/batch).
(3) – Mark (X) this column if entries in columns (1) and (2) are confidential business information (CBI).
(4) – Identify the media (air, land, or water) to which the new substance will be released from that release point.
(5) – a. Describe control technology, if any, and control efficiency that will be used to limit the release of the new substance to the environment. For releases disposed of on land, characterize the disposal method and state whether it is approved for disposal of RCRA hazardous waste. On a continuation sheet, for each site describe any additional disposal methods that will be used and whether the waste is subject to secondary or tertiary on-site treatment. b. Estimate the amount released to the environment after control technology (in kg/day).
(6) – Mark (X) this column if entries in columns (4) and (5) are confidential business information (CBI).
(7) – Identify the destination(s) of releases to water. Please supply NPDES (National Pollutant Discharge Elimination System) numbers for direct dischargers or NPDES numbers of the POTW (Publicly Owned Treatment Works). Mark (X) if the POTW name or NPDES # is confidential business information (CBI).

Release Number (1)	Amount of new substance released (2a)	(2b)	CBI (3)	Media of release (4)	Control technology and efficiency (5a)	Binding Mark (x)	(5b)	CBI (6)

7) Mark (X) the destination(s) of releases to water.	☐ POTW provide name(s) below: _____	CBI	☐ Navigable waterway	☐ Other - Specify	NPDES #	CBI

☐ Mark (X) this box if you attach a continuation sheet.

Part II – HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE – Continued

Section B – INDUSTRIAL SITES CONTROLLED BY OTHERS

Complete section B for typical processing or use operations involving the new chemical substance at sites you do not control. Complete a separate section B for each type of processing, or use operation involving the new chemical substance. If the same operation is performed at more than one site describe the typical operation common to these sites and enter the number of sites _____. Identify additional sites on a continuation sheet.

1. Operation Description - To claim information in this section as confidential, circle or bracket the specific information that you claim as confidential.
(1) – Diagram the major unit operation steps and chemical conversions. On the diagram, identify by letter and briefly describe each worker activity.
(2) – Provide the identity, the approximate weight (by kg/day or kg/batch), and entry point of all feedstocks (including reactants, solvents, and catalysts, etc). (3) – Identify by number the points of release to the environment of the new chemical substance.

☐ Mark (X) this box if you attach a continuation sheet.

2. Worker Exposure/Environmental Release
(1) – From the diagram above, provide the letter for each worker activity. Complete 2-8 for each worker activity described.
(2) – Estimate the number of workers exposed.
(4) – Estimate the typical duration of exposure per worker in (a) hours per day and (b) days per year.
(6) – Describe any protective equipment and engineering controls, if any, used to protect workers.
(7) – Estimate the percent of the new substance as formulated when packaged or used as a final product.
(9) – From the process diagram above, enter the number of each release point. Complete 9-13 for each release point identified.
(10) – Estimate the amount of the new substance released (a) directly to the environment or (b) into control technology to the environment (in kg/day or kg/batch).
(12) – Describe control technology, if any, that will be used to limit the release of the new substance to the environment.
(14) – Identify byproducts which may result from the operation.
(3), (5), (8), (11), (13) and (15) - Mark (X) this column if any of the preceding entries are confidential business information (CBI).

Letter of Activity (1)	# of Workers Exposed (2)	CBI (3)	Duration of Exposure (4a)	Duration of Exposure (4b)	CBI (5)	Protective Equip./ Engineering Controls (6)	% in Formulation (7)	CBI (8)	Release Number (9)	Amount of New Substance Released (10a)	Amount of New Substance Released (10b)	CBI (11)	Control Technology (12)	CBI (13)

(14) – Byproducts:

☐ Mark (X) this box if you attach a continuation sheet.

OPTIONAL POLLUTION PREVENTION INFORMATION

To claim information in this section as confidential circle or bracket the specific information that you claim as confidential.

In this section you may provide information not reported elsewhere in this form regarding your efforts to reduce or minimize potential risks associated with activities surrounding manufacturing, processing, use and disposal of the PMN substance. Please include new information pertinent to pollution prevention, including source reduction, recycling activities and safer processes or products available due to the new chemical substance. Source reduction includes the reduction in the amount or toxicity of chemical wastes by technological modification, process and procedure modification, product reformulation, raw materials substitution, and/or inventory control. Recycling refers to the reclamation of useful chemical components from wastes that would otherwise be treated or released as air emissions or water discharges, or land disposal. Descriptions of pollution prevention, source reduction and recycling should emphasize potential risk reduction subsequent to compliance with existing regulatory requirements and can be either quantitative or qualitative. The EPA is interested in this information to assess overall net reductions in toxicity or environmental releases and exposures, not the shifting of risks to other environmental media or non-environmental areas (e.g., occupational or consumer exposure). In addition, information on the relative cost or performance characteristics of the PMN substance to potential alternatives may be provided. **All information provided in this section will be taken into consideration during the review of this substance.**

Describe the expected net benefits, such as (1) an overall reduction in risk to human health or the environment; (2) a reduction in the volume manufactured; (3) a reduction in the generation of waste materials through recycling, source reduction or other means; (4) a reduction in potential toxicity or human exposure and/or environmental release; (5) an increase in product performance, a decrease in the cost of production and/or improved operation efficiency of the new chemical substance in comparison to existing chemical substances used in similar applications; or (6) the extent to which the new chemical substance may be a substitute for an existing substance that poses a greater overall risk to human health or the environment.

☐ Mark (X) this box if you attach a continuation sheet.

Part III -- LIST OF ATTACHMENTS

Attach continuation sheets for sections of the form and test data and other data (including physical/chemical properties and structure/activity information), and optional information after this page. Clearly identify the attachment and the section of the form to which it relates, if appropriate. Number consecutively the pages of the attachments. In the column below, enter the inclusive page numbers of each attachment.
Mark (X) the "Confidential" box next to any attachment name you claim as confidential. Read the Instructions Manual for guidance on how to claim any information in an attachment as confidential. You must include with the sanitized copy of the notice form a sanitized version of any attachment in which you claim information as confidential.

Attachment name	Attachment page number(s)	Confidential

☐ Mark (X) this box if you attach a continuation sheet. Enter the attachment name and number.

PHYSICAL AND CHEMICAL PROPERTIES WORKSHEET

To assist EPA's review of physical and chemical properties data, please complete the following worksheet for data you provide and include it in the notice. Identify the property measured, the page of the notice on which the property appears, the value of the property, the units in which the property is measured (as necessary), and whether or not the property is claimed as confidential. You are not required to submit this worksheet; however, EPA strongly recommends that you do so, as it will simplify review and ensure that confidential information is properly protected. You should submit this worksheet as a supplement to your submission of test data. This worksheet is not a substitute for submission of test data.

Property (a)	Mark (X) if provided	Page number (b)	Value (c)	Confidential Mark (X) (d)
Vapor pressure ● Temperature _____ ℃			Torr	
Density/relative density			g/cm3	
Solubility ● Temperature _____ ℃ Solvent _____			g/L	
Solubility in water ● Temperature _____ ℃			℃	
Melting temperature			℃	
Boiling/sublimation temperature @ _____ torr pressure				
Spectra				
Dissociation constant				
Particle size distribution				
Octanol/water partition coefficient				
Henry's Law constant				
Volitalization from water				
Volitalization from soil				
pH ● concentration _____				
Flammability				
Explodability				
Adsorption/coefficient				
Other - Specify				

APPENDIX 9

GLOVE TESTING GUIDELINE

[This document has been re-keyed for improved legibility.]

MEMORANDUM

SUBJECT: Glove Requirements for Section 5(e) Orders

FROM: A. E. Conroy II, Director
Office of Compliance Monitoring

TO: Addresses

The attached TSCA section 5 inspection guidance applies to section 5(e) orders which require the use of gloves as protective equipment during the handling of the Premanufacture Notice (PMN) chemical. The guidelines should be inserted into the TSCA Inspection Manual, Volume Four, Section 5 Inspection Manual, September, 1981 as Appendix 5 under the heading "Documentation for Glove Requirements in 5(e) Orders".

The insert will be issued with the section 5(e) order inspection targeting packages for those orders which require the use of gloves. The inspector should become familiar with information during these inspections.

The key element of the inspection will be to document the glove requirements as outlined in the insert in addition to determining if the company is in compliance with all other restrictions outlined in the section 5(e) order. The inspector should submit the final report to the Office of Compliance Monitoring. Information in the report concerning glove requirements will be forwarded to the Economics and Technology Division of OTS for their information and review.

These section 5(e) inspection procedures are effective immediately. If you have any questions, please contact Michael Hackettt of my staff at 382-7861.

Attachment

Documentation for Glove Requirements in 5(e) Orders

Consent 5(e) orders under TSCA often require that gloves be used to prevent dermal contact and that the submitter of a PMN determine the type of gloves to use. Glove selection is to be based on evaluating the permeability, penetration and degradation of glove materials.

There are 2 types of information which can be used to substantiate determinations that the gloves selected are impervious to the chemical of concern: 1) actual laboratory test results on the glove material when challenged by the PMN chemical (including protocol for the test); and 2) published results of testing glove materials with analogues of the PMN chemical (i.e., chemical is in the same chemical class evaluated by glove manufacturers or other experts). The record documenting glove selection should include:

1) an analysis of conditions of potential dermal contact (e.g. associated solvents and other chemicals, purity of the material) and the duration of potential contact;

2) any permeability, penetration and degradation test results (and protocols) on the PMN itself or analogues (if tested by the submitter);

3) any published data (on analogues or the PMN) used by the submitter in determining the acceptability of the glove selected; and

4) a statement describing the specific glove material(s) selected and the reasons for concluding that the material(s) will provide protection during the full period of potential contact. This statement would include interpretation of the data in points 2 and 3 in terms of the conditions of exposure noted in point 1, in particular reconciling and difference between chemical substances as tested and the substance as expected to be encountered by workers (e.g., test of pure compound but contact with a solution).

For each 5(e) investigation where use of gloves are required, the inspector should collect documentation on glove selection and use and include this information as an exhibit to the facility inspection report. This report should be forwarded to OCM for compliance review as soon as possible. OCM will forward informal on glove selection and use to OTS for their information and review.

APPENDIX 100

PAIR FORM

IMPORTANT: Before completing this form, please read the accompanying instructions carefully. OMB No. 2000-0420: Approval Expires 3/31/84

EPA U.S. ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

MANUFACTURER'S REPORT PRELIMINARY ASSESSMENT INFORMATION

This information is required under the authority of Section 8(a), Toxic Substances Control Act, 15 U.S.C. 2607

When completed send this form to:
Document Control Officer
Office of Pesticides and Toxic Substances
U.S.E.P.A.
P.O. Box 2080
Rockville, Md. 20852

CONTROL NUMBER

PERIOD COVERED
FROM Mo. | Yr | TO Mo. | Yr

Section I — CERTIFICATION

TECHNICAL CERTIFICATION STATEMENT

I hereby certify that, to the best of my knowledge and belief, all information entered on this form is complete and accurate. I agree to permit access to, and the copying of records by, a duly authorized representative of the EPA Administrator, in accordance with the Toxic Substances Control Act, to document any information reported here.

Signature | Date

Name and title — *Please print or type*

CONCERNING EPA DISCLOSURE OF INFORMATION

Any person who submits information to EPA under the Preliminary Assessment Information Rule (40 CFR 712) should be aware of EPA regulations (40 CFR Part 2) which govern disclosure of such information. Those regulations provide that such person may, if he or she desires, assert a confidentiality claim covering part or all of the information submitted. Information covered by such a claim will be publicly disclosed by EPA only to the extent, and by means of the procedures, set forth in 40 CFR Part 2. However, if no such claim accompanies the information when it is received, EPA may make that information public without notifying the submitter.

CONFIDENTIALITY STATEMENTS

Information disclosed to EPA on this form may be claimed confidential by marking the appropriate boxes below. The person signing the Confidentiality Certification Statement attests to the truth of the following four statements concerning all information that is claimed confidential. Note that chemical substance identity may not be claimed confidential for this rule.

1. My company has taken measures to protect the confidentiality of the information, and it intends to continue to take such measures.
2. The information is not, and has not been, reasonably obtainable without our consent by other persons (other than governmental bodies) by use of legitimate means (other than discovery based on a showing of special need in a judicial or quasi-judicial proceeding).
3. The information is not publicly available elsewhere.
4. Disclosure of the information would cause substantial harm to our competitive position.

CONFIDENTIALITY CERTIFICATION STATEMENT

I hereby certify that the Confidentiality Statements on this form are true as to that information below for which I have asserted a confidentiality claim.

Signature | Date

Name and title — *Please print or type*

Section II — CHEMICAL IDENTIFICATION

Part A

CAS No. | | | — | | | — | | |

Chemical name (first 15 characters)

Part B

Category name (first 15 characters)

Inventory Form C number

Section III — RESPONDENT IDENTIFICATION

☐ *MARK THIS BOX TO CLAIM THIS SECTION CONFIDENTIAL*

Part A — Plant Site — Physical location

Name

Number and street

City

County

State | ZIP code

Dun and Bradstreet number | | — | | | | — | | | | |

Part B — Mailing Address of:

☐ Corporate Headquarters ☐ Plant Site

Name

Number and street

City

State | ZIP code

Dun and Bradstreet number (for corporate headquarters only) | | — | | | | — | | | | |

Part C — Technical Contact

Name and title

Telephone (*Area code/number*)

☐ At headquarters

☐ At plant site

Part D — Acknowledgement

EPA will send acknowledgement to - *Name and title*

Section IV — PRELIMINARY ASSESSMENT INFORMATION

NOTE Mark the box to the left of any item below to claim the answer to the item as confidential. Report all quantities in kilograms (1 kilogram = 2.2 pounds). Enter N/A for any item that does not apply to you; do not leave any blanks.

Part A — Plant Site Activities — *Information in part A must be your best estimate from readily obtainable data. For items 3b, 3c, and 3d, specify the accuracy of your answers*

☐ 1. Total quantity imported	kg	☐ 2. Quantity manufactured for sale or use	kg
☐ 3a. Quantity lost during manufacture (3b + 3c + 3d must equal 3a)	kg	3e. Quantity in wastes treated to destroy the chemical	kg ± %
3b. Quantity lost to the environment	kg ± %	3d. Quantity in wastes not treated to destroy the chemical	kg ± %

Activity (1)	Process category (2)	Quantity (kilograms) (3)	Total worker-hours (4)	Total workers (5)
☐ 4. Manufacture of the chemical	a. Enclosed			
	b. Controlled release			
	c. Open			
☐ 5. On-site use as reactant	a. Enclosed			
	b. Controlled release			
Total Quantity _____ kg	c. Open			
☐ 6. On-site nonreactant use of the chemical substance	a. Enclosed			
	b. Controlled release			
Total Quantity _____ kg	c. Open			
☐ 7. On-site preparation of products	a. Enclosed			
	b. Controlled release			
Total Quantity _____ kg	c. Open			

☐ 8. MANUFACTURER'S PRODUCTS — Report the quantity of the chemical substance that you prepare for each of the following.

INDUSTRIAL PRODUCTS (domestic)	a. Chemical or mixture	kg	CONSUMER PRODUCTS (domestic)	d. Chemical or mixture	
	b. Article with some release	kg		e. Article with some release	
	c. Article with no release	kg		f. Article with no release	
g. Products for export →					

Part B — Chemical Substance Processing by Customers — *Information in part B must be accurate to within ± 50%*

☐ 9. CUSTOMERS' USES AND PRODUCTS — Estimate the quantity of the chemical substance that your customers use or prepare for each of the following.

INDUSTRIAL PRODUCTS (domestic)	a. Chemical or mixture	kg	CONSUMER PRODUCTS (domestic)	d. Chemical or mixture	
	b. Article with some release	kg		e. Article with some release	
	c. Article with no release	kg		f. Article with no release	
g. Products for export →					
h. Quantity of chemical consumed as reactant →					
i. Unknown customer uses →					

☐ 10. MARKET NAMES — If you report your customers' uses as unknown (9i above) for more than 20% of the total quantity of chemical substance that you manufacture or import (20% of items 1 and 2 above), list the market names under which you distribute the chemical. (If you need more space attach an additional sheet.)

a.	c.
b.	d.

☐ 11. CUSTOMERS' PROCESS CATEGORIES — Based on your knowledge of general industry practices estimate the quantity of chemical substance that you sell to customers as the chemical and that your customers further process in each of the following categories.

a. Enclosed processes	kg	c. Open processes	
b. Controlled release processes	kg	d. Unknown	

APPENDIX [illegible]

EPA POLICY: STATEMENT OF INTERPRETATION AND ENFORCEMENT POLICY; NOTIFICATION OF SUBSTANTIAL RISK

43 FR 11110-[illegible]

APPENDIX A

federal register

THURSDAY, MARCH 16, 1978
PART V

ENVIRONMENTAL PROTECTION AGENCY

TOXIC SUBSTANCES CONTROL ACT

Statement of Interpretation and Enforcement Policy; Notification of Substantial Risk

[6560-01]

ENVIRONMENTAL PROTECTION AGENCY

[FRL 849-2]

TOXIC SUBSTANCES CONTROL ACT

Notification of Substantial Risk Under Section 8(e)

AGENCY: Environmental Protection Agency.

ACTION: Statement of interpretation and enforcement policy.

SUMMARY: This action states EPA's interpretation of, and enforcement policy concerning, section 8(e) of the Toxic Substances Control Act (TSCA) (90 Stat. 2029, 15 U.S.C. 2607). The provisions of that section went into effect on January 1, 1977.

Section 8(e) states that "any person who manufactures, processes, or distributes in commerce a chemical substance or mixture and who obtains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment shall immediately inform the Administrator of such information unless such person has actual knowledge that the Administrator has been adequately informed of such information."

DATES: The policy expressed in this document is in effect as of the date of publication.

FOR FURTHER INFORMATION CONTACT:

Frank D. Kover, Assessment Division, Office of Toxic Substances (WH-557), Environmental Protection Agency, 401 M Street SW., Washington, D.C. 20460, 202-755-2110.

SUPPLEMENTARY INFORMATION: On September 9, 1977, the Agency proposed guidance (42 FR 45362) on its interpretation of and policy concerning the provisions of section 8(e). Although the proposed "guidance" was an interpretive rule and statement of policy exempt from the notice and public comment provisions of the Administrative Procedure Act (5 U.S.C. 553), the Agency solicited comments on several issues to make more informed decisions. On October 11, the comment period was extended from October 15 to October 31, 1977 (42 FR 54857). On November 4, 1977, a supplemental notice to the proposed guidance was published (42 FR 57744), deleting the November 15 date for reporting certain information obtained before 1977 and stating that a new date would be established in the final guidance.

In developing this policy statement, two meetings have been held (February 1, 1977, and October 26, 1977) with selected representatives of industry and environmental and other interested groups. Comments submitted pursuant to the February 1 meeting were addressed in the preamble to the September 9 proposal. Over 100 written comments have been submitted pursuant to the September 9 proposal from trade associations, businesses, environmental groups, labor unions, State and Federal agencies, and other interested parties. Appendix B describes significant issues raised in these comments and the Agency's response to them.

The major modifications to the September 9 proposal are summarized in points 1 through 7 below.

(1) Pursuant to some question over the definition and nature of "guidance," this document is now described more accurately as a "policy statement." It is exempt from the notice and public comment provisions of the Administrative Procedure Act, as well as provisions concerning delayed effective dates.

(2) Many commenters expressed the view that to apply these requirements to officers and employees of a business organization would result in ill-considered, premature reports and would unfairly subject employees to conflicting responsibilities as individual respondents and as corporate agents. Other commenters expressed support for the view that certain employees have a responsibility to report pertinent information, and felt that the phrase "capable of appreciating pertinent information" appropriately described those employees.

The September 9 proposal would have applied section 8(e) requirements to commercial establishments as well as to employees capable of appreciating pertinent information, but stipulated enforcement priorities intended to encourage corporate processing and centralized reporting of such information (42 FR 45363). The intent was to ensure that pertinent information obtained by employees is promptly and appropriately considered, while minimizing duplicative or ill-considered submissions.

The Agency now feels that these objectives would best be served by allowing commercial establishments—under certain conditions designed to ensure full disclosure—to assume exclusive responsibility for reporting to EPA any substantial-risk information obtained by individual officers or employees. Accordingly, this policy statement stipulates that individual officers and employees will have fully discharged their section 8(e) obligations once they have notified the designated responsible company supervisor or official of pertinent information, *provided*, that the employing company or firm has established, internally publicizes, and affirmatively implements procedures governing such notifications. These procedures, at a minimum, must: (1) Specify the information that must be reported; (2) indicate how the notifications are to be prepared and submitted; (3) note the Federal penalties for failing to report; and (4) provide a mechanism for promptly notifying officers and employees who have submitted reports of the company's disposition of those reports, including whether or not they were submitted to EPA (and if not, informing employees of their right to report to EPA, as protected by TSCA section 23). EPA believes these four criteria will ensure prompt and appropriate processing of pertinent information.

Establishment of such procedures notwithstanding, all officials responsible and having authority for the organization's execution of its section 8(e) obligations retain personal liability for ensuring that substantial-risk information is reported to EPA.

(3) The September 9 proposal stated, in Part III, that a person obtains information when he is aware that it "may suggest" substantial risk. Numerous commenters questioned the Administrator's authority to compel the reporting of information which "may suggest" substantial risk. The Administrator agrees that section 8(e) addresses information that "reasonably supports the conclusion" of substantial risk and has deleted the "may suggest" provision, but emphasizes that "reasonably supports the conclusion" of substantial risk is not identical to a conclusive demonstration of substantial risk. The former typically occurs, and must be reported, at an earlier stage. Part VI in this policy statement provides Agency interpretation of the types of information that "reasonably support" such a conclusion.

(4) Numerous commenters requested clarification of different aspects of Part V of the September 9 proposal ("Information Which Reasonably Supports a Conclusion of Substantial Risk"), particularly concerning environmental effects, and suggested different interpretations of what constitutes a "substantial risk". The Agency continues to focus in this policy statement on the effects set forth in the September 9 proposal, but clarifies that the substantiality of a risk is a function of both the seriousness of the effect and the probability of its occurrence (see Part V).

(5) Numerous commenters maintained that section 8(e) only applies prospectively to information obtained after January 1, 1977. The Agency disagrees, as explained in the preamble to the September 9 proposal. This policy statement continues to apply section 8(e) to information obtained before 1977 of which a person has

been aware since January 1, 1977. In response to requests for clarification, the statement defines what constitutes such awareness. In this manner, EPA intends to limit the need for searches of historical records and files.

(6) This policy statement now provides that any information published in scientific literature, in any language, is exempt if it is referred to in abstracts published by specified abstracting services.

(7) This policy statement describes in a new Part X how to submit claims of confidentiality.

Accordingly, the Administrator's interpretation of and policy towards section 8(e) is set forth below.

Dated: February 24, 1978.

DOUGLAS COSTLE
Administrator.

I. DEFINITIONS

The definitions set forth in TSCA section 3 apply to these requirements. In addition, the following definitions are provided for purposes of this policy statement:

The term "manufacture or process 'for commercial purposes' " means to manufacture or process: (1) For distribution in commerce, including for test marketing purposes, (2) for use as a catalyst or an intermediate, (3) for the exclusive use by the manufacturer or processor, or (4) for product research and development.

The term "person" includes any natural person, corporation, firm, company, joint-venture, partnership, sole proprietorship, association, or any other business entity, any State or political subdivision thereof, any municipality, any interstate body and any department, agency, or instrumentality of the Federal Government.

The term "substantial-risk information" means information which reasonably supports the conclusion that a chemical substance or mixture presents a substantial risk of injury to health or the environment.

II. PERSONS SUBJECT TO THE REQUIREMENT

Persons subject to section 8(e) requirements include both natural persons and business entities engaged in manufacturing, processing, or distributing in commerce a chemical substance or mixture. In the case of business entities, the president, chief executive officer, and any other officers responsible and having authority for the organization's execution of its section 8(e) obligations must ensure that the organization reports substantial-risk information to EPA. The business organization is considered to have obtained any information which any officer or employee capable of appreciating the significance of that information has obtained. It is therefore incumbent upon business organizations to establish procedures for expeditiously processing pertinent information in order to comply with the schedule set forth in Part IV.

Those officers and employees of business organizations who are capable of appreciating the significance of pertinent information are also subject to these reporting requirements. An employing organization may relieve its individual officers and employees of any responsibility for reporting substantial-risk information directly to EPA by establishing, internally publicizing, and affirmatively implementing procedures for employee submission and corporate processing of pertinent information. These procedures, at a minimum, must: (1) Specify the information that officers and employees must submit; (2) indicate how such submissions are to be prepared and the company official to whom they are to be submitted; (3) note the Federal penalties for failing to report; and (4) provide a mechanism for promptly advising officers and employees in writing of the company's disposition of the report, including whether or not the report was submitted to EPA (and if not informing employees of their right to report to EPA, as protected by TSCA section 23). An employee of any company that has established and publicized such procedures, who has internally submitted pertinent information in accordance with them, shall have discharged his section 8(e) obligation. Establishment of such procedures notwithstanding, all officials responsible and having authority for the organization's execution of its section 8(e) obligations retain personal liability for ensuring that the appropriate substantial-risk information is reported to EPA.

Business organizations that do not establish such procedures cannot relieve their individual officers and employees of the responsibility for ensuring that substantial-risk information they obtain is reported to EPA. While officers and employees of such organizations may also elect to submit substantial-risk information to their superiors for corporate processing and reporting, rather than to EPA directly, they have not discharged their individual section 8(e) obligation until EPA has received the information.

NOTE.—Irrespective of a business organization's decision to establish and publicize the procedures described above, it is responsible for becoming cognizant of any substantial-risk information obtained by its officers and employees, and for ensuring that such information is reported to EPA within 15 working days.

III. WHEN A PERSON WILL BE REGARDED AS HAVING OBTAINED INFORMATION

A person obtains substantial-risk information at the time he first comes into possession of or knows of such information.

NOTE.—This includes information of which a prudent person similarly situated could reasonably be expected to possess or have knowledge.

An establishment obtains information at the time any officer or employee capable of appreciating the significance of such information obtains it.

IV. REQUIREMENT THAT A PERSON "IMMEDIATELY INFORM" THE ADMINISTRATOR

With the exception of information on emergency incidents of environmental contamination [see Part V(c)] a person has "immediately informed" the Administrator if information is received by EPA not later than the 15th working day after the date the person obtained such information. Supplementary information generated after a section 8(e) notification should, if appropriate, be immediately reported. For emergency incidents of environmental contamination, a person shall report the incident to the Administrator by telephone as soon as he has knowledge of the incident (see Part IX for appropriate telephone contacts). The report should contain as much of the information required by Part IX as possible. A written report in accordance with Part IX (a) through (f) is to be submitted within 15 days.

Information currently in the possession of a person who is subject to reporting must be reported within 60 days of publication of this policy statement.

V. WHAT CONSTITUTES SUBSTANTIAL RISKS

A "substantial risk of injury to health or the environment" is a risk of considerable concern because of (a) the seriousness of the effect [see Subparts (a), (b), and (c) below for an illustrative list of effects of concern], and (b) the fact or probability of its occurrence. (Economic or social benefits of use, or costs of restricting use, are not to be considered in determining whether a risk is "substantial".) These two criteria are differentially weighted for different types of effects. The human health effects listed in Subpart (a) below, for example, are so serious that relatively little weight is given to exposure; the mere fact the implicated chemical is in commerce constitutes sufficient evidence of exposure. In contrast, the remaining effects listed in Subparts (b) and (c) below must involve, or be accompanied by the potential for, significant levels of exposure (because of general production levels, persistence, typical uses, common means of disposal, or other pertinent factors).

Note that: (i) The effects outlined below should not be reported if the re-

spondent has actual knowledge that the Administrator is already informed of them.

(ii) Information respecting these effects can be obtained either directly, by observation of their occurrence, or inferred from designed studies as discussed in Part VI.

The Agency considers effects for which substantial-risk information must be reported to include the following:

(a) *Human health effects*—(1) Any instance of cancer, birth defects, mutagenicity, death, or serious or prolonged incapacitation, including the loss of or inability to use a normal bodily function with a consequent relatively serious impairment of normal activities, if one (or a few) chemical(s) is strongly implicated.

(2) Any pattern of effects or evidence which reasonably supports the conclusion that the chemical substance or mixture can produce cancer, mutation, birth defects or toxic effects resulting in death, or serious or prolonged incapacitation.

(b) *Environmental effects*—(1) Widespread and previously unsuspected distribution in environmental media, as indicated in studies (excluding materials contained within appropriate disposal facilities).

(2) Pronounced bioaccumulation. Measurements and indicators of pronounced bioaccumulation heretofore unknown to the Administrator (including bioaccumulation in fish beyond 5,000 times water concentration in a 30-day exposure or having an n-octanol/water partition coefficient greater than 28,000) should be reported when coupled with potential for widespread exposure and any non-trivial adverse effect.

(3) Any non-trivial adverse effect, heretofore unknown to the Administrator, associated with a chemical known to have bioaccumulated to a pronounced degree or to be widespread in environmental media.

(4) Ecologically significant changes in species' interrelationships; that is, changes in population behavior, growth, survival, etc. that in turn affect other species' behavior, growth, or survival.

Examples include: (i) Excessive stimulation of primary producers (algae, macrophytes) in aquatic ecosystems, e.g., resulting in nutrient enrichment, or eutrophication, of aquatic ecosystems.

(ii) Interference with critical biogeochemical cycles, such as the nitrogen cycle.

(5) Facile transformation or degradation to a chemical having an unacceptable risk as defined above.

(c) *Emergency incidents of environmental contamination*—Any environmental contamination by a chemical substance or mixture to which any of the above adverse effects has been ascribed and which because of the pattern, extent, and amount of contamination (1) seriously threatens humans with cancer, birth defects, mutation, death, or serious or prolonged incapacitation, or (2) seriously threatens non-human organisms with large-scale or ecologically significant population destruction.

VI. Nature and Sources of Information Which "Reasonably Supports the Conclusion" of Substantial Risk

Information attributing any of the effects described in Part V above to a chemical substance or mixture is to be reported if it is one of the types listed below and if it is not exempt from the reporting requirement by reason of Part VII of this policy statement. A person is not to delay reporting until he obtains conclusive information that a substantial risk exists, but is to immediately report any evidence which "reasonably supports" that conclusion. Such evidence will generally not be conclusive as to the substantiality of the risk; it should, however, reliably ascribe the effect to the chemical.

Information from the following sources concerning the effects described in Part V will often "reasonably support" a conclusion of substantial risk. Consideration of corroborative information before reporting can only occur where it is indicated below.

(1) *Designed, controlled studies.* In assessing the quality of information, the respondent is to consider whether it contains reliable evidence ascribing the effect to the chemical. Not only should final results from such studies be reported, but also preliminary results from incomplete studies where appropriate. Designed, controlled studies include:

(i) In vivo experiments and tests.

(ii) In vitro experiments and tests. Consideration may be given to the existence of corroborative information, if necessary to reasonably support the conclusion that a chemical presents a substantial risk.

(iii) Epidemiological studies.

(iv) Environmental monitoring studies.

(2) *Reports concerning and studies of undesigned, uncontrolled circumstances.* It is anticipated here that reportable effects will generally occur in a pattern, where a significant common feature is exposure to the chemical. However, a single instance of cancer, birth defects, mutation, death, or serious incapacitation in a human would be reportable if one (or a few) chemical(s) was strongly implicated. In addition, it is possible that effects less serious than those described in Part V(a) may be preliminary manifestations of the more serious effects and, together with another triggering piece of information, constitute reportable information; an example would be a group of exposed workers experiencing dizziness together with preliminary experimental results demonstrating neurological dysfunctions.

Reports and studies of undesigned circumstances include:

(i) Medical and health surveys.

(ii) Clinical studies.

(iii) Reports concerning and evidence of effects in consumers, workers, or the environment.

VII. Information Which Need Not Be Reported

Information need not be reported if it:

(a) Has been published by EPA in reports;

(b) Has been submitted in writing to EPA pursuant to mandatory reporting requirements under TSCA or any other authority administered by EPA (including the Federal Insecticide, Fungicide and Rodenticide Act, the Clean Air Act, the Federal Water Pollution Control Act, the Marine Protection, Research, and Sanctuaries Act, the Safe Drinking Water Act, and the Resource Conservation and Recovery Act), provided that the information: (1) Encompasses that required by Part IX (c) through (f); and (2) is from now on submitted within the time constraints set forth in Part IV and identified as a section 8(e) notice in accordance with Part IX(b);

(c) Has been published in the scientific literature and referenced by the following abstract services: (1) Agricola, (2) Biological Abstracts, (3) Chemical Abstracts, (4) Dissertation Abstracts, (5) Index Medicus, (6) National Technical Information Service.

(d) Is corroborative of well-established adverse effects already documented in the scientific literature and referenced as described in (c) above, unless such information concerns emergency incidents of environmental contamination as described in Part V(c), or

(e) Is contained in notification of spills under section 311(b)(5) of the Federal Water Pollution Control Act.

VIII. Information First Received by a Person Prior to the Effective Date of TSCA

Any substantial risk information possessed by a person prior to January 1, 1977, of which he is aware after that date shall be reported within 60 days of publication of this policy statement. The Agency considers that a person is "aware" of:

(a) Any information reviewed after January 1, 1977, including not only written reports, memoranda and other documents examined after January 1, 1977, but also information referred to in discussions and conferences in which the person participated after January 1, 1977;

(b) Any information the contents of which a person has been alerted to by date received after January 1, 1977, including any information concerning a chemical for which the person is presently assessing health and environmental effects;

(c) Any other information of which the person has actual knowledge.

IX. Reporting Requirements

Notices shall be delivered to the Document Control Officer, Chemical Information Division, Office of Toxic Substances (WH-557), Environmental Protection Agency, 401 M Street SW., Washington, D.C. 20460. (****)

A notice should:

(a) Be sent by certified mail, or in any other way permitting verification of its receipt by the Agency,

(b) State that it is being submitted in accordance with section 8(e),

(c) Contain the job title, name, address, telephone number, and signature of the person reporting and the name and address of the manufacturing, processing, or distributing establishment with which he is associated,

(d) Identify the chemical substance or mixture (including, if known, the CAS Registry Number),

(e) Summarize the adverse effects being reported, describing the nature and the extent of the risk involved, and

(f) Contain the specific source of the information together with a summary and the source of any available supporting technical data.

For emergency incidents of environmental contamination (see Part V(c)), a person shall report the incident to the Administrator by telephone as soon as he has knowledge of the incident (see below for appropriate telephone contacts). The report should contain as much of the information required by instructions (b) through (f) above as possible. A written report, in accordance with instructions (a) through (f) above, is to be submitted within 15 days. Twenty-four hour emergency telephone numbers are:

Region I (Maine, Rhode Island, Connecticut, Vermont, Massachusetts, New Hampshire), 617-223-7265.
Region II (New York, New Jersey, Puerto Rico, Virgin Islands), 201-548-8730.
Region III (Pennsylvania, West Virginia, Virginia, Maryland, Delaware, District of Columbia), 215-597-9898.
Region IV (Kentucky, Tennessee, North Carolina, South Carolina, Georgia, Alabama, Mississippi, Florida), 404-881-4062.
Region V (Wisconsin, Illinois, Indiana, Michigan, Ohio, Minnesota), 312-353-2318.
Region VI (New Mexico, Texas, Oklahoma, Arkansas, Louisiana), 214-749-3840.
Region VII (Nebraska, Iowa, Missouri, Kansas), 816-374-3778.
Region VIII (Colorado, Utah, Wyoming, Montana, North Dakota, South Dakota), 303-837-3880.
Region IX (California, Nevada, Arizona, Hawaii, Guam), 415-556-6284.
Region X (Washington, Oregon, Idaho, Alaska), 206-442-1200.

X. Confidentiality Claims

(a) Any person submitting a notice to EPA under section 8(e) of TSCA may assert a business confidentiality claim covering all or part of the information contained in the notice. Any information covered by a claim will be disclosed by EPA only to the extent, and by means of the procedures, set forth in 40 CFR Part 2 (41 FR 36902, September 1, 1976).

(b) If no claim accompanies the notice at the time it is submitted to EPA, the notice will be placed in an open file to be available to the public without further notice to the submitter.

(c) To assert a claim of confidentiality for information contained in a notice, the submitter must submit two copies of the notice.

(1) One copy must be complete. In that copy the submitter must indicate what information, if any, is claimed as confidential by marking the specified information on each page with a label such as "confidential," "proprietary," or "trade secret."

(2) If some information in the notice is claimed as confidential, the submitter must submit a second copy. The second copy must be complete except that all information claimed as confidential in the first copy must be deleted.

(3) The first copy of the notice will be disclosed by EPA only to the extent, and by means of the procedures, set forth in 40 CFR Part 2. The second copy will be placed in an open file to be available to the public.

(d) Any person submitting a notice containing information for which they are asserting a confidentiality claim should send the notice in a double envelope.

(1) The outside envelope should bear the same address outlined in section IX of this policy statement.

(2) The inside envelope should be clearly marked "To be opened only by the OTS Document Control Officer."

XI. Failure To Report Information

Section 15(3) of TSCA makes it unlawful for any person to fail or refuse to submit information required under section 8(e). Section 16 provides that a violation of section 15 renders a person liable to the United States for a civil penalty and possible criminal prosecution. Pursuant to section 17, the Government may seek judicial relief to compel submittal of section 8(e) information and to otherwise restrain any violation of section 8(e).

Appendix A.—Quick Reference Summary for Emergency Incidents of Environmental Contamination

A. What Should Be Reported As an Emergency Incident

An emergency incident of environmental contamination is "any environmental contamination by a chemical substance or mixture . . . which, because of the pattern, extent and amount of contamination, (1) Seriously threatens humans with cancer, birth defects, mutation, death, or serious or prolonged incapacitation, or (2) seriously threatens non-human organisms with large scale or ecologically significant population destruction". (See Part V(c) for complete description.)

B. What Need Not Be Reported As an Emergency Incident

Information contained in notification of spills under section 311(b)(5) of the Federal Water Pollution Control Act (FWPCA). (For a complete list of exemptions to reporting, see Part VII.)

C. When and Where To Report Emergency Incidents

Emergency incidents of environmental contamination are to be reported immediately by telephone to the appropriate EPA Regional 24-hour telephone emergency line listed below.

Region I (Maine, Rhode Island, Connecticut, Vermont, Massachusetts, New Hampshire), 617-223-7265.
Region II (New York, New Jersey, Puerto Rico, Virgin Islands), 201-548-8730.
Region III (Pennsylvania, West Virginia, Virginia, Maryland, Delaware, District of Columbia), 215-597-9898.
Region IV (Kentucky, Tennessee, North Carolina, South Carolina, Georgia, Alabama, Mississippi, Florida), 404-881-4062.
Region V (Wisconsin, Illinois, Indiana, Michigan, Ohio, Minnesota), 312-353-2318.
Region VI (New Mexico, Texas, Oklahoma, Arkansas, Louisiana), 214-749-3840.
Region VII (Nebraska, Iowa, Missouri, Kansas), 816-374-3778.
Region VIII (Colorado, Utah, Wyoming, Montana, North Dakota, South Dakota), 303-837-3880.
Region IX (California, Nevada, Arizona, Hawaii, Guam), 415-556-6284.
Region X (Washington, Oregon, Idaho, Alaska), 206-442-1200.

In addition, a written report, in accordance with instructions (a) through (f) of Part IX, is to be submitted within 15 days to the Document Control Officer, Chemical Information Division, Office of Toxic Substances (WH-557), 401 M Street SW., Washington, D.C. 20460.

Appendix B—Significant Comments and Responses

A. Persons Subject to These Requirements

Comment 1: Employees cannot be held subject to these requirements, since: (a) They only have a partial role in the manufacture, processing, or distribution of chemicals, (b) in other sections of TSCA, the term "person who manufactures, processes, or distributes" chemicals clearly refers to business organizations; "persons" should be consistently defined, and (c) the application of criminal penalties mandates a strict interpretation of this word.

(****) See NOTE on last page of Appendix A

Response: The Agency considers that different sections of TSCA, having different purposes, are appropriately directed to different responsibilities. In the case of section 8(e), officers and employees who are capable of appreciating the significance of information have a legitimate responsibility to be alert to and report substantial-risk information. The guidance has been modified so that natural persons and business entities can fulfill their section 8(e) obligations in different ways. Most officers and employees can discharge their section 8(e) obligations by submitting pertinent information to corporate superiors, provided that the company has established the risk-evaluation procedures characterized in Part II. In the case of a business organization, its president, chief executive officer, and other officials responsible and having authority for the business organization's execution of its section 8(e) obligations must ensure that the organization reports substantial-risk information to EPA.

Comment 2: Even if employees can be held subject to these requirements, they should not be. To do so would force employees and employers into conflicting positions, inviting internal corporate dissension and over-reporting. Further, individuals often do not have the overview necessary to reach considered, well-supported decisions. Corporate reporting by designated officials will provide EPA with more reliable data.

Response: The Agency considers that employees have a legitimate role in risk reporting; it is imperative that risk information obtained by employees be appropriately considered. Officers and employees can fulfill their role in the reporting of substantial-risk information, without the disadvantages described above, by reporting information to superiors for corporate consideration, and, having done so, will have discharged their obligation to EPA. This is contingent upon the establishment by the business organization of certain procedures for risk-evaluation, thereby assuring the appropriate consideration of such reports. Those officers responsible and having authority for the organization's execution of its section 8(e) obligations must ensure that the organization reports substantial-risk information to EPA.

Comment 3: Clarify which employees are covered, and the extent of their obligation. Are employees "capable of appreciating pertinent information" by virtue of rank, or knowledge? Are rank and file employees subject to these requirements, or just supervisory and managerial personnel, company toxicologists, etc.? Is an employee absolved of further responsibility if he reports to his supervisor?

Response: The Agency considers that the phrase "capable of appreciating the significance of pertinent information" appropriately describes those officers and employees who have a responsibility to be alert to and report substantial-risk information, including not only relatively senior corporate officers but also many corporate employees. The policy statement modifies the September 9 proposal, in response to the concerns expressed in Comments 2 and 3, to permit most officers and employees to discharge their obligation by submitting information to corporate superiors, subject to the conditions described in Part II.

Comment 4: Consultants and independent labs should not be subject to these requirements.

Response: Contractors and independent labs are not responsible for reporting information they have obtained directly to EPA; rather, their client manufacturers, processors and distributors are responsible for reporting such information.

B. THE "OBTAINING" OF INFORMATION

Comment 5: The "may suggest" criterion in Part III of the proposal serves to compel further examination of information that by itself is not subject to section 8(e) requirements. The statutory language calling for "reasonable support" does not support this. Further, risk assessment often requires anywhere from months to several years of study after preliminary results "suggest" risk, far exceeding the 15-day compliance period.

Response: The Agency does not intend to compel under section 8(e) examination of information that by itself is not subject to section 8(e) requirements and has deleted the "may suggest" provision, providing its interpretation of what constitutes evidence that "reasonably supports the conclusion" of substantial risk in a new Part VI.

Comment 6: Section 8(e) obligations are incurred upon obtaining conclusory substantial-risk information.

Response: The Agency disagrees, and considers that "reasonable support" of a conclusion of substantial risk is not identical to the conclusion itself. The former typically occurs, and must be reported, at an earlier stage.

Comment 7: The statement, in Part III of the proposal that a person has obtained information if he ". . . should know of the existence of such information not in his possession but which would be delivered to him on request," tends to compel an active search for substantial-risk information rather than the reporting of substantial-risk information a person "obtains." This is of particular concern to importers with limited access to information possessed by their suppliers.

Response: The Agency considers that section 8(e) applies to information which a person possesses or of which he knows. It is not intended to compel searches for information or extraordinary efforts to acquire information. The Agency further considers, however, that "known" information includes information which a prudent person similarly situated could reasonably be expected to know. Negligence or intentional avoidance of information does not absolve a person of his section 8(e) obligation. Part III has been modified to express these intentions.

Comment 8: Circumstances can exist when coming "into possession" of risk information does not correspond to an understanding of the implications of the information; "obtains" should be defined in terms of possession of information and awareness of its import.

Response: The "obtaining" of information occurs via persons who are "capable of appreciating the significance of pertinent information." There will likely be circumstances in which the evaluation of information clarifies its full import; the establishment of corporate procedures for processing risk-information prescribed in Part II will expedite this.

C. TIME ALLOWED FOR COMPLIANCE

Comment 9: Fifteen calendar days is insufficient to determine whether information which "may suggest" substantial risk should be reported; it is even insufficient to accommodate normal procedural time constraints (corporate processing, mailing, holidays, etc.).

Response: The Agency has changed the compliance period to 15 business days. It is imperative that procedures be established to expedite the reporting of substantial-risk information, not that reporting conform to existing procedures.

Comment 10: Allow from 30 to 90 days for the second phase of reporting; alternatively, do not prescribe a time limit for additional reporting.

Response: Having deleted the "may suggest" criterion, the Agency sees no need to provide a second phase to the reporting period. Supplemental information that is generated after a section 8(e) notification should, if appropriate, be immediately reported.

Comment 11: Allow from 30 to 120 days to report pre-1977 information; this period should commence: (a) upon final publication, (b) January 1, 1978, (c) following the inventory reporting period since many of the same corporate personnel will be implementing both requirements.

Response: The policy statement prescribes a 60 day reporting period, commencing immediately upon publication. Section 8(e) has been in effect since January 1, 1977; postponement in reporting substantial-risk information is not warranted.

D. EFFECTS AND INFORMATION THAT MUST BE REPORTED

Comment 12: The reporting of "any instance" of cancer, birth defects, etc., in humans is too broad and such information will be of little use; chemical workers, like the general population, develop cancers and other ailments of uncertain etiology.

Response: This policy statement clarifies that the reporting of single occurrences of human cancer or other serious effects will depend upon evidence strongly implicating one (or a few) chemical(s).

Comment 13: Dermal ailments and nausea are poorly chosen examples of precursor symptoms. Deleting these examples will avoid unduly emphasizing them when other symptoms may be more important, yet will not eliminate the obligation to report them if they are suspected precursors.

Response: The Agency agrees.

Comment 14: How are reportable data distinguished from routine tests including range tests such as LD_{50}'s?

Response: This policy statement directs the reporting of specified effects when unknown to the Administrator. Many routine tests are based on a knowledge of toxicity associated with a chemical; unknown effects occurring during such a range test may have to be reported if they are those of concern to the Agency and if the information meets the criteria set forth in Parts V and VI.

Comment 15: The most widespread "in vitro" test is the Ames test, which is subject to considerable debate. Clarify the circumstances under which positive results of in vitro tests must be reported.

Response: Part VI clarifies that the reporting of in vitro tests will depend upon the existence of corroborative information if necessary to reasonably support the conclusion of substantial risk.

Comment 16: The description of "extreme persistence" as a substantial risk is an example of the need to redefine Part V(c)(1 Environmental Effects"). Persistence and bio accumulation should be considered risks only when coupled with toxicity and significant exposure.

Response: Part V now clarifies those effects for which reporting depends upon a significant exposure potential. Persistence by itself is no longer itemized as a reportable effect but rather is considered to be a component of exposure potential; it may also underlie the measurements described in Part V(b)(1). Laboratory indicators of pronounced bioaccumulation are to be reported when coupled with potential for widespread exposure and any non-trivial adverse effect.

Comment 17: The n-octanol/water partition coefficient addresses a physico-chemical property, not biological effects, and is not alone an indicator of substantial risk; further, the values stated for the coefficient and the bioaccumulation factor in fish do not correspond.

Response: The Agency acknowledges the numerical error and has amended the values to correspond. This policy statement now directs the reporting of an experimental measurement of bioaccumulation when coupled with an adverse effect and potential for widespread exposure.

Comment 18: The requirement that information which "links" an effect to a chemical be reported is too broad and contradicts the statutory language of "reasonably supports".

Response: The Agency has provided in a new Part VI its interpretation of "reasonably supports".

Comment 19: A determination that information "reasonably supports the conclusion" of substantial risk cannot be made independently of considerations of use since the method and manner of using a chemical may influence the occurrence of an effect; in particular, the criteria should reflect a distinction between normal and abnormal uses of chemicals.

Response: The Agency considers that the appropriate components of a "substantial risk" with respect to a chemical are (a) the seriousness of the effect, and (b) total exposure potential. The method and manner of using a chemical is one of several factors determining its exposure potential. As described in Part V, the importance of exposure potential as a component of "substantial risk" depends upon the kind of effect of concern. Thus, the effects described in Part V(a) are so serious that relatively little weight is given to exposure; the effects described in Parts V (b) and (c) involve a significant exposure or exposure potential.

The Agency further considers that a definition of "normal" use for a particular chemical will often depend upon a knowledge of the risks associated with the chemical.

E. Information That Need Not Be Reported

Comment 20: Information published in scientific literature in languages other than English should be exempted if published in summary form by abstracting services. Can the accuracy of English language abstracts and commercial translations of foreign literature be assumed?

Response: This policy statement now provides that information published in scientific literature, whether in English or another language, is exempt from reporting if published in summary form by certain specified abstract services.

Comment 21: Information exchange systems with other Federal agencies should be immediately established so that respondents need not report to EPA information already reported to other Agencies, and vice versa. Such duplicative reports are unduly burdensome.

Response: EPA is coordinating this program with other agencies now. When this coordination is successfully completed, the policy statement will be amended to exempt from the reporting requirement information that has been submitted to other specified agencies. In the meantime, substantial-risk information must be reported directly to EPA; such a report does not discharge any reporting obligation to other agencies.

F. Information First Received Prior to the Effective Date of TSCA

Comment 22: The tense of the verb "obtains" reveals that section 8(e) was intended to be applied prospectively to information newly acquired after January 1, 1977. Utilize section 8(d) or other rules to acquire information obtained before then.

Response: As discussed in the preamble to the September 9 proposal, the Agency considers section 8(e) to apply to risk information possessed by or known to a person before, on, or after January 1, 1977. Concerning information first obtained before 1977, this policy statement continues to require reporting of information received if a person has been aware of it since January 1, 1977, for the reasons discussed in the September 9 preamble.

Comment 23: The term "aware" is too vague to be of any help in responding to these requirements. Since many corporate employees are potentially subject to these requirements, and given uncertainty over the extent to which they ought to be aware of pre-1977 information, this provision tends to compel the very file search it was intended to avoid. The term "aware" should be further defined, possibly in terms of actual knowledge.

Response: The Agency in Part VIII of this policy statement now defines the pre-1977 information of which a person is considered to be aware.

G. Confidential Information

Comment 24: EPA should delay guidance until procedures are published governing the treatment of confidential submissions.

Comment 25. EPA should treat all submissions as confidential until the information is verified.

Comment 26. EPA should automatically publish section 8(e) notices.

Response to Comments 24 through 26: EPA has included a new Part X which describes how to submit a claim of confidentiality and states that any or all of the information submitted may be claimed as confidential. Such information will be disclosed by EPA only to the extent, and by means of the procedures, set forth in 40 CFR Part 2.

H. Miscellaneous

Comment 27: What is the statutory basis or need for guidance? What is its exact status under the Administrative Procedure Act?

Response: This policy statement sets forth EPA's interpretation of and policy concerning TSCA section 8(e). As an interpretive rule and statement of policy it is not subject to the comment period and delayed effective date provisions of the Administrative Procedure Act (5 U.S.C. 553). Although TSCA does not mandate a policy statement, the Agency of necessity must develop the criteria which will govern enforcement activities. Trade associations and businesses were among those who previously expressed interest in such a statement to guide their compliance.

Comment 28: Clarify whether these requirements apply to chemicals previously but no longer manufactured, processed, or distributed in commerce by a person.

Response: Information obtained before 1977 must be reported if the person has been aware of it since January 1, 1977, as prescribed by Part VIII. Concerning chemicals which a person has discontinued manufacturing, processing, or distributing since January 1, 1977, information obtained before the time of discontinuation is subject to these requirements. It is expected that the acquisition of information after that time will be minimal; however, should additional information be acquired, it may trigger the reporting described in Part VIII.

Comment 29: Clarify the meaning of "substantial risk" relative to other risks addressed by TSCA.

Response: A substantial risk is defined in Part V(a) of this policy statement as a risk of considerable concern because of (a) the seriousness of the effect, and (b) the fact or probability of its occurrence. As opposed to other risks addressed by TSCA, economic or social benefits of use, or costs of restricting use, are not to be considered in determining whether a risk is "substantial".

Comment 30: To what extent are "users" of chemicals subject to these requirements?

Response: The Agency considers that many industrial uses of chemicals actually fall within the scope of "processing" chemicals. A manufacturer, processor, or distributor who obtains substantial-risk information concerning chemicals he handles should be alert to the possibility he may have to report it.

Comment 31: Are chemicals manufactured, processed and distributed in commerce in small quantities solely for purposes of research and development subject to these requirements?

Response: In general, the Agency considers that such manufacturing, processing, and distribution in commerce of chemicals in small quantities solely for purposes of research and development is conducted for "commercial purposes". Such purposes would include the sale and distribution of such materials, as well as their use by the manufacturer or processor in activities (for example, product research and development and studies assessing the feasibility and safety of using chemicals) preceding his or a client's commercial use of such materials or others on a larger scale.

As described in Part V, the Agency considers that "substantial risks" depend in part upon an exposure potential. Thus, the occurrence of the effects described in Part V(a) presuppose exposure to the chemical and must be reported; reporting of the other effects will depend upon a potential for significant levels of exposure.

Comment 32: Are raw materials, intermediates, and inert ingredients produced or used in the manufacture of a pesticide subject to TSCA?

Response: The Administrator considers that raw materials, intermediates and inert ingredients produced or used in the manufacture of a pesticide are substances or mixtures which can be regulated under TSCA.

In order to be considered a pesticide a substance must be intended for use as a pesticide. Raw materials, intermediates, and inert ingredients produced or used in the manufacture of a pesticide are not themselves regulated under FIFRA (unless they happen to be pesticides themselves) and, therefore, are subject to TSCA. The

cide regulations at 40 CFR 162.6 are consistent with this view.

Comment 33: Are intermediates and catalysts intended solely for use in the production of a food, food additive, drug, cosmetic, or device subject to TSCA?

Response: The Administrator considers that intermediates and catalysts intended solely for use in the production of a food, food additive, drug, cosmetic, or device are excluded from regulation under TSCA. The definitions of the FFDCA provide that chemical substances which are intended for use as a component of a food, food additive, drug, cosmetic, or device are encompassed within the meaning of such terms, respectively. The FDA considers intermediates and catalysts to be such components. Therefore, they are subject to regulation under the FFDCA. Any such substance is excluded from regulation under TSCA insofar as it is actually manufactured, processed, or distributed in commerce solely for use in the production of a food, food additive, drug, cosmetic, or device.

Comment 34: Employees should have the option to submit reports anonymously.

Response: EPA considers that any person may report information to EPA under TSCA. Those who are required to do so under section 8(e) are persons who manufacture, process, or distribute in commerce chemical substances or mixtures, including not only business entities but also such employees as described in Part II. In order to establish that such persons have discharged their obligations, and in order to encourage responsible review of the quality of information and the substantiality of risks, EPA believes that notifiers should identify themselves. Section 23 will adequately protect employees from discrimination pursuant to notifications they have made under section 8(e).

[FR Doc. 78-7064 Filed 3-15-78; 8:45 am]

NOTE

According to technical amendments published by EPA in the May 29, 1987 FEDERAL REGISTER (52 FR 20083), TSCA Section 8(e) submissions are to be addressed to the Agency as follows:

Document Processing Center (TS-790)
(Attn: Section 8(e) Coordinator)
Office of Toxic Substances
U.S. Environmental Protection Agency
401 "M" Street, S.W.
Washington, D.C. 20460

APPENDIX A

REPORTING GUIDANCE: TSCA SECTION 5(e) COMPLIANCE AUDIT PROGRAM (CAP)

TSCA Section 8(e) Reporting Guide

June 1991

NOTICE TO ADMINISTRATOR OF SUBSTANTIAL RISKS. Any person who manufactures, [imports,] processes, or distributes in commerce a chemical substance or mixture and who obtains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment shall immediately inform the [EPA] Administrator of such information unless such person has actual knowledge that the Administrator has been adequately informed of such information.

-- Section 8(e), Toxic Substances Control Act (1976)

Office of Toxic Substances
Office of Pesticides and Toxic Substances
U.S. Environmental Protection Agency
Washington, D.C. 20460

Preface

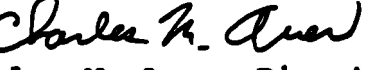
This "reporting guide" has been compiled by EPA's Office of Toxic Substances (OTS) to assist potential respondents who manufacture, import, process or distribute chemical substances in complying with Section 8(e), the substantial risk information reporting provision of the Toxic Substances Control Act (TSCA).

There are two major objectives for presenting this guide. First, the guide will make certain information pertaining to Section 8(e) reporting even more accessible to members of the the regulated community and others. Second, the guide will provide reference to both general and specific examples of submitted information as well as EPA's comments regarding such submissions. The examples are intended to help persons who are subject to Section 8(e) understand better the types of information that should be submitted to the Agency under this very important mandatory hazard/risk information reporting provision of TSCA.

Most of this TSCA Section 8(e) reporting guide is presented in a basic question and answer format reflecting primarily the most common questions asked about Section 8(e) of TSCA. In addition, this reporting guide contains EPA's comments regarding the TSCA Section 8(e)-applicability/reportability of a number of toxicologic "case studies" provided by the Chemical Manufacturers Association (CMA). The guide also contains an index of Section 8(e) "status reports" reflecting Section 8(e) reporting guidance (Appendix A) and an index of all status reports prepared to date arranged by submitted information type (Appendix B).

EPA recommends that this TSCA Section 8(e) reporting guide be used as a tool in conjunction with EPA's March 16, 1978, Section 8(e) policy statement ("Statement of Interpretation and Enforcement Policy; Notification of Substantial Risk" 43 FR 11110). EPA's TSCA Section 8(e) policy statement is included as Appendix C at the back of this reporting guide. Also included is Appendix D which contains a copy of a February 1, 1991 Federal Register notice that announced EPA's TSCA Section 8(e) "Compliance Audit Program" (CAP) and copies of EPA's April 26, 1991 and encoded June 20, 1991 Federal Register notices announcing certain modifications to the CAP.

This reporting guide is being distributed publicly through the TSCA Assistance Information Service (TSCA Hotline) in the Environmental Assistance Division (EAD/OTS). Persons wishing to obtain a copy of the guide should contact the TSCA Hotline. The telephone numbers, telefax numbers and/or addresses of the TSCA Hotline, other EPA Offices, and other organizations cited throughout this guide are presented for the reader's convenience on the next few pages.



Charles M. Auer, Director
Existing Chemical Assessment Division/OTS

TSCA Hotline

Phone: (202) 554-1404

Telefax: (202) 554-5603

Address: TSCA Assistance Information Service
Environmental Assistance Division
Office of Toxic Substances (TS-799)
U.S. Environmental Protection Agency
401 "M" Street, S.W.
Washington, D.C. 20460

TSCA Section 8(e) Document Processing Center

Address: Document Processing Center (TS-790)
(Attn: Section 8(e) Coordinator)
Office of Toxic Substances
U.S. Environmental Protection Agency
401 "M" Street, S.W.
Washington, D.C. 20460

"For Your Information" (FYI) Document Processing Center

Address: Document Processing Center (TS-790)
(Attn: FYI Coordinator)
Office of Toxic Substances
U.S. Environmental Protection Agency
401 "M" Street, S.W.
Washington, D.C. 20460

TSCA Section 8(e) and FYI Document Control Officer

Name: Michel Stewart

Phone: (202) 382-3532
(202) 260-1532 (after 8/24/91)

TSCA Confidential Business Information (CBI) Issues

Address: Confidential Data Branch
Information Management Division
Office of Toxic Substances
U.S. Environmental Protection Agency
401 "M" Street, S.W.
Washington, D.C. 20460

Phone: (202) 475-7425
(202) 260-0425 (after 8/24/91)

TSCA Section 8(e) Coordinator

Name: David Williams

Phone: (202) 382-3468
(202) 260-3468 (after 8/24/91)

FYI Coordinator

Name: Jacqueline Favilla

Phone: (202) 475-8823
(202) 260-8823 (after 8/24/91)

Public Docket/Office of Toxic Substances

Address: OTS Public Docket
Room G-004, NorthEast Mall
U.S. Environmental Protection Agency
401 "M" Street S.W.
Washington, D.C. 20460

Hours of Operation: 8-12 and 1-4 Monday through Friday
(Closed on Federal Holidays)

Freedom of Information Office/EPA

Address: Freedom of Information Office (A-101)
U.S. Environmental Protection Agency
401 "M" Street, S.W.
Washington, D.C. 20460

Office of Compliance Monitoring

Address: Office of Compliance Monitoring (EN-342)
U.S. Environmental Protection Agency
401 "M" Street, S.W.
Washington, D.C. 20460

Phone: (202) 382-3807
(202) 260-3807 (after 8/24/91)

Office of General Counsel

Address: Pesticides and Toxic Substances Division
Office of General Counsel (LE-132-P)
U.S. Environmental Protection Agency
401 "M" Street, S.W.
Washington, D.C. 20460

Phone: (202) 382-7505
(202) 260-7505 (after 8/24/91)

Office of Enforcement

Address: Pesticides and Toxics Enforcement Division
Office of Enforcement (LE-134-P)
U.S. Environmental Protection Agency
401 "M" Street, S.W.
Washington, D.C. 20460

Phone: (202) 475-8690
(202) 260-8690 (after 8/24/91)

National Response Center

Toll-Free: (800) 424-8802

Local: (202) 426-2675

EPA Regional Office 24-Hour Phone Numbers

Region 1	(617) 223-7265	Region 6	(214) 655-2222
Region 2	(201) 548-8730	Region 7	(913) 236-3778
Region 3	(215) 597-9898	Region 8	(303) 293-1788
Region 4	(404) 347-4062	Region 9	(415) 744-2000
Region 5	(312) 353-2318	Region 10	(206) 442-1263

National Technical Information Service

Address: National Technical Information Service (NTIS)
U.S. Department of Commerce
5285 Port Royal Road
Springfield, Virginia 22161

Phone: (703) 487-4600

National Library of Medicine (NLM)

Address: National Library of Medicine
U.S. Department of Health and Human Services
8600 Rockville Pike
Bethesda, Maryland 20894

Phone: (301) 496-6193

Chemical Information Systems, Inc. (CIS)

Address: Chemical Information Systems, Inc.
7215 York Road
Baltimore, Maryland 21212

Phone: (800) CIS-USER (Toll-Free)

(301) 321-8440 (Local)

Contents

Preface i

Important Addresses and Telephone Numbers ii

Reporting Under Section 8(e) of TSCA 1

What is the Statutory Language of TSCA Section 8(e)? 1

Why is Section 8(e) Reporting Important? 1

How was EPA's Section 8(e) Policy Statement Developed? .. 1

What is "Substantial Risk" Information? 2

Who is Subject to Section 8(e) Reporting? 3

What Chemicals are Subject to Section 8(e) Reporting? ... 5

What does the Term "Obtains Information" Mean? 6

What are the Sources Of 8(e)-Reportable Information? 7

What Information is Not Reportable Under Section 8(e)? .. 8

How does 8(e) Relate to Section 4, 5 & 8(d) Reporting? .. 10

Does a "For Your Information" Notice Satisfy 8(e)? 10

Does Reporting to Another Agency Satisfy 8(e)? 11

When Must Section 8(e) Information be Reported to EPA? .. 11

Where Must Section 8(e) Information be Reported? 12

How Must Section 8(e) Information be Reported? 13

How can Confidential Data be Claimed/Sent Under 8(e)? ... 14

How does EPA Track/Identify Section 8(e) Notices? 14

How does OTS Review/Use Section 8(e) Information? 15

Do Status Reports Represent EPA's Bottom-Line on Risk? .. 19

Has EPA Issued Other Section 8(e) Reporting Guidance? ... 20

Reporting Under Section 8(e) of TSCA (Continued)

How can the Public Obtain Section 8(e) Submissions? 24

Is there a Section 8(e) Enforcement Response Policy? 25

Has EPA Taken Formal Section 8(e) Enforcement Actions? .. 27

Does 8(e) Implementation Encourage Pollution Prevention? 27

Case Studies 29

A. Numerical Reporting Guidance for Lethality Information .. 29

B. Acute Tests with Non-Lethal Neurobehavioral Findings 31

C. Skin/Eye Irritation and Skin Sensitization Tests..... 34

D. Subchronic Toxicity 36

APPENDIX A

Index of 8(e) Status Reports Containing Policy/Guidance 39

I. Toxicological/Exposure Findings 39

A. Acute Toxicity (animal) 39

B. Acute Toxicity (human) 39

C. Subacute Toxicity (animal) 40

D. Immunotoxicity (animal) 40

E. Neurotoxicity (animal) 40

F. Neurotoxicity (human) 40

G. Oncogenicity (animal) 40

H. Oncogenicity (human) 41

I. Reproductive/Developmental Toxicity (animal) 41

J. Reproductive/Developmental Toxicity (human) 41

K. Genotoxicity (in vitro) 41

L. Genotoxicity (in vivo) 42

I. Toxicological/Exposure Findings (Continued)

M. Aquatic Toxicity/Bioconcentration 42

N. Emergency Incidents of Environmental Contamination . 42

O. General (NonEmergency) Environmental Contamination . 42

II. General Section 8(e) Reporting Issues 42

A. Intracorporate Reporting Procedures 42

B. Subject Persons 43

C. Subject Chemicals 43

D. Research & Development Chemicals 43

E. Drug Export 43

F. Pesticide Export 43

G. Previous Manufacture/Import/Process/Distribution ... 44

H. Obtaining Information 44

I. Pre-1977 Information 44

J. Actual Knowledge by EPA 44

K. Published Scientific Literature 45

L. Information Obtained from Other Federal Agencies ... 45

M. Information Corroborating Well-Established Effects . 45

N. Relationship to Other TSCA Reporting Requirements .. 45

O. Relationship to Other EPA Administered Authorities . 46

P. Relationship to Non-EPA Administered Authorities ... 46

Q. Section 8(e) Reporting Procedures 47

APPENDIX B

Index of All Section 8(e) Status Reports
Arranged by Submitted Information Type 49

APPENDIX C

TSCA Section 8(e) Policy Statement 91
(March 16, 1978; 43 FR 11110)

Technical Amendment Citation 98
(May 29, 1987; 52 FR 20083)

APPENDIX D

TSCA Section 8(e) Compliance Audit Program Notice 99
(February 1, 1991; 56 FR 4128)

Compliance Audit Program Modifications 104
(April 26, 1991; 56 FR 19514)

Compliance Audit Program Modifications 107
(encoded version June 20, 1991; 56 FR Part IV)

APPENDIX E

Support Information for Confidentiality Claims 111

REPORTING UNDER SECTION 8(E) OF TSCA

WHAT IS THE STATUTORY LANGUAGE OF TSCA SECTION 8(E)?

Section 8(e) of the Toxic Substances Control Act (TSCA) states that "any person who manufactures [including imports], processes, or distributes in commerce a chemical substance or mixture and who obtains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment shall immediately inform the [EPA] Administrator of such information unless such person has actual knowledge that the Administrator has been adequately informed of such information." [90 Stat. 2029, 15 U.S.C. 2607(e)]

WHY IS SECTION 8(E) REPORTING IMPORTANT?

In general, EPA considers Section 8(e) of TSCA to be a critically important information gathering tool that serves as an "early warning" mechanism for keeping the Agency and others apprised of new-found serious chemical hazards and/or exposures; Section 8(e) data are extremely valuable input for the hazard identification and risk assessment activities within and outside EPA.

HOW WAS EPA'S SECTION 8(E) POLICY STATEMENT DEVELOPED?

The Section 8(e) information reporting requirement took effect on January 1, 1977, the effective date of TSCA. Although Section 8(e) contains self-implementing reporting requirements, EPA sought public comment and input in order to make more informed decisions regarding implementation of Section 8(e). Following receipt and consideration of numerous public comments on a September 9, 1977 proposed policy statement, EPA published its March 16, 1978 final Section 8(e) policy statement ("Statement of Interpretation and Enforcement Policy; Notification of Substantial Risk" 43 FEDERAL REGISTER 11110). The 1978 policy statement clarifies the types of information that are required for submission under Section 8(e), and describes the procedures for reporting such information to EPA. A minor technical amendment to EPA's 1978 TSCA Section 8(e) policy statement involved a change in the address to which Section 8(e) notices are to be sent (52 FEDERAL REGISTER 20083; May 29, 1987). For easy referral when using this reporting guide, the Agency's Section 8(e) policy statement has been reproduced as Appendix C at the back of the guide.

WHAT IS "SUBSTANTIAL RISK" INFORMATION?

The term "substantial risk" information refers to that information which reasonably supports a conclusion that the subject chemical or mixture presents a substantial risk of injury to health or the environment; however, such information need not and most typically does not establish conclusively that a substantial risk exists.

In deciding whether information is "substantial risk" information, one must consider 1) the seriousness of the adverse effect, and 2) the fact or probability of the effect's occurrence. In determining TSCA Section 8(e)-applicability/reportability, these two criteria should be weighted differently depending upon the seriousness of the effect or the extent of the exposure, i.e., the more serious the effect, the less heavily one should weigh actual or potential exposure, and vice versa. For example, in cases where serious effects such as birth defects or cancer (as evidenced by benign and/or malignant tumors) are observed, the mere fact that the implicated chemical is in commerce (including chemicals at the research and development stage) constitutes sufficient evidence of exposure to submit the new-found toxicity data.

EPA has also received numerous Section 8(e) submissions alerting the Agency that chemical substances already known to be capable of causing serious health and/or environmental effects were detected in significant amounts in environmental media (e.g., soil, surface waters, groundwater, air (including workplace air)) or in products not known previously by the Agency to contain such chemicals. In such cases, the discovery of previously unknown and significant human and/or environmental exposure, when combined with knowledge that the subject chemical is already recognized or suspected as being capable of causing serious adverse health effects (e.g., cancer, birth defects, neurotoxicity) or serious environmental effects (e.g., non-trivial aquatic species toxicity), can provide a sufficient basis to report the new-found exposure data to EPA under Section 8(e) of TSCA.

The decision-making process for Section 8(e)-reportability should focus primarily on whether the toxicity or exposure information offers reasonable support for a conclusion of substantial risk under the criteria described above, but should not focus at all on whether the information is conclusive regarding the risk. A

---

[1] "Substantial risk" information must be reported to EPA unless the subject person has actual knowledge that the Agency has been adequately informed of such information. A detailed discussion of the types of information about which EPA considers itself to be adequately informed is presented on Page 8 of this reporting guide under WHAT INFORMATION IS NOT REPORTABLE UNDER SECTION 8(E)?

decision to report information to the Agency under Section 8(e) should not involve exhaustive health and/or environmental risk assessments of the subject chemical(s). Further, determining reasonable support for a conclusion of substantial risk should not include any evaluation of either the economic or social benefits of the use(s) of the subject chemical substance(s). Finally, determining whether reasonable support exists for "substantial risk" is not synonymous with the determination of an "unreasonable risk" as that term is used elsewhere in TSCA.

WHO IS SUBJECT TO SECTION 8(E) REPORTING?

For the purposes of Section 8(e), the term "person" includes the following: any natural person, corporation, firm, company, sole-proprietorship, joint-venture, partnership, association, or any other business entity, any State or political subdivision of a State, any municipality, any interstate body, and any department or agency of the Federal Government.

Such "persons" are subject to TSCA Section 8(e) only to the extent they are engaged in commercial activities involving manufacture, importation, processing or distribution of chemical substances or mixtures under the jurisdiction of TSCA and therefore covered by Section 8(e) of TSCA. While it is clear that entities such as labor unions, trade associations, contract testing laboratories and agencies of the Federal Government are "persons" covered by TSCA Section 8(e), the mandatory obligation to report substantial risk information is incurred only to the extent that the entity is engaged commercially in manufacturing, importing, processing or distribution of the chemical substance or mixture about which substantial risk information is obtained; however, these particular entities are not typically involved in such commercial activities.

Under Section 8(e), there are no exemptions for small businesses, small production or importation volumes, or commercial activities such as manufacture for export only or research and development. However, Section 8(e) does not require a subject person to submit information about a chemical substance or mixture that the person does not manufacture, import, process or distribute commercially. Further, a person who obtains substantial risk information about a chemical or mixture that the person did at one time, but does not any longer, manufacture, import, process or distribute in commerce, is not required to submit the information under Section 8(e).

Despite these limitations in coverage, EPA has received numerous Section 8(e) submissions from respondents who obtained otherwise reportable Section 8(e) information but for some technical reason did not have any statutory obligation to submit the information to EPA pursuant to Section 8(e). EPA believes that such submissions are of significant benefit, in many cases, to others who currently

handle the subject chemical(s) and who can take actions that are designed generally or specifically to reduce or eliminate health or environmental hazards/risks. A formal TSCA Section 8(e) or "For Your Information" (FYI) notice under these circumstances is a clear demonstration of the respondent's stewardship. EPA encourages and welcomes these technically voluntary submissions either pursuant to Section 8(e) or on an FYI basis.

In implementing Section 8(e) of TSCA, EPA strives to ensure that pertinent information is reviewed promptly, and given appropriate consideration, by subject persons for submission to EPA, while at the same time minimizing duplicative or ill-considered notices. The Agency believes these objectives are served best by allowing commercial establishments to assume the exclusive responsibility to submit substantial risk information that is obtained by individual employees and officials. Accordingly, EPA's Section 8(e) policy statement explains that individual officers/employees are viewed as having discharged their individual Section 8(e) responsibilities once they notify a designated supervisor or official in full about pertinent information, provided that the employing entity has an established, internally publicized and affirmatively implemented procedure governing such notices. The Agency's Section 8(e) policy statement specifies that such procedures, at a minimum, must:

(1) specify the information that must be reported;

(2) indicate how the reports are to be prepared and submitted internally;

(3) note the Federal civil and criminal penalties for failure to report substantial risk information; and

(4) provide a mechanism for the timely notification of officers and employees who submitted reports about the disposition of those reports. Such notification should inform the reporting employee/officer as to whether or not the information was submitted to EPA, and if not, inform the employee or officer of their protected right (under Section 23 of TSCA) to report the information directly to EPA.

The Agency believes that the above procedures serve to ensure prompt and appropriate processing and consideration of pertinent information by persons subject to Section 8(e) of TSCA. It is important to note, however, that despite the establishment of such procedures, those employees and officers who are responsible for actual management of the organizations's Section 8(e) reporting obligations retain personal civil and/or criminal liability for ensuring that substantial risk information is submitted to the Agency. In the absence of such established internal procedures, all employees and officers retain their individual responsibilities and liabilities for ensuring that substantial risk information is reported to EPA.

WHAT CHEMICALS ARE SUBJECT TO SECTION 8(E) REPORTING?

Chemicals not under TSCA jurisdiction and therefore not covered by Section 8(e) are discussed in Section 3 of TSCA and include:

(1) pesticides (as defined in the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)) when manufactured, processed, or distributed in commerce for use as a pesticide;

(2) tobacco and tobacco products;

(3) source materials, special nuclear materials and byproducts (as defined in the 1954 Atomic Energy Act (AEA) and regulations issued under the AEA);

(4) foods, food additives, drugs, cosmetics, and devices (as defined in the Federal Food, Drug and Cosmetic Act (FFDCA)) when manufactured, processed or distributed in commerce as a food, food additive, drug, cosmetic or device.

Except for those chemicals specifically excluded by definition from TSCA jurisdiction, Section 8(e) of TSCA pertains to all chemical substances and mixtures including but not limited to the following:

(1) research and development (R&D) chemicals (including those intended for use as pesticides prior to application for an Experimental Use Permit (EUP) or a registration under FIFRA);

(2) laboratory reagents;

(3) low volume chemicals;

(4) polymers;

(5) chemicals that are manufactured solely for export;

(6) intermediates (including non-isolated intermediates as well as pesticide intermediates);

(7) catalysts;

(8) byproducts;

(9) impurities;

(10) TSCA-covered microorganisms and products therefrom.

Specifically with regard to "pesticides," a chemical substance that is manufactured, processed or distributed in commerce <u>solely</u> as a pesticide is excluded by Section 3 of TSCA from TSCA regulation. However, a chemical substance which is in the process of research and development (R&D) as a pesticide is subject to TSCA <u>until</u> such time as the manufacturer or importer demonstrates the intent to

produce a pesticide by submitting to the Agency an application for an "Experimental Use Permit" (EUP) or registration under FIFRA. For further information about this TSCA/FIFRA jurisdictional issue, the reader is directed to EPA's initial TSCA Chemical Substance Inventory reporting regulation (43 FR 64585; December 23, 1977; Appendix A Comment 37, 38 and 39) and the 1986 amendments to the TSCA Section 5 "Premanufacture Notification Rule" (51 FR 15098; April 22, 1986). Prior to the FIFRA EUP or registration stage, such R&D materials are chemical substances under the jurisdiction of TSCA including Section 8(e).

It is important to note also that while some rules promulgated by EPA under other sections of TSCA, or under other authorities which are administered by EPA, may exempt certain chemical substances and/or mixtures or certain types of commercial activities, such exemptions typically apply only to the rule issued by the Agency and not to TSCA in general or Section 8(e) of TSCA specifically.

WHAT DOES THE TERM "OBTAINS INFORMATION" MEAN?

Section 8(e) pertains to information that a person possesses or about which the person knows. The Section 8(e) policy statement explains that an establishment obtains information at the time any officer or employee who is capable of appreciating the significance of the information obtains that information. "Known" information includes that information about which a prudent person of similar training, job function, etc., could be reasonably expected to know. Although Section 8(e) of TSCA does not compel subject persons to actively search for reportable information or to undertake extraordinary efforts to retrieve reportable information, negligence or the intentional avoidance of information does not absolve a person of his/her individual Section 8(e) reporting obligations. TSCA Section 8(e)-reportable information that is "obtained" by a company includes:

a) information obtained before January 1, 1977 and reviewed after January 1, 1977, but prior to March 16, 1978 (the publication date of EPA's TSCA Section 8(e) policy statement);

b) information obtained for the first time after January 1, 1977 but before March 16, 1978; or

c) information obtained by the company for the first time after March 16, 1978.

NOTE: For information regarding the specific time frames for reporting such "obtained" information, the reader's attention is directed to WHEN MUST TSCA SECTION 8(E) INFORMATION BE REPORTED TO EPA? on Page 11 of this guide.

With regard to a), b) and c) on the preceding page, Section 8(e)-reportable information includes not only written reports, memoranda and other such documents examined after January 1, 1977, but also information referred to in formal or informal discussions and conferences in which a company participated after January 1, 1977.

Specifically with regard to a public scientific conference/meeting, visually or verbally obtained information from such a meeting is subject to Section 8(e) reporting unless the obtained information is captured accurately/adequately in a meeting transcript, abstract or other such written record or document that is to be formally released to the public within a reasonable time frame. Information obtained from a private conference or meeting, however, should be considered for reporting under Section 8(e) within 15 working days.

WHAT ARE THE SOURCES OF SECTION 8(E)-REPORTABLE INFORMATION?

TSCA Section 8(e)-reportable information can come from a variety of sources including, but not limited to draft, interim or final written reports (including study reports, letters, telegrams, telex reports) or verbal reports (received at meetings or by phone) that involve observations (including preliminary observations) from, for example, controlled or uncontrolled:

(1) human or animal studies/events (including but not limited to studies/events that involve high dose levels or non-routine routes of exposure); or

(2) environmental events/studies (including but not limited to aquatic toxicity studies, bioaccumulation studies, chemical monitoring studies (supplemented if need be by information derived from computer modeling studies based on actual or reasonably anticipated chemical exposures and exposure-related parameters)). It is important to note, however, that modeling studies, including those based solely on theoretical exposure data (e.g., "worst-case" scenarios), are not considered by EPA to be sufficient in and of themselves to meet the Section 8(e) reporting requirements. Further, environmental or health risk assessments (including those using computer modeling) based on either 1) theoretical exposure data, or 2) actual exposure data submitted on a mandatory basis under an EPA-administered statute typically need not be reported under Section 8(e).

The evidence that offers reasonable support for a conclusion of substantial risk need not be complete nor definitive but should provide a plausible link between 1) an observed serious effect and one or few chemicals (e.g., in a discrete process/operation), or 2) a specific product/activity and a previously unrecognized exposure to a chemical that is known or reasonably anticipated to cause serious adverse health or environmental effects.

EPA's March 16, 1978 Section 8(e) policy statement ("Statement of Interpretation and Enforcement Policy; Notification of Substantial Risk" 43 FR 11110) also requires immediate reporting of "Emergency Incidents of Environmental Contamination" (EIEC). An EIEC is an environmental contamination (accidental or intentional in nature) involving a chemical known to be a serious human or environmental toxicant and which because of the extent, pattern and amount of the contamination (1) seriously threatens humans with cancer, birth defects, mutation, death or serious or prolonged incapacitation (e.g., neurotoxicologic effects, serious reproductive system effects), or (2) seriously threatens non-human organisms with large-scale or ecologically significant population destruction.

WHAT INFORMATION IS NOT REPORTABLE UNDER SECTION 8(E)?

There are several kinds of information about wh the Agency considers itself to be adequately informed already f the purposes of Section 8(e) of TSCA. For example, information at otherwise meets the criteria for Section 8(e) reporting need not be submitted if the information meets one or more of the following criteria:

(1) is contained in an EPA study or report.

(2) is published in the open scientific literature.

(3) has been submitted already to EPA under another mandatory reporting provision of 1) TSCA, or 2) some other authority that is administered by EPA.

(4) is contained in a formal publication/report or a formal statement made available to the general public by another Federal agency.

(5) is corroborative (in terms of, for example, route of exposure, dose, species, time to onset, severity, species, strain, etc.) of a well-established adverse effect.

It is important to note, however, that information that newly identifies a serious toxic effect at a lower dose level for example, or confirms a serious effect that was previously only suspected, is not considered by EPA to be corroborative and should be reported under Section 8(e) of TSCA.

(6) is information for which the EPA Administrator has waived compliance with TSCA in general or Section 8(e) specifically upon a request and determination of the President of the United States that such a waiver is required in the interest of the national defense; Section 22 of TSCA outlines the procedures by which such waivers are to be requested/issued.

With regard to item (2) on the preceding page, EPA believes that for the purposes of Section 8(e) reporting, a subject person need not report information that is obtained from well-established/well-recognized scientific journals, such as those typically abstracted in a) major computerized abstract data bases, or 2) publications such as Current Contents published by the Institute for Scientific Information (ISI), Inc. (Philadelphia, Pennsylvania). Similarly, information that is obtained from major U.S. news publications (e.g., newspapers or news magazines with national circulation) or nationally broadcast U.S. radio and/or television news reports typically need not be submitted to EPA under Section 8(e) of TSCA. However, with regard to information obtained from lesser known scientific journals, or from other magazines, newspapers, radio or television reports, a subject person must have actual knowledge that EPA has been adequately informed about such information.

Specifically with regard to item (3) on the preceding page, it is clear that information submitted or otherwise formally reported (within 15 working days of obtaining the information) pursuant to a mandatory reporting requirement of a statute administered by EPA need not be submitted duplicatively under Section 8(e) of TSCA. Part VII(b) of EPA's March 16, 1978 Section 8(e) policy statement is illustrative in that it provides a list of only a few such EPA-administered statutes. The following is a more current list of the statutes administered by EPA.

Toxic Substances Control Act (TSCA)

Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)

Clean Air Act (CAA)

Clean Water Act (CWA)

Safe Drinking Water Act (SDWA)

Federal Water Pollution Control Act (FWPCA)

Marine Protection, Research and Sanctuaries Act (MPRSA)

Resource Conservation and Recovery Act (RCRA)

RCRA Hazardous and Solid Waste Amendments (HSWA)

Comprehensive Environmental Response,
Compensation and Liability Act (CERCLA; SUPERFUND)

Superfund Amendments Reauthorization Act (SARA)

Specifically with regard to item (4) on Page 8, it cannot be automatically assumed that the Agency has been adequately informed about information in a report or study by another Federal or other governmental agency if the report or study has not been formally published or otherwise released to the general public. Therefore, if a person obtains (i.e., possesses or knows of), for example, certain unpublished Section 8(e)-reportable information from a study that is conducted by or for an agency of the U.S. Government (other than EPA), that person must consider the need to immediately submit those findings under Section 8(e). Since 1977, EPA has received a number of Section 8(e) notices filed by companies who had obtained unpublished results of studies conducted by or for other Federal or other governmental agencies. In most cases, such submissions are limited to 1-2 pages and the Agency immediately establishes direct contact with the responsible agency to minimize or eliminate the company's Section 8(e) reporting burden.

HOW DOES 8(E) RELATE TO TSCA SECTIONS 4, 5 & 8(D) REPORTING?

The TSCA Section 8(e) reporting requirement applies to "substantial risk" information obtained during any study conducted under TSCA Sections 4 or 5, or any study "listed" under TSCA Section 8(d) as being underway unless such information is otherwise required to be reported immediately to EPA under 1) Sections 4, 5 or 8(d) of TSCA, 2) some other section of TSCA, or 3) some other authority that is administered by EPA. To date, the Agency has received numerous TSCA Section 8(e) notices concerning the interim results of studies conducted pursuant to Sections 4 or 5 of TSCA, or listed under Section 8(d) of TSCA. The Section 8(e) reporting that took place in these instances typically occurred because the obligation to report under Section 8(e) was incurred before reporting of the study findings was required under Sections 4, 5 or 8(d) of TSCA. If other required reporting occurs before or coincidental with incurring a Section 8(e) reporting obligation, that information does not need to be reported also under Section 8(e) of TSCA. This exemption does not change substantially the Section 8(e) reporting obligation; it is designed merely to avoid duplicative notices except in cases where timeliness considerations become paramount.

DOES A "FOR YOUR INFORMATION" SUBMISSION SATISFY 8(E) REQUIREMENTS?

Section 8(e)-reportable information submitted to EPA on a "For Your Information" (FYI) basis does not satisfy the requirements for the submission of information under Section 8(e). TSCA Section 8(e) information must be reported to EPA in full accordance with the procedures outlined in Part IX of the Agency's March 16, 1978 Section 8(e) policy statement ("Statement of Interpretation and Enforcement Policy; Notification of Substantial Risk" 43 FR 11110)

and its technical amendment (52 FR 20083). The TSCA Section 8(e) policy statement/technical amendment appear at the back of this reporting guide as Appendix C. In addition, the reader's attention is directed to WHERE MUST SECTION 8(E) INFORMATION BE REPORTED? and HOW MUST SECTION 8(E) INFORMATION BE REPORTED? found on Page 12 and Page 13 of this reporting guide, respectively. Finally, it should be noted that EPA's Office of Compliance Monitoring (OCM/OPTS) has issued a number of "Notices of Non-Compliance" to companies that have submitted TSCA Section 8(e)-reportable information in a timely manner but simply on an FYI basis and not under Section 8(e). For further information with regard to EPA's enforcement activities relating to TSCA Section 8(e), the reader's attention is directed also to HAS EPA TAKEN FORMAL SECTION 8(E) ENFORCEMENT ACTIONS? which can be found on Page 27 of this reporting guide.

DOES REPORTING TO ANOTHER AGENCY SATISFY SECTION 8(E) REQUIREMENTS?

Mandatory or other reporting of information to another agency does not satisfy a company's obligation to immediately inform EPA under Section 8(e) of TSCA. EPA's TSCA Section 8(e) policy statement ("Statement of Interpretation and Enforcement Policy; Notification of Substantial Risk" 43 FR 11110), which appears as Appendix C at the back of this guide, explains clearly that "substantial risk information must be reported to EPA." (emphasis added)

WHEN MUST SECTION 8(E) INFORMATION BE REPORTED?

A person is considered to have discharged the TSCA Section 8(e) reporting obligation if the information is received at EPA Headquarters in writing within 15 working days after the person obtained the information. Relevant or significant supplemental data obtained after an initial Section 8(e) submission should also be reported in writing to EPA immediately (i.e., within 15 working days). The reader's attention is directed to WHAT DOES THE TERM "OBTAINS INFORMATION" MEAN? found on Page 6 of this reporting guide.

For an "Emergency Incident of Environmental Contamination" (EIEC), a telephone call to the appropriate EPA Regional Office must be placed immediately (i.e., as soon as reasonably possible); these phone numbers are given in the next section of this guide. A written follow-up report must also sent to EPA Headquarters within 15 working days of the date on which the telephone report was made.

Specifically with regard to 1) Section 8(e)-reportable information obtained before January 1, 1977 and reviewed after January 1, 1977, but prior to March 16, 1978 (the publication date of EPA's TSCA Section 8(e) policy statement), or 2) Section 8(e)-reportabl-

information obtained for the first time after January 1, 1977 but before March 16, 1978, such information should have been submitted already to EPA on or before the 60th day following March 16, 1978.

TSCA Section 8(e)-reportable information (including pre-1977 information) that is (was) obtained by a company for the first time following March 16, 1978 should be submitted (or should have been submitted already) to EPA within 15 working days of the date on which the information is (was) obtained by the company for the first time after March 16, 1978.

WHERE MUST SECTION 8(E) INFORMATION BE REPORTED?

As explained in a technical amendment (52 FR 20083; May 29, 1987) to EPA's Section 8(e) policy statement, Section 8(e) submissions (including written follow-up reports for "Emergency Incidents of Environmental Contamination" (EIEC)) must be transmitted to EPA at the following address:

Document Processing Center (TS-790)
(Attn: Section 8(e) Coordinator)
Office of Toxic Substances
U.S. Environmental Protection Agency
401 "M" Street, S.W.
Washington, D.C. 20460

The initial phone report for an EIEC should be placed immediately (i.e., as soon as is reasonably possible) to the EPA Regional Office in whose jurisdiction the EIEC occurred or was discovered; the current 24-hour phone numbers for EPA's 10 Regional Offices are as follows.

Region 1	(617) 223-7265	Region 6	(214) 655-2222
Region 2	(201) 548-8730	Region 7	(913) 236-3778
Region 3	(215) 597-9898	Region 8	(303) 293-1788
Region 4	(404) 347-4062	Region 9	(415) 744-2000
Region 5	(312) 353-2318	Region 10	(206) 442-1263

In the event that a respondent cannot reach the EPA Regional Office in whose jurisdiction the EIEC occurred or was discovered, the respondent should immediately call the National Response Center at (800)-424-8802 or 202-426-2675 and provide all known information

requested by the officer on duty. Under these circumstances, the respondent will be considered to have satisfied the initial phase of the Section 8(e) reporting obligation; a written "follow-up" report regarding the EIEC, however, must still be submitted to EPA Headquarters within 15 working days of the EIEC phone report.

Persons wishing to submit data to EPA's Office of Toxic Substances simply on a "For Your Information" (FYI) basis and not pursuant to Section 8(e) of TSCA should send the information to:

Document Processing Center (TS-790)
(Attn: FYI Coordinator)
Office of Toxic Substances
U.S. Environmental Protection Agency
401 "M" Street, S.W.
Washington, D.C. 20460

Persons submitting information to EPA on an FYI basis should be aware that the Agency's processing of documents received under mandatory reporting provisions of TSCA always takes precedence over those submitted simply as FYI. The reader should also be aware that the submission of data to the Agency on an FYI basis does not satisfy a TSCA Section 8(e) reporting obligation. For further information on this particular subject, the reader's attention is directed to DOES A FOR YOUR INFORMATION SUBMISSION SATISFY SECTION 8(E) REQUIREMENTS? found on Page 10 of this reporting guide.

HOW MUST SECTION 8(E) INFORMATION BE REPORTED?

Section 8(e) submissions must be transmitted to EPA in a manner that permits the Agency to verify receipt of the submission (e.g., certified or registered mail). In addition, the submission must state clearly that it is being provided under Section 8(e) of TSCA. Further, the submission must contain the name, title and telephone number of the person sending the information, the name and address of the establishment with which the reporting person is affiliated, the name(s) (including Chemical Abstract Service (CAS) Registry Number(s), if known) of the subject chemical(s), and a summary describing the nature of adverse effects or exposure being reported together with the source of any supporting technical data.

For an "Emergency Incident of Environmental Contamination" (EIEC), the initial telephone report must provide the time and location of the incident and as much of the above information as is known at the time. A written EIEC follow-up report to EPA Headquarters must contain the same types of information that are required in a non-EIEC initial Section 8(e) submission.

HOW CAN CONFIDENTIAL DATA BE CLAIMED/SENT UNDER SECTION 8(E)?

In claiming any submitted information to be "Confidential Business Information" (CBI) under TSCA, respondents should be aware that all of the information reported under specific TSCA requirements (e.g., Section 8(e)) or in support of TSCA is subject to 1) provisions of Section 14 of TSCA, and 2) EPA's regulations on confidentiality of business information (40 CFR Part 2). Any person who submits CBI to EPA under Section 8(e) should be aware that two copies must be provided. The first copy should be complete, with all CBI marked carefully and clearly by boxing, circling or underlining; all of the pages containing CBI should be stamped "CONFIDENTIAL". The other copy should have all of the confidential information excised; this "sanitized" version is required for EPA's public files. Any person who submits CBI to EPA under Section 8(e) of TSCA should also be aware that the Agency does request a detailed written substantiation for all TSCA CBI claims. (A copy of a two-page document entitled "Support Information for Confidentiality Claims" is included as Appendix E to this reporting guide.) Finally, a person who submits TSCA CBI to EPA under Section 8(e) should also be aware that the Agency is under no formal obligation to review, and typically does not review, company-sanitized documents for errors made in sanitizing those documents.

HOW DOES EPA IDENTIFY/TRACK INCOMING SECTION 8(E) NOTICES?

A Document Control Number is used by EPA to identify TSCA Section 8(e) submissions and takes the following form: 8EHQ-0000-0000. Starting at the left, the first four symbols identify the information as a Section 8(e) submission received by EPA Headquarters; the next four digits identify the month and year (e.g., -0591-) of the Agency's receipt of the information; the final four digits identify the submission's chronological number. In addition to the basic numerical sequence, additional characters may be added to the right end of the Document Control Number to convey other information. These additional characters and their meaning are as follows:

- **S:** indicates that the Section 8(e) notice was sanitized to delete information claimed by the submitter to be TSCA Confidential Business Information (TSCA CBI);

- **P:** indicates that the Section 8(e) notice contained a name or other identification (e.g., a Social Security Number) of an individual, the release of which may violate the Privacy Act; such documents are sanitized by EPA to remove such identifiers;

*: indicates that based on EPA's preliminary evaluation, the submission was either considered to be unwarranted for reporting under Section 8(e) of TSCA or that it was not clear to EPA that submission was warranted and further clarifying information was requested from the submitter.

INIT: denotes that the submission is an initial submission;

FLWP: indicates that the submission is a followup response; and

SUPP: indicates that the notice is a supplemental submission.

By definition, follow-up response submissions contain information submitted directly in response to a specific EPA request, whereas supplemental submissions are those that contain information not specifically requested by the Agency.

HOW DOES OTS REVIEW/USE SECTION 8(E) INFORMATION?

Although EPA's receipt of information under Section 8(e) of TSCA does not necessarily trigger immediate regulatory action under TSCA or another authority administered by EPA, the submitted information is processed and evaluated on a priority basis to determine an appropriate level of concern and initial course of Agency action.

Thus far, EPA and the chemical industry have devoted significant efforts in fulfilling their respective responsibilities under Section 8(e) of TSCA. Since January 1, 1977, over 1250 initial Section 8(e) notices covering a broad range of toxicity and exposure-related data on a wide variety of chemicals have been received by OTS and been given priority evaluation and follow-up attention.

In general, each initial TSCA Section 8(e) submission is promptly reviewed and evaluated by OTS scientific staff to determine both the degree of concern that should be attached to the submitted information and the initial course of any warranted OTS follow-up action(s). A "status report" is prepared containing a brief description of the submitted information, the results of the OTS preliminary evaluation, a statement regarding production and use of the subject chemical(s) and recommendations for appropriate follow-

up actions.[2] Upon approval of the status report, recommended follow-up actions are initiated. A letter forwarding the status report and any EPA requests for additional information is sent to the submitting organization. In addition, copies of all status reports are transmitted to EPA's public files, other designated EPA Program Offices and Federal Agencies, and to the OTS Environmental Assistance Division (EAD/OTS) for further distribution.

Other OTS follow-up actions include the consideration of further, more in-depth assessment of the reported chemical's hazard or risk. OTS staff also immediately reviews, evaluates, and initiates appropriate follow-up actions or activities on information that is contained in "follow-up" and "supplemental" TSCA Section 8(e) submissions; over 2000 TSCA Section 8(e) supplemental and follow-up submissions have been received and promptly evaluated by OTS staff since January 1, 1977.

OTS utilizes TSCA Section 8(e) submission data for hazard/risk identification purposes primarily in the initial stages of the OTS Existing Chemical Program (ECP). OTS also uses these data in ongoing health and exposure assessments of both existing and new chemicals and in support of regulation development under TSCA, e.g., development of chemical testing rules under TSCA Section 4.

EPA's proactive implementation of Section 8(e) of TSCA has resulted in heightened overall awareness of the risks posed by exposure to chemical substances and mixtures. Many benefits and impacts are evident from EPA's dissemination of TSCA Section 8(e) and related information to other EPA Offices, other Federal agencies, the general public and the international community. This heightened awareness has led, in many cases, to specific activities designed to directly or indirectly protect health and/or the environment.

OTS has established high level scientific and administrative contacts in each of the major EPA Program Offices and Regional Offices to provide a mechanism for the timely and prioritized dissemination of information about newly discovered chemical hazards or risks. These other EPA Program and Regional Offices effectively and routinely utilize TSCA Section 8(e) information in

---

[2] As of October 1, 1990, OTS began to issue "summaries" rather than "status reports" for incoming initial Section 8(e) submissions. These summaries contain a detailed accounting of toxicologic and other information (e.g., voluntary pollution prevention/risk reduction information, exposure data) presented in the initial TSCA Section 8(e) submission. The summaries do not reflect, however, the Agency's evaluation or disposition of the reported information. Copies of Section 8(e) submission summaries can be obtained in the same manner used to obtain copies of Section 8(e) status reports.

implementing their regulatory programs. The following examples illustrate just some of the actions/activities initiated by other EPA Offices in response to Section 8(e) and related data.

Office of Water (OW/EPA)

- preparing/revising Water Quality Criteria Documents and Drinking Water Standards.

Office of Solid Waste and Emergency Response (OSWER/EPA)

- determining the need for/revision of listing and delisting actions under the Resource Conservation and Recovery Act (RCRA); and
- establishing/revising "Reportable Quantities" (RQs) and "Threshold Planning Quantities" (TPQs) for the chemicals that are under the jurisdiction of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA; "Superfund").

Office of Research and Development (ORD/EPA)

- preparing/revising Health and Environmental Effects Profiles (HEEPs), Health Effects Assessments (HEAs) and Acceptable Daily Intakes (ADIs) for use by other EPA Program Offices; and
- determining the need for new EPA research or impact on ongoing EPA research activities.

Office of Air and Radiation (OAR/EPA)

- determining the need for and revising rules which govern chemical substances released to the air from stationary and/or mobile sources.

Office of Pesticide Programs (OPP/OPTS/EPA)

- assessing or reassessing the toxicity of or exposure to active ingredients/inerts in pesticides under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

EPA Regional Offices

- EPA's 10 Regional Offices routinely receive copies of all updated indices for OTS holdings of Section 8(e) and FYI notices. In addition to providing new information about reported chemical hazards/risks, Regional receipt of this information has led numerous cases to compliance inspections under TSCA and other EPA administered authorities.

EPA has also established high level scientific and administrative contacts in other Federal agencies in order to provide a mechanism for the timely and prioritized dissemination of new information on chemical hazards/risks. The following examples illustrate some of the activities that have been initiated by other Federal agencies in direct response to TSCA Section 8(e) and related information supplied to those agencies by EPA.

National Institute for Occupational Safety and Health (NIOSH)

- preparing/revising Current Intelligence Bulletins;
- determining the need for workplace investigations leading to published Health Hazard Evaluations;
- recommending to OSHA the need for new workplace standards or revisions to existing workplace standards;
- determining the need for new research or the impact on ongoing chemical research activities; and
- input of data into the Registry of Toxic Effects of Chemical Substances (RTECS) publication and on-line computerized data base.

Occupational Safety and Health Administration (OSHA)

- internally reviewing and distributing information to OSHA Regional/Area Offices and inspectors;
- filling data gaps in ongoing OSHA assessments/studies or determining the need for such assessments/studies; and
- determining the need for new OSHA workplace standards or revising existing workplace standards.

Consumer Product Safety Commission (CPSC)

- determining the need for new CPSC regulatory efforts or the revision of existing CPSC regulations; and
- internal and external information circulation as part of CPSC's "Current Awareness Activities."

National Library of Medicine (NLM)

- input of toxicologic/exposure information to the NLM's publicly accessible computerized data bases.

National Toxicology Program (NTP)

- evaluating chemicals for toxicologic testing;
- monitoring results of non-NTP toxicity studies; and
- supplementing results of ongoing NTP studies.

Interagency Testing Committee (ITC)

- determining need for recommending chemicals for TSCA Section 4 health/environmental effects testing.

DO STATUS REPORTS REPRESENT EPA'S "BOTTOM LINE" REGARDING RISK?

When reviewing TSCA Section 8(e) status reports, the reader should realize that the purpose of the OTS preliminary evaluation is to determine the significance of the submitted information in terms of a need for possible follow-up action by EPA. This determination involves a critical analysis of the submitted data to assess the extent that the reported hazard/risk is supported by the provided information. The scope of this initial evaluation, however, is generally limited to the submitted documents and to any closely related information known by and/or readily available to the OTS staff reviewer. Neither a literature search to identify other reported effects nor an in-depth analysis of possible sources of exposure to subject chemicals is part of the initial evaluation process. Therefore, a status report should be viewed only as a preliminary evaluation of the submitted information and not as a comprehensive assessment of the chemical substance or mixture for which a TSCA Section 8(e) notice has been filed.

HAS EPA ISSUED OTHER SECTION 8(E) GUIDANCE-RELATED INFORMATION?

The 1978 Section 8(e) policy statement, as frequently cited and quoted in 1) publicly available EPA "Question and Answer" (Q&A) documents on TSCA implementation issues raised at periodic public and individual meetings with Agency staff and management, and 2) numerous publicly available Section 8(e) "status reports" that provide illustrative examples of Section 8(e)-applicability, continues to serve as a sound and adequate basis for potential respondents to determine their mandatory reporting obligations under Section 8(e) of TSCA. In addition, EPA's publication of bound volumes of Section 8(e) status reports serves a two-fold purpose. First, volumes of status reports with indices help to make the information reported under Section 8(e) more readily accessible. Second, these Section 8(e) status report volumes, by providing easy access to specific examples of submitted information and EPA's preliminary evaluation of the information, help subject persons to understand better the kinds of information that should be reported to EPA under Section 8(e) of TSCA. The six (6) bound Section 8(e) status report volumes published by the Agency to date can be purchased directly from the National Technical Information Service (NTIS). The NTIS publication numbers of, and the TSCA Section 8(e) submission numbers covered by, these volumes are as follows:

NTIS Publication Number	Submission Numbers
PB# 80-221609	8EHQ-0777-0001 to 8EHQ-0679-0291
PB# 81-145732	8EHQ-0779-0292 to 8EHQ-0180-0330
PB# 83-187815	8EHQ-0280-0331 to 8EHQ-1282-0467
PB# 87-129409	8EHQ-0183-0468 to 8EHQ-1284-0541
PB# 87-176004	8EHQ-0185-0542 to 8EHQ-1286-0648
PB# 89-182687	8EHQ-0187-0649 to 8EHQ-1288-0778

It should be noted that a seventh Section 8(e) status report volume covering initial Section 8(e) submission numbers 8EHQ-0189-0779 to 8EHQ-0989-1084 should be published by EPA in the summer of 1991; notice of the availability of this new status report compendium will be given in the OTS "Chemicals-in-Progress Bulletin." EPA plans to print only a limited number of copies of the new status report volume for distribution by the TSCA Hotline. After that supply is exhausted, copies of the new compendium can be purchased from NTIS. The addresses and telephone numbers for NTIS as well as the TSCA Hotline can be found in the "Preface" to this guide.

With the exception of certain TSCA Section 8(e) Q&As that were made available by EPA in July 1989, all of the Agency's other published Section 8(e)-related Q&As (1986 and 1987) are embodied in full or in part in other sections of this reporting guide. For the sake of completeness, the specific Q&As from that July 1989 Section 8(e) Q&A document follow.

Q. Does Section 8(e) of TSCA intend the submission of animal test information: (a) when a determination of "substantial risk" has been made, or (b) where merely a finding of positive animal test results useful in the further assessment of human risk has been determined?

A. TSCA Section 8(e) requires the timely submission of evidence (including preliminary evidence) from animal studies that implicates the tested chemical as causing serious toxicologic effects (e.g., cancer, neurotoxicity, birth defects). A decision to report the observance of such serious toxicological effects should not hinge in any way on a judgement of either the actual or potential exposure to the chemical or a judgement about the degree of relevancy of the findings to an overall assessment of human risk. In other words, the decision to report under Section 8(e) in such cases should be based simply on the observance of the serious toxicologic effects.

Q. What criteria should be used to determine if the results from cancer bioassay studies in animals should be submitted to the Agency under Section 8(e) of TSCA? For example, when should animal studies showing only a significant increase in benign tumors over controls be submitted?

A. Reporting of benign and/or malignant tumors should take place, for example, when either statistically or biologically significant increases over controls are observed. The observation of such increases are made in many cases at interim sacrifices performed typically during long term exposure studies in animals.

Q. How should reproductive or developmental toxicity data be evaluated for possible Section 8(e) submission if maternal toxicity is also present?

A. Statistically or biologically significant increases in teratogenic effects or other serious embryotoxic or fetotoxic effects (e.g., significant embryo or fetal lethality, spontaneous abortion) should be reported under Section 8(e) regardless of the level of maternal toxicity observed in the study.

Q. What are the criteria that should be used to determine which reproductive/developmental effects observed in animal tests are reportable under Section 8(e)? For example, should reversible developmental effects, such as reduced birth weight and/or incomplete ossification, trigger TSCA Section 8(e) reporting?

A. In addition to teratogenic effects, serious adverse developmental effects (e.g., significant embryo or fetal lethality, significantly reduced fetal/birth weights, significantly retarded/incomplete skeletal ossification) should be reported. In addition, serious adverse effects on the male/female reproductive system (e.g., significant testicular or ovarian atrophy, significantly reduced fertility, sterility) should be reported under Section 8(e).

Q. What criteria should be used in determining if results of acute toxicity studies constitute information that reasonably supports a conclusion of substantial risk?

A. Criteria used to determine Section 8(e) reporting in the case of acute/subacute toxicity findings will depend on the nature of the effects observed and the dose at which the effects occurred. For example, information that shows a tested chemical to be extremely toxic (e.g., causes lethality at very low doses) by, for example, inhalation, dermal application or oral administration should be reported. On the other hand, the reporting of information showing a chemical to be moderately toxic will depend on the degree of actual or potential exposure to the tested chemical. Information showing a chemical to be slightly or minimally toxic on an acute/subacute basis is not considered typically to be reportable. In addition to extreme toxicity, certain other serious toxicologic effects (e.g., neurotoxicity, adverse reproductive system effects) seen in an acute or subacute animal study should be reported under Section 8(e).

Q. When evaluating subchronic animal studies, what criteria should be used to determine reportability of adverse effects? For example, should increased or decreased organ(s) size in the absence of histopathological changes be reported to EPA under Section 8(e) of TSCA?

A. Serious toxic effects (e.g., neurotoxic effects, serious reproductive system effects) observed during the conduct of subchronic studies should be reported. This includes readily observable serious effects or serious effects seen only as the result of gross and/or histopathological examination. As is the case for acute and

subacute toxicity studies, the degree of the observed toxicity is important. The more serious (or significant) the observed effect, the less heavily one should consider actual/potential exposure for Section 8(e) reporting and vice versa.

Q. What criteria constitute evidence of reportable neurotoxicity in animal studies? For example, are reversible effects such as narcosis or effects observed in the presence of marked systemic toxicity considered reportable?

A. Typically, neurotoxic effects seen in dying animals are not, in and of themselves, considered by EPA to be reportable under Section 8(e). In many cases, however, already reportable data regarding extremely or highly toxic (lethal) substances will be accompanied by information concerning observed neurotoxic effects. In short or long term exposure studies in which serious neurotoxic signs and symptoms (e.g., convulsions, sleep induction, motor dysfunction, narcosis, behavioral dysfunction) are seen in non-moribund animals, however, specific reporting of the neurotoxic effects should occur.

Q. What criteria should be applied in determining whether positive results of <u>in vivo</u> or <u>in vitro</u> mutagenicity assays trigger Section 8(e) reporting?

A. Serious <u>in vivo</u> genotoxicological effects (e.g., gene or chromosomal mutations) are reportable in and of themselves under Section 8(e). On the other hand, a positive <u>in vitro</u> genotoxicity test, when considered alone, is usually insufficient to cause reporting under Section 8(e). However, EPA believes that such information is of value in assessing the possible risk(s) posed by exposure to the tested chemical or mixture. Further, the Agency believes that a positive <u>in vitro</u> genotoxicity test result, in combination with other information (e.g., knowledge of actual/potential exposure to and/or high production of the tested chemical), would suggest the need, in many cases, to conduct further studies designed to determine the toxicity of or the exposure to that chemical. EPA expects the results of such additional studies to be considered also for 8(e) submission.

Any person wishing to obtain full copies of the 1986 and 1987 Q&A documents (which also contain numerous Q&As related to rules that have been promulgated by EPA under other sections of TSCA) should contact the TSCA Hotline at the address or the telephone/telefax numbers listed in the "Preface" to this reporting guide.

HOW CAN THE PUBLIC OBTAIN SECTION 8(E) SUBMISSIONS?

Non-confidential versions of TSCA Section 8(e) initial, followup response and supplemental submissions, status reports, submission summaries, and EPA followup letters can be viewed/copied in the OTS Public Docket. Copies of non-confidential Section 8(e) documents can also be obtained by writing to EPA's Freedom of Information Office. The addresses of the OTS Public Docket and the Freedom of Information Office are given in the "Preface" to this guide.

Information on each new initial Section 8(e) and FYI submission (i.e., submission number, name of the subject chemical(s), and nature of the information received) is presented in index form in the OTS "Chemicals-In-Progress Bulletin" published periodically by the Environmental Assistance Division (EAD/OTS) and sent by the TSCA Assistance Information Service (TSCA Hotline) to over 9,000 individuals in industry, environmental groups, labor, academia and Federal, State, and Local Governments. Persons who wish to receive the "Bulletin" should contact the TSCA Hotline via the addresses or phone/telefax numbers in the "Preface" to this guide.

As explained in more detail in HAS EPA ISSUED OTHER SECTION 8(E)-RELATED GUIDANCE? on Page 20 of this reporting guide, volumes of TSCA Section 8(e) status reports have been published by OTS on a biannual basis; six volumes have been published to date and contain status reports covering the first 778 initial TSCA Section 8(e) submissions) and a seventh volume is scheduled to be published by OTS during the summer of 1991. Persons interested in obtaining copies of these TSCA Section 8(e) status report volumes should contact the TSCA Hotline or the National Technical Information Service (NTIS) at the addresses and phone numbers given in the "Preface" to this reporting guide.

Data from TSCA Section 8(e) and FYI submissions are entered into TSCATS (Toxic Substances Control Act Test Submissions), a publicly available computerized data base that serves as an on-line index of unpublished health and safety studies submitted to EPA under or in conjunction with TSCA. The submitted studies themselves are stored on microfiche. Persons who wish to obtain access to the on-line TSCATS should contact either the National Library of Medicine (NLM) located in Rockville, Maryland, or Chemical Information Systems, Inc. (CIS) located in Baltimore, Maryland. Microfiche copies of the submitted studies cited in TSCATS can be obtained from either CIS or the National Technical Information Service (NTIS) located in Springfield, Virginia. The addresses/telephone numbers for NLM, CIS and NTIS are presented in the "Preface" to this reporting guide.

In order to assure that the public sector is kept apprised about new adverse health effects and exposure information, OTS actively disseminates TSCA Section 8(e) and FYI submission information to many individuals and organizations in the following ways.

- all non-confidential TSCA Section 8(e) and FYI notices, status reports, summaries and follow-up letters are placed in public files located at EPA Headquarters.

- volumes of Section 8(e) status reports are published by OTS on a biannual basis; six volumes have been published to date and contain status reports covering the first 778 initial TSCA Section 8(e) submissions); a seventh volume is scheduled to be published by the Agency during the summer of 1991.

- in response to numerous "Freedom of Information Act" (FOIA) requests that are received by OTS and that mention a chemical that is the subject of a TSCA Section 8(e) or FYI submission, OTS staff provides appropriate citations for, and in some cases full copies of, all such relevant documents;

- American Conference of Governmental Industrial Hygienists (ACGIH) publishes on occasion complete copies of selected Section 8(e) "Status Reports" in the ACGIH scientific journal, Applied Industrial Hygiene.

The international community is routinely notified by EPA about the availability of TSCA Section 8(e) and FYI submissions via the OTS "Chemicals-In-Progress Bulletin." Approximately 1000 persons in international organizations, foreign governments, agencies and companies are on the mailing list. The "Bulletin" is also used to routinely solicit unpublished chemical toxicity/exposure data from the international community. Under the established "Freedom of Information Act" (FOIA) procedures as well as the Organization for Economic Cooperation and Development (OECD) information-gathering "Switchboard" project, OTS responds to numerous international requests for unpublished health and safety data on chemicals of concern to OECD members.

IS THERE A SECTION 8(E) ENFORCEMENT RESPONSE POLICY?

On May 15, 1987, EPA's Office of Compliance Monitoring (OCM) issued a final "Enforcement Response Policy" (ERP) covering Section 8(e) as well as the record-keeping and reporting rules issued by EPA under Sections 8, 12 and 13 of TSCA. This ERP describes various enforcement alternatives (including notices of non-compliance, civil penalties, criminal action and injunctive relief) available to the Agency in enforcing these TSCA record-keeping/reporting provisions. Copies of the TSCA Sections 8, 12 and 13 ERP can be obtained from OCM or the TSCA Hotline; the addresses and/or phone numbers for these EPA offices are presented in the "PREFACE" to this reporting guide.

On Friday, February 1, 1991, EPA announced in the Federal Register (56 FR 4128), a one-time voluntary TSCA Section 8(e) "Compliance Audit Program" (CAP). The Section 8(e) CAP, which incorporates stipulated monetary penalties and an overall monetary penalty ceiling, is designed primarily to 1) achieve the Agency's goal of obtaining any outstanding Section 8(e) information, and 2) provide maximum encouragement to companies to voluntarily audit their files for Section 8(e)-reportable information.

Modifications made to the Section 8(e) CAP were announced by EPA in the Federal Register on Friday, April 26, 1991 (56 FR 19514). The major modifications were 1) an extension of the CAP registration and termination dates, 2) addition of an opportunity to petition EPA for a case-by-case extension of the CAP termination date, 3) modification of the CAP "Agreement" provision involving admission of a Section 8(e) violation, and 4) an announcement of the Agency's plans to prepare and disseminate this TSCA Section 8(e) reporting guide.

Additional modifications to the Section 8(e) CAP were announced in the Federal Register on Thursday, June 20, 1991 (56 FR Part IV). The additional modifications announced by EPA were 1) an extension of the Section 8(e) CAP registration deadline, 2) announcement of the availability of this Section 8(e) reporting guide, 3) addition to the CAP of a "listing" provision and reduced stipulated penalty for certain types of Section 8(e)-reportable information now in EPA's possession as the result of either i) formal submission under a mandatory reporting provision of TSCA or other EPA-administered statute, or ii) submission to EPA and filing within EPA's Office of Toxic Substances formal "For Your Information" (FYI) submission filing system, and 4) suspension of Parts V(b)(1) and V(c) of EPA's TSCA Section 8(e) policy statement for purposes of judging the reportability of information concerning "widespread and previously unsuspected distribution in environmental media" and "emergency incidents of environmental contamination" under the Section 8(e) CAP.

With regard to Parts V(b)(1) and V(c) of the Section 8(e) policy statement, the June 20, 1991 Federal Register announcement also informed the regulated community that until such time as the Agency determines with greater specificity what types of environmental release, environmental detection and environmental contamination information should be submitted under Section 8(e) of TSCA, the statutory language of Section 8(e) was to be utilized to determine reportability of such information for purposes of the Section 8(e) CAP as well as ongoing compliance with Section 8(e).

For the reader's ease, complete copies of EPA's Federal Register announcements of the Section 8(e) CAP and the CAP modifications are presented in chronological order in Appendix D at the back of this reporting guide.

HAS EPA TAKEN FORMAL SECTION 8(E) ENFORCEMENT ACTIONS?

Since 1977, EPA has initiated a number of formal enforcement actions relating to Section 8(e) of TSCA. In almost all cases, EPA's actions have dealt with the late reporting of animal study findings that offer reasonable support for the conclusion that the tested chemical substance(s) presents a substantial risk of injury to health. Persons interested in reviewing the filings pertaining to specific Section 8(e) enforcement-related actions should contact either the Office of Compliance Monitoring (OCM) or the Office of Enforcement (OE) at the addresses in the "Preface" to this guide.

DOES EPA'S 8(E) IMPLEMENTATION ENCOURAGE POLLUTION PREVENTION?

EPA's longstanding proactive implementation of Section 8(e) of TSCA has resulted in heightened overall chemical industry awareness of risks posed by exposure to chemical substances and mixtures. This heightened awareness has led, in many cases, to specific voluntary pollution prevention/risk reduction activities designed to directly or indirectly protect health and the environment. It can be argued that EPA's Section 8(e) implementation encourages these voluntary actions to occur earlier than they might occur otherwise. The following discussion describes some of these voluntary actions.

The chemical industry's increased awareness of the potential hazards/risks posed by chemical substances is evidenced in part by the voluntary reporting of over 800 initial "For Your Information" (FYI) submissions containing valuable toxicity and exposure data. In direct response to OTS followup efforts, many chemical companies have established review committees responsible for evaluating chemical toxicity and exposure information to consider the need to report to EPA (e.g., under Section 8(e) of TSCA) or to initiate actions designed to minimize or eliminate chemical exposure. Many companies have also established information distribution networks to facilitate the flow of health/safety data to workers, customers and other producers. Many companies have reported that in direct response to new chemical toxicity or exposure data reported under Section 8(e) or on an FYI basis, the following types of health and/or environmental protection measures have been initiated on a voluntary basis:

Notification

- formal notification of workers, customers, others
- changes made to product labels and/or Material Safety Data Sheets (MSDSs) to ensure proper and safe handling

Further Study

- additional studies performed in order to determine better the toxicity of and/or the exposure to chemicals

Pollution Prevention/Exposure Reduction

- engineering changes made in manufacturing and processing facilities to reduce/eliminate chemical exposure
- chemical manufacture or use halted temporarily or discontinued altogether.

* * * * *

TSCA-SECTION 8(E)-REPORTABILITY OF TOXICOLOGIC CASE STUDIES

A. NUMERICAL REPORTING GUIDANCE FOR LETHALITY INFORMATION

Case Study

"An acute oral (gavage) LD50 study was conducted on a commercial chemical. Following administration of the test material, rats were observed for 14 days for clinical signs of toxicity. At the end of this observation period, all surviving rats were sacrificed and examined for gross pathological changes. Rats found dead were also subjected to gross pathological examination. The oral LD50 was calculated to be 40 mg/kg. Nonspecific clinical signs were initially observed in all treated rats; all signs had receded by Day 14 in those animals which survived. Gross pathology revealed nothing unexpected."

The case study did not contain any other relevant information for EPA to consider in judging the Section 8(e)-reportability of this acute oral toxicity study of a commercial chemical substance. Also at issue for this particular case study is the perceived need to have 1) numerical guidance for reporting lethality seen in acute and other types of animal toxicity studies, and 2) reaffirmation of EPA's policy on whether and how exposure should be considered by companies in evaluating acute lethality data for reporting.

EPA Discussion

The Agency believes that the following general "rules-of-thumb" should be used in determining the Section 8(e)-reportability of significant lethality observed in any animal study (including acute, sub-acute and other types of studies such as teratology studies) of a TSCA-covered chemical substance (including a research and development [R&D] chemical):

- Significant lethality which is observed at a dose or concentration comparable to an acute oral LD50 value of $\leq$5 mg/kg, an acute dermal LD50 value of $\leq$20 mg/kg, or an acute (generally 4-hour) inhalation LC50 value of $\leq$50 ppm (or $\leq$0.5 mg/l) should be recognized immediately as being

indicative of "extreme" toxicity and should be considered for immediate reporting to EPA under Section 8(e) of TSCA without any consideration of actual or potential exposure or other factors.

- Significant lethality observed at a dose or concentration comparable to an acute oral LD50 value in the range of >5 mg/kg to ≤50 mg/kg, an acute dermal LD50 value in the range of >20 mg/kg to ≤200 mg/kg, or an acute (generally 4-hour) inhalation LC50 value in the range of >50 ppm (or >.0.5 mg/l) to ≤200 ppm (or ≤2 mg/l) should be recognized as indicating "high" toxicity and should be considered for immediate reporting under Section 8(e) if there is actual or reasonably anticipated exposure to the subject chemical substance.

- Significant lethality observed at doses greater than those cited previously (i.e., doses indicating "moderate" toxicity) should be considered for reporting to EPA under Section 8(e) based on the company's review of additional information (including but not limited to information about actual or potential exposure to the tested chemical substance or mixture).

Specifically regarding findings of "high" toxicity, EPA expects a company to be especially prudent and to err on the side of caution for reporting (i.e., there is a clear bias toward reporting). EPA also believes that the greater the toxicity, the less heavily one should weigh the actual or potential exposure to (or other factors involving) the tested chemical. Further, if the tested chemical is a "commercial" substance (e.g., not one that is exclusively R&D), there must be a strong presumption of actual or potential exposure for reporting toxicity data in this range. On the other hand, many exclusively R&D chemical substances with toxicities in the "high" range, would not typically be reported under Section 8(e) of TSCA. It should be noted also that any consideration of exposure and additional information in cases involving the "high" toxicity range should be accomplished expeditiously and should not be exhaustive nor equated in any way with the need to conduct a full scale risk assessment for the tested chemical(s).

The preface to Part V of the Agency's March 16, 1978 Section 8(e) policy statement provides further guidance regarding the types of additional factors to consider in determining the need to report information under Section 8(e) of TSCA. For the reader's ease in use, the specific lethality values/ranges discussed herein are presented in Table 1 at the top of the next page.

Table 1 Factors to Consider in Determining Reportability of Lethality Information Under TSCA Section 8(e)

LD50 Oral Dose	LD50 Dermal Dose	4-Hour LC50 Inhalation Dose	Consider Exposure/Other Factors?
≤5 mg/kg	≤20 mg/kg	≤50 ppm (≤.5 mg/l)	No (EXTREMELY TOXIC)
>5 mg/kg to ≤50 mg/kg	>20 mg/kg to ≤200 mg/kg	>50 ppm (>.5 mg/l) to ≤200 ppm (≤2 mg/l)	Only to Some Reasonable Degree (HIGHLY TOXIC)
>50 mg/kg	>200 mg/kg	>200 ppm (>2 mg/l)	Yes (MODERATELY TOXIC)

EPA Conclusion

Based on the preceding discussion and EPA's review of this acute animal lethality study, the oral LD50 value of 40 mg/kg indicates that the tested chemical substance is "highly" toxic (i.e., an oral LD50 of less than 50 mg/kg but greater than 5 mg/kg). Considering that the tested chemical is "commercial," and in the absence of any relevant exposure-related information to the contrary, EPA makes the prudent assumption that there is or there reasonably could be exposure to the tested chemical. Therefore, EPA believes that these acute lethality findings showing the chemical to be highly toxic should be reported immediately under Section 8(e) of TSCA.

B. ACUTE TOXICITY TESTS WITH NON-LETHAL NEUROBEHAVIORAL FINDINGS

Case Study

"An oral LD50 study is conducted in which animals [(rats)] are administered 50, 200, 500, 1000, or 2000 mg/kg of a test material. Shortly after dosing, intermittent lethargy, ataxia and convulsions

are observed in the 1000 and 2000 mg/kg groups. Salivation, ataxia and lethargy are observed in animals in the 200 and 500 mg/kg groups. No effects are observed in the 50 mg/kg dose group. All rats died at the 2000 mg/kg dose level. The lower dose animals survived to necropsy."

The case study did not contain any other relevant information for EPA to consider in judging the Section 8(e)-reportability of the findings from this acute oral toxicity study. Also at issue for this study is the need for EPA to verify that statistically or biologically significant "frank" neurotoxicologic effects seen in acute or other animal studies should be reported immediately.

EPA Discussion

In reviewing these results of this acute oral toxicity study, EPA made the following assumptions about the study conduct/findings:

1. the study had a 14-day post-dosing observation period;

2. no animals in the 50, 200, 500 or 1000 mg/kg dose groups were found moribund during the 14-day observation period;

3. "shortly" means a time period of less than a day;

4. "intermittent" means on a number of occasions throughout the observation period;

5. the terms "convulsions" and "ataxia" accurately reflect the observations made during the study; and

6. a significant (biologically or statistically) number of rats in the study were affected.

Given the above assumptions, EPA believes that the findings from this acute oral toxicity study can be meaningfully interpreted. Shortly after dosing and at some unknown time prior to death, the animals in the 2000 mg/kg group exhibited intermittent lethargy, ataxia and convulsions; all of the animals in the 2000 mg/kg dose group died at some unknown point after dosing. Although interpretation of the findings for the 2000 mg/kg dose group animals would depend upon whether the adverse effects were observed in moribund or non-moribund animals, by considering the information provided for the lower dose groups, it is possible to determine that the tested chemical substance caused distinct neurotoxicologic effects. Based on EPA's assumption that no animals in the 1000 mg/kg dose were found moribund during the study, the observations that a significant number of animals at this dose exhibited intermittent lethargy, convulsions and ataxia, show that the tested chemical caused serious neurotoxicologic effects. Furthermore, although the

animals in the 200 and 500 mg/kg dose groups did not exhibit convulsions, the animals in both of these groups exhibited a combination of signs indicating a neurotoxicologic effect (i.e., salivation, lethargy and ataxia.) Considering that the oral LD50 of the test material is somewhere between 1000 and 2000 mg/kg, the finding of distinct neurotoxic effects at doses that are perhaps between 10% and 25% of the lethal dose further heightens concern for the tested chemical substance.

In general, the Agency would agree that it may not be possible to distinguish or attribute neurobehavioral effects or neurological signs in moribund animals to a direct neurotoxic action of the tested chemical substance. However, statistically or biologically significant neurotoxic effects observed in non-moribund animals (including animals in groups receiving doses equal to or greater than lethal doses) in any type of study cannot be dismissed simply as reflecting a "system overload" and should be considered for immediate reporting to the Agency under Section 8(e) of TSCA. Further, EPA believes that good product stewardship dictates that studies designed to more specifically assess neurotoxic effects should be considered for any chemical found to produce possible neurotoxic effects during an acute or other general toxicity test.

EPA Conclusion

Based on the preceding discussion and EPA's review of this acute oral toxicity case study, the distinguishable neurotoxicological effects caused by the subject chemical should be reported under Section 8(e). The reportability of the findings would simply be enhanced if the tested chemical was already on the market.

To provide a sense of scale for the Section 8(e)-reportability of neurotoxic/neurobehavioral findings from acute and other types of animal toxicity studies (e.g., 28-day studies, teratology studies), the Agency is most interested in receiving reports that involve "serious or prolonged effects." In general, the acute toxicity LD50 values/ranges listed in Table 1 (found on Page 31 of this reporting guide) should be consulted first and an appropriate level of consideration should be given to exposure and/or other factors in determining reportability based solely on lethality in acute or other types of animal toxicity studies. In those cases involving biologically or statistically significant evidence of serious neurotoxicological effects (e.g., paralysis, convulsions, ataxia), virtually no consideration of exposure or other factors should be given in determining the TSCA Section 8(e)-reportability of such serious toxic effects. As neurotoxicologic observations become more limited or as confidence in the accuracy of such observations becomes more uncertain, the Section 8(e)-reportability of such findings diminishes. In some studies, for example, it may not be possible to determine with any degree of precision if observations

such as ataxia accurately characterize the study findings or the testing laboratory simply recorded ataxia as indicating a state other than normal. In the above case study, however, the observed convulsions and ataxia were judged by the Agency as being serious neurotoxic effects and the other effects (lethargy and salivation) were viewed as providing additional evidence of neurotoxicity. In the absence of other more serious effects, however, observations of lethargy and/or salivation, in and of themselves, would not be viewed typically as providing reasonable support for a conclusion of substantial risk. Similarly, the Section 8(e)-reportability of effects such as convulsions or ataxia would be diminished if such effects 1) were seen only in moribund animals or in only one or a few isolated cases in non-moribund animals, or 2) were found simply to be transient rather than either intermittent or continuous in nature.

C. SKIN/EYE IRRITATION AND SKIN SENSITIZATION TESTS

Note

For the following case study involving three tests on a "moderately acidic" chemical, it was reported that the tests were "performed during the development phase of a new product for primary use as an industrial intermediate, with some consumer use probable." It was also reported that the "present production quantities are therefore quite small, but [are] expected to increase." Also at issue for this particular case study is the need for EPA to 1) reaffirm its position that results from acute skin or eye irritation tests do not routinely warrant submission under Section 8(e) of TSCA, 2) discuss the reportability of skin sensitization study findings, and 3) reaffirm that lethality caused at doses indicative of extreme toxicity or serious or prolonged adverse effects in organs/systems away from the site of exposure may indeed warrant the immediate reporting of such findings.

Skin Irritation Test

"A skin irritation assay is conducted on rabbit skin (in vivo). A series of ten applications are applied to the skin of the abdomen. After three applications, the skin is described as having moderate degrees of hyperemia, edema and necrosis. At the end of the 14 day observation period, the skin reaction is still present, and now includes scab and scar formation. Gross pathological examination reveals no systemic toxicity but does confirm the topical corrosive lesion at the site of application."

Eye Irritation Test

"An eye irritation study is conducted in the rabbit eye. Instillation of 0.1 ml into the washed and unwashed eye elicits immediate pain and irritation of the conjunctiva, cornea, and iris after days 1, 2, and 9. The animal appears to not to be able to see through the treated eye and is sent to necropsy on day 9 because of the advanced state of inflammation in the treated eye."

Skin Sensitization Test

"A guinea pig [dermal] sensitization assay is performed. The test material is applied to the clipped integument of 10 guinea pigs during the induction phase. This is followed by a rest period of 10 days. A challenge application is applied to a previously untreated skin site. The skin response is evaluated at 25 and 48 hours after application. Eight of the 10 animals are considered to have been sensitized by the test material based on the presence of erythema at the challenge site."

EPA Discussion

As stated in EPA's March 16, 1978 Section 8(e) policy statement, as well as numerous Section 8(e) "status reports," the Section 8(e)-reportability of irritation and/or corrosivity findings from acute animal eye or skin irritation studies is quite limited. This should not be interpreted to mean, however, that EPA is not concerned in general about the irritation/corrosion findings from such studies. Further, previously unknown or unexpected effects that occur and are observed/determined during such routine tests may have to be submitted under Section 8(e) if the effects are serious and meet the reporting criteria outlined in Part V of EPA's Section 8(e) policy statement (e.g., lethality, neurotoxicity). Therefore, when evaluating the results of skin and eye irritation studies, EPA expects a company to consider such factors as lethal dose, pH of the test material, the route(s) of administration, occurrence of unexpected serious effects (which can be determined via "cage-side" observation or during necropsy), and the extent and pattern of the actual or potential exposure to the tested chemical or mixture. When evaluating such information for possible TSCA Section 8(e) reporting, the greater the acute toxicity, the less heavily one should weigh the actual or potential exposure to the test materials and vice versa.

With regard to sensitization studies, it must be noted that sensitization is a systemic reaction that is manifested in many cases locally (i.e., directly at the site of re-exposure) but may be manifested also away from the site of exposure. Further, the

nature of the reaction can vary from slight to severe and can, in some cases, result in death. In reviewing results of sensitization studies for submission under Section 8(e), EPA expects companies to evaluate a variety of factors including, but not limited to, the severity of the response, the site(s) of the response, the number of animals affected, and/or the actual or potential exposure to the tested chemical substance(s). In general, the more severe the observed sensitization response(s) and the greater the number of animals affected, the less heavily one should weigh the actual or potential exposure to the tested chemical(s) and vice versa.

EPA Conclusion

Based on an evaluation of the eye and skin irritation studies and the skin sensitization study, and considering the above discussion, it is the Agency's opinion that, based on the provided information on current exposure, the results of these studies do not appear to be reportable now under Section 8(e) of TSCA. The findings may be reportable, however, at some future date under Section 8(e); this would depend upon an evaluation of new information reflecting a significant change in the magnitude/type of exposure and/or the consideration of other factors such as those previously cited.

D. SUBCHRONIC TOXICITY

Case Study

"A subchronic dermal repeated dose study in rats was conducted at doses of 0, 100, 300, and 1000 mg/kg. The tested material is extensively used in consumer products and exposure to the chemical is exclusively dermal. A statistically significant 25% increase in liver weight was observed at the high dose. A statistically significant incidence of clear signs of liver pathology typical of cirrhosis was observed at the mid and high doses. The NOAEL [(No-Observable-Adverse-Effect-Level)] was determined to be 100 mg/kg. No other effects were observed."

As background, it was reported that acute and range-finding data on the tested chemical indicate "it is relatively nontoxic" and the high dose, which was chosen for the subchronic dermal study, was the OECD ([Organization for European Cooperation and Development)] recommended limit of 1 g/kg. Also at issue for this case study is the need for EPA to reaffirm its position that organ weight changes in the absence of concurrent pathology may not routinely reflect serious or prolonged incapacitation and that other factors (e.g., histopathologic findings, dose, or actual/expected exposure, etc.)

may need to be considered in deciding whether to report such organ weight changes. There is also a need to discuss and reaffirm EPA's position that a statistically or biologically significant histopathologic finding indicating a serious or prolonged incapacitation should be immediately reported with little if any consideration of factors such as exposure.

EPA Discussion

Although an organ weight change, in an of itself, may not reflect a serious or prolonged incapacitation, the reportability of such a finding could depend upon an evaluation of one or more factors, such as, but not limited to, the overall magnitude of the organ weight change, the biological significance of the change, blood chemistry, dose, route of administration, actual or expected exposure, etc. However, the more significant the magnitude of the organ weight change (e.g., severe atrophy of the testes, thymus, kidneys), much less consideration should be given to such factors in determining reportability of the findings. On the other hand, a statistically or biologically significant histopathologic finding indicating a serious or prolonged incapacitation should be reported with little if any consideration given to factors such as exposure. When the histopathologic findings are of a less serious or less significant nature, other relevant factors (e.g., actual/expected exposure, dose, etc.) should be considered in determining the TSCA Section 8(e)-reportability of the study results.

The subchronic dermal application case study results clearly show a statistically significant, dose-dependent, relatively rare, and serious toxic effect (cirrhosis) in the liver, accompanied by a 25% increase in liver weight in the high dose animals.

EPA Conclusion

Based on an evaluation of the provided toxicologic findings, and considering the above discussion, it is EPA's position that the results of the subchronic dermal application study are reportable pursuant to Section 8(e) of TSCA. The facts that 1) the tested chemical is a commercial substance, and 2) consumers are dermally exposed to the chemical, simply enhance the reportability of the observed serious toxic effects in the liver.

* * * * *

APPENDIX A

SECTION 8(E) GUIDANCE/POLICY REFLECTED IN STATUS REPORTS

This index is divided into the following two (2) major areas: "TOXICOLOGICAL/EXPOSURE FINDINGS" and "GENERAL ISSUES." In using this particular index, please note that the numbers in the column on the right represent the last four (4) digits of the chronological Section 8(e) submission file number displayed on all status reports; the ascending numerical sequence, therefore, is also chronological. Please note that due to the fact that the majority of the first 200 Section 8(e) notices were submitted by a single company and EPA had asked that company for additional information about the Section 8(e)-applicability of the provided findings, the Agency has chosen to not include in this index any status reports pertaining to those first 200 notices.

I. TOXICOLOGICAL/EXPOSURE FINDINGS

A. ACUTE TOXICITY (ANIMAL)

0259
0282
0380
0408
0428
0429
0430
0431
0432
0433
0436
0456
0487
0531
0540
0638
0665
0669
0985
1059

B. ACUTE TOXICITY (HUMAN)

0258
0315
0344
0493
0502

B. ACUTE TOXICITY (HUMAN) [CON'T]

0508
0612
0622
0632
0694
0885
0905
0929

C. SUBACUTE TOXICITY (ANIMAL)

0325
0653

D. IMMUNOTOXICITY (ANIMAL)

0585

E. NEUROTOXICITY (ANIMAL)

0369
0706
0815
0867
1041
1043
1065

F. NEUROTOXICITY (HUMAN)

0641
1041
1065

G. ONCOGENICITY (ANIMAL)

0234
0401
0503
0509
0583
0600
0619
0681
0763
0847

H. ONCOGENICITY (HUMAN)

0641

I. REPRODUCTIVE/DEVELOPMENTAL (ANIMAL)

0211
0213
0572
0626
0653
0764
0807
0820
0835
0842
0872
0999
1042
1043

J. REPRODUCTIVE/DEVELOPMENTAL (HUMAN)

0551

K. GENOTOXICITY (IN VITRO)

0213
0214
0383
0396

NOTE: Almost all of the TSCA Section 8(e) status reports pertaining to *in vitro* genotoxicity test findings contain the following language:

"Although a positive *in vitro* genotoxicity test result, when considered alone, may not be sufficient to offer reasonable support for a conclusion of substantial risk (as that term is defined in EPA's Section 8(e) policy statement ("Statement of Interpretation and Enforcement Policy; Notification of Substantial Risk" 43 FR 11110; March 16, 1978)), EPA does believe that such information is of value in assessing the possible risk(s) posed by exposure to the tested chemical or mixture. Further, the Agency believes that a positive genotoxicity test result, in combination with other important information (e.g., knowledge of the actual/ potential exposure to and/or high production of the tested chemical or mixture),

suggests the need, in many cases, to conduct further studies that are designed to determine the toxicity of and/or exposure to that chemical substance or mixture. EPA expects the results of such additional studies to be considered also for submission pursuant to Section 8(e) of TSCA."

L. GENOTOXICITY (IN VIVO)

0208
0213

M. AQUATIC TOXICITY/BIOCONCENTRATION

0209
0249
0899
0994

N. EMERGENCY INCIDENTS OF ENVIRONMENTAL CONTAMINATION

0255
0260
0277
0466
0566
0769

O. GENERAL/NON-EMERGENCY ENVIRONMENTAL CONTAMINATION

0209
0720

II. GENERAL REPORTING ISSUES

A. INTRACORPORATE REPORTING PROCEDURES

0358
0672
0681
0698
0701
0705
0835

B. SUBJECT PERSONS

0543
0546
0551
0577
0587
0642
0689
0818
0823
0824
0846

C. SUBJECT CHEMICALS

0325
0543
0545
0546
0551
0583
0587
0698
0701
0705
0706
0763
0818
0823
0824
0835

D. RESEARCH & DEVELOPMENT CHEMICALS

0545
0583
0763
0815
0824
0835

E. DRUG EXPORT

0818

F. PESTICIDE EXPORT

0823

G. PREVIOUS MANUFACTURE/IMPORT/PROCESS/DISTRIBUTION

0698
0701
0705
0847

H. OBTAINING INFORMATION

0315
0325
0358
0503
0543
0546
0572
0587
0619
0626
0653
0681
0698
0701
0704
0705
0713
0847
1041
1043
1065

I. PRE-1977 INFORMATION

0213
0369
0847
1041
1043
1065

J. ACTUAL KNOWLEDGE BY EPA

0467
0509
0600
0641
0672
0689

J. ACTUAL KNOWLEDGE BY EPA (CON'T)

0704
0706
0712
0713
0718
0720
0807
0809
0835
0847

K. PUBLISHED SCIENTIFIC LITERATURE

0383
0588
0600
0641
0672

L. INFORMATION OBTAINED FROM OTHER FEDERAL AGENCIES

0467
0689
0704

M. INFORMATION CORROBORATING WELL-ESTABLISHED EFFECTS

0509
0706
0807
0835

N. RELATIONSHIP TO OTHER TSCA REPORTING REQUIREMENTS

0493
0600
0612
0622
0632
0667
0675
0694
0706
0718

M. RELATIONSHIP TO OTHER TSCA REPORTING REQUIREMENTS (CON'T)

0720
0769
0797
0800
0813
0817
0824
0846
0856
0876
0884
0900
0905
0929

O. RELATIONSHIP TO OTHER EPA ADMINISTERED AUTHORITIES

0466
0485
0494
0502
0508
0542
0566
0583
0600
0706
0712
0718
0720
0726
0769
0797
0800
0813
0815
0818
0823
0824
0835
1034

P. RELATIONSHIP TO AUTHORITIES NOT ADMINISTERED BY EPA

0551
0706
1043

Q. SECTION 8(E) REPORTING PROCEDURES

0234
0324
0330
0369
0400
0543
0546
0566
0587
0626
0653
0681
0698
0701
0705
0855

* * * * *

APPENDIX (D): STATUS REPORTS BY INFORMATION TYPE

ACUTE TOXICITY (ANIMAL)

SUBMISSION 0:	8EHQ-0977-0004		8EHQ-0977-0005		8EHQ-0377-0035	
	8EHQ-0178-0039 P		8EHQ-0178-0041		8EHQ-0278-0042	
	8EHQ-0278-0050		8EHQ-0278-0062		8EHQ-0278-0064	
	8EHQ-0278-0065		8EHQ-0278-0066		8EHQ-0278-0070	
	8EHQ-0278-0072		8EHQ-0278-0074		8EHQ-0378-0087	
	8EHQ-0378-0088		8EHQ-0378-0090		8EHQ-0378-0091	
	8EHQ-0378-0092		8EHQ-0378-0094		8EHQ-0378-0103	
	8EHQ-0478-0131		8EHQ-0478-0134		8EHQ-0478-0137	
	8EHQ-0578-0143		8EHQ-0578-0144		8EHQ-0578-0151	
	8EHQ-0578-0152		8EHQ-0578-0153 S		8EHQ-0578-0154 P	
	8EHQ-0578-0155		8EHQ-0578-0158 S		8EHQ-0578-0159 S	
	8EHQ-0578-0162 S		8EHQ-0578-0163		8EHQ-0578-0166	
	8EHQ-0578-0169 S		8EHQ-0678-0172		8EHQ-0678-0174	
	8EHQ-0678-0175		8EHQ-0678-0176		8EHQ-0678-0177	
	8EHQ-0678-0178		8EHQ-0678-0184		8EHQ-0678-0185	
	8EHQ-0678-0193		8EHQ-0678-0194		8EHQ-0678-0195	
	8EHQ-0678-0196		8EHQ-0678-0197		8EHQ-0678-0198	
	8EHQ-0678-0199		8EHQ-0678-0200		8EHQ-0678-0203	
	8EHQ-0678-0204		8EHQ-0678-0205		8EHQ-0678-0206	
	8EHQ-0678-0207		8EHQ-0778-0209		8EHQ-0778-0210	
	8EHQ-0778-0217		8EHQ-0778-0220		8EHQ-0778-0222	
	8EHQ-0778-0224		8EHQ-0778-0225		8EHQ-0778-0226	
	8EHQ-0778-0227		8EHQ-0778-0229		8EHQ-1178-0256	
	8EHQ-1178-0259		8EHQ-1178-0261		8EHQ-1278-0263	
	8EHQ-0179-0271		8EHQ-0179-0273		8EHQ-0279-0274	

ACUTE TOXICITY (ANIMAL)

SUBMISSION 8: 8EHQ-0479-0278
8EHQ-0579-0284
8EHQ-0979-0311
8EHQ-0680-0347
8EHQ-0980-0362
8EHQ-1180-0372
8EHQ-0281-0382
8EHQ-0581-0400
8EHQ-1081-0417
8EHQ-0282-0428 M
8EHQ-0282-0431 M
8EHQ-0282-0435
8EHQ-0382-0438 S
8EHQ-0982-0456 S M
8EHQ-1182-0462
8EHQ-0483-0476 S
8EHQ-0683-0482
8EHQ-0783-0487 S M
8EHQ-1083-0494 M
8EHQ-1083-0497
8EHQ-0484-0513
8EHQ-0984-0530
8EHQ-1084-0535
8EHQ-0485-0549 S
8EHQ-0685-0559
8EHQ-0479-0279
8EHQ-0779-0293
8EHQ-0380-0335 S
8EHQ-0680-0349
8EHQ-0980-0365
8EHQ-0181-0380 M
8EHQ-0381-0392
8EHQ-0881-0408 S M
8EHQ-1081-0418
8EHQ-0282-0429 M
8EHQ-0282-0432 M
8EHQ-0282-0436 M
8EHQ-0382-0440 S
8EHQ-1082-0459
8EHQ-0183-0468
8EHQ-0583-0478 S
8EHQ-0783-0485 S M
8EHQ-0883-0490
8EHQ-1083-0495
8EHQ-1283-0501
8EHQ-0584-0519
8EHQ-0984-0531 S M
8EHQ-1284-0540 S M
8EHQ-0485-0550
8EHQ-0785-0563
8EHQ-0479-0282 S
8EHQ-0779-0296
8EHQ-0480-0340
8EHQ-0980-0359
8EHQ-0780-0369
8EHQ-0181-0381
8EHQ-0581-0398
8EHQ-0981-0409
8EHQ-0282-0427 S
8EHQ-0282-0430 M
8EHQ-0282-0433 M
8EHQ-0282-0437
8EHQ-0682-0448 S
8EHQ-1082-0460
8EHQ-0283-0471 S
8EHQ-0583-0479 S
8EHQ-0783-0486
8EHQ-0983-0492 S
8EHQ-1083-0496
8EHQ-0484-0510
8EHQ-0884-0528
8EHQ-1084-0532
8EHQ-0485-0548
8EHQ-0585-0556 S
8EHQ-0885-0565 S

APPENDIX (D): STATUS REPORTS BY INFORMATION TYPE

ACUTE TOXICITY (ANIMAL)

SUBMISSION 8:	8EHQ-0985-0568	S		8EHQ-1085-0569		8EHQ-1085-0571	S	
	8EHQ-1185-0573			8EHQ-1185-0575		8EHQ-1285-0578		
	8EHQ-1285-0579	S		8EHQ-1285-0580		8EHQ-1285-0581		
	8EHQ-0186-0584			8EHQ-8186-0585	S	8EHQ-0386-0589	S	
	8EHQ-0486-0596			8EHQ-0486-0597		8EHQ-0486-0599		
	8EHQ-0786-0607	S		8EHQ-0786-0609	S	8EHQ-0786-0616		
	8EHQ-0886-0621			8EHQ-0986-0631	S	8EHQ-1086-0636	S	
	8EHQ-1086-0638		M	8EHQ-1086-0639	S	8EHQ-1086-0640	S	M
	8EHQ-1186-0644			8EHQ-1186-0647		8EHQ-0287-0652	S	
	8EHQ-0287-0653			8EHQ-0287-0654		8EHQ-0287-0655	S	
	8EHQ-0387-0656			8EHQ-0287-0657	S	8EHQ-0387-0659		
	8EHQ-0387-0660			8EHQ-0487-0661	S	8EHQ-0487-0663		
	8EHQ-0487-0665	S	M	8EHQ-0487-0666	S	8EHQ-0487-0667	S	M
	8EHQ-0487-0669		M	8EHQ-0487-0670	S	8EHQ-0587-0673		
	8EHQ-0587-0678			8EHQ-0687-0680		8EHQ-0787-0686	S	
	8EHQ-1087-0696			8EHQ-1287-0700		8EHQ-1287-0706		
	8EHQ-1287-0707	S		8EHQ-0188-0714		8EHQ-0388-0721		
	8EHQ-0388-0723			8EHQ-0588-0732		8EHQ-0688-0739		
	8EHQ-0688-0740	S		8EHQ-0788-0742	M	8EHQ-0788-0744	S	
	8EHQ-0988-0753	S		8EHQ-0988-0754		8EHQ-1088-0760	S	
	8EHQ-1088-0762			8EHQ-1188-0768	S	8EHQ-1288-0778		
	8EHQ-0189-0779			8EHQ-0389-0780		8EHQ-0389-0787	S	
	8EHQ-0389-0788	S		8EHQ-0589-0800		8EHQ-0689-0803		
	8EHQ-0789-0806	S		8EHQ-0789-0808	S	8EHQ-0789-0809		M
	8EHQ-0889-0810	S		8EHQ-0889-0818	S	8EHQ-0889-0819	S	

APPENDIX (D): STATUS REPORTS BY INFORMATION TYPE

ACUTE TOXICITY (ANIMAL)

SUBMISSION 0:	8EHQ-0989-0826 S	8EHQ-1089-0830	8EHQ-1089-0833 S
	8EHQ-1089-0834 S	8EHQ-1089-0837 S	8EHQ-1089-0838 S
	8EHQ-1189-0841	8EHQ-1189-0845	8EHQ-1189-0848 S
	8EHQ-1289-0850	8EHQ-1289-0852 S	8EHQ-1289-0857 S
	8EHQ-1289-0859	8EHQ-0190-0860 S	8EHQ-0190-0867 *
	8EHQ-0290-0893	8EHQ-0390-0898	8EHQ-0490-0919 S
	8EHQ-0490-0920 S	8EHQ-0490-0954 S	8EHQ-0490-0957 S
	8EHQ-0490-0958 S	8EHQ-0490-0959 S	8EHQ-0590-0964
	8EHQ-0590-0985 *	8EHQ-0590-0991 S	8EHQ-0690-1003
	8EHQ-0690-1004 S	8EHQ-0690-1005 S	8EHQ-0690-1009
	8EHQ-0690-1016 S	8EHQ-0790-1021	8EHQ-0790-1023 S
	8EHQ-0790-1031 S	8EHQ-0790-1035	8EHQ-0790-1036 S
	8EHQ-0890-1040	8EHQ-0890-1045	8EHQ-0890-1047
	8EHQ-0890-1048 S	8EHQ-0890-1852 S	8EHQ-0890-1054 S
	8EHQ-0990-1057	8EHQ-0990-1058 S	8EHQ-0990-1059 S *
	8EHQ-0990-1060 S	8EHQ-0990-1061	8EHQ-0990-1062
	8EHQ-0990-1068	8EHQ-0990-1076 S	8EHQ-0990-1084

ACUTE TOXICITY (HUMAN)

SUBMISSION 0:	8EHQ-0178-0036 *	8EHQ-0178-0038	8EHQ-0178-0039 P *
	8EHQ-0178-0040 P	8EHQ-0278-0052 P	8EHQ-0278-0063 *
	8EHQ-0278-0067 P *	8EHQ-0278-0075 P *	8EHQ-0278-0076 P *
	8EHQ-0278-0077 P *	8EHQ-0278-0078 P *	8EHQ-0278-0079 P *
	8EHQ-0278-0080 P *	8EHQ-0278-0081 P *	8EHQ-0378-0086 *
	8EHQ-0378-0097 *	8EHQ-0378-0105	8EHQ-0478-0118 P *

ACUTE TOXICITY (HUMAN)

SUBMISSION 0:	8EHQ-0478-0138	P	*	8EHQ-0578-0141		*	8EHQ-0578-0142	*
	8EHQ-0578-0145		*	8EHQ-0578-0146			8EHQ-0578-0149	
	8EHQ-0578-0154	P		8EHQ-0578-0165			8EHQ-0678-0180	*
	8EHQ-0678-0181		*	8EHQ-0678-0182	P	*	8EHQ-0678-0184	*
	8EHQ-0778-0217			8EHQ-0978-0238		*	8EHQ-1178-0258	*
	8EHQ-1178-0260		*	8EHQ-0179-0273			8EHQ-0879-0304	*
	8EHQ-1079-0315		*	8EHQ-1279-0322		*	8EHQ-0180-0324	
	8EHQ-0280-0333			8EHQ-0480-0338			8EHQ-0580-0341	
	8EHQ-0680-0344	P	*	8EHQ-0880-0355			8EHQ-0881-0407	
	8EHQ-0981-0409			8EHQ-1182-0466		*	8EHQ-0283-0471	S
	8EHQ-0783-0486			8EHQ-0983-0493	S	*	8EHQ-1283-0502	P *
	8EHQ-0384-0508	P	*	8EHQ-0484-0513			8EHQ-0984-0529	
	8EHQ-1084-0532			8EHQ-1084-0535			8EHQ-0485-0552	
	8EHQ-0985-0566			8EHQ-0186-0585	S		8EHQ-0886-0622	S
	8EHQ-0986-0632			8EHQ-0487-0666	S		8EHQ-0487-0671	
	8EHQ-1287-0700			8EHQ-0688-0736			8EHQ-1088-0755	
	8EHQ-0889-0818	S		8EHQ-1089-0832			8EHQ-0290-0885	
	8EHQ-0390-0905	S	*	8EHQ-0490-0929	S	*	8EHQ-0590-0991	S
	8EHQ-0890-1042			8EHQ-0990-1071			8EHQ-0990-1078	

ALLERGENICITY (ANIMAL)

SUBMISSION 0:	8EHQ-0578-0152			8EHQ-0578-0156		*	8EHQ-0578-0166	
	8EHQ-0678-0184		*	8EHQ-0678-0185		*	8EHQ-0678-0206	*
	8EHQ-0480-0340			8EHQ-1180-0371			8EHQ-0282-0427	S
	8EHQ-0682-0448	S		8EHQ-1182-0462			8EHQ-0283-0471	S

APPENDIX (D): STATUS REPORTS BY INFORMATION TYPE

ALLERGENICITY (ANIMAL)

SUBMISSION 0:	8EHQ-0683-0482	8EHQ-0783-0486	8EHQ-0883-0490
	8EHQ-1083-0495	8EHQ-1084-0532	8EHQ-0485-0550
	8EHQ-1285-0580	8EHQ-0186-0585 S	8EHQ-0386-0589 S
	8EHQ-0486-0597	8EHQ-1186-0647	8EHQ-0287-0653
	8EHQ-0287-0657 S	8EHQ-0487-0661 S	8EHQ-0687-0680
	8EHQ-0787-0686 S	8EHQ-0887-0690	8EHQ-1287-0700
	8EHQ-1287-0711	8EHQ-0188-0712 N	8EHQ-0388-0721
	8EHQ-0588-0733	8EHQ-0688-0739	8EHQ-0688-0740 S
	8EHQ-1188-0768 S	8EHQ-1288-0777	8EHQ-1288-0778
	8EHQ-0489-0795	8EHQ-0589-0796	8EHQ-0689-0802
	8EHQ-0989-0826 S	8EHQ-1189-0839	8EHQ-1189-0845
	8EHQ-1289-0852 S	8EHQ-0290-0876	8EHQ-0290-0894
	8EHQ-0490-0919 S	8EHQ-0790-1033	8EHQ-0990-1062
	8EHQ-0990-1069	8EHQ-0990-1082	

ALLERGENICITY (HUMAN)

SUBMISSION 0:	8EHQ-1177-0817 PS N	8EHQ-1177-0818 PS N	8EHQ-0178-0831 P N
	8EHQ-0178-0840 P	8EHQ-0278-0881 P N	8EHQ-0578-0164
	8EHQ-0578-0165	8EHQ-0678-0181 N	8EHQ-0678-0182 P N
	8EHQ-0678-0184 N	8EHQ-0678-0185 N	8EHQ-0279-0274
	8EHQ-0379-0280	8EHQ-0779-0292	8EHQ-0880-0355
	8EHQ-0282-0427 S	8EHQ-0283-0471 S	8EHQ-1084-0532
	8EHQ-0485-0550	8EHQ-0186-0585 S	8EHQ-0386-0589 S
	8EHQ-0786-0612	8EHQ-0886-0622 S	8EHQ-0987-0694 N
	8EHQ-0488-0728	8EHQ-0290-0885	8EHQ-0590-0991 S

APPENDIX (D): STATUS REPORTS BY INFORMATION TYPE

ALLERGENICITY (HUMAN)

SUBMISSION #: 8EHQ-0890-1039 S

CELL TRANSFORMATION (IN VITRO)

SUBMISSION #:	8EHQ-1277-0022		8EHQ-0278-0071		8EHQ-0378-0094	*		
	8EHQ-0378-0098	*	8EHQ-0378-0100	*	8EHQ-0478-0132	*		
	8EHQ-0578-0141	*	8EHQ-0578-0164		8EHQ-0578-0166			
	8EHQ-0179-0268 S		8EHQ-0479-0278		8EHQ-0479-0279			
	8EHQ-0579-0286		8EHQ-0579-0287		8EHQ-0579-0288			
	8EHQ-0579-0289		8EHQ-0679-0291		8EHQ-0779-0294			
	8EHQ-0280-0334		8EHQ-0281-0385		8EHQ-1280-0401 S			
	8EHQ-0681-0404		8EHQ-0981-0412		8EHQ-1081-0415			
	8EHQ-1081-0418		8EHQ-0982-0455		8EHQ-0583-0477 S			
	8EHQ-0883-0490		8EHQ-1083-0495		8EHQ-1083-0496			
	8EHQ-1083-0498		8EHQ-0484-0511		8EHQ-0484-0512			
	8EHQ-0584-0516 S		8EHQ-1184-0536		8EHQ-1184-0537			
	8EHQ-0685-0558 S		8EHQ-0785-0561 S		8EHQ-0786-0610			
	8EHQ-0786-0613		8EHQ-0886-0620		8EHQ-0886-0621			
	8EHQ-0986-0630		8EHQ-0687-0679		8EHQ-0889-0814			
	8EHQ-0690-1018							

CHEMICAL/PHYSICAL PROPERTIES

SUBMISSION #:	8EHQ-0178-0034	8EHQ-0278-0044	8EHQ-0279-0274		
	8EHQ-0879-0301	8EHQ-1179-0317	8EHQ-0280-0333		
	8EHQ-0480-0340	8EHQ-0680-0348	8EHQ-0780-0353		
	8EHQ-1080-0366	8EHQ-0481-0397	8EHQ-0382-0440 S		

CHEMICAL/PHYSICAL PROPERTIES

SUBMISSION 0: 8EHQ-0483-0475

CHRONIC TOXICITY (ANIMAL)

SUBMISSION 0:	8EHQ-1277-0026 S	8EHQ-0478-0117 N	8EHQ-0578-0140
	8EHQ-0578-0148	8EHQ-0578-0165	8EHQ-0578-0170
	8EHQ-0678-0202	8EHQ-0778-0209	8EHQ-0778-0212
	8EHQ-0778-0215	8EHQ-0878-0234	8EHQ-0878-0236 N
	8EHQ-1078-0248	8EHQ-1078-0250	8EHQ-1078-0251
	8EHQ-1078-0253	8EHQ-1278-0262	8EHQ-0179-0269 S
	8EHQ-0279-0274	8EHQ-0479-0281	8EHQ-0579-0283
	8EHQ-0779-0297	8EHQ-0979-0305	8EHQ-0580-0342
	8EHQ-0481-0397	8EHQ-0282-0439	8EHQ-1282-0467
	8EHQ-0283-0469 S	8EHQ-0283-0472 S	8EHQ-0383-0474
	8EHQ-0683-0480	8EHQ-0683-0483 S	8EHQ-0783-0488
	8EHQ-1083-0497	8EHQ-1283-0503	8EHQ-1083-0509
	8EHQ-0584-0514	8EHQ-0584-0517	8EHQ-0884-0525
	8EHQ-0884-0526	8EHQ-0984-0530	8EHQ-1284-0538
	8EHQ-0285-0545 S	8EHQ-0485-0550	8EHQ-0485-0553
	8EHQ-0785-0562 S	8EHQ-0985-0567	8EHQ-0685-0583 S
	8EHQ-0386-0592	8EHQ-0486-0600	8EHQ-0686-0604
	8EHQ-0786-0606 S	8EHQ-0786-0614	8EHQ-0886-0618 S
	8EHQ-0386-0619	8EHQ-0986-0624 S	8EHQ-0986-0625 S
	8EHQ-1086-0642	8EHQ-0187-0650	8EHQ-0487-0668
	8EHQ-0587-0675 N	8EHQ-0786-0681	8EHQ-0787-0684 S
	8EHQ-0887-0687	8EHQ-0887-0691 S	8EHQ-0987-0692
	8EHQ-1187-0697	8EHQ-1287-0704	8EHQ-1287-0708 S

APPENDIX (D): STATUS REPORTS BY INFORMATION TYPE

CHRONIC TOXICITY (ANIMAL)

SUBMISSION 8:	8EHQ-1287-0710	8EHQ-0188-0713	8EHQ-0388-0725
	8EHQ-0588-0730	8EHQ-0788-0741	8EHQ-0788-0745 S
	8EHQ-0988-0752 S	8EHQ-1088-0760 S	8EHQ-1288-0773
	8EHQ-1288-0774	8EHQ-1288-0775	8EHQ-0589-0797
	8EHQ-0889-0812	8EHQ-0989-0822	8EHQ-1189-0847
	8EHQ-1289-0856	8EHQ-1289-0858 S	8EHQ-0290-0873 S
	8EHQ-0290-0881 S	8EHQ-0390-0900	8EHQ-0390-0914 S
	8EHQ-0490-0930 S	8EHQ-0490-0952 S	8EHQ-0490-0960
	8EHQ-0590-0968	8EHQ-0590-0993 S	8EHQ-0790-1029
	8EHQ-0890-1043	8EHQ-0890-1050 S	8EHQ-0890-1053
	8EHQ-0890-1056 S		

CHRONIC TOXICITY (HUMAN)

SUBMISSION 8:	8EHQ-0378-0096	N	8EHQ-0878-0230		8EHQ-0978-0241
	8EHQ-0981-0489		8EHQ-0383-0473		8EHQ-0884-0523
	8EHQ-0285-0546		8EHQ-0585-0557		8EHQ-0486-0598
	8EHQ-0586-0601		8EHQ-0786-0615		8EHQ-0986-0629
	8EHQ-0986-0634		8EHQ-0187-0651	N	8EHQ-0887-0688
	8EHQ-0987-0694	N	8EHQ-1187-0698		8EHQ-1287-0699
	8EHQ-1287-0701	N	8EHQ-1188-0772		8EHQ-1089-0831
	8EHQ-0190-0863		8EHQ-0190-0864		8EHQ-0290-0886
	8EHQ-0390-0915		8EHQ-0490-0917		8EHQ-0490-0924
	8EHQ-0790-1034		8EHQ-0990-1072		8EHQ-0990-1080 S

SUBMISSION 0: 8EHQ-0483-0476 S

CLASTOGENICITY (IN VITRO)

SUBMISSION 0:	8EHQ-0579-0287	8EHQ-0779-0294	8EHQ-1082-0459
	8EHQ-1082-0460	8EHQ-0683-0481	8EHQ-1283-0500 S
	8EHQ-0384-0506 S	8EHQ-1083-0509	8EHQ-0484-0510
	8EHQ-0584-0515 S	8EHQ-0584-0516 S	8EHQ-0584-0518 S
	8EHQ-0784-0522	8EHQ-1084-0533 S	8EHQ-1284-0539
	8EHQ-0685-0558 S	8EHQ-1285-0580	8EHQ-0386-0595
	8EHQ-0586-0602 S	8EHQ-0786-0608 S	8EHQ-0786-0610
	8EHQ-0886-0621	8EHQ-0986-0630	8EHQ-1186-0646 S
	8EHQ-1186-0647	8EHQ-0687-0679	8EHQ-0787-0685
	8EHQ-0787-0686 S	8EHQ-0987-0693	8EHQ-0288-0715
	8EHQ-1088-0758 S	8EHQ-0389-0780	8EHQ-0389-0791 S
	8EHQ-0789-0805 S	8EHQ-0889-0814	8EHQ-1189-0847
	8EHQ-0890-1051 S	8EHQ-0990-1079 S	

DNA ADDUCT (IN VITRO)

SUBMISSION 0: 8EHQ-0586-0592

DNA DAMAGE/REPAIR

SUBMISSION 0:	8EHQ-0478-0132	N	8EHQ-0578-0165	8EHQ-0678-0191	N
	8EHQ-0678-0206	N	8EHQ-0778-0213	8EHQ-0778-0221	N
	8EHQ-0579-0285		8EHQ-0579-0288	8EHQ-0679-0291	
	8EHQ-0583-0477 S		8EHQ-0683-0481	8EHQ-1283-0503	
	8EHQ-0384-0506 S		8EHQ-1083-0509	8EHQ-0484-0511	
	[illegible] 0512		8EHQ-1184-0536	8EHQ-1184-0537	

APPENDIX (D): STATUS REPORTS BY INFORMATION TYPE

DNA DAMAGE/REPAIR

SUBMISSION #:	8EHQ-0785-0561 S	8EHQ-0586-0602 S	8EHQ-0786-0613
	8EHQ-0886-0621	8EHQ-1186-0646 S	8EHQ-0187-0649 S
	8EHQ-0687-0679	8EHQ-0787-0685	8EHQ-0987-0692
	8EHQ-0288-0715	8EHQ-0688-0737	8EHQ-0889-0814
	8EHQ-1289-0853 S	8EHQ-0890-1051 S	

DNA REPAIR (IN VITRO)

SUBMISSION #:	8EHQ-0280-0334	8EHQ-0980-0359	8EHQ-1080-0366

ECOTOXICITY/AQUATIC TOXICITY

SUBMISSION #:	8EHQ-0178-0032		8EHQ-0278-0048		8EHQ-0278-0058	*
	8EHQ-0278-0059	*	8EHQ-1277-0060	*	8EHQ-0278-0061	
	8EHQ-0378-0108	*	8EHQ-0378-0111	*	8EHQ-0378-0114	*
	8EHQ-0478-0119	*	8EHQ-0478-0120	*	8EHQ-0478-0121	*
	8EHQ-0478-0124	*	8EHQ-0478-0125	*	8EHQ-0478-0126	*
	8EHQ-0478-0132	*	8EHQ-0578-0141	*	8EHQ-0578-0142	*
	8EHQ-0578-0150	*	8EHQ-0678-0171	*	8EHQ-0678-0184	*
	8EHQ-0678-0185	*	8EHQ-0678-0201	*	8EHQ-0778-0209	
	8EHQ-0778-0223	*	8EHQ-1078-0249		8EHQ-1178-0260	*
	8EHQ-0881-0407		8EHQ-0783-0486		8EHQ-0983-0491 S	
	8EHQ-1083-0495		8EHQ-0486-0597		8EHQ-0287-0653	
	8EHQ-0487-0666 S		8EHQ-0288-0718	*	8EHQ-0989-0826 S	
	8EHQ-0390-0899	*	8EHQ-0390-0906 S		8EHQ-0390-0908 S	
	8EHQ-0590-0994	*	8EHQ-0690-1017		8EHQ-0790-1032	
	8EHQ-0990-1083 S					

EMERGENCY INCIDENT OF ENV. CONTAMINATION

SUBMISSION #:	8EHQ-0378-0084	N	8EHQ-0678-0183		8EHQ-0878-0237		
	8EHQ-0978-0240		8EHQ-1078-0255	N	8EHQ-1178-0260	N	
	8EHQ-0379-0277		8EHQ-0779-0299	N	8EHQ-0879-0300	N	
	8EHQ-1179-0319		8EHQ-1279-0322	N	8EHQ-1279-0329	N	
	8EHQ-0580-0343		8EHQ-0181-0378		8EHQ-0881-0407		
	8EHQ-1182-0466	N	8EHQ-0985-0566		8EHQ-0386-0593		
	8EHQ-0786-0617		8EHQ-1188-0769	N	8EHQ-0490-0921 S		
	8EHQ-0490-0933		8EHQ-0790-1032				

ENV. OCCURRENCE/RELEASE/FATE

SUBMISSION #:	8EHQ-1077-0008		8EHQ-1177-0013		8EHQ-0178-0037		
	8EHQ-0178-0038		8EHQ-0278-0043		8EHQ-0278-0045	N	
	8EHQ-0278-0054		8EHQ-0378-0085		8EHQ-0378-0089	N	
	8EHQ-0378-0093	N	8EHQ-0378-0099		8EHQ-0378-0110		
	8EHQ-0478-0129		8EHQ-0578-0146		8EHQ-0578-0147		
	8EHQ-0578-0168		8EHQ-0678-0179	N	8EHQ-0678-0183		
	8EHQ-0678-0184	N	8EHQ-0678-0189 P		8EHQ-0678-0208		
	8EHQ-0778-0209		8EHQ-0878-0237		8EHQ-0978-0240		
	8EHQ-1078-0245		8EHQ-1078-0249		8EHQ-1078-0255	N	
	8EHQ-1178-0256		8EHQ-1178-0260	N	8EHQ-1278-0264		
	8EHQ-0179-0266		8EHQ-0379-0277		8EHQ-0779-0299	N	
	8EHQ-0879-0300	N	8EHQ-0979-0310		8EHQ-1279-0329	N	
	8EHQ-0180-0330		8EHQ-0580-0343		8EHQ-0680-0345		
	8EHQ-0880-0358	N	8EHQ-1080-0368		8EHQ-0181-0378		
	8EHQ-0881-0407		8EHQ-0981-0409		8EHQ-0981-0413		

ENV. OCCURRENCE/RELEASE/FATE

SUBMISSION 8:	8EHQ-1081-0416	8EHQ-0982-0457	8EHQ-1182-0462
	8EHQ-1182-0466 M	8EHQ-0983-0491 S	8EHQ-1083-0495
	8EHQ-0384-0508 P M	8EHQ-0784-0521 S	8EHQ-0985-0566
	8EHQ-0386-0593	8EHQ-0486-0597	8EHQ-0786-0617
	8EHQ-0287-0653	8EHQ-0487-0662	8EHQ-0487-0671
	8EHQ-0688-0735	8EHQ-1088-0759	8EHQ-1088-0761
	8EHQ-1188-0769 M	8EHQ-0589-0799	8EHQ-0989-0826 S
	8EHQ-0290-0882	8EHQ-0390-0905 S M	8EHQ-0490-0921 S
	8EHQ-0490-0933	8EHQ-0490-0953	8EHQ-0790-1032
	8EHQ-0890-1038	8EHQ-0990-1077	

EPIDEMIOLOGY/CLINICAL

SUBMISSION 8:	8EHQ-1177-0016	8EHQ-1277-0021	8EHQ-0278-0056
	8EHQ-0378-0096 M	8EHQ-0378-0105	8EHQ-0478-0117 M
	8EHQ-0478-0123	8EHQ-0478-0128	8EHQ-0478-0135
	8EHQ-0578-0146	8EHQ-0578-0149	8EHQ-0578-0167 P
	8EHQ-0578-0168	8EHQ-0678-0192 S	8EHQ-0878-0230
	8EHQ-0978-0241	8EHQ-0978-0246	8EHQ-0379-0280
	8EHQ-0280-0332	8EHQ-0580-0341	8EHQ-1080-0366
	8EHQ-1080-0367	8EHQ-1180-0374 S	8EHQ-0281-0382
	8EHQ-0381-0390	8EHQ-0381-0394 S	8EHQ-1280-0401 S
	8EHQ-0282-0427 S	8EHQ-0382-0440 S	8EHQ-0582-0444
	8EHQ-0383-0473	8EHQ-1083-0497	8EHQ-0884-0523
	8EHQ-0285-0546	8EHQ-0485-0551 M	8EHQ-0485-0552
	8EHQ-0585-0557	8EHQ-0985-0567	8EHQ-0186-0585 S

EPIDEMIOLOGY/CLINICAL

SUBMISSION 0:	8EHQ-0286-0588 M	8EHQ-0386-0589 S	8EHQ-0486-0598
	8EHQ-0586-0601	8EHQ-0786-0611	8EHQ-0786-0612
	8EHQ-0786-0615	8EHQ-0986-0629	8EHQ-0986-0632
	8EHQ-0986-0634	8EHQ-1086-0641	8EHQ-0187-0651 M
	8EHQ-0487-0671	8EHQ-0887-0688	8EHQ-0987-0694 M
	8EHQ-1187-0698	8EHQ-1287-0699	8EHQ-1287-0701 M
	8EHQ-0288-0722	8EHQ-0688-0736	8EHQ-1088-0755
	8EHQ-1188-0772	8EHQ-0889-0818 S	8EHQ-0989-0821 S
	8EHQ-1089-0831	8EHQ-1089-0832	8EHQ-0190-0863
	8EHQ-0190-0864	8EHQ-0290-0886	8EHQ-0390-0905 S M
	8EHQ-0390-0915	8EHQ-0490-0917	8EHQ-0490-0924
	8EHQ-0490-0929 S M	8EHQ-0590-0991 S	8EHQ-0790-1034
	8EHQ-0890-1053	8EHQ-0990-1065	8EHQ-0990-1071
	8EHQ-0990-1072	8EHQ-0990-1078	8EHQ-0990-1080 S

GROUNDWATER CONTAMINATION

SUBMISSION 0:	8EHQ-0578-0147	8EHQ-0678-0189 P	8EHQ-0979-0310
	8EHQ-0180-0330	8EHQ-0680-0345	8EHQ-1080-0368
	8EHQ-0982-0457	8EHQ-0487-0662	8EHQ-1088-0759
	8EHQ-0490-0953		

8EHQ-0990-1077

HUMAN EXPOSURE (ACCIDENTAL)

SUBMISSION 0:	8EHQ-1077-0008	8EHQ-1077-0011	8EHQ-0178-0038
	8EHQ-0278-0067 P M	8EHQ-0278-0075 P M	8EHQ-0278-0076 P M
	8EHQ-0278-0077 P M	8EHQ-0278-0078 P M	8EHQ-0278-0079 P M

HUMAN EXPOSURE (ACCIDENTAL)

SUBMISSION 0:	8EHQ-0278-0080 P	*	8EHQ-0378-0086	*	8EHQ-0478-0118 P	*
	8EHQ-0578-0146		8EHQ-0578-0149		8EHQ-0578-0154 P	
	8EHQ-0678-0180	*	8EHQ-0778-0217		8EHQ-0978-0238	*
	8EHQ-0978-0240		8EHQ-1178-0260	*	8EHQ-0179-0273	
	8EHQ-0379-0277		8EHQ-0879-0304	*	8EHQ-1079-0315	*
	8EHQ-1279-0322	*	8EHQ-0180-0324		8EHQ-0480-0338	
	8EHQ-0580-0341		8EHQ-0580-0343		8EHQ-0381-0390	
	8EHQ-0981-0413		8EHQ-1081-0416		8EHQ-1182-0466	*
	8EHQ-0384-0508 P	*	8EHQ-0484-0513		8EHQ-0985-0566	
	8EHQ-0786-0617		8EHQ-0487-0671		8EHQ-0688-0736	
	8EHQ-1089-0832		8EHQ-0290-0885		8EHQ-0390-0905 S	*
	8EHQ-0490-0929 S	*	8EHQ-0490-0933		8EHQ-0490-0962	
	8EHQ-0990-1065					

HUMAN EXPOSURE (MONITORING)

SUBMISSION 0:	8EHQ-1277-0021		8EHQ-0378-0096	*	8EHQ-0378-0109	
	8EHQ-0378-0110		8EHQ-0378-0112	*	8EHQ-0378-0113	
	8EHQ-0478-0115	*	8EHQ-0578-0146		8EHQ-0578-0147	
	8EHQ-0578-0168		8EHQ-0578-0170		8EHQ-0678-0179	*
	8EHQ-0678-0189 P		8EHQ-0678-0208		8EHQ-0778-0209	
	8EHQ-0778-0213		8EHQ-0778-0219	*	8EHQ-0778-0228	*
	8EHQ-1278-0264		8EHQ-0179-0267		8EHQ-0479-0281	
	8EHQ-0779-0292		8EHQ-0779-0293		8EHQ-0979-0310	
	8EHQ-1179-0320		8EHQ-0979-0326 S		8EHQ-0180-0330	
	8EHQ-0280-0331 S		8EHQ-0380-0336 S		8EHQ-0580-0343	

HUMAN EXPOSURE (MONITORING)

SUBMISSION 0:	8EHQ-0680-0345	8EHQ-0680-0348	8EHQ-1080-0367
	8EHQ-1080-0368	8EHQ-1280-0376	8EHQ-1280-0401 S
	8EHQ-0981-0413	8EHQ-0382-0440 S	8EHQ-0482-0442
	8EHQ-0982-0457	8EHQ-1182-0462	8EHQ-0383-0473
	8EHQ-1083-0495	8EHQ-1083-0497	8EHQ-0184-0504
	8EHQ-0784-0521 S	8EHQ-1084-0535	8EHQ-0185-0542 S
	8EHQ-0285-0546	8EHQ-0385-0547	8EHQ-0485-0558
	8EHQ-0485-0551 N	8EHQ-0485-0553	8EHQ-0585-0554 S
	8EHQ-0985-0566	8EHQ-0286-0588 N	8EHQ-0586-0601
	8EHQ-0986-0633 S	8EHQ-1286-0648	8EHQ-0487-0662
	8EHQ-0487-0671	8EHQ-0587-0672 S	8EHQ-0687-0682
	8EHQ-0288-0722	8EHQ-0688-0735	8EHQ-0988-0752 S
	8EHQ-1088-0761	8EHQ-0289-0784	8EHQ-0389-0789
	8EHQ-0489-0793	8EHQ-0589-0801	8EHQ-0889-0818 S
	8EHQ-1289-0856	8EHQ-0190-0863	8EHQ-0290-0882
	8EHQ-0490-0924	8EHQ-0490-0933	8EHQ-0490-0953
	8EHQ-0490-0962	8EHQ-0690-1018	8EHQ-0890-1038
	8EHQ-0898-1053	8EHQ-0998-1077	8EHQ-0990-1078

HUMAN EXPOSURE (PRODUCT CONTAMINATION)

SUBMISSION 0:	8EHQ-1077-0012	8EHQ-0378-0104	8EHQ-0378-0113
	8EHQ-0478-0117 N	8EHQ-0478-0133	8EHQ-0578-0139
	8EHQ-0778-0219 N	8EHQ-1278-0264	8EHQ-0579-0284
	8EHQ-0779-0292	8EHQ-1179-0320	8EHQ-0979-0326 S
	8EHQ-0288-0331 S	8EHQ-0388-0336 S	8EHQ-0680-0348

APPENDIX (D): STATUS REPORTS BY INFORMATION TYPE

HUMAN EXPOSURE (PRODUCT CONTAMINATION)

SUBMISSION #:	8EHQ-0780-0352	8EHQ-0880-0358 N	8EHQ-1280-0376
	8EHQ-0381-0390	8EHQ-0981-0409	8EHQ-1281-0420
	8EHQ-0482-0442	8EHQ-0682-0449 S	8EHQ-0283-0469 S
	8EHQ-0383-0473	8EHQ-0784-0521 S	8EHQ-0185-0542 S
	8EHQ-0585-0554 S	8EHQ-0885-0564 S	8EHQ-1186-0643
	8EHQ-1186-0644	8EHQ-0288-0720	8EHQ-0688-0735
	8EHQ-1088-0761	8EHQ-0589-0799	8EHQ-0689-0804
	8EHQ-0490-0962		

IMMUNOTOXICITY (ANIMAL)

SUBMISSION #:	8EHQ-0186-0585 S	8EHQ-0386-0594 S	8EHQ-0588-0732
	8EHQ-0889-0817		

IMMUNOTOXICITY (HUMAN)

SUBMISSION #: 8EHQ-0290-0876

MATERIAL SAFETY DATA SHEETS/LABELS

SUBMISSION #:	8EHQ-0190-0867 N	8EHQ-0390-0903 S	8EHQ-0490-0919 S
	8EHQ-0490-0945	8EHQ-0590-0967	8EHQ-0590-0969
	8EHQ-0590-0983	8EHQ-0590-0991 S	8EHQ-0590-1001 S
	8EHQ-0690-1017	8EHQ-0690-1018	8EHQ-0990-1062
	8EHQ-0990-1071	8EHQ-0990-1078	

METABOLISM/PHARMACOKINETICS (ANIMAL)

SUBMISSION #: 8EHQ-0780-0350
8EHQ 1280-0401 S

METABOLISM/PHARMACOKINETICS (HUMAN)

SUBMISSION 0:	8EHQ-0578-0149	8EHQ-0379-0277	8EHQ-0484-0513
	8EHQ-0285-0546	8EHQ-0485-0551 M	8EHQ-0486-0600

MUTAGENICITY (IN VITRO)

SUBMISSION 0:	8EHQ-1077-0010	8EHQ-1277-0025	8EHQ-1277-0026 S
	8EHQ-0178-0030	8EHQ-0278-0047	8EHQ-0278-0051 M
	8EHQ-0278-0053	8EHQ-0278-0057	8EHQ-0278-0073
	8EHQ-0278-0082	8EHQ-0378-0102	8EHQ-0378-0107 M
	8EHQ-0478-0127 M	8EHQ-0478-0136 M	8EHQ-0578-0164
	8EHQ-0578-0165	8EHQ-0578-0166	8EHQ-0678-0184 M
	8EHQ-0678-0185 M	8EHQ-0678-0187 M	8EHQ-0778-0213
	8EHQ-0778-0214	8EHQ-0778-0216	8EHQ-0978-0239
	8EHQ-1078-0254	8EHQ-0179-0266	8EHQ-0179-0267
	8EHQ-0179-0268 S	8EHQ-0179-0270	8EHQ-0479-0278
	8EHQ-0479-0279	8EHQ-0579-0285	8EHQ-0579-0286
	8EHQ-0579-0287	8EHQ-0579-0288	8EHQ-0579-0289
	8EHQ-0679-0291	8EHQ-0779-0293	8EHQ-0779-0294
	8EHQ-0879-0301	8EHQ-1179-0321	8EHQ-1279-0323
	8EHQ-0180-0328	8EHQ-0280-0333	8EHQ-0280-0334
	8EHQ-0480-0339	8EHQ-0480-0340	8EHQ-0780-0350
	8EHQ-0780-0351	8EHQ-0980-0359	8EHQ-0980-0361 S
	8EHQ-0980-0363	8EHQ-1080-0366	8EHQ-0281-0383 M
	8EHQ-0281-0385	8EHQ-0381-0391	8EHQ-0481-0396 M
	8EHQ-0581-0400	8EHQ-0681-0402	8EHQ-0681-0403 S
	8EHQ-0681-0404	8EHQ-0781-0406 S	8EHQ-0981-0412

MUTAGENICITY (IN VITRO)

SUBMISSION 8:	8EHQ-1081-0415	8EHQ-1081-0417	8EHQ-1081-0418
	8EHQ-1281-0426	8EHQ-0282-0427 S	8EHQ-0682-0448 S
	8EHQ-0982-0455	8EHQ-0982-0458	8EHQ-1082-0459
	8EHQ-1082-0460	8EHQ-1182-0465	8EHQ-0183-0468
	8EHQ-0283-0478	8EHQ-0283-0471 S	8EHQ-0483-0476 S
	8EHQ-0583-0477 S	8EHQ-0683-0481	8EHQ-0683-0482
	8EHQ-0783-0486	8EHQ-0883-0489	8EHQ-0883-0490
	8EHQ-1083-0495	8EHQ-1083-0496	8EHQ-1283-0500 S
	8EHQ-1283-0503	8EHQ-0384-0506 S	8EHQ-1083-0509
	8EHQ-0484-0510	8EHQ-0484-0511	8EHQ-0484-0512
	8EHQ-0584-0515 S	8EHQ-0584-0516 S	8EHQ-0584-0518 S
	8EHQ-0584-0519	8EHQ-0784-0522	8EHQ-0984-0530
	8EHQ-1084-0532	8EHQ-1084-0533 S	8EHQ-1184-0537
	8EHQ-1284-0539	8EHQ-1284-0541 S	8EHQ-0685-0558 S
	8EHQ-0785-0561 S	8EHQ-1085-0571 S	8EHQ-1285-0579 S
	8EHQ-1285-0580	8EHQ-0186-0584	8EHQ-0186-0585 S
	8EHQ-0486-0597	8EHQ-0586-0602 S	8EHQ-0786-0606 S
	8EHQ-0786-0608 S	8EHQ-0786-0610	8EHQ-0786-0613
	8EHQ-0886-0620	8EHQ-0886-0621	8EHQ-0986-0627
	8EHQ-1286-0645	8EHQ-1186-0646 S	8EHQ-1186-0647
	8EHQ-0187-0649 S	8EHQ-0287-0653	8EHQ-0287-0654
	8EHQ-0687-0677	8EHQ-0687-0679	8EHQ-0787-0685
	8EHQ-0787-0686 S	8EHQ-0987-0692	8EHQ-0987-0693
	8EHQ-1287-0706	8EHQ-1287-0709 S	8EHQ-0288-0715
	AA 0719	8EHQ-0688-0737	8EHQ-0788-0743

MUTAGENICITY (IN VITRO)

SUBMISSION 0:	8EHQ-1088-0758 S	8EHQ-1088-0760 S	8EHQ-0389-0780
	8EHQ-0389-0791 S	8EHQ-0589-0798 S	8EHQ-0789-0805 S
	8EHQ-0889-0814	8EHQ-0989-0826 S	8EHQ-1089-0837 S
	8EHQ-1289-0854 S	8EHQ-1289-0858 S	8EHQ-0390-0903 S
	8EHQ-0390-0916 S N	8EHQ-0490-0930 S	8EHQ-0490-0932
	8EHQ-0490-0960	8EHQ-0690-1009	8EHQ-0690-1015
	8EHQ-0690-1016 S	8EHQ-0890-1044 S	8EHQ-0890-1051 S
	8EHQ-0990-1066 S	8EHQ-0990-1067	8EHQ-0990-1079 S

MUTAGENICITY (IN VIVO)

SUBMISSION 0:	8EHQ-0278-0082	8EHQ-0378-0107 N	8EHQ-0578-0170
	8EHQ-0678-0208	8EHQ-0778-0213	8EHQ-1078-0248
	8EHQ-0179-0267	8EHQ-0579-0285	8EHQ-0579-0287
	8EHQ-0579-0288	8EHQ-0679-0291	8EHQ-0879-0301
	8EHQ-1179-0321	8EHQ-1279-0323	8EHQ-0780-0350
	8EHQ-0980-0359	8EHQ-1080-0366	8EHQ-0281-0384
	8EHQ-0381-0387	8EHQ-0981-0412	8EHQ-1081-0418
	8EHQ-1281-0426	8EHQ-0483-0476 S	8EHQ-1083-0499
	8EHQ-0785-0560	8EHQ-1285-0577	8EHQ-0786-0613
	8EHQ-0290-0892	8EHQ-0390-0916 S N	8EHQ-0590-0981

NEUROTOXICITY (ANIMAL)

SUBMISSION 0:	8EHQ-1177-0015 S	8EHQ-0278-0055	8EHQ-0678-0173 N
	8EHQ-0678-0188 N	8EHQ-0778-0218	8EHQ-0279-0275
	8EHQ-0880-0356	8EHQ-0880-0357	8EHQ-0780-0369

NEUROTOXICITY (ANIMAL)

SUBMISSION #:	8EHQ-0382-0440 S	8EHQ-0682-0451	8EHQ-1182-0462
	8EHQ-0583-0478 S	8EHQ-1083-0494 N	8EHQ-1283-0501
	8EHQ-0684-0520	8EHQ-1084-0532	8EHQ-0585-0556 S
	8EHQ-1085-0571 S	8EHQ-0186-0584	8EHQ-0386-0590
	8EHQ-0486-0599	8EHQ-0886-0628	8EHQ-0287-0655 S
	8EHQ-0587-0678	8EHQ-1287-0706	8EHQ-0188-0714
	8EHQ-0588-0733	8EHQ-0688-0739	8EHQ-0688-0740 S
	8EHQ-0788-0744 S	8EHQ-1088-0757	8EHQ-1288-0776
	8EHQ-0489-0793	8EHQ-0489-0794 S	8EHQ-0889-0811 S
	8EHQ-0886-0815	8EHQ-1089-0837 S	8EHQ-1089-0838 S
	8EHQ-1189-0841	8EHQ-1189-0843 S	8EHQ-1189-0846
	8EHQ-1189-0848 S	8EHQ-0190-0867 N	8EHQ-0290-0893
	8EHQ-0390-0898	8EHQ-0390-0913 S	8EHQ-0390-0914 S
	8EHQ-0490-0919 S	8EHQ-0490-0931 S	8EHQ-0490-0934 S
	8EHQ-0490-0936	8EHQ-0490-0954 S	8EHQ-0490-0957 S
	8EHQ-0490-0958 S	8EHQ-0490-0959 S	8EHQ-0490-0963
	8EHQ-0590-0964	8EHQ-0590-0996	8EHQ-0590-1001 S
	8EHQ-0690-1002	8EHQ-0690-1003	8EHQ-0690-1004 S
	8EHQ-0690-1005 S	8EHQ-0690-1007	8EHQ-0790-1028 S
	8EHQ-0890-1041	8EHQ-0890-1043	8EHQ-0890-1052 S
	8EHQ-0990-1057	8EHQ-0990-1063	8EHQ-0990-1076 S

NEUROTOXICITY (HUMAN)

SUBMISSION #:	8EHQ-1277-0021	8EHQ-0378-0105	8EHQ-0478-0118 P N
	8EHQ-0578-0146	8EHQ-0480-0338	8EHQ-0786-0611

NEUROTOXICITY (HUMAN)

SUBMISSION 0:	8EHQ-1086-0641		8EHQ-0590-0991	S	8EHQ-0990-1065

ONCOGENICITY (ANIMAL)

SUBMISSION 0:	8EHQ-0877-0002		8EHQ-1077-0006		8EHQ-1077-0012
	8EHQ-1177-0016		8EHQ-1177-L019		8EHQ-1277-0026 S
	8EHQ-0178-0028		8EHQ-0178-0029		8EHQ-0278-0044
	8EHQ-0278-0046	N	8EHQ-0278-0083		8EHQ-0478-0117 N
	8EHQ-0578-0140		8EHQ-0578-0148		8EHQ-0578-0165
	8EHQ-0578-0170		8EHQ-0678-0202		8EHQ-0778-0209
	8EHQ-0778-0212		8EHQ-0778-0215		8EHQ-0878-0234
	8EHQ-0878-0236	N	8EHQ-0978-0246		8EHQ-1078-0248
	8EHQ-1078-0251		8EHQ-1078-0253		8EHQ-1278-0262
	8EHQ-0279-0274		8EHQ-0479-0281		8EHQ-0579-0283
	8EHQ-0779-0297		8EHQ-0979-0305		8EHQ-0979-0306
	8EHQ-1079-0314		8EHQ-1179-0316		8EHQ-1179-0318
	8EHQ-0180-0327		8EHQ-0180-0328		8EHQ-0480-0337
	8EHQ-0580-0342		8EHQ-0780-0350		8EHQ-0780-0353
	8EHQ-0980-0360		8EHQ-1080-0370		8EHQ-0381-0389
	8EHQ-0381-0393		8EHQ-0481-0397		8EHQ-0581-0400
	8EHQ-1280-0401 S		8EHQ-0681-0402		8EHQ-0981-0410
	8EHQ-0981-0411		8EHQ-1281-0422		8EHQ-1281-0423
	8EHQ-0282-0434		8EHQ-0282-0439		8EHQ-0482-0443
	8EHQ-0682-0447		8EHQ-0882-0453		8EHQ-0882-0454
	8EHQ-1082-0461		8EHQ-1182-0463		8EHQ-1282-0467
	8EHQ-0283-0469 S		8EHQ-0283-0472 S		8EHQ-0383-0474

ONCOGENICITY (ANIMAL)

SUBMISSION #:	8EHQ-0683-0480	8EHQ-0683-0483 S	8EHQ-0783-0486
	8EHQ-0783-0488	8EHQ-1083-0497	8EHQ-1283-0503
	8EHQ-0384-0507	8EHQ-1083-0509	8EHQ-0584-0514
	8EHQ-0584-0517	8EHQ-0884-0525	8EHQ-0884-0526
	8EHQ-0984-0530	8EHQ-1284-0538	8EHQ-0485-0550
	8EHQ-0485-0553	8EHQ-0785-0561 S	8EHQ-0785-0562 S
	8EHQ-0985-0567	8EHQ-0685-0583 S	8EHQ-0386-0592
	8EHQ-0486-0600	8EHQ-0686-0604	8EHQ-0786-0606 S
	8EHQ-0786-0614	8EHQ-0886-0618 S	8EHQ-0386-0619
	8EHQ-1086-0642	8EHQ-0187-0650	8EHQ-0587-0675 N
	8EHQ-0786-0681	8EHQ-0787-0684 S	8EHQ-0887-0687
	8EHQ-0887-0691 S	8EHQ-0987-0692	8EHQ-1187-0697
	8EHQ-1287-0704	8EHQ-1287-0708 S	8EHQ-1287-0710
	8EHQ-0188-0713	8EHQ-0388-0725	8EHQ-0588-0730
	8EHQ-0788-0741	8EHQ-0788-0745 S	8EHQ-1088-0760 S
	8EHQ-1088-0763 S	8EHQ-1288-0773	8EHQ-1288-0774
	8EHQ-1288-0775	8EHQ-0789-0809 N	8EHQ-0889-0812
	8EHQ-0989-0822	8EHQ-1189-0847	8EHQ-1289-0856
	8EHQ-1289-0858 S	8EHQ-0290-0873 S	8EHQ-0290-0881 S
	8EHQ-0490-0952 S	8EHQ-0490-0960	8EHQ-0590-0993 S
	8EHQ-0790-1029	8EHQ-0890-1050 S	

ONCOGENICITY (HUMAN)

SUBMISSION #:	8EHQ-0777-0001	8EHQ-0378-0096 N	8EHQ-0478-0117 N
	8EHQ-0478-0135	8EHQ-0578-0167 P	8EHQ-0578-0168

ONCOGENICITY (HUMAN)

SUBMISSION #:	8EHQ-0878-0230		8EHQ-0978-0241		8EHQ-0978-0246	
	8EHQ-0582-0444		8EHQ-0383-0473		8EHQ-0884-0523	
	8EHQ-0285-0546		8EHQ-0585-0557		8EHQ-0486-0598	
	8EHQ-0586-0601		8EHQ-0786-0615		8EHQ-0986-0629	
	8EHQ-0986-0634		8EHQ-0187-0651	X	8EHQ-0887-0688	
	8EHQ-1187-0698		8EHQ-1287-0699		8EHQ-1287-0701	X
	8EHQ-1188-0772		8EHQ-0190-0863		8EHQ-0190-0864	
	8EHQ-0290-0886		8EHQ-0390-0915		8EHQ-0490-0917	
	8EHQ-0490-0924		8EHQ-0790-1034		8EHQ-0890-1053	
	8EHQ-0990-1080 S					

PRODUCT COMPOSITION/CHEMICAL IDENTITY

SUBMISSION #:	8EHQ-1077-0008		8EHQ-1077-0011		8EHQ-1177-0014	
	8EHQ-1177-0016		8EHQ-1277-0021		8EHQ-1277-0026 S	
	8EHQ-0278-0044		8EHQ-0278-0045	X	8EHQ-0278-0054	
	8EHQ-0378-0085		8EHQ-0378-0089	X	8EHQ-0378-0093	X
	8EHQ-0378-0104		8EHQ-0378-0105		8EHQ-0478-0117	X
	8EHQ-0478-0133		8EHQ-0578-0139		8EHQ-0578-0150	X
	8EHQ-0578-0153 S	X	8EHQ-0578-0155	X	8EHQ-0578-0163	
	8EHQ-0578-0164		8EHQ-0578-0165		8EHQ-0578-0169 S	X
	8EHQ-0678-0187	X	8EHQ-0678-0200	X	8EHQ-0678-0205	X
	8EHQ-0778-0209		8EHQ-0778-0214		8EHQ-0778-0219	X
	8EHQ-0778-0220	X	8EHQ-0778-0228	X	8EHQ-0978-0240	
	8EHQ-1078-0245		8EHQ-1078-0249		8EHQ-1078-0251	
	8EHQ-1078-0253		8EHQ-1078-0255	X	8EHQ-1178-0256	

APPENDIX (D): STATUS REPORTS BY INFORMATION TYPE

PRODUCT COMPOSITION/CHEMICAL IDENTITY

SUBMISSION #:	8EHQ-1178-0260		M	8EHQ-1178-0261			8EHQ-1278-0264	
	8EHQ-0179-0268	S		8EHQ-0179-0269	S		8EHQ-0179-0272	
	8EHQ-0279-0275			8EHQ-0479-0278			8EHQ-0379-0280	
	8EHQ-0579-0283			8EHQ-0579-0288			8EHQ-0779-0292	
	8EHQ-0779-0293			8EHQ-0879-0301			8EHQ-1179-0317	
	8EHQ-1179-0321			8EHQ-1279-0323			8EHQ-0180-0328	
	8EHQ-0280-0331	S		8EHQ-0280-0333			8EHQ-0380-0335	S
	8EHQ-0380-0336	S		8EHQ-0780-0350			8EHQ-0880-0358	M
	8EHQ-1180-0373	S		8EHQ-1180-0374	S		8EHQ-1180-0375	S
	8EHQ-0381-0394	S		8EHQ-0481-0397			8EHQ-0581-0399	
	8EHQ-0781-0406	S		8EHQ-0482-0442			8EHQ-0682-0446	S
	8EHQ-0882-0454			8EHQ-0982-0456	S	M	8EHQ-0283-0469	S
	8EHQ-0283-0471	S		8EHQ-0583-0477	S		8EHQ-0583-0479	S
	8EHQ-0683-0480			8EHQ-0683-0483	S		8EHQ-0683-0484	S
	8EHQ-0783-0485	S	M	8EHQ-0783-0487	S	M	8EHQ-0983-0491	S
	8EHQ-0983-0492	S		8EHQ-0983-0493	S	M	8EHQ-1283-0500	S
	8EHQ-1283-0501			8EHQ-1283-0502	P	M	8EHQ-1283-0503	
	8EHQ-0384-0508	P	M	8EHQ-0484-0510			8EHQ-0484-0511	
	8EHQ-0484-0513			8EHQ-0584-0515	S		8EHQ-0584-0516	S
	8EHQ-0584-0517			8EHQ-0584-0519			8EHQ-0784-0521	S
	8EHQ-0884-0526			8EHQ-1284-0540	S	M	8EHQ-0185-0542	S
	8EHQ-0285-0545	S		8EHQ-0485-0548			8EHQ-0485-0551	M
	8EHQ-0485-0553			8EHQ-0585-0554	S		8EHQ-0585-0555	
	8EHQ-0585-0556	S		8EHQ-0785-0562	S		8EHQ-0885-0564	S
	8EHQ-0985-0568	S		8EHQ-1085-0571	S		8EHQ-0585-0572	

PRODUCT COMPOSITION/CHEMICAL IDENTITY

SUBMISSION 0:	8EHQ-1185-0576	8EHQ-1285-0577	8EHQ-0186-0582 S
	8EHQ-0685-0583 S	8EHQ-0386-0589 S	8EHQ-0386-0594 S
	8EHQ-0486-0597	8EHQ-0586-0602 S	8EHQ-0686-0605 S
	8EHQ-0786-0606 S	8EHQ-0786-0608 S	8EHQ-0786-0609 S
	8EHQ-0786-0610	8EHQ-0786-0614	8EHQ-0886-0621
	8EHQ-0986-0623 S	8EHQ-0986-0624 S	8EHQ-0986-0625 S
	8EHQ-0986-0626 S	8EHQ-0986-0627	8EHQ-0986-0631 S
	8EHQ-0986-0632	8EHQ-0986-0633 S	8EHQ-1086-0636 S
	8EHQ-1086-0637	8EHQ-1086-0639 S	8EHQ-1086-0640 S N
	8EHQ-1186-0643	8EHQ-1186-0644	8EHQ-1186-0646 S
	8EHQ-0187-0649 S	8EHQ-0287-0652 S	8EHQ-0287-0655 S
	8EHQ-0387-0656	8EHQ-0487-0661 S	8EHQ-0487-0664 S
	8EHQ-0487-0665 S N	8EHQ-0487-0667 S N	8EHQ-0487-0668
	8EHQ-0487-0669 N	8EHQ-0487-0670 S	8EHQ-0487-0671
	8EHQ-0587-0674 S	8EHQ-0687-0680	8EHQ-0787-0684 S
	8EHQ-0787-0686 S	8EHQ-1187-0697	8EHQ-1287-0707 S
	8EHQ-1287-0708 S	8EHQ-1287-0709 S	8EHQ-0188-0714
	8EHQ-0288-0716 S	8EHQ-0288-0717 S	8EHQ-0288-0720
	8EHQ-0388-0724 S	8EHQ-0388-0725	8EHQ-0488-0727
	8EHQ-0488-0728	8EHQ-0488-0729 S	8EHQ-0588-0731 S
	8EHQ-0588-0733	8EHQ-0688-0734 S	8EHQ-0688-0735
	8EHQ-0688-0740 S	8EHQ-0788-0744 S	8EHQ-0788-0745 S
	8EHQ-0988-0749 S	8EHQ-0988-0750 S	8EHQ-0988-0751 S
	8EHQ-0988-0752 S	8EHQ-0988-0753 S	8EHQ-1088-0755
	8EHQ-1088-0758 S	8EHQ-1088-0760 S	8EHQ-1088-0761

APPENDIX (D): STATUS REPORTS BY INFORMATION TYPE

PRODUCT COMPOSITION/CHEMICAL IDENTITY

SUBMISSION 0: 8EHQ-1088-0763 S, 8EHQ-1088-0764 S, 8EHQ-1188-0765 S, 8EHQ-1188-0766 S, 8EHQ-1188-0767 S, 8EHQ-1188-0768 S, 8EHQ-1188-0770 S, 8EHQ-1188-0771 S, 8EHQ-1288-0776, 8EHQ-0389-0780, 8EHQ-0289-0782 S, 8EHQ-0289-0783 S, 8EHQ-0289-0784, 8EHQ-0289-0785 S, 8EHQ-0389-0787 S, 8EHQ-0389-0788 S, 8EHQ-0389-0789, 8EHQ-0389-0790 S, 8EHQ-0389-0791 S, 8EHQ-0489-0794 S, 8EHQ-0589-0798 S, 8EHQ-0589-0799, 8EHQ-0689-0804, 8EHQ-0789-0805 S, 8EHQ-0789-0806 S, 8EHQ-0789-0808 S, 8EHQ-0889-0811 S, 8EHQ-0889-0816 S, 8EHQ-0889-0817, 8EHQ-0889-0819 S, 8EHQ-0989-0821 S, 8EHQ-0989-0824 S, 8EHQ-0989-0825 S, 8EHQ-0989-0827 S, 8EHQ-0989-0828 S, 8EHQ-1089-0833 S, 8EHQ-1089-0834 S, 8EHQ-1089-0835 S, 8EHQ-1089-0837 S, 8EHQ-1089-0838 S, 8EHQ-1189-0840 S, 8EHQ-1189-0842 S, 8EHQ-1189-0843 S, 8EHQ-1189-0844, 8EHQ-1189-0847, 8EHQ-1189-0848 S, 8EHQ-1289-0849 S, 8EHQ-1289-0851 S, 8EHQ-1289-0853 S, 8EHQ-1289-0854 S, 8EHQ-1289-0857 S, 8EHQ-1289-0858 S, 8EHQ-1289-0859, 8EHQ-0190-0861 S, 8EHQ-0190-0862 S, 8EHQ-0190-0865 S, 8EHQ-0190-0866 S, 8EHQ-0190-0868 S, 8EHQ-0190-0869 S, 8EHQ-0190-0870 S, 8EHQ-0190-0871 S, 8EHQ-0290-0872 S, 8EHQ-0290-0873 S, 8EHQ-0290-0874 S, 8EHQ-0290-0875 S, 8EHQ-0290-0879 S, 8EHQ-0290-0880, 8EHQ-0290-0881 S, 8EHQ-0290-0883 S, 8EHQ-0290-0887 S, 8EHQ-0290-0888 S, 8EHQ-0290-0889 S, 8EHQ-0290-0890 S, 8EHQ-0290-0891 S, 8EHQ-0390-0895 S

PRODUCT COMPOSITION/CHEMICAL IDENTITY

SUBMISSION 0:	8EHQ-0390-0896 S	8EHQ-0390-0897 S	8EHQ-0390-0903 S
	8EHQ-0390-0905 S N	8EHQ-0390-0906 S	8EHQ-0390-0907 S
	8EHQ-0390-0908 S	8EHQ-0390-0913 S	8EHQ-0390-0914 S
	8EHQ-0390-0916 S N	8EHQ-0490-0918 S	8EHQ-0490-0919 S
	8EHQ-0490-0920 S	8EHQ-0490-0921 S	8EHQ-0490-0922 S
	8EHQ-0490-0923 S	8EHQ-0490-0925 S	8EHQ-0490-0926 S
	8EHQ-0490-0927 S	8EHQ-0490-0928 S	8EHQ-0490-0929 S N
	8EHQ-0490-0930 S	8EHQ-0490-0931 S	8EHQ-0490-0932
	8EHQ-0490-0934 S	8EHQ-0490-0935 S	8EHQ-0490-0938
	8EHQ-0490-0952 S	8EHQ-0490-0955 S	8EHQ-0490-0956 S
	8EHQ-0490-0957 S	8EHQ-0490-0958 S	8EHQ-0490-0959 S
	8EHQ-0490-0961 S	8EHQ-0490-0962	8EHQ-0590-0983
	8EHQ-0590-0986 S	8EHQ-0590-0987 S	8EHQ-0590-0988 S
	8EHQ-0590-0989 S	8EHQ-0590-0990	8EHQ-0590-0992 S
	8EHQ-0590-0993 S	8EHQ-0590-0995 S	8EHQ-0590-0997 S
	8EHQ-0590-0998 S	8EHQ-0590-1001 S	8EHQ-0690-1004 S
	8EHQ-0690-1005 S	8EHQ-0690-1006 S	8EHQ-0690-1010 S
	8EHQ-0690-1011 S	8EHQ-0690-1012 S	8EHQ-0690-1013 S
	8EHQ-0690-1014 S	8EHQ-0690-1016 S	8EHQ-0790-1022 S
	8EHQ-0790-1023 S	8EHQ-0790-1025 S	8EHQ-0790-1026 S
	8EHQ-0790-1028 S	8EHQ-0790-1029	8EHQ-0790-1031 S
	8EHQ-0790-1036 S	8EHQ-0790-1037 S	8EHQ-0890-1039 S
	8EHQ-0890-1042	8EHQ-0890-1044 S	8EHQ-0890-1048 S
	8EHQ-0890-1049 S	8EHQ-0890-1050 S	8EHQ-0890-1052 S
	8EHQ-0890-1054 S	8EHQ-0890-1056 S	8EHQ-0990-1058 S

APPENDIX (D): STATUS REPORTS BY INFORMATION TYPE

PRODUCT COMPOSITION/CHEMICAL IDENTITY

SUBMISSION 8:	8EHQ-0990-1059 S *	8EHQ-0990-1060 S	8EHQ-0990-1062
	8EHQ-0990-1063	8EHQ-0990-1066 S	8EHQ-0990-1070 S
	8EHQ-0990-1071	8EHQ-0990-1073 S	8EHQ-0990-1075 S
	8EHQ-0990-1076 S	8EHQ-0990-1078	8EHQ-0990-1079 S
	8EHQ-0990-1083 S		

PRODUCTION/USE/PROCESS

SUBMISSION 8:	8EHQ-1277-0026 S	8EHQ-0378-0096 *	8EHQ-0378-0097 *
	8EHQ-0378-0104	8EHQ-0378-0105	8EHQ-0378-0109
	8EHQ-0378-0110	8EHQ-0378-0112 *	8EHQ-0378-0113
	8EHQ-0478-0115 *	8EHQ-0478-0117 *	8EHQ-0478-0118 P *
	8EHQ-0478-0123	8EHQ-0478-0138 P *	8EHQ-0578-0139
	8EHQ-0578-0146	8EHQ-0578-0148	8EHQ-0578-0152
	8EHQ-0578-0155 *	8EHQ-0578-0157 *	8EHQ-0578-0158 S *
	8EHQ-0578-0159 S *	8EHQ-0578-0162 S *	8EHQ-0578-0163
	8EHQ-0578-0164	8EHQ-0578-0165	8EHQ-0578-0166
	8EHQ-0578-0167 P	8EHQ-0578-0168	8EHQ-0578-0169 S *
	8EHQ-0678-0179 *	8EHQ-0678-0180 *	8EHQ-0678-0200 *
	8EHQ-0678-0202	8EHQ-0778-0209	8EHQ-0778-0217
	8EHQ-0778-0219 *	8EHQ-0778-0228 *	8EHQ-0878-0230
	8EHQ-0978-0239	8EHQ-1078-0245	8EHQ-0978-0246
	8EHQ-1078-0247	8EHQ-1078-0251	8EHQ-1078-0252
	8EHQ-1078-0253	8EHQ-1178-0256	8EHQ-1178-0261
	8EHQ-1278-0264	8EHQ-0179-0267	8EHQ-0179-0268 S
	8EHQ-0179-0270	8EHQ-0179-0271	8EHQ-0179-0272

APPENDIX (D): STATUS REPORTS BY INFORMATION TYPE

PRODUCTION/USE/PROCESS

SUBMISSION 0: 8EHQ-0279-0275
8EHQ-0479-0282 S
8EHQ-0679-0291
8EHQ-0779-0294
8EHQ-0583-0477 S
8EHQ-0683-0481
8EHQ-0783-0487 S *
8EHQ-0983-0493 S *
8EHQ-1083-0496
8EHQ-1283-0500 S
8EHQ-1283-0503
8EHQ-0384-0506 S
8EHQ-0484-0513
8EHQ-0584-0516 S
8EHQ-0684-0520
8EHQ-0884-0523
8EHQ-0884-0528
8EHQ-1084-0532
8EHQ-1084-0535
8EHQ-0285-0545 S
8EHQ-0485-0548
8EHQ-0485-0551 *
8EHQ-0585-0554 S
8EHQ-0585-0557
8EHQ-0785-0561 S

8EHQ-0479-0278
8EHQ-0579-0283
8EHQ-0779-0292
8EHQ-0779-0296
8EHQ-0583-0479 S
8EHQ-0683-0483 S
8EHQ-0883-0490
8EHQ-1083-0494 *
8EHQ-1083-0497
8EHQ-1283-0501
8EHQ-0184-0504
8EHQ-1083-0509
8EHQ-0584-0514
8EHQ-0584-0517
8EHQ-0784-0521 S
8EHQ-0884-0524
8EHQ-0984-0529
8EHQ-1084-0533 S
8EHQ-0185-0542 S
8EHQ-0285-0546
8EHQ-0485-0549 S
8EHQ-0485-0552
8EHQ-0585-0555
8EHQ-0685-0558 S
8EHQ-0785-0562 S

8EHQ-0379-0280
8EHQ-0579-0288
8EHQ-0779-0293
8EHQ-0779-0297
8EHQ-0683-0480
8EHQ-0783-0485 S *
8EHQ-0983-0492 S
8EHQ-1083-0495
8EHQ-1083-0498
8EHQ-1283-0502 P *
8EHQ-0284-0505
8EHQ-0484-0510
8EHQ-0584-0515 S
8EHQ-0584-0519
8EHQ-0784-0522
8EHQ-0884-0526
8EHQ-0984-0531 S *
8EHQ-1084-0534
8EHQ-0285-0544
8EHQ-0385-0547
8EHQ-0485-0550
8EHQ-0485-0553
8EHQ-0585-0556 S
8EHQ-0685-0559
8EHQ-0785-0563

PRODUCTION/USE/PROCESS

SUBMISSION #:	8EHQ-0885-0564 S	8EHQ-0885-0565 S	8EHQ-0985-0566
	8EHQ-0985-0568 S	8EHQ-1085-0569	8EHQ-1085-0570
	8EHQ-1085-0571 S	8EHQ-0585-0572	8EHQ-1185-0573
	8EHQ-1185-0574	8EHQ-1185-0575	8EHQ-1185-0576
	8EHQ-1285-0577	8EHQ-1285-0578	8EHQ-1285-0579 S
	8EHQ-1285-0580	8EHQ-1285-0581	8EHQ-0186-0582 S
	8EHQ-0685-0583 S	8EHQ-0186-0584	8EHQ-0186-0585 S
	8EHQ-0186-0586 S	8EHQ-0286-0588 N	8EHQ-0386-0589 S
	8EHQ-0386-0591	8EHQ-0386-0594 S	8EHQ-0486-0596
	8EHQ-0486-0597	8EHQ-0486-0599	8EHQ-0486-0600
	8EHQ-0586-0601	8EHQ-0586-0602 S	8EHQ-0686-0603
	8EHQ-0786-0606 S	8EHQ-0786-0607 S	8EHQ-0786-0608 S
	8EHQ-0786-0609 S	8EHQ-0786-0613	8EHQ-0786-0614
	8EHQ-0786-0615	8EHQ-0786-0616	8EHQ-0886-0621
	8EHQ-0886-0622 S	8EHQ-0986-0623 S	8EHQ-0986-0624 S
	8EHQ-0986-0625 S	8EHQ-0986-0627	8EHQ-0986-0629
	8EHQ-0986-0630	8EHQ-0986-0631 S	8EHQ-0986-0633 S
	8EHQ-0986-0634	8EHQ-1086-0635	8EHQ-1086-0636 S
	8EHQ-1086-0637	8EHQ-1086-0639 S	8EHQ-1086-0640 S N
	8EHQ-1086-0641	8EHQ-1086-0642	8EHQ-1186-0643
	8EHQ-1186-0644	8EHQ-1286-0645	8EHQ-1286-0648
	8EHQ-0187-0649 S	8EHQ-0287-0653	8EHQ-0287-0654
	8EHQ-0287-0655 S	8EHQ-0287-0657 S	8EHQ-0287-0658
	8EHQ-0387-0659	8EHQ-0487-0661 S	8EHQ-0487-0663
	8EHQ-0487-0664 S	8EHQ-0487-0665 S N	8EHQ-0487-0667 S N

PRODUCTION/USE/PROCESS

SUBMISSION #:	8EHQ-0487-0669 M	8EHQ-0487-0670 S	8EHQ-0487-0671
	8EHQ-0587-0672 S	8EHQ-0587-0673	8EHQ-0587-0674 S
	8EHQ-0587-0675 M	8EHQ-0587-0676	8EHQ-0687-0677
	8EHQ-0587-0678	8EHQ-0687-0679	8EHQ-0687-0680
	8EHQ-0687-0682	8EHQ-0687-0683	8EHQ-0787-0684 S
	8EHQ-0787-0685	8EHQ-0787-0686 S	8EHQ-0887-0687
	8EHQ-0887-0688	8EHQ-0887-0689 M	8EHQ-0887-0690
	8EHQ-0887-0691 S	8EHQ-0987-0692	8EHQ-0987-0694 M
	8EHQ-1087-0695	8EHQ-1187-0698	8EHQ-1287-0699
	8EHQ-1287-0700	8EHQ-1287-0701 M	8EHQ-1287-0704
	8EHQ-1287-0706	8EHQ-1287-0709 S	8EHQ-1287-0710
	8EHQ-0188-0714	8EHQ-0288-0715	8EHQ-0288-0716 S
	8EHQ-0288-0717 S	8EHQ-0288-0719	8EHQ-0288-0720
	8EHQ-0388-0721	8EHQ-0288-0722	8EHQ-0388-0723
	8EHQ-0388-0724 S	8EHQ-0388-0725	8EHQ-0488-0729 S
	8EHQ-0588-0730	8EHQ-0588-0731 S	8EHQ-0588-0732
	8EHQ-0588-0733	8EHQ-0688-0734 S	8EHQ-0688-0735
	8EHQ-0688-0738	8EHQ-0688-0739	8EHQ-0688-0740 S
	8EHQ-0788-0742 M	8EHQ-0788-0744 S	8EHQ-0788-0745 S
	8EHQ-0888-0746	8EHQ-0888-0747	8EHQ-0988-0748
	8EHQ-0988-0749 S	8EHQ-0988-0750 S	8EHQ-0988-0751 S
	8EHQ-0988-0752 S	8EHQ-0988-0753 S	8EHQ-0988-0754
	8EHQ-1088-0755	8EHQ-1088-0756	8EHQ-1088-0757
	8EHQ-1088-0758 S	8EHQ-1088-0759	8EHQ-1088-0760 S
	8EHQ-1088-0763 S	8EHQ-1188-0765 S	8EHQ-1188-0766 S

PRODUCTION/USE/PROCESS

SUBMISSION #:	8EHQ-1188-0767 S	8EHQ-1188-0768 S	8EHQ-1188-0770 S
	8EHQ-1188-0771 S	8EHQ-1288-0775	8EHQ-1288-0776
	8EHQ-1288-0778	8EHQ-0189-0779	8EHQ-0189-0781 S
	8EHQ-0289-0782 S	8EHQ-0289-0783 S	8EHQ-0289-0784
	8EHQ-0289-0785 S	8EHQ-0389-0787 S	8EHQ-0389-0788 S
	8EHQ-0389-0789	8EHQ-0389-0790 S	8EHQ-0389-0791 S
	8EHQ-0489-0792	8EHQ-0489-0793	8EHQ-0489-0794 S
	8EHQ-0589-0798 S	8EHQ-0589-0799	8EHQ-0589-0800
	8EHQ-0689-0802	8EHQ-0689-0804	8EHQ-0789-0805 S
	8EHQ-0789-0806 S	8EHQ-0789-0807 S	8EHQ-0789-0808 S
	8EHQ-0889-0810 S	8EHQ-0889-0811 S	8EHQ-0889-0813
	8EHQ-0889-0814	8EHQ-0886-0815	8EHQ-0889-0816 S
	8EHQ-0889-0817	8EHQ-0889-0818 S	8EHQ-0889-0819 S
	8EHQ-0889-0820	8EHQ-0989-0821 S	8EHQ-0989-0823
	8EHQ-0989-0824 S	8EHQ-0989-0825 S	8EHQ-0989-0826 S
	8EHQ-0989-0827 S	8EHQ-0989-0828 S	8EHQ-1089-0829
	8EHQ-1089-0831	8EHQ-1089-0832	8EHQ-1089-0833 S
	8EHQ-1089-0834 S	8EHQ-1089-0835 S	8EHQ-1089-0836
	8EHQ-1089-0838 S	8EHQ-1189-0839	8EHQ-1189-0840 S
	8EHQ-1189-0841	8EHQ-1189-0842 S	8EHQ-1189-0843 S
	8EHQ-1189-0845	8EHQ-1189-0847	8EHQ-1189-0848 S
	8EHQ-1289-0849 S	8EHQ-1289-0850	8EHQ-1289-0851 S
	8EHQ-1289-0852 S	8EHQ-1289-0853 S	8EHQ-1289-0854 S
	8EHQ-1289-0856	8EHQ-1289-0857 S	8EHQ-1289-0858 S
	8EHQ-0190-0861 S	8EHQ-0190-0862 S	8EHQ-0190-0863

PRODUCTION/USE/PROCESS

SUBMISSION #:	8EHQ-0190-0864	8EHQ-0190-0865 S	8EHQ-0190-0866 S
	8EHQ-0190-0867 M	8EHQ-0190-0868 S	8EHQ-0190-0869 S
	8EHQ-0190-0870 S	8EHQ-0190-0871 S	8EHQ-0290-0872 S
	8EHQ-0290-0874 S	8EHQ-0290-0875 S	8EHQ-0290-0877
	8EHQ-0290-0879 S	8EHQ-0290-0881 S	8EHQ-0290-0882
	8EHQ-0290-0883 S	8EHQ-0290-0885	8EHQ-0290-0886
	8EHQ-0290-0887 S	8EHQ-0290-0888 S	8EHQ-0290-0889 S
	8EHQ-0290-0890 S	8EHQ-0290-0891 S	8EHQ-0290-0894
	8EHQ-0390-0898	8EHQ-0390-0899 M	8EHQ-0390-0900
	8EHQ-0390-0901	8EHQ-0390-0902	8EHQ-0390-0903 S
	8EHQ-0390-0907 S	8EHQ-0390-0913 S	8EHQ-0390-0914 S
	8EHQ-0390-0915	8EHQ-0390-0916 S M	8EHQ-0490-0917
	8EHQ-0490-0918 S	8EHQ-0490-0919 S	8EHQ-0490-0924
	8EHQ-0490-0925 S	8EHQ-0490-0926 S	8EHQ-0490-0928 S
	8EHQ-0490-0930 S	8EHQ-0490-0931 S	8EHQ-0490-0932
	8EHQ-0490-0933	8EHQ-0490-0934 S	8EHQ-0490-0935 S
	8EHQ-0490-0936	8EHQ-0490-0937	8EHQ-0490-0938
	8EHQ-0490-0939	8EHQ-0490-0940	8EHQ-0490-0941
	8EHQ-0490-0943	8EHQ-0490-0944	8EHQ-0490-0945
	8EHQ-0490-0950	8EHQ-0490-0951	8EHQ-0490-0954 S
	8EHQ-0490-0955 S	8EHQ-0490-0956 S	8EHQ-0490-0957 S
	8EHQ-0490-0958 S	8EHQ-0490-0959 S	8EHQ-0490-0960
	8EHQ-0490-0962	8EHQ-0590-0964	8EHQ-0590-0968
	8EHQ-0590-0971	8EHQ-0590-0972	8EHQ-0590-0974
	8EHQ-0590-0975	8EHQ-0590-0976	8EHQ-0590-0981

PRODUCTION/USE/PROCESS

SUBMISSION #: 8EHQ-0590-0983
8EHQ-0590-0985 N
8EHQ-0590-0992 S
8EHQ-0590-0994 N
8EHQ-0590-0995 S
8EHQ-0590-0996
8EHQ-0590-0997 S
8EHQ-0590-0998 S
8EHQ-0690-0999 N
8EHQ-0590-1001 S
8EHQ-0690-1002
8EHQ-0690-1003
8EHQ-0690-1004 S
8EHQ-0690-1005 S
8EHQ-0690-1006 S
8EHQ-0690-1010 S
8EHQ-0690-1011 S
8EHQ-0690-1012 S
8EHQ-0690-1013 S
8EHQ-0690-1014 S
8EHQ-0690-1015
8EHQ-0690-1016 S
8EHQ-0690-1018
8EHQ-0690-1019
8EHQ-0790-1021
8EHQ-0790-1023 S
8EHQ-0790-1024
8EHQ-0790-1025 S
8EHQ-0790-1026 S
8EHQ-0790-1027
8EHQ-0790-1028 S
8EHQ-0790-1029
8EHQ-0790-1031 S
8EHQ-0790-1033
8EHQ-0790-1034
8EHQ-0790-1036 S
8EHQ-0790-1037 S
8EHQ-0890-1039 S
8EHQ-0890-1040
8EHQ-0890-1041
8EHQ-0890-1042
8EHQ-0890-1043
8EHQ-0890-1044 S
8EHQ-0890-1045
8EHQ-0890-1046
8EHQ-0890-1047
8EHQ-0890-1048 S
8EHQ-0890-1049 S
8EHQ-0890-1050 S
8EHQ-0890-1052 S
8EHQ-0890-1053
8EHQ-0890-1054 S
8EHQ-0890-1055 S
8EHQ-0890-1056 S
8EHQ-0990-1058 S
8EHQ-0990-1060 S
8EHQ-0990-1061
8EHQ-0990-1062
8EHQ-0990-1063
8EHQ-0990-1065
8EHQ-0990-1066 S
8EHQ-0990-1069
8EHQ-0990-1070 S
8EHQ-0990-1071
8EHQ-0990-1072
8EHQ-0990-1073 S
8EHQ-0990-1074
8EHQ-0990-1075 S
8EHQ-0990-1076 S
8EHQ-0990-1078
8EHQ-0990-1079 S
8EHQ-0990-1080 S
8EHQ-0990-1081
8EHQ-0990-1083 S

REPORTING RATIONALE

SUBMISSION 0:	8EHQ-1078-0249			8EHQ-0880-0358		M	8EHQ-0783-0485	S	M
	8EHQ-1083-0494		M	8EHQ-0384-0508	P	M	8EHQ-0587-0672	S	
	8EHQ-1287-0706			8EHQ-0488-0729	S		8EHQ-1188-0772		
	8EHQ-0889-0813			8EHQ-0886-0815			8EHQ-0490-0933		

REPRODUCTIVE TOXICITY/TERATO. (ANIMAL)

SUBMISSION 0:	8EHQ-1077-0807			8EHQ-1277-0827			8EHQ-0278-0049		
	8EHQ-0378-0095		M	8EHQ-0378-0101		M	8EHQ-0378-0103		M
	8EHQ-0478-0122		M	8EHQ-0478-0129			8EHQ-0478-0130		M
	8EHQ-0578-0160	S	M	8EHQ-0678-0185		M	8EHQ-0678-0206		M
	8EHQ-0678-0208			8EHQ-0778-0209			8EHQ-0778-0211		
	8EHQ-0978-0244			8EHQ-1078-0245			8EHQ-1078-0247		
	8EHQ-1078-0248			8EHQ-1078-0252			8EHQ-0179-0267		
	8EHQ-0179-0269	S		8EHQ-0779-0293			8EHQ-0680-0346		
	8EHQ-1180-0373	S		8EHQ-1180-0374	S		8EHQ-1180-0375	S	
	8EHQ-0181-0379			8EHQ-0281-0384			8EHQ-0381-0386		
	8EHQ-0381-0388	S		8EHQ-0381-0394	S		8EHQ-0581-0399		
	8EHQ-0781-0405	S		8EHQ-1081-0414			8EHQ-1281-0421	S	
	8EHQ-1281-0424			8EHQ-0382-0448	S		8EHQ-0382-0441		
	8EHQ-0682-0458			8EHQ-0882-0452			8EHQ-1182-0462		
	8EHQ-1182-0464			8EHQ-0483-0475			8EHQ-0783-0485	S	M
	8EHQ-1083-0499			8EHQ-0284-0505			8EHQ-0884-0527		
	8EHQ-0884-0528			8EHQ-1084-0532			8EHQ-1084-0534		
	8EHQ-0185-0543			8EHQ-0285-0544			8EHQ-0385-0547		
	8EHQ-0485-0548			8EHQ-0585-0555			8EHQ-0785-0560		

REPRODUCTIVE TOXICITY/TERATO. (ANIMAL)

SUBMISSION 0:	8EHQ-0785-0562 S	8EHQ-1085-0570	8EHQ-0585-0572
	8EHQ-1285-0577	8EHQ-0186-0587	8EHQ-0986-0623 S
	8EHQ-0986-0626 S	8EHQ-0886-0628	8EHQ-0986-0633 S
	8EHQ-0287-0653	8EHQ-0287-0658	8EHQ-0487-0664 S
	8EHQ-0487-0666 S	8EHQ-0587-0672 S	8EHQ-0587-0676
	8EHQ-0687-0682	8EHQ-1087-0695	8EHQ-1287-0706
	8EHQ-0288-0716 S	8EHQ-0288-0717 S	8EHQ-0388-0721
	8EHQ-0388-0726	8EHQ-0488-0727	8EHQ-0488-0729 S
	8EHQ-0588-0731 S	8EHQ-0688-0738	8EHQ-0888-0746
	8EHQ-0988-0748	8EHQ-0988-0749 S	8EHQ-0988-0750 S
	8EHQ-0988-0751 S	8EHQ-1088-0758 S	8EHQ-1088-0760 S
	8EHQ-1088-0764 S	8EHQ-1188-0765 S	8EHQ-1188-0766 S
	8EHQ-1188-0767 S	8EHQ-1188-0770 S	8EHQ-1188-0771 S
	8EHQ-1288-0778	8EHQ-0289-0783 S	8EHQ-0289-0785 S
	8EHQ-0389-0786 S	8EHQ-0389-0790 S	8EHQ-0489-0792
	8EHQ-0489-0794 S	8EHQ-0789-0807 S	8EHQ-0889-0810 S
	8EHQ-0889-0811 S	8EHQ-0889-0813	8EHQ-0889-0816 S
	8EHQ-0889-0820	8EHQ-0989-0823	8EHQ-0989-0824 S
	8EHQ-0989-0825 S	8EHQ-0989-0827 S	8EHQ-0989-0828 S
	8EHQ-1089-0829	8EHQ-1089-0835 S	8EHQ-1189-0842 S
	8EHQ-1189-0844	8EHQ-1289-0849 S	8EHQ-1289-0851 S
	8EHQ-1289-0852 S	8EHQ-1289-0855	8EHQ-1289-0858 S
	8EHQ-0190-0861 S	8EHQ-0190-0862 S	8EHQ-0190-0865 S
	8EHQ-0190-0868 S	8EHQ-0190-0869 S	8EHQ-0190-0870 S
	8EHQ-0190-0871 S	8EHQ-0290-0872 S	8EHQ-0290-0874 S

REPRODUCTIVE TOXICITY/TERATO. (ANIMAL)

SUBMISSION 0:	8EHQ-0290-0875 S	8EHQ-0290-0877	8EHQ-0290-0878
	8EHQ-0290-0879 S	8EHQ-0290-0881 S	8EHQ-0290-0883 S
	8EHQ-0290-0884	8EHQ-0290-0887 S	8EHQ-0290-0888 S
	8EHQ-0290-0889 S	8EHQ-0290-0890 S	8EHQ-0290-0891 S
	8EHQ-0290-0892	8EHQ-0390-0895 S	8EHQ-0390-0896 S
	8EHQ-0390-0897 S	8EHQ-0390-0904	8EHQ-0390-0907 S
	8EHQ-0390-0910 S	8EHQ-0390-0911 S	8EHQ-0390-0912 S
	8EHQ-0490-0918 S	8EHQ-0490-0922 S	8EHQ-0490-0923 S
	8EHQ-0490-0925 S	8EHQ-0490-0927 S	8EHQ-0490-0928 S
	8EHQ-0490-0930 S	8EHQ-0490-0931 S	8EHQ-0490-0932
	8EHQ-0490-0935 S	8EHQ-0490-0937	8EHQ-0490-0938
	8EHQ-0490-0939	8EHQ-0490-0940	8EHQ-0490-0941
	8EHQ-0490-0942	8EHQ-0490-0943	8EHQ-0490-0944
	8EHQ-0490-0945	8EHQ-0490-0946	8EHQ-0490-0947
	8EHQ-0490-0948	8EHQ-0490-0949	8EHQ-0490-0950
	8EHQ-0490-0951	8EHQ-0490-0955 S	8EHQ-0490-0956 S
	8EHQ-0490-0961 S	8EHQ-0590-0965	8EHQ-0590-0966
	8EHQ-0590-0967	8EHQ-0590-0968	8EHQ-0590-0969
	8EHQ-0590-0970	8EHQ-0590-0971	8EHQ-0590-0972
	8EHQ-0590-0973	8EHQ-0590-0974	8EHQ-0590-0975
	8EHQ-0590-0976	8EHQ-0590-0977	8EHQ-0590-0978
	8EHQ-0590-0979	8EHQ-0590-0980	8EHQ-0590-0981
	8EHQ-0590-0982	8EHQ-0590-0983	8EHQ-0590-0984
	8EHQ-0590-0986 S	8EHQ-0590-0987 S	8EHQ-0590-0988 S
	8EHQ-0590-0989 S	8EHQ-0590-0990	8EHQ-0590-0992 S

REPRODUCTIVE TOXICITY/TERATO. (ANIMAL)

SUBMISSION #:	8EHQ-0590-0995 S	8EHQ-0590-0997 S	8EHQ-0590-0998 S
	8EHQ-0690-0999 N	8EHQ-0690-1000 S	8EHQ-0690-1002
	8EHQ-0690-1003	8EHQ-0690-1006 S	8EHQ-0690-1008
	8EHQ-0690-1010 S	8EHQ-0690-1011 S	8EHQ-0690-1012 S
	8EHQ-0690-1013 S	8EHQ-0690-1014 S	8EHQ-0790-1024
	8EHQ-0790-1025 S	8EHQ-0790-1026 S	8EHQ-0790-1030
	8EHQ-0790-1037 S	8EHQ-0890-1042	8EHQ-0890-1043
	8EHQ-0890-1046	8EHQ-0890-1055 S	8EHQ-0990-1063
	8EHQ-0990-1064	8EHQ-0990-1073 S	8EHQ-0990-1075 S

REPRODUCTIVE TOXICITY/TERATO. (HUMAN)

SUBMISSION #:	8EHQ-0877-0003	8EHQ-1277-0021	8EHQ-0278-0056
	8EHQ-0478-0123	8EHQ-0478-0128	8EHQ-0578-0146
	8EHQ-0678-0192 S	8EHQ-1078-0245	8EHQ-1080-0367
	8EHQ-0382-0440 S	8EHQ-0286-0588 N	8EHQ-0288-0722
	8EHQ-0989-0821 S		

SUBACUTE TOXICITY (ANIMAL)

SUBMISSION #:	8EHQ-1277-0023	8EHQ-1277-0024	8EHQ-0178-0068 N
	8EHQ-0178-0069	8EHQ-0578-0157 N	8EHQ-0678-0178
	8EHQ-0678-0184 N	8EHQ-0678-0185 N	8EHQ-0279-0274
	8EHQ-0679-0291	8EHQ-0779-0293	8EHQ-1279-0325
	8EHQ-0680-0346	8EHQ-1080-0366	8EHQ-0780-0369
	8EHQ-0181-0377	8EHQ-0281-0384	8EHQ-0381-0392
	8EHQ-1081-0419	8EHQ-1281-0425 S	8EHQ-0382-0438 S

SUBACUTE TOXICITY (ANIMAL)

SUBMISSION #:								
	8EHQ-0582-0445			8EHQ-0682-0446	S		8EHQ-1182-0462	
	8EHQ-0483-0476	S		8EHQ-0583-0478	S		8EHQ-0683-0483	S
	8EHQ-0683-0484	S		8EHQ-0783-0485	S	N	8EHQ-1083-0495	
	8EHQ-1083-0498			8EHQ-0284-0505			8EHQ-0684-0520	
	8EHQ-1084-0532			8EHQ-1084-0534			8EHQ-0385-0547	
	8EHQ-0485-0549	S		8EHQ-0485-0550			8EHQ-0585-0556	S
	8EHQ-0785-0561	S		8EHQ-0785-0562	S		8EHQ-1085-0571	S
	8EHQ-0186-0585	S		8EHQ-0386-0590			8EHQ-0386-0591	
	8EHQ-0486-0597			8EHQ-0686-0603			8EHQ-0686-0605	S
	8EHQ-0786-0608	S		8EHQ-0986-0627			8EHQ-0986-0633	S
	8EHQ-1086-0637			8EHQ-0287-0653			8EHQ-0487-0664	S
	8EHQ-0587-0674	S		8EHQ-0687-0680			8EHQ-0687-0683	
	8EHQ-0787-0686	S		8EHQ-1287-0700			8EHQ-1287-0703	
	8EHQ-1287-0705			8EHQ-0188-0714			8EHQ-0388-0724	S
	8EHQ-0488-0727			8EHQ-0688-0734	S		8EHQ-1088-0757	
	8EHQ-1288-0777			8EHQ-0389-0780			8EHQ-0189-0781	S
	8EHQ-0289-0782	S		8EHQ-0389-0789			8EHQ-0689-0803	
	8EHQ-0989-0826	S		8EHQ-1089-0837	S		8EHQ-1189-0845	
	8EHQ-0290-0880			8EHQ-0290-0884			8EHQ-0390-0908	S
	8EHQ-0490-0926	S		8EHQ-0490-0931	S		8EHQ-0490-0934	S
	8EHQ-0690-0999		N	8EHQ-0690-1003			8EHQ-0690-1007	
	8EHQ-0698-1019			8EHQ-0690-1020			8EHQ-0790-1022	S
	8EHQ-0790-1027			8EHQ-0790-1028	S		8EHQ-0790-1033	
	8EHQ-0790-1037	S		8EHQ-0890-1041			8EHQ-0890-1046	
	[illegible] 0890 1055	S		8EHQ-0890-1056	S		8EHQ-0990-1061	

SUBACUTE TOXICITY (ANIMAL)

SUBMISSION 0:	8EHQ-0990-1062	8EHQ-0990-1070 S	8EHQ-0990-1081

SUBCHRONIC TOXICITY (ANIMAL)

SUBMISSION 0:	8EHQ-1177-0014	8EHQ-0178-0033	8EHQ-0578-0160 S N
	8EHQ-0578-0161 S N	8EHQ-0678-0184 N	8EHQ-0678-0190 N
	8EHQ-0778-0289	8EHQ-0878-0231 N	8EHQ-0279-0274
	8EHQ-0279-0275	8EHQ-1079-0312	8EHQ-0680-0347
	8EHQ-0780-0394	8EHQ-0980-0364	8EHQ-0281-0384
	8EHQ-0682-0446 S	8EHQ-0683-0483 S	8EHQ-1083-0494 N
	8EHQ-0184-0504	8EHQ-0384-0507	8EHQ-0884-0524
	8EHQ-0984-0529	8EHQ-0785-0561 S	8EHQ-0785-0562 S
	8EHQ-1185-0574	8EHQ-1185-0576	8EHQ-0186-0582 S
	8EHQ-0186-0586 S	8EHQ-0386-0594 S	8EHQ-0486-0600
	8EHQ-1086-0635	8EHQ-1286-0648	8EHQ-0487-0668
	8EHQ-0587-0676	8EHQ-1287-0702	8EHQ-1287-0706
	8EHQ-0488-0729 S	8EHQ-0788-0744 S	8EHQ-0888-0747
	8EHQ-0988-0748	8EHQ-1088-0756	8EHQ-1088-0760 S
	8EHQ-1088-0763 S	8EHQ-0489-0793	8EHQ-0889-0817
	8EHQ-1089-0836	8EHQ-1189-0840 S	8EHQ-1189-0843 S
	8EHQ-1189-0846	8EHQ-1289-0855	8EHQ-0190-0866 S
	8EHQ-0290-0881 S	8EHQ-0490-0930 S	8EHQ-0490-0931 S
	8EHQ-0490-0932	8EHQ-0490-0936	8EHQ-0690-1002
	8EHQ-0890-1049 S	8EHQ-0990-1063	8EHQ-0990-1074

TSCA 8(C) ALLEGATION

APPENDIX (D): STAIUS REPORTS BY INFORMATION TYPE

SUBMISSION 0:	8EHQ-0378-0097 M	8EHQ-0478-0118 P M	8EHQ-0478-0129
	8EHQ-0478-0135	8EHQ-1084-0532	8EHQ-0386-0589 S
	8EHQ-0786-0612	8EHQ-0886-0622 S	8EHQ-0986-0632
	8EHQ-0887-0690	8EHQ-0987-0694 M	8EHQ-0889-0818 S
	8EHQ-0989-0821 S	8EHQ-0398-0905 S M	8EHQ-0490-0929 S M
	8EHQ-0590-0991 S	8EHQ-0990-1071	8EHQ-0990-1078

federal register

THURSDAY, MARCH 16, 1978
PART V

ENVIRONMENTAL PROTECTION AGENCY

■

TOXIC SUBSTANCES CONTROL ACT

Statement of Interpretation and Enforcement Policy; Notification of Substantial Risk

[6560-01]

ENVIRONMENTAL PROTECTION AGENCY

[FRL 849-2]

TOXIC SUBSTANCES CONTROL ACT

Notification of Substantial Risk Under Section 8(e)

AGENCY: Environmental Protection Agency.

ACTION: Statement of interpretation and enforcement policy.

SUMMARY: This action states EPA's interpretation of, and enforcement policy concerning, section 8(e) of the Toxic Substances Control Act (TSCA) (90 Stat. 2029, 15 U.S.C. 2607). The provisions of that section went into effect on January 1, 1977.

Section 8(e) states that "any person who manufactures, processes, or distributes in commerce a chemical substance or mixture and who obtains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment shall immediately inform the Administrator of such information unless such person has actual knowledge that the Administrator has been adequately informed of such information."

DATES: The policy expressed in this document is in effect as of the date of publication.

FOR FURTHER INFORMATION CONTACT:

Frank D. Kover, Assessment Division, Office of Toxic Substances (WH-557), Environmental Protection Agency, 401 M Street SW., Washington, D.C. 20460, 202-755-2110.

SUPPLEMENTARY INFORMATION: On September 9, 1977, the Agency proposed guidance (42 FR 45362) on its interpretation of and policy concerning the provisions of section 8(e). Although the proposed "guidance" was an interpretive rule and statement of policy exempt from the notice and public comment provisions of the Administrative Procedure Act (5 U.S.C. 553), the Agency solicited comments on several issues to make more informed decisions. On October 11, the comment period was extended from October 15 to October 31, 1977 (42 FR 54857). On November 4, 1977, a supplemental notice to the proposed guidance was published (42 FR 57744), deleting the November 15 date for reporting certain information obtained before 1977 and stating that a new date would be established in the final guidance.

In developing this policy statement, two meetings have been held (February 1, 1977, and October 26, 1977) with selected representatives of industry and environmental and other interested groups. Comments submitted pursuant to the February 1 meeting were addressed in the preamble to the September 9 proposal. Over 100 written comments have been submitted pursuant to the September 9 proposal from trade associations, businesses, environmental groups, labor unions, State and Federal agencies, and other interested parties. Appendix B describes significant issues raised in these comments and the Agency's response to them.

The major modifications to the September 9 proposal are summarized in points 1 through 7 below.

(1) Pursuant to some question over the definition and nature of "guidance," this document is now described more accurately as a "policy statement." It is exempt from the notice and public comment provisions of the Administrative Procedure Act, as well as provisions concerning delayed effective dates.

(2) Many commenters expressed the view that to apply these requirements to officers and employees of a business organization would result in ill-considered, premature reports and would unfairly subject employees to conflicting responsibilities as individual respondents and as corporate agents. Other commenters expressed support for the view that certain employees have a responsibility to report pertinent information, and felt that the phrase "capable of appreciating pertinent information" appropriately described those employees.

The September 9 proposal would have applied section 8(e) requirements to commercial establishments as well as to employees capable of appreciating pertinent information, but stipulated enforcement priorities intended to encourage corporate processing and centralized reporting of such information (42 FR 45363). The intent was to ensure that pertinent information obtained by employees is promptly and appropriately considered, while minimizing duplicative or ill-considered submissions.

The Agency now feels that these objectives would best be served by allowing commercial establishments—under certain conditions designed to ensure full disclosure—to assume exclusive responsibility for reporting to EPA any substantial-risk information obtained by individual officers or employees. Accordingly, this policy statement stipulates that individual officers and employees will have fully discharged their section 8(e) obligations once they have notified the designated responsible company supervisor or official of pertinent information, *provided*, that the employing company or firm has established, internally publicizes, and affirmatively implements procedures governing such notifications. These procedures, at a minimum, must: (1) Specify the information that must be reported; (2) indicate how the notifications are to be prepared and submitted; (3) note the Federal penalties for failing to report; and (4) provide a mechanism for promptly notifying officers and employees who have submitted reports of the company's disposition of those reports, including whether or not they were submitted to EPA (and if not, informing employees of their right to report to EPA, as protected by TSCA section 23). EPA believes these four criteria will ensure prompt and appropriate processing of pertinent information.

Establishment of such procedures notwithstanding, all officials responsible and having authority for the organization's execution of its section 8(e) obligations retain personal liability for ensuring that substantial-risk information is reported to EPA.

(3) The September 9 proposal stated, in Part III, that a person obtains information when he is aware that it "may suggest" substantial risk. Numerous commenters questioned the Administrator's authority to compel the reporting of information which "may suggest" substantial risk. The Administrator agrees that section 8(e) addresses information that "reasonably supports the conclusion" of substantial risk and has deleted the "may suggest" provision, but emphasizes that "reasonably supports the conclusion" of substantial risk is not identical to a conclusive demonstration of substantial risk. The former typically occurs, and must be reported, at an earlier stage. Part VI in this policy statement provides Agency interpretation of the types of information that "reasonably support" such a conclusion.

(4) Numerous commenters requested clarification of different aspects of Part V of the September 9 proposal ("Information Which Reasonably Supports a Conclusion of Substantial Risk"), particularly concerning environmental effects, and suggested different interpretations of what constitutes a "substantial risk". The Agency continues to focus in this policy statement on the effects set forth in the September 9 proposal, but clarifies that the substantiality of a risk is a function of both the seriousness of the effect and the probability of its occurrence (see Part V).

(5) Numerous commenters maintained that section 8(e) only applies prospectively to information obtained after January 1, 1977. The Agency disagrees, as explained in the preamble to the September 9 proposal. This policy statement continues to apply section 8(e) to information obtained before 1977 of which a person has

been aware since January 1, 1977. In response to requests for clarification, the statement defines what constitutes such awareness. In this manner, EPA intends to limit the need for searches of historical records and files.

(6) This policy statement now provides that any information published in scientific literature, in any language, is exempt if it is referred to in abstracts published by specified abstracting services.

(7) This policy statement describes in a new Part X how to submit claims of confidentiality.

Accordingly, the Administrator's interpretation of and policy towards section 8(e) is set forth below.

Dated: February 24, 1978.

DOUGLAS COSTLE
Administrator.

I. DEFINITIONS

The definitions set forth in TSCA section 3 apply to these requirements. In addition, the following definitions are provided for purposes of this policy statement:

The term "manufacture or process 'for commercial purposes' " means to manufacture or process: (1) For distribution in commerce, including for test marketing purposes, (2) for use as a catalyst or an intermediate, (3) for the exclusive use by the manufacturer or processor, or (4) for product research and development.

The term "person" includes any natural person, corporation, firm, company, joint-venture, partnership, sole proprietorship, association, or any other business entity, any State or political subdivision thereof, any municipality, any interstate body and any department, agency, or instrumentality of the Federal Government.

The term "substantial-risk information" means information which reasonably supports the conclusion that a chemical substance or mixture presents a substantial risk of injury to health or the environment.

II. PERSONS SUBJECT TO THE REQUIREMENT

Persons subject to section 8(e) requirements include both natural persons and business entities engaged in manufacturing, processing, or distributing in commerce a chemical substance or mixture. In the case of business entities, the president, chief executive officer, and any other officers responsible and having authority for the organization's execution of its section 8(e) obligations must ensure that the organization reports substantial-risk information to EPA. The business organization is considered to have obtained any information which any officer or employee capable of appreciating the significance of that information has obtained. It is therefore incumbent upon business organizations to establish procedures for expeditiously processing pertinent information in order to comply with the schedule set forth in Part IV.

Those officers and employees of business organizations who are capable of appreciating the significance of pertinent information are also subject to these reporting requirements. An employing organization may relieve its individual officers and employees of any responsibility for reporting substantial-risk information directly to EPA by establishing, internally publicizing, and affirmatively implementing procedures for employee submission and corporate processing of pertinent information. These procedures, at a minimum, must: (1) Specify the information that officers and employees must submit; (2) indicate how such submissions are to be prepared and the company official to whom they are to be submitted; (3) note the Federal penalties for failing to report; and (4) provide a mechanism for promptly advising officers and employees in writing of the company's disposition of the report, including whether or not the report was submitted to EPA (and if not informing employees of their right to report to EPA, as protected by TSCA section 23). An employee of any company that has established and publicized such procedures, who has internally submitted pertinent information in accordance with them, shall have discharged his section 8(e) obligation. Establishment of such procedures notwithstanding, all officials responsible and having authority for the organization's execution of its section 8(e) obligations retain personal liability for ensuring that the appropriate substantial-risk information is reported to EPA.

Business organizations that do not establish such procedures cannot relieve their individual officers and employees of the responsibility for ensuring that substantial-risk information they obtain is reported to EPA. While officers and employees of such organizations may also elect to submit substantial-risk information to their superiors for corporate processing and reporting, rather than to EPA directly, they have not discharged their individual section 8(e) obligation until EPA has received the information.

NOTE.—Irrespective of a business organization's decision to establish and publicize the procedures described above, it is responsible for becoming cognizant of any substantial-risk information obtained by its officers and employees, and for ensuring that such information is reported to EPA within 15 working days.

III. WHEN A PERSON WILL BE REGARDED AS HAVING OBTAINED INFORMATION

A person obtains substantial-risk information at the time he first comes into possession of or knows of such information.

NOTE.—This includes information of which a prudent person similarly situated could reasonably be expected to possess or have knowledge.

An establishment obtains information at the time any officer or employee capable of appreciating the significance of such information obtains it.

IV. REQUIREMENT THAT A PERSON "IMMEDIATELY INFORM" THE ADMINISTRATOR

With the exception of information on emergency incidents of environmental contamination [see Part V(c)] a person has "immediately informed" the Administrator if information is received by EPA not later than the 15th working day after the date the person obtained such information. Supplementary information generated after a section 8(e) notification should, if appropriate, be immediately reported. For emergency incidents of environmental contamination, a person shall report the incident to the Administrator by telephone as soon as he has knowledge of the incident (see Part IX for appropriate telephone contacts). The report should contain as much of the information required by Part IX as possible. A written report in accordance with Part IX (a) through (f) is to be submitted within 15 days.

Information currently in the possession of a person who is subject to reporting must be reported within 60 days of publication of this policy statement.

V. WHAT CONSTITUTES SUBSTANTIAL RISKS

A "substantial risk of injury to health or the environment" is a risk of considerable concern because of (a) the seriousness of the effect [see Subparts (a), (b), and (c) below for an illustrative list of effects of concern], and (b) the fact or probability of its occurrence. (Economic or social benefits of use, or costs of restricting use, are not to be considered in determining whether a risk is "substantial".) These two criteria are differentially weighted for different types of effects. The human health effects listed in Subpart (a) below, for example, are so serious that relatively little weight is given to exposure; the mere fact the implicated chemical is in commerce constitutes sufficient evidence of exposure. In contrast, the remaining effects listed in Subparts (b) and (c) below must involve, or be accompanied by the potential for, significant levels of exposure (because of general production levels, persistence, typical uses, common means of disposal or other pertinent factors).

Note that: (1) The effects ou[illegible] below should not be reported if [illegible]

spondent has actual knowledge that the Administrator is already informed of them.

(ii) Information respecting these effects can be obtained either directly, by observation of their occurrence, or inferred from designed studies as discussed in Part VI.

The Agency considers effects for which substantial-risk information must be reported to include the following:

(a) *Human health effects*—(1) Any instance of cancer, birth defects, mutagenicity, death, or serious or prolonged incapacitation, including the loss of or inability to use a normal bodily function with a consequent relatively serious impairment of normal activities, if one (or a few) chemical(s) is strongly implicated.

(2) Any pattern of effects or evidence which reasonably supports the conclusion that the chemical substance or mixture can produce cancer, mutation, birth defects or toxic effects resulting in death, or serious or prolonged incapacitation.

(b) *Environmental effects*—(1) Widespread and previously unsuspected distribution in environmental media, as indicated in studies (excluding materials contained within appropriate disposal facilities).

(2) Pronounced bioaccumulation. Measurements and indicators of pronounced bioaccumulation heretofore unknown to the Administrator (including bioaccumulation in fish beyond 5,000 times water concentration in a 30-day exposure or having an n-octanol/water partition coefficient greater than 25,000) should be reported when coupled with potential for widespread exposure and any non-trivial adverse effect.

(3) Any non-trivial adverse effect, heretofore unknown to the Administrator, associated with a chemical known to have bioaccumulated to a pronounced degree or to be widespread in environmental media.

(4) Ecologically significant changes in species' interrelationships; that is, changes in population behavior, growth, survival, etc. that in turn affect other species' behavior, growth, or survival.

Examples include: (i) Excessive stimulation of primary producers (algae, macrophytes) in aquatic ecosystems, e.g., resulting in nutrient enrichment, or eutrophication, of aquatic ecosystems.

(ii) Interference with critical biogeochemical cycles, such as the nitrogen cycle.

(5) Facile transformation or degradation to a chemical having an unacceptable risk as defined above.

(c) *Emergency incidents of environmental contamination*—Any environmental contamination by a chemical substance or mixture to which any of the above adverse effects has been ascribed and which because of the pattern, extent, and amount of contamination (1) seriously threatens humans with cancer, birth defects, mutation, death, or serious or prolonged incapacitation, or (2) seriously threatens non-human organisms with large-scale or ecologically significant population destruction.

VI. Nature and Sources of Information Which "Reasonably Supports the Conclusion" of Substantial Risk

Information attributing any of the effects described in Part V above to a chemical substance or mixture is to be reported if it is one of the types listed below and if it is not exempt from the reporting requirement by reason of Part VII of this policy statement. A person is not to delay reporting until he obtains conclusive information that a substantial risk exists, but is to immediately report any evidence which "reasonably supports" that conclusion. Such evidence will generally not be conclusive as to the substantiality of the risk; it should, however, reliably ascribe the effect to the chemical.

Information from the following sources concerning the effects described in Part V will often "reasonably support" a conclusion of substantial risk. Consideration of corroborative information before reporting can only occur where it is indicated below.

(1) *Designed, controlled studies.* In assessing the quality of information, the respondent is to consider whether it contains reliable evidence ascribing the effect to the chemical. Not only should final results from such studies be reported, but also preliminary results from incomplete studies where appropriate. Designed, controlled studies include:

(i) In vivo experiments and tests.

(ii) In vitro experiments and tests. Consideration may be given to the existence of corroborative information, if necessary to reasonably support the conclusion that a chemical presents a substantial risk.

(iii) Epidemiological studies.

(iv) Environmental monitoring studies.

(2) *Reports concerning and studies of undesigned, uncontrolled circumstances.* It is anticipated here that reportable effects will generally occur in a pattern, where a significant common feature is exposure to the chemical. However, a single instance of cancer, birth defects, mutation, death, or serious incapacitation in a human would be reportable if one (or a few) chemical(s) was strongly implicated. In addition, it is possible that effects less serious than those described in Part V(a) may be preliminary manifestations of the more serious effects and, together with another triggering piece of information, constitute reportable information; an example would be a group of exposed workers experiencing dizziness together with preliminary experimental results demonstrating neurological dysfunctions.

Reports and studies of undesigned circumstances include:

(i) Medical and health surveys.

(ii) Clinical studies.

(iii) Reports concerning and evidence of effects in consumers, workers, or the environment.

VII. Information Which Need Not Be Reported

Information need not be reported if it:

(a) Has been published by EPA in reports;

(b) Has been submitted in writing to EPA pursuant to mandatory reporting requirements under TSCA or any other authority administered by EPA (including the Federal Insecticide, Fungicide and Rodenticide Act, the Clean Air Act, the Federal Water Pollution Control Act, the Marine Protection, Research, and Sanctuaries Act, the Safe Drinking Water Act, and the Resource Conservation and Recovery Act), provided that the information: (1) Encompasses that required by Part IX (c) through (f); and (2) is from now on submitted within the time constraints set forth in Part IV and identified as a section 8(e) notice in accordance with Part IX(b);

(c) Has been published in the scientific literature and referenced by the following abstract services: (1) Agricola, (2) Biological Abstracts, (3) Chemical Abstracts, (4) Dissertation Abstracts, (5) Index Medicus, (6) National Technical Information Service.

(d) Is corroborative of well-established adverse effects already documented in the scientific literature and referenced as described in (c) above, unless such information concerns emergency incidents of environmental contamination as described in Part V(c), or

(e) Is contained in notification of spills under section 311(b)(5) of the Federal Water Pollution Control Act.

VIII. Information First Received by a Person Prior to the Effective Date of TSCA

Any substantial risk information possessed by a person prior to January 1, 1977, of which he is aware after that date shall be reported within 60 days of publication of this policy statement. The Agency considers that a person is "aware" of:

(a) Any information reviewed after January 1, 1977, including notes, memoranda written reports, memoranda and other documents examined after January 1, 1977, but also information referred to in discussions and conferences in which the person participated after January 1, 1977;

(b) Any information the contents of which a person has been alerted to by date received after January 1, 1977, including any information concerning a chemical for which the person is presently assessing health and environmental effects;

(c) Any other information of which the person has actual knowledge.

IX. Reporting Requirements

Notices shall be delivered to the Document Control Officer, Chemical Information Division, Office of Toxic Substances (WH-557), Environmental Protection Agency, 401 M Street SW., Washington, D.C. 20460. (****)

A notice should:

(a) Be sent by certified mail, or in any other way permitting verification of its receipt by the Agency.

(b) State that it is being submitted in accordance with section 8(e).

(c) Contain the job title, name, address, telephone number, and signature of the person reporting and the name and address of the manufacturing, processing, or distributing establishment with which he is associated.

(d) Identify the chemical substance or mixture (including, if known, the CAS Registry Number).

(e) Summarize the adverse effects being reported, describing the nature and the extent of the risk involved, and

(f) Contain the specific source of the information together with a summary and the source of any available supporting technical data.

For emergency incidents of environmental contamination (see Part VI(c)), a person shall report the incident to the Administrator by telephone as soon as he has knowledge of the incident (see below for appropriate telephone contacts). The report should contain as much of the information required by instructions (b) through (f) above as possible. A written report, in accordance with instructions (a) through (f) above, is to be submitted within 15 days. Twenty-four hour emergency telephone numbers are:

Region I (Maine, Rhode Island, Connecticut, Vermont, Massachusetts, New Hampshire), 617-223-7265.
Region II (New York, New Jersey, Puerto Rico, Virgin Islands), 201-548-8730.
Region III (Pennsylvania, West Virginia, Virginia, Maryland, Delaware, District of Columbia), 215-597-9898.
Region IV (Kentucky, Tennessee, North Carolina, South Carolina, Georgia, Alabama, Mississippi, Florida), 404-881-4062.
Region V (Wisconsin, Illinois, Indiana, Michigan, Ohio, Minnesota), 312-353-2318.
Region VI (New Mexico, Texas, Oklahoma, Arkansas, Louisiana), 214-749-3840.
Region VII (Nebraska, Iowa, Missouri, Kansas), 816-374-3778.
Region VIII (Colorado, Utah, Wyoming, Montana, North Dakota, South Dakota), 303-837-3880.
Region IX (California, Nevada, Arizona, Hawaii, Guam), 415-556-6234.
Region X (Washington, Oregon, Idaho, Alaska), 206-442-1200.

X. Confidentiality Claims

(a) Any person submitting a notice to EPA under section 8(e) of TSCA may assert a business confidentiality claim covering all or part of the information contained in the notice. Any information covered by a claim will be disclosed by EPA only to the extent, and by means of the procedures, set forth in 40 CFR Part 2 (41 FR 36902, September 1, 1976).

(b) If no claim accompanies the notice at the time it is submitted to EPA, the notice will be placed in an open file to be available to the public without further notice to the submitter.

(c) To assert a claim of confidentiality for information contained in a notice, the submitter must submit two copies of the notice.

(1) One copy must be complete. In that copy the submitter must indicate what information, if any, is claimed as confidential by marking the specified information on each page with a label such as "confidential," "proprietary," or "trade secret."

(2) If some information in the notice is claimed as confidential, the submitter must submit a second copy. The second copy must be complete except that all information claimed as confidential in the first copy must be deleted.

(3) The first copy of the notice will be disclosed by EPA only to the extent, and by means of the procedures, set forth in 40 CFR Part 2. The second copy will be placed in an open file to be available to the public.

(d) Any person submitting a notice containing information for which they are asserting a confidentiality claim should send the notice in a double envelope.

(1) The outside envelope should bear the same address outlined in section IX of this policy statement.

(2) The inside envelope should be clearly marked "To be opened only by the OTS Document Control Officer."

XI. Failure To Report Information

Section 15(3) of TSCA makes it unlawful for any person to fail or refuse to submit information required under section 8(e). Section 16 provides that a violation of section 15 renders a person liable to the United States for a civil penalty and possible criminal prosecution. Pursuant to section 17, the Government may seek judicial relief to compel submittal of section 8(e) information and to otherwise restrain any violation of section 8(e).

Appendix A—Quick Reference Summary for Emergency Incidents of Environmental Contamination

A. What Should Be Reported as an Emergency Incident

An emergency incident of environmental contamination is "any environmental contamination by a chemical substance or mixture . . . which, because of the pattern, extent and amount of contamination, (1) Seriously threatens humans with cancer, birth defects, mutation, death, or serious or prolonged incapacitation, or (2) seriously threatens non-human organisms with large scale or ecologically significant population destruction". (See Part V(c) for complete description.)

B. What Need Not Be Reported as an Emergency Incident

Information contained in notification of spills under section 311(b)(5) of the Federal Water Pollution Control Act (FWPCA). (For a complete list of exemptions to reporting, see Part VII.)

C. When and Where To Report Emergency Incidents

Emergency incidents of environmental contamination are to be reported immediately by telephone to the appropriate EPA Regional 24-hour telephone emergency line listed below.

Region I (Maine, Rhode Island, Connecticut, Vermont, Massachusetts, New Hampshire), 617-223-7265.
Region II (New York, New Jersey, Puerto Rico, Virgin Islands), 201-548-8730.
Region III (Pennsylvania, West Virginia, Virginia, Maryland, Delaware, District of Columbia), 215-597-9898.
Region IV (Kentucky, Tennessee, North Carolina, South Carolina, Georgia, Alabama, Mississippi, Florida), 404-881-4062.
Region V (Wisconsin, Illinois, Indiana, Michigan, Ohio, Minnesota), 312-353-2318.
Region VI (New Mexico, Texas, Oklahoma, Arkansas, Louisiana), 214-749-3840.
Region VII (Nebraska, Iowa, Missouri, Kansas), 816-374-3778.
Region VIII (Colorado, Utah, Wyoming, Montana, North Dakota, South Dakota), 303-837-3880.
Region IX (California, Nevada, Arizona, Hawaii, Guam), 415-556-6234.
Region X (Washington, Oregon, Idaho, Alaska), 206-442-1200.

In addition, a written report, in accordance with instructions (a) through (f) of Part IX, is to be submitted within 15 days to the Document Control Officer, Chemical Information Division, Office of Toxic Substances (WH-557), 401 M Street SW., Washington, D.C. 20460.

Appendix B—Significant Comments and Responses

A. Persons Subject to These Requirements

Comment 1: Employees cannot be held subject to these requirements, since (a) They only have a partial role in the manufacture, processing, or distribution of chemicals, (b) in other sections of TSCA, the term "person who manufactures, processes, or distributes" chemicals clearly refers to business organizations; "persons" should be consistently defined, and (c) the application of criminal penalties mandates a strict interpretation of this word.

(****) See NOTE on last page of Appendix C

Response: The Agency considers that different sections of TSCA, having different purposes, are appropriately directed to different respondents. In the case of section 8(e), officers and employees who are capable of appreciating the significance of information have a legitimate responsibility to be alert to and report substantial-risk information. The guidance has been modified so that natural persons and business entities can fulfill their section 8(e) obligations in different ways. Most officers and employees can discharge their section 8(e) obligations by submitting pertinent information to corporate superiors, provided that the company has established the risk-evaluation procedures characterized in Part II. In the case of a business organization, its president, chief executive officer, and other officials responsible and having authority for the business organization's execution of its section 8(e) obligations must ensure that the organization reports su stantial-risk information to EPA.

Comment 2: Even if employees can be held subject to these requirements, they should not be. To do so would force employees and employers into conflicting positions, inviting internal corporate dissension and over- reporting. Further, individuals often do not have the overview necessary to reach considered, well-supported decisions. Corporate reporting by designated officials will provide EPA with more reliable data.

Response: The Agency considers that employees have a legitimate role in risk reporting; it is imperative that risk information obtained by employees be appropriately considered. Officers and employees can fulfill their role in the reporting of substantial-risk information, without the disadvantages described above, by reporting information to superiors for corporate consideration, and, having done so, will have discharged their obligation to EPA. This is contingent upon the establishment by the business organization of certain procedures for risk-evaluation, thereby assuring the appropriate consideration of such reports. Those officers responsible and having authority for the organization's execution of its section 8(e) obligations must ensure that the organization reports substantial-risk information to EPA.

Comment 3: Clarify which employees are covered, and the extent of their obligation. Are employees "capable of appreciating pertinent information" by virtue of rank, or knowledge? Are rank and file employees subject to these requirements, or just supervisory and managerial personnel, company toxicologists, etc.? Is an employee absolved of further responsibility if he reports to his supervisor?

Response: The Agency considers that the phrase "capable of appreciating the significance of pertinent information" appropriately describes those officers and employees who have a responsibility to be alert to and report substantial-risk information, including not only relatively senior corporate officers but also many corporate employees. The policy statement modifies the September 9 proposal, in response to the concerns expressed in Comments 2 and 3, to permit most officers and employees to discharge their obligation by submitting information to corporate superiors, subject to the conditions described in Part II.

Comment 4: Consultants and independent labs should not be subject to these requirements.

Response: Contractors and independent labs are not responsible for reporting information they have obtained directly to EPA; rather, their client manufacturers, processors and distributors are responsible for reporting such information.

B. THE "OBTAINING" OF INFORMATION

Comment 5: The "may suggest" criterion in Part III of the proposal serves to compel further examination of information that by itself is not subject to section 8(e) requirements. The statutory language calling for "reasonable support" does not support this. Further, risk assessment often requires anywhere from months to several years of study after preliminary results "suggest" risk, far exceeding the 15-day compliance period.

Response: The Agency does not intend to compel under section 8(e) examination of information that by itself is not subject to section 8(e) requirements and has deleted the "may suggest" provision, providing its interpretation of what constitutes evidence that "reasonably supports the conclusion" of substantial risk in a new Part VI.

Comment 6: Section 8(e) obligations are incurred upon obtaining conclusory substantial-risk information.

Response: The Agency disagrees, and considers that "reasonable support" of a conclusion of substantial risk is not identical to the conclusion itself. The former typically occurs, and must be reported, at an earlier stage.

Comment 7: The statement, in Part III of the proposal that a person has obtained information if he ". . . should know of the existence of such information not in his possession but which would be delivered to him on request," tends to compel an active search for substantial-risk information rather than the reporting of substantial-risk information a person "obtains." This is of particular concern to importers with limited access to information possessed by their suppliers.

Response: The Agency considers that section 8(e) applies to information which a person possesses or of which he knows. It is not intended to compel searches for information or extraordinary efforts to acquire information. The Agency further considers, however, that "known" information includes information which a prudent person similarly situated could reasonably be expected to know. Negligence or intentional avoidance of information does not absolve a person of his section 8(e) obligation. Part III has been modified to express these intentions.

Comment 8: Circumstances can exist when coming "into possession" of risk information does not correspond to an understanding of the implications of the information; "obtains" should be defined in terms of possession of information and awareness of its import.

Response: The "obtaining" of information occurs via persons who are "capable of appreciating the significance of pertinent information." There will likely be circumstances in which the evaluation of information clarifies its full import; the establishment of corporate procedures for processing risk-information prescribed in Part II will expedite this.

C. TIME ALLOWED FOR COMPLIANCE

Comment 9: Fifteen calendar days is insufficient to determine whether information which "may suggest" substantial risk should be reported; it is even insufficient to accommodate normal procedural time constraints (corporate processing, mailing, holidays, etc.).

Response: The Agency has changed the compliance period to 15 business days. It is imperative that procedures be established to expedite the reporting of substantial-risk information, not that reporting conform to existing procedures.

Comment 10: Allow from 30 to 90 days for the second phase of reporting; alternatively, do not prescribe a time limit for additional reporting.

Response: Having deleted the "may suggest" criterion, the Agency sees no need to provide a second phase to the reporting period. Supplemental information that is generated after a section 8(e) notification should, if appropriate, be immediately reported.

Comment 11: Allow from 30 to 120 days to report pre-1977 information; this period should commence: (a) upon final publication, (b) January 1, 1978, (c) following the inventory reporting period since many of the same corporate personnel will be implementing both requirements.

Response: The policy statement prescribes a 60 day reporting period, commencing immediately upon publication. Section 8(e) has been in effect since January 1, 1977; postponement in reporting substantial-risk information is not warranted.

D. EFFECTS AND INFORMATION THAT MUST BE REPORTED

Comment 12: The reporting of "any instance" of cancer, birth defects, etc., in humans is too broad and such information will be of little use; chemical workers, like the general population, develop cancers and other ailments of uncertain etiology.

Response: This policy statement clarifies that the reporting of single occurrences of human cancer or other serious effects will depend upon evidence strongly implicating one (or a few) chemical(s).

Comment 13: Dermal ailments and nausea are poorly chosen examples of precursor symptoms. Deleting these examples will avoid unduly emphasizing them when other symptoms may be more important, yet will not eliminate the obligation to report them if they are suspected precursors.

Response: The Agency agrees.

Comment 14: How are reportable data distinguished from routine tests including range tests such as LD_{50}'s?

Response: This policy statement directs the reporting of specified effects when unknown to the Administrator. Many routine tests are based on a knowledge of toxicity associated with a chemical; unknown effects occurring during such a range test may have to be reported if they are those of concern to the Agency and if the information meets the criteria set forth in Parts V and VI.

Comment 15: The most widespread "in vitro" test is the Ames test, which is subject to considerable debate. Clarify the circumstances under which positive results of in vitro tests must be reported.

Response: Part VI clarifies that the reporting of in vitro tests will depend upon the existence of corroborative information if necessary to reasonably support the conclusion of substantial risk.

Comment 16: The description of "extreme persistence" as a substantial risk is an example of the need to redefine Part V(2) ("Environmental Effects"). Persistence and bioaccumulation should be considered risks only when coupled with toxicity and significant exposure.

Response: Part V now clarifies those effects for which reporting depends upon a significant exposure potential. Persistence by itself is no longer itemized as a reportable effect but rather is considered to be a component of exposure potential; it may also underlie the measurements described in Part V(b)(1). Laboratory indicators of pronounced bioaccumulation are to be reported when coupled with potential for widespread exposure and any non-trivial adverse effect.

Comment 17: The n-octanol/water partition coefficient addresses a physico-chemical property, not biological effects, and is not alone an indicator of substantial risk; further, the values stated for the coefficient and the bioaccumulation factor in fish do not correspond.

Response: The Agency acknowledges the numerical error and has amended the values to correspond. This policy statement now directs the reporting of an experimental measurement of bioaccumulation when coupled with an adverse effect and potential for widespread exposure.

Comment 18: The requirement that information which "links" an effect to a chemical be reported is too broad and contradicts the statutory language of "reasonably supports".

Response: The Agency has provided in a new Part VI its interpretation of "reasonably supports".

Comment 19: A determination that information "reasonably supports the conclusion" of substantial risk cannot be made independently of considerations of use since the method and manner of using a chemical may influence the occurrence of an effect; in particular, the criteria should reflect a distinction between normal and abnormal uses of chemicals.

Response: The Agency considers that the appropriate components of a "substantial risk" with respect to a chemical are (a) the seriousness of the effect, and (b) total exposure potential. The method and manner of using a chemical is one of several factors determining its exposure potential. As described in Part V, the importance of exposure potential as a component of "substantial risk" depends upon the kind of effect of concern. Thus, the effects described in Part V(a) are so serious that relatively little weight is given to exposure; the effects described in Parts V (b) and (c) involve a significant exposure or exposure potential.

The Agency further considers that a definition of "normal" use for a particular chemical will often depend upon a knowledge of the risks associated with the chemical.

E. INFORMATION THAT NEED NOT BE REPORTED

Comment 20: Information published in scientific literature in languages other than English should be exempted if published in summary form by abstracting services. Can the accuracy of English language abstracts and commercial translations of foreign literature be assumed?

Response: This policy statement now provides that information published in scientific literature, whether in English or another language, is exempt from reporting if published in summary form by certain specified abstract services.

Comment 21: Information exchange systems with other Federal agencies should be immediately established so that respondents need not report to EPA information already reported to other Agencies, and vice versa. Such duplicative reports are unduly burdensome.

Response: EPA is coordinating this program with other agencies now. When this coordination is successfully completed, the policy statement will be amended to exempt from the reporting requirement information that has been submitted to other specified agencies. In the meantime, substantial-risk information must be reported directly to EPA; such a report does not discharge any reporting obligation to other agencies.

F. INFORMATION FIRST RECEIVED PRIOR TO THE EFFECTIVE DATE OF TSCA

Comment 22: The tense of the verb "obtains" reveals that section 8(e) was intended to be applied prospectively to information newly acquired after January 1, 1977. Utilize section 8(d) or other rules to acquire information obtained before then.

Response: As discussed in the preamble to the September 9 proposal, the Agency considers section 8(e) to apply to risk information possessed by or known to a person before, on, or after January 1, 1977. Concerning information first obtained before 1977, this policy statement continues to require reporting of information received if a person has been aware of it since January 1, 1977, for the reasons discussed in the September 9 preamble.

Comment 23: The term "aware" is too vague to be of any help in responding to these requirements. Since many corporate employees are potentially subject to these requirements, and given uncertainty over the extent to which they ought to be aware of pre-1977 information, this provision tends to compel the very file search it was intended to avoid. The term "aware" should be further defined, possibly in terms of actual knowledge.

Response: The Agency in Part VIII of this policy statement now defines the pre-1977 information of which a person is considered to be aware.

G. CONFIDENTIAL INFORMATION

Comment 24: EPA should delay guidance until procedures are published governing the treatment of confidential submissions.

Comment 25: EPA should treat all submissions as confidential until the information is verified.

Comment 26: EPA should automatically publish section 8(e) notices.

Response to Comments 24 through 26: EPA has included a new Part X which describes how to submit a claim of confidentiality and states that any or all of the information submitted may be claimed as confidential. Such information will be disclosed by EPA only to the extent, and by means of the procedures, set forth in 40 CFR Part 2.

H. MISCELLANEOUS

Comment 27: What is the statutory basis or need for guidance? What is its exact status under the Administrative Procedure Act?

Response: This policy statement sets forth EPA's interpretation of and policy concerning TSCA section 8(e). As an interpretive rule and statement of policy it is not subject to the comment period and delayed effective date provisions of the Administrative Procedure Act (5 U.S.C. 553). Although TSCA does not mandate a policy statement, the Agency of necessity must develop the criteria which will govern enforcement activities. Trade associations and businesses were among those who previously expressed interest in such a statement to guide their compliance.

Comment 28: Clarify whether these requirements apply to chemicals previously but no longer manufactured, processed, or distributed in commerce by a person.

Response: Information obtained before 1977 must be reported if the person has been aware of it since January 1, 1977, as prescribed by Part VIII. Concerning chemicals which a person has discontinued manufacturing, processing, or distributing since January 1, 1977, information obtained before the time of discontinuation is subject to these requirements. It is expected that the acquisition of information after that time will be minimal; however, should additional information be acquired, it may trigger the reporting described in Part VIII.

Comment 29: Clarify the meaning of "substantial risk" relative to other risks addressed by TSCA.

Response: A substantial risk is defined in Part V(a) of this policy statement as a risk of considerable concern because of (a) the seriousness of the effect, and (b) the fact or probability of its occurrence. As opposed to other risks addressed by TSCA, economic or social benefits of use, or costs of restricting use, are not to be considered in determining whether a risk is "substantial".

Comment 30: To what extent are "users" of chemicals subject to these requirements?

Response: The Agency considers that many industrial uses of chemicals actually fall within the scope of "processing" chemicals. A manufacturer, processor, or distributor who obtains substantial-risk information concerning chemicals he handles should be alert to the possibility he may have to report it.

Comment 31: Are chemicals manufactured, processed and distributed in commerce in small quantities solely for purposes of research and development subject to these requirements?

Response: In general, the Agency considers that much manufacturing, processing, and distribution in commerce of chemicals in small quantities solely for purposes of research and development is conducted for "commercial purposes". Such purposes would include the sale and distribution of such materials, as well as their use by the manufacturer or processor in activities (for example, product research and development and studies assessing the feasibility and safety of using chemicals) preceding his or a client's commercial use of such materials or others on a larger scale.

As described in Part V, the Agency considers that "substantial risks" depend in part upon an exposure potential. Thus, the occurrence of the effects described in Part V(a) presuppose exposure to the chemical and must be reported; reporting of the other effects will depend upon a potential for significant levels of exposure.

Comment 32: Are raw materials, intermediates, and inert ingredients produced or used in the manufacture of a pesticide subject to TSCA?

Response: The Administrator considers that raw materials, intermediates and inert ingredients produced or used in the manufacture of a pesticide are substances or mixtures which can be regulated under TSCA.

In order to be considered a pesticide a substance must be intended for use as a pesticide. Raw materials, intermediates and inert ingredients produced or used in the manufacture of a pesticide are not themselves regulated under FIFRA (although they happen to be pesticides themselves) and, therefore, are subject to TSCA.

cide regulations at 40 CFR 162.4 are consistent with this view.

Comment 33: Are intermediates and catalysts intended solely for use in the production of a food, food additive, drug, cosmetic, or device subject to TSCA?

Response: The Administrator considers that intermediates and catalysts intended solely for use in the production of a food, food additive, drug, cosmetic, or device are excluded from regulation under TSCA. The definitions of the FFDCA provide that chemical substances which are intended for use as a component of a food, food additive, drug, cosmetic, or device are encompassed within the meaning of such terms, respectively. The FDA considers intermediates and catalysts to be such components. Therefore, they are subject to regulation under the FFDCA. Any such substance is excluded from regulation under TSCA insofar as it is actually manufactured, processed, or distributed in commerce solely for use in the production of a food, food additive, drug, cosmetic, or device.

Comment 34: Employees should have the option to submit reports anonymously.

Response: EPA considers that any person may report information to EPA under TSCA. Those who are required to do so under section 8(e) are persons who manufacture, process, or distribute in commerce chemical substances or mixtures, including not only business entities but also such employees as described in Part II. In order to establish that such persons have discharged their obligations, and in order to encourage responsible review of the quality of information and the substantiality of risks, EPA believes that notifiers should identify themselves. Section 23 will adequately protect employees from discrimination pursuant to notifications they have made under section 8(e).

[FR Doc. 78-7064 Filed 3-13-78; 8:45 am]

NOTE

According to technical amendments published by EPA in the May 29, 1987 FEDERAL REGISTER (52 FR 20083), TSCA Section 8(e) submissions are to be addressed to the Agency as follows:

Document Processing Center (TS-790)
(Attn: Section 8(e) Coordinator)
Office of Toxic Substances
U.S. Environmental Protection Agency
401 "M" Street, S.W.
Washington, D.C. 20460

federal register

Friday,
February 1, 1991

APPENDIX D
(CAP Notice)

Part II

Environmental Protection Agency

Registration and Agreement for TSCA Section 8(e) Compliance Audit Program; Notice

ENVIRONMENTAL PROTECTION AGENCY

[OPTS-60015; FRL-3844-4]

Registration and Agreement for TSCA Section 8(e) Compliance Audit Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This Notice, pursuant to sections 15 and 16 of the Toxic Substances Control Act (TSCA), 15 U.S.C. 2601 *et seq.*, announces the opportunity to register for EPA's TSCA Section 8(e) Compliance Audit Program. This Notice also contains the text of an Agreement for the TSCA Section 8(e) Compliance Audit Program ("CAP Agreement"). The TSCA Section 8(e) Compliance Audit Program and the registration provisions and CAP Agreement conditions are described below.

DATES: The Registration period for the TSCA Section 8(e) Compliance Audit Program commences February 1, 1991, and closes May 2, 1991. Persons interested in registering for the voluntary TSCA Section 8(e) Compliance Audit Program must request a CAP Agreement and submit a signed CAP Agreement to EPA no later than May 2, 1991.

ADDRESSES: Copies of the CAP Agreement may be obtained from the TSCA Assistance Information Service, Environmental Assistance Division (TS-799), Office of Toxic Substances, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, (202) 554-1404, TDD: (202) 554-0551.

FOR FURTHER INFORMATION CONTACT: Michael M. Stahl, Director, Environmental Assistance Division (TS-799), Office of Toxic Substances, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, (202) 554-1404, TDD: (202) 554-0551.

SUPPLEMENTARY INFORMATION:

I. Background

Section 8(e) of TSCA states that "any person who manufactures, [imports,] processes, or distributes in commerce a chemical substance or mixture and who obtains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment shall immediately inform the [EPA] Administrator of such information unless such person has actual knowledge that the Administrator has been adequately informed of such information."

"Substantial risk information" reportable to EPA under section 8(e) of TSCA refers to new information that reasonably supports a conclusion that a chemical substance or mixture presents a substantial risk of injury to health or the environment. (The term new information refers to information (including preliminary data) about which EPA has not already been adequately informed.) Such information need not and most typically does not establish conclusively that such a risk exists. In other words, reasonable support for a conclusion is not synonymous with the conclusion itself and usually precedes the conclusion.

In deciding whether new information reasonably supports a conclusion of substantial risk, one must consider (1) The seriousness of the adverse effect, and (2) the fact or probability of the effect's occurrence. These two criteria should be weighed differently depending upon the seriousness of the effect and the extent of the exposure; i.e., the more serious the effect, the less heavily one should weigh the actual or potential exposure, and vice versa.

In some cases, e.g., the observance of certain types of serious toxicologic effects in animals or humans, exposure to the chemical substance(s) or mixtures is presupposed and will constitute sufficient evidence of exposure for a determination to be made to submit the new-found toxicological data. Such serious effects include, but are not limited to, (1) Birth defects and/or serious developmental effects (including those observed in the presence of maternal toxicity), and (2) cancer (as evidenced by benign and/or malignant tumors).

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. Therefore, a decision to report pursuant to section 8(e) should not involve (1) Exhaustive health or environmental assessments, or (2) any evaluation of the economic or social benefits of the use(s) of the subject chemical(s).

In reviewing recent enforcement cases, EPA has found that some companies may be misinterpreting TSCA section 8(e) and EPA's "Statement of Interpretation and Enforcement Policy: Notification of Substantial Risk," ("Section 8(e) Policy Statement," March 16, 1978, 43 FR 11110). Some companies obtaining information on certain serious health effects appear to be further evaluating and wrongly discounting the significance of the information on the basis of a "weight-of-the-evidence" risk assessment. It is EPA's position, however, that if certain serious health effects are discovered, the information should be considered for immediate reporting under section 8(e) without further evaluation. The following are examples of information that should be considered immediately for reporting under section 8(e) of TSCA.

1. New information concerning statistically or biologically significant increases in benign and/or malignant tumors in an animal study; a "weight-of-the-evidence" risk assessment should not be used to discount the findings.

2. Statistically or biologically significant increases in teratologic or other serious reproductive effects observed in animals; the level of maternal toxicity observed in the study should not be used to discount the findings.

3. Serious toxic effects (e.g., cancer, birth defects, and neurotoxicity) observed in tests of chemical substances or mixtures at the research and development stage; such findings should not be discounted because the company believes that there is no exposure to the chemical(s).

Up-to-date information on hazard and exposure is vital in supporting EPA efforts to protect human health and the environment from risks from toxic chemicals. EPA has the responsibility under TSCA to perform needed risk assessments on chemicals. Section 8(e) is a very important part of TSCA's section 8 information reporting and recordkeeping provisions that enable EPA to obtain and disseminate information needed to set priorities and perform risk assessments that may be national in scope. Companies that do not report vital information are undermining the effectiveness of the early warning system intended under section 8(e).

In the past year, some companies have alleged that EPA has changed its interpretation of TSCA section 8(e) thereby creating vulnerability that was not previously contemplated for reporting. These same entities have said that EPA's TSCA Sections 8, 12, and 13 Enforcement Response Policy contains significant disincentives (namely very high monetary penalties) to dissuade auditing of past studies and reporting them to EPA.

EPA has not changed its interpretation of TSCA section 8(e). EPA's implementation of the TSCA section 8(e) program is based on sound guidance

that is and has been consistent with the statutory language and intent of section 8(e), as well as EPA's Section 8(e) Policy Statement. Nevertheless, to achieve the Agency's goal of obtaining any outstanding section 8(e) data, EPA has developed this one-time voluntary compliance program designed to strongly encourage companies to voluntarily audit their files for studies reportable under section 8(e). This program is known as the TSCA Section 8(e) Compliance Audit Program.

The TSCA Section 8(e) Compliance Audit Program has been developed to encourage industry reporting by setting forth guidelines that identify in advance EPA's enforcement response and allow companies to assess liability prior to electing to participate. Companies that do not participate in the TSCA Section 8(e) Compliance Audit Program should be aware that EPA intends to actively pursue violations of the TSCA section 8(e) reporting requirement.

I. Text of the Registration/CAP Agreement

The text of the Registration and CAP Agreement for the TSCA Section 8(e) Compliance Audit Program:

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticides and Toxic Substances

Registration and Agreement for TSCA Section 8(e) Compliance Audit Program

The United States Environmental Protection Agency ("EPA") and the Registratee, the Parties herein, wishing to enter for and enter into this Agreement for a Toxic Substances Control Act ("TSCA") Section 8(e) Compliance Audit Program ("CAP Agreement") and having consented to the terms of this CAP Agreement do hereby agree to fully comply with the terms of this CAP Agreement.

Registration Requirements

A. The Regulatee agrees to conduct a TSCA Section 8(e) Compliance Audit Program to determine its compliance status with TSCA section 8(e).

B. To register for the TSCA Section 8(e) Compliance Audit Program, the Regulatee must, no later than May 2, 1991, sign and return this CAP Agreement by certified mail-return receipt requested to: Michael F. Wood, Director, Compliance Division (EN-342), Office of Compliance Monitoring, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

C. After EPA receives this signed CAP Agreement from the Regulatee, EPA will sign this CAP Agreement and enter the following identification number (_____) to the copy of this CAP Agreement which will be returned to the Regulatee. The Final Report and all other documents submitted pursuant to Unit II.C of this CAP Agreement must display the identification number established by this paragraph.

D. The TSCA Section 8(e) Compliance Audit Program shall commence no later than May 2, 1991.

E. The TSCA Section 8(e) Compliance Audit Program shall terminate within 180 days of May 2, 1991. Thus, all submissions under this TSCA Section 8(e) Compliance Audit Program must be delivered to EPA no later than October 29, 1991.

II. Terms of Agreement

EPA and the Regulatee mutually initiated this TSCA Section 8(e) Compliance Audit Program in response to a February 1, 1991, Federal Register notice announcing the opportunity to participate in the TSCA Section 8(e) Compliance Audit Program. As part of this CAP Agreement, EPA and the Regulatee agree to the following:

A. General Provisions

1. This CAP Agreement and the Consent Agreement and Consent Order in this matter shall be a complete settlement of all civil and administrative claims and causes of action which arose or could have arisen under TSCA section 8(e) in connection with any study or report submitted pursuant to the terms of this CAP Agreement. Pursuant to TSCA, EPA will consider ability to pay/effect on ability to continue to do business claims during the course of development of the Consent Agreement and Consent Order in this matter. The Regulatee will be responsible for submitting adequate documentation of such claims to EPA at the time of submission of the Final Report required by this CAP Agreement.

2. For purposes of this CAP Agreement and any subsequent proceeding, without trial or any adjudication of the facts, the Regulatee admits that EPA has jurisdiction over the subject matter of the terms of this CAP Agreement and any study or report submitted pursuant to this CAP Agreement.

3. The Regulatee waives its right to request a judicial or administrative hearing on any issue of law or fact that has arisen or may arise during the conduct of the TSCA Section 8(e) Compliance Audit Program conducted pursuant to the terms of this CAP Agreement, or that may arise in any subsequent proceeding involving the Consent Agreement and Consent Order resulting from and entered into pursuant to the terms of this CAP Agreement, including but not limited to the Regulatee's right under TSCA section 16(a)(2)(A) to request a hearing.

4. The Parties agree that any study or report submitted by the Regulatee under this TSCA Section 8(e) Compliance Audit Program and pursuant to the terms of this CAP Agreement constitute a violation of TSCA sections 8(e) and 15(3)(B), for which a civil penalty will be assessed against the Regulatee. Any study or report submitted under TSCA section 8(e) prior to the date of commencement of the TSCA Section 8(e) Compliance Audit Program is not subject to the terms of this CAP Agreement or the TSCA Section 8(e) Compliance Audit Program.

5. EPA reserves its rights under TSCA section 16 to take appropriate enforcement action if EPA determines later that the Regulatee was required to submit under TSCA section 8(e) a study or report determined by the Regulatee to be not reportable and therefore not submitted under the TSCA Section 8(e) Compliance Audit Program. In such event, the terms of the EPA TSCA Sections 8, 12, and 13 Enforcement Response Policy will apply to such proceeding.

6. EPA reserves its rights to challenge the categorization of studies or reports submitted under this TSCA Section 8(e) Compliance Audit Program pursuant to the requirements of Unit II.B.2.a and b of this CAP Agreement.

7. EPA agrees that any submissions made pursuant to the terms of this CAP Agreement and the TSCA Section 8(e) Compliance Audit Program will be viewed by EPA as "prior such violations" under TSCA section 16(a)(2)(B) for future violations of TSCA section 8(e) only.

8. The Final Report submitted pursuant to Unit II.C.4 of this CAP Agreement shall be the controlling document for purposes of determining what was submitted under the TSCA Section 8(e) Compliance Audit Program and this CAP Agreement.

9. Any submission made by the Regulatee to EPA that does not meet all of the requirements of the TSCA Section 8(e) Compliance Audit Program and this CAP Agreement is subject to the EPA TSCA Sections 8, 12, and 13 Enforcement Response Policy.

B. TSCA Section 8(e) Compliance Audit Program and Civil Penalties

1. In conducting the TSCA Section 8(e) Compliance Audit Program, the Regulatee shall use EPA's March 16, 1978, "Statement of Interpretation and Enforcement Policy; Notification of

Substantial Risk" (43 FR 11110) ("TSCA Section 8(e) Policy Statement") to determine whether the reviewed study or report is:

a. *Not reportable under TSCA Section 8(e)*: The Regulatee will not submit the study or report.

b. *Reportable under TSCA Section 8(e)*: The Regulatee will submit the study or report.

Upon Registration for the TSCA Section 8(e) Compliance Audit Program, the Regulatee will receive a copy of the TSCA Section 8(e) Policy Statement, the publication numbers of publicly available and previously published volumes of Section 8(e) "Status Reports" available through the National Technical Information Service, copies of Question and Answer documents developed in response to specific questions involving section 8(e), and a document entitled "Substantiating Claims of Confidentiality."

2. The Regulatee agrees to pay the following stipulated civil penalties for all studies or reports submitted under this TSCA Section 8(e) Compliance Audit Program as TSCA section 8(e) data:

a. $15,000 per study for any submitted study or report involving effects in humans.

b. $8,000 per study for any other submitted study or report submitted as TSCA section 8(e) data.

As a matter of policy under this TSCA Section 8(e) Compliance Audit Program, EPA agrees to a $1,000,000 cap on the total civil penalty for the Regulatee.

3. The Regulatee shall be exempt from any additional late and/or nonreporting TSCA section 8(e) civil liability which arose or could have arisen for any study or report submitted under this TSCA Section 8(e) Compliance Audit Program.

4. Upon termination of the TSCA Section 8(e) Compliance Audit Program, the Regulatee shall provide EPA with a Final Report certifying that the TSCA Section 8(e) Compliance Audit Program has been completed. Such Final Report shall be signed and certified by the appropriate corporate official with authority to settle claims on behalf of the Regulatee. Such Final Report shall also comply with the requirements of Unit II.C.4 of this CAP Agreement.

5. Following termination of the audit, EPA will present the Regulatee with a Consent Agreement and Consent Order summarizing the results of the TSCA Section 8(e) Compliance Audit Program and specifying the terms of payment of stipulated civil penalties. The Regulatee will have 30 calendar days from its receipt of an executed copy of the Consent Order to pay any stipulated civil penalties.

C. Information Submission and Final Report

1. All studies or reports submitted to EPA by the Regulatee under the terms of this CAP Agreement shall be identified pursuant to the categories established in Unit II.B.2.a and b of this CAP Agreement, and shall be sent to the following address: Document Processing Center (TS-790), Office of Toxic Substances, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, Attn: Section 8(e) Coordinator (CAP Agreement).

2. The Regulatee shall submit one original and two full copies of all cover letters, studies, reports, substantiations of confidentiality claims, and, as appropriate, sanitized copies of cover letters, studies, reports, or substantiations of confidentiality claims.

3. In accordance with Part IX of the TSCA Section 8(e) Policy Statement, each study or report submitted to EPA by the Regulatee under the terms of this CAP Agreement shall be accompanied by a separate cover letter containing the following information:

a. Company name, address and telephone number.

b. The signature and printed name, title and telephone number of the person submitting the study or report.

c. A clear statement that the document, identified on the cover letter by the identification number established by Unit I.C of this CAP Agreement, is being submitted pursuant to the TSCA Section 8(e) Compliance Audit Program and this CAP Agreement.

d. The exact identity of each tested chemical or mixture or component of a tested mixture including the CAS Registry Number, if known.

e. The title of the accompanying study or report.

f. A full summary of the reportable adverse effect(s) or exposure(s) observed in the accompanying study or report. In addition, the cover letter should identify by EPA Document Control Number any previous TSCA section 8(e) submission(s) or premanufacture notification(s) (PMN(s)) submitted by the Regulatee on the subject chemical substance(s) or mixture or component(s) of such mixture.

4. Each study or report submitted to EPA by the Regulatee under the terms of this CAP Agreement shall be listed in a Final Report. Such Final Report shall list each submitted study or report by title pursuant to the categories established in Unit II.B.2.a and b of this CAP Agreement, and shall display the identification number established by Unit I.C of this CAP Agreement. Such Final Report shall certify that the TSCA Section 8(e) Compliance Audit has been completed and include the following statement: "I certify that the information contained in or accompanying this Final Report is true, accurate, and complete. As to any identified portion(s) of this Final Report for which I cannot personally verify its truth and accuracy, I certify as the company official having supervisory responsibility for the person(s) who, acting under my direct instructions, made the verification, that this information is true, accurate, and complete." The Final Report will be the controlling document as to what was or was not submitted under the terms of this CAP Agreement and shall be sent to the address specified in Unit I.B of this CAP Agreement.

D. Other Matters

1. Nothing in this CAP Agreement shall relieve the Regulatee from complying with all applicable TSCA regulations or other applicable environmental statutes.

2. This CAP Agreement shall be binding upon the Parties and in full effect pursuant to the requirements specified in Unit I. of this CAP Agreement.

3. The Regulatee's obligations under this CAP Agreement shall end when the Final Report required by Unit II.C.4 of this CAP Agreement has been submitted to EPA and stipulated civil penalties paid.

4. Failure to comply with the terms of this CAP Agreement permits EPA to proceed under TSCA section 16 to impose the civil penalties allowable under the existing EPA TSCA Sections 8, 12, and 13 Enforcement Response Policy for any study or report submitted pursuant to Unit II.C of this CAP Agreement.

5. All of the terms and conditions of this CAP Agreement together comprise one agreement, and each of the terms and conditions is in consideration for all of the other terms and conditions. In the event that this CAP Agreement (or one or more of its terms and conditions) is held invalid, or is not executed by all of the signatory parties in identical form, then the entire CAP Agreement shall be null and void.

6. The Regulatee may assert claims of confidentiality under TSCA section 14 for submissions under this CAP Agreement. The Regulatee must, at the time of submission, provide substantiation for all information claimed as confidential. The Regulatee agrees that the failure to assert a claim of confidentiality for studies, reports, or information submitted under the terms

of this CAP Agreement shall be interpreted by EPA as a waiver by the Regulatee of the right to assert a claim of confidentiality.

7. Submissions containing information claimed as TSCA Confidential Business Information (TSCA CBI) shall contain cover sheets bearing the typed or stamped legend "company confidential," "proprietary," or "trade secret." Information contained in the submission which is claimed as TSCA CBI must be clearly marked by boxing, circling, or underlining the specific text so claimed. All pages containing such information shall also be marked "CONFIDENTIAL." Care should be taken to ensure that these markings do not obscure the text of the submission. Submissions directed to EPA in this manner should be sent by certified mail-return receipt requested or in any other way which will permit verification by the Regulatee of its receipt by EPA.

8. If the Regulatee chooses to assert a confidentiality claim, the Regulatee shall provide two sets of each such submission: one set shall have the TSCA CBI material marked in the manner contemplated under 40 CFR 2.203(b) and Unit II.D.7 of this CAP Agreement; the second set shall have the TSCA CBI material excised. The Regulatee is advised that the second, "sanitized" set will be available for public review without further notice to the Regulatee and therefore care should be exercised in the creation of this set. Each sanitized and unsanitized submission must comply with Unit II.C.2 of this CAP Agreement and thus will consist of one original and two copies.

9. The Regulatee is advised to review carefully the confidentiality claim procedures at 40 CFR 2.201. Specific information concerning TSCA section 8(e) confidentiality claims is contained at Part X of the TSCA Section 8(e) Policy Statement.

10. The Regulatee agrees that if the specific chemical identity is claimed as confidential in a submission, a generic nonconfidential chemical identity will be included on the sanitized version of the submission. Guidance for developing appropriate generic chemical identities may be obtained by consulting the TSCA Chemical Substance Inventory: 1985 Edition, or by contacting the Office of Toxic Substances' Chemical Inventory Section at (202) 382-3527.

11. The Regulatee agrees that confidentiality claims will be honored by EPA only if each claim is accompanied by responses to the questions in the document provided with this CAP Agreement entitled "Substantiating Claims of Confidentiality." The Regulatee shall provide an original and two copies of these responses in accordance with Unit II.C.2 of this CAP Agreement. The Regulatee shall also, in the event the Regulatee desires information in these responses to be considered TSCA CBI, provide a sanitized original and two copies in accordance with Unit II.C.2 and Unit II.D.8 of this CAP Agreement.

12. The Regulatee agrees that failure to adhere to each requirement pertaining to TSCA CBI may result in forfeiture of the CBI protection for the submission and its subsequent availability in its entirety for public review.

WE AGREE TO THIS:

For Regulatee:

[Signing official]
[Title]
[Company name]

[Signing official]
[Title]
[Company name]

For EPA:

Michael E. Wood,
Director, Compliance Division, Office of Compliance Monitoring.

Michael J. Walker,
Associate Enforcement Counsel for Pesticides and Toxic Substances.

III. Conclusions

EPA has announced the opportunity to register for the TSCA Section 8(e) Compliance Audit Program. Any further information regarding this Audit Program or the CAP Agreement may be obtained from the contact person noted above.

Dated: January 25, 1991.

Linda J. Fisher,
Assistant Administrator for Pesticides and Toxic Substances.

[FR Doc. 91-2299 Filed 1-31-91; 8:45 am]
BILLING CODE 6560-50-F

federal register

Friday
April 26, 1991

APPENDIX D
(CAP Modifications)

Part VI

Environmental Protection Agency

Registration and Agreement for TSCA Section 8(e) Compliance Audit Program Modification; Notice

ENVIRONMENTAL PROTECTION AGENCY

[OPTS-60015A; FRL-3891-6]

Registration and Agreement for TSCA Section 8(e) Compliance Audit Program Modification

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This Notice, pursuant to sections 13 and 16 of the Toxic Substances Control Act (TSCA), 15 U.S.C. 2601 et seq., announces modifications to EPA's TSCA Section 8(e) Compliance Audit Program and the Agreement for the TSCA Section 8(e) Compliance Audit Program ("CAP Agreement"). The modifications to the TSCA Section 8(e) Compliance Audit Program and the CAP Agreement include extension of the registration and termination dates, the opportunity to petition EPA for a case-by-case extension of the termination date, modifications to the CAP Agreement provisions regarding admission of a violation of TSCA section 8(e) and waiver of right to a hearing, and EPA's development of a TSCA section 8(e) reporting guide.

DATES: The Registration period for the TSCA Section 8(e) Compliance Audit Program closes on June 18, 1991. Persons interested in registering for the TSCA Section 8(e) Compliance Audit Program must request a CAP Agreement and submit a signed CAP Agreement to EPA no later than June 18, 1991.

ADDRESSES: Copies of the CAP Agreement may be obtained from the TSCA Assistance Information Service, Environmental Assistance Division (TS-799), Office of Toxic Substances, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, (202) 554-1404, TDD: (202) 554-0551.

FOR FURTHER INFORMATION CONTACT: David Kling, Acting Director, Environmental Assistance Division (TS-799), Office of Toxic Substances, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, (202) 554-1404, TDD: (202) 554-0551.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of February 1, 1991 (56 FR 4128), EPA announced the opportunity to register for the TSCA Section 8(e) Compliance Audit Program. The TSCA Section 8(e) Compliance Audit Program is a one-time voluntary compliance audit program developed in order to achieve EPA's goal of obtaining any outstanding TSCA section 8(e) data. The TSCA Section 8(e) Compliance Audit Program has been initiated to foster compliance with the statutory obligations of TSCA section 8(e), and to obtain critical information about potential risks of chemical substances. In designing the TSCA Section 8(e) Compliance Audit Program EPA's objective was to provide, in the context of an enforcement initiative, positive incentives for companies to conduct audits of their data and to submit to the Agency the type of information required under section 8(e) of TSCA.

EPA recognizes that proper application of section 8(e) requires the exercise of scientific judgement. EPA is not interested in creating an atmosphere in which companies view a "data dump" strategy as the best course of action for meeting their obligations. The Agency hopes that cooperative consultation among EPA, data submitters, and other interested parties can lead to a more successful TSCA Section 8(e) Compliance Audit Program and ultimately a better understanding of the section 8(e) program. Based on written communications with the regulated industry, EPA has made the following modifications to the TSCA Section 8(e) Compliance Audit Program and CAP Agreement that was published on February 1, 1991.

II. Modifications to the TSCA Section 8(e) Compliance Audit Program and the CAP Agreement

A. Registration Requirements

The registration deadline/audit commencement date has been extended for 45 days to June 18, 1991. Thus, Units I.B and D of the CAP Agreement have been modified to read as follows:

B. To register for the TSCA Section 8(e) Compliance Audit Program, the Regulatee must, no later June 18, 1991, sign and return this CAP Agreement by certified mail-return receipt requested to...

D. The TSCA Section 8(e) Compliance Audit Program shall commence no later than June 18, 1991.

The audit termination date/deadline has been extended for approximately 90 days, to February 28, 1992. Procedures for case-by-case extensions have also been added. A Regulatee can petition EPA in writing no later than November 29, 1991, for an additional extension of the audit termination date (i.e., beyond February 28, 1992). Extension petitions must contain an adequate justification for the request, and will be favorably viewed if based on difficulties experienced by a Regulatee with the volume of information being reviewed and not because the Regulatee delayed initiation of the audit. Companies are urged to submit studies or reports as they are determined to be reportable, and extension petitions will be viewed with disfavor if a Regulatee has not submitted any information by the November 29, 1991, deadline for extension requests. In this way EPA encourages the phased receipt of information over time while recognizing the need for appropriate time extensions for Regulatees that have a large amount of records to review. Thus, Unit I.E of the CAP Agreement has been modified to read as follows:

E. The TSCA Section 8(e) Compliance Audit Program shall terminate on February 28, 1992, and all submissions under this TSCA Section 8(e) Compliance Audit Program must be delivered to EPA no later than February 28, 1992. The Regulatee may petition EPA in writing at the address specified in Unit I.B of this CAP Agreement for an extension of the February 28, 1992, termination date. Extension requests must be received by EPA no later than November 29, 1991, and must contain an adequate justification for the extension.

No other modifications to the "registration requirements" portion of the CAP Agreement have been made.

B. Terms of Agreement—General Provisions

The provision of the CAP Agreement regarding an admission of violation or a "violation of TSCA" has been changed and Unit II.A.4 of the CAP Agreement has been modified to read as follows:

4. The Regulatee neither admits nor denies that the submission of studies or reports by the Regulatee under this TSCA Section 8(e) Compliance Audit Program and pursuant to the terms of this CAP Agreement constitutes admission of a violation of TSCA sections 8(e) and 15(3)(B), but agrees to pay a stipulated civil penalty for each study or report in accordance with Unit II.B.2 of this CAP Agreement. Any study or report submitted under TSCA section 8(e) prior to the date of commencement of the TSCA Section 8(e) Compliance Audit Program is not subject to the terms of this CAP Agreement or the TSCA Section 8(e) Compliance Audit Program.

The provision of the CAP Agreement regarding waiver of rights has been changed and Unit II.A.3 of the CAP Agreement has been modified to read as follows:

3. The Regulatee waives its right to request a judicial or administrative hearing, under TSCA section 16(a)(2)(A) or other provisions of law, on any issue of law or fact that has arisen or may arise regarding the application of TSCA section 8(e) to any study or report submitted pursuant to Unit II.B.1 of this CAP Agreement.

The provision of the CAP Agreement regarding "prior violations" has been

modified slightly to make it clear that submissions under the CAP Agreement will count as one "prior violation" of 8(e) only. Thus, Unit II.A.7 of the CAP Agreement has been modified to read as follows:

7. EPA agrees that any submissions made pursuant to the terms of this CAP Agreement and the TSCA Section 8(e) Compliance Audit Program will be viewed by EPA as one "prior such violation" under TSCA section 16(a)(2)(B) for future violations of TSCA section 8(e) only.

No other modifications to the "terms of agreement—general provisions" portion of the CAP Agreement have been made.

C. Terms of Agreement—TSCA Section 8(e) Compliance Audit Program and Civil Penalties

In order to facilitate participation in the TSCA Section 8(e) Compliance Audit Program as well as to improve section 8(e) compliance in general, EPA is preparing and plans to disseminate a section 8(e) reporting "guide" comprised primarily of approximately 150 existing TSCA section 8(e) submission "Status Reports" which contain useful reporting and implementation guidance. This guide will include two indices. The first index, which pertains to the 150 "Status Reports," will be arranged by toxicologic study type and other important subheadings related to reporting criteria. The second index will be cumulative and arranged by type of study for all initial submissions received under section 8(e) to date. An additional component of the guide will be a consolidated presentation of section 8(e) question and answer (Q&A) documents arranged under subheadings similar to the indices described above.

In response to a written request from the Chemical Manufacturers Association (CMA) for additional guidance in the areas of neurotoxic effects and environmental effects/releases, EPA agreed to perform an expedited review of a limited number of case histories to be submitted by CMA in early May. The Office of Pesticides and Toxic Substances (OPTS) is establishing a panel of EPA staff scientists to perform the expedited review of the case histories which are submitted. While the EPA panel can address endpoints of concern, CMA was asked to prioritize the submissions to focus attention on the key scientific questions, especially neurotoxicity/acute toxicity concerns. The EPA review will focus primarily on whether the case-studies would be reportable under section 8(e). The rationale for EPA's conclusions and responses concerning the appropriateness of reporting will be provided as part of the section 8(e) reporting guide which has been described above. EPA will make every effort to complete the guide in early June and release it prior to the revised June 18, 1991, registration deadline/audit commencement date.

EPA requested that the environmental effects/release cases focus on areas that industry believes are problematic in terms of what is reportable under section 8(e). In order for EPA to respond more completely about the section 8(e) reportability of the provided environmental effects/release information cases, EPA also asked if the information is required to be submitted to another governmental authority and, if so, the identity of that authority and the timeframe for the reporting. The rationale for EPA's conclusions and responses concerning the appropriateness of reporting will be provided as part of the section 8(e) reporting guide described above. EPA will make every effort to complete the guide in early June and release it prior to the revised June 18, 1991, registration deadline/audit commencement date. However, if necessary because of a delay in completion of the guidance on the environmental effects/release information, reporting of this information under the TSCA Section 8(e) Compliance Audit Program will be put on a specific schedule which will be determined later based on when EPA completes and disseminates the guidance in this area.

Thus, to reflect the availability of the TSCA section 8(e) reporting guide, the second portion of the CAP Agreement language at Unit II.B.1 has been modified to read as follows:

—Upon Registration for the TSCA Section 8(e) Compliance Audit Program, the Regulatee will receive a copy of the TSCA Section 8(e) Policy Statement, the publication numbers of publicly available and previously published volumes of Section 8(e) "Status Reports" available through the National Technical Information Service, copies of Question and Answer documents developed in response to specific questions involving section 8(e), a document entitled "Substantiating Claims of Confidentiality," and the TSCA section 8(e) reporting guide.

EPA believes that the actions described above emphasize the Agency's strong commitment to making the TSCA Section 8(e) Compliance Audit Program a successful initiative. EPA hopes that providing the selected case histories and the section 8(e) reporting guide will enhance understanding of the TSCA section 8(e) program, and assist the regulated community as they participate in the TSCA Section 8(e) Compliance Audit Program.

III. Conclusions

EPA has announced modifications to the TSCA Section 8(e) Compliance Audit Program and the CAP Agreement. Any further information regarding this Audit Program or the CAP Agreement may be obtained from the contact person noted above.

Dated: April 24, 1991.

Victor J. Kimm,

Acting Assistant Administrator for Pesticides and Toxic Substances.

[FR Doc. 91-10083 Filed 4-25-91; 8:45 am]

BILLING CODE 6560-50-F

federal register

Thursday
June 20, 1991
(Encoded Version)

APPENDIX D
(CAP Modifications)

Part IV

Environmental Protection Agency

Registration and Agreement for TSCA Section 8(e) Compliance Audit Program Modification; Notice

ENVIRONMENTAL PROTECTION AGENCY

[OPTS-800158; FRL-3932-1]

Registration and Agreement for TSCA Section 8(e) Compliance Audit Program Modification

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This Notice, pursuant to sections 15 and 16 of the Toxic Substances Control Act (TSCA), 15 U.S.C. 2601 et seq., announces the availability of the TSCA section 8(e) reporting guide and modifications to EPA's TSCA Section 8(e) Compliance Audit Program and the Agreement for the TSCA Section 8(e) Compliance Audit Program ("CAP Agreement"). The modifications to the TSCA Section 8(e) Compliance Audit Program and the CAP Agreement include the extension of the registration deadline until July 1, 1991, the addition of provisions for listing of certain types of previously reportable TSCA section 8(e) information now in EPA's possession, and modification of EPA's guidance for reporting information concerning "widespread and previously unsuspected distribution in environmental media" and "emergency incidents of environmental contamination" under TSCA section 8(e).

DATES: The Registration period for the TSCA Section 8(e) Compliance Audit Program commences on July 1, 1991. All persons interested in registering for the TSCA Section 8(e) Compliance Audit Program must request a CAP Agreement and submit a signed CAP Agreement to EPA no later than July 1, 1991.

ADDRESSES: Copies of the modified CAP Agreement and the TSCA section 8(e) reporting guide may be obtained from the TSCA Assistance Information Service, Environmental Assistance Division (TS-799), Office of Toxic Substances, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, (202) 554-1404, TDD: (202) 554-0551.

FOR FURTHER INFORMATION CONTACT: David Kling, Acting Director, Environmental Assistance Division (TS-799), Office of Toxic Substances, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, (202) 554-1404, TDD: (202) 554-0551.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of February 1, 1991 (56 FR 4128), EPA announced the opportunity to register for the TSCA Section 8(e) Compliance Audit Program. The TSCA Section 8(e) Compliance Audit Program is a one-time voluntary compliance audit program developed to obtain outstanding TSCA section 8(e) data and foster compliance with the statutory obligations of TSCA section 8(e).

On April 26, 1991 (56 FR 19514), EPA modified the TSCA Section 8(e) Compliance Audit Program and the CAP Agreement. The modifications included extension of the registration and termination dates, the opportunity to petition EPA for a case-by-case extension of the termination date, modifications to the CAP Agreement provisions regarding admission of a violation of TSCA section 8(e) and waiver of right to a hearing, and EPA's development of a TSCA section 8(e) reporting guide.

II. TSCA Section 8(e) Reporting Guide

Since the April 26, 1991 modifications were announced, EPA completed development of the TSCA section 8(e) reporting guide. The guide contains useful reporting and implementation guidance and includes two major indices. The first index, which references approximately 150 section 8(e) "Status Reports," is arranged by toxicologic study type with subheadings related to section 8(e) reporting 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.

There are two major objectives for presenting the guide. First, the guide makes certain information pertaining to section 8(e) reporting more accessible to members of the regulated community and others. Second, the guide provides reference to both general and specific examples of submitted information as well as EPA's comments regarding such submissions. The examples are intended to help persons who are subject to section 8(e) understand better the types of information that should be submitted to EPA under this important mandatory chemical hazard/risk information reporting provision of TSCA.

Most of the guide is presented in a basic question and answer format reflecting primarily the most common questions asked about section 8(e) of TSCA. The guide also contains EPA's comments regarding the TSCA section 8(e)-applicability/reportablity of a number of toxicologic "case studies" provided to the Agency by the Chemical Manufacturers Association (CMA).

Copies of the TSCA section 8(e) reporting guide may be obtained from the TSCA Assistance Information Service, Environmental Assistance Division (TS-799), Office of Toxic Substances, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, (202) 554-1404, TDD: (202) 554-0551.

III. Modifications to the TSCA Section 8(e) Compliance Audit Program and the CAP Agreement

A. Registration Requirements

The registration deadline/audit commencement date has been extended for approximately two weeks to July 1, 1991. Thus, Units I.B and D of the CAP Agreement have been modified to read as follows:

> B. To register for the TSCA Section 8(e) Compliance Audit Program, the Regulatee must, no later than July 1, 1991, sign and return this CAP Agreement by certified mail-return receipt requested to....
>
> D. The TSCA Section 8(e) Compliance Audit Program shall commence no later than July 1, 1991.

No other modifications to the "Registration Requirements" portion of the CAP Agreement have been made.

B. Terms of Agreement--TSCA Section 8(e) Compliance Audit Program and Civil Penalties Concerning Late Reporters

EPA has received inquiries regarding instances of late reporting of section 8(e) information when such studies or reports were (1) received by the Office of Toxic Substances (OTS) on a "For Your Information" ("FYI") basis and included in the formal OTS "FYI" filing system, or (2) submitted to EPA pursuant to a mandatory reporting obligation under a statute administered by EPA. By late reporting, EPA is referring to information received beyond the 15 working days deadline as set forth in Part IV of EPA's March 16, 1978, "Statement of Interpretation and Enforcement Policy; Notification of Substantial Risk" (43 FR 11110) ("TSCA Section 8(e) Policy Statement"). After evaluation of the issue, EPA has determined that a reduced penalty scheme is appropriate for instances of late reporting of section 8(e) information when the studies or reports were (1) submitted in writing to and received by EPA prior to June 18, 1991, pursuant to a mandatory reporting obligation under TSCA or another EPA-administered statute, or (2) received by OTS on an "FYI" basis and included in the formal OTS "FYI" filing system, prior to June 18, 1991. This approach meets EPA's TSCA Section 8(e) Compliance Audit Program goal of obtaining, in the context of an enforcement initiative, outstanding section 8(e) information. Instead of resubmitting copies of these types of studies or reports, the information may simply be listed under the TSCA Section 8(e) Compliance Audit Program and identified by cover letter. A $5,000 stipulated civil penalty will be assessed for each study or report listed. Thus, Unit II.B.1.c has been added to the CAP Agreement to read as follows:

> c. Data that would have been reportable under TSCA Section 8(e) when initially obtained by the Regulatee, and that subsequent to the section 8(e) reporting deadline (and before June 18, 1991), were (i) submitted in writing to and received by EPA pursuant to a mandatory reporting requirement under TSCA or another statute administered by EPA, or (ii) received by the Office of Toxic Substances (OTS) on a "For Your Information" ("FYI") basis and included in the formal OTS "FYI" filing system: The Regulatee will list ...

study or report pu to Unit II.B.3 of this CAP Agreement. Only information that meets the requirements of Unit II.B.1.c is eligible for this listing provision.

Unit II.B.3 has been added to the CAP Agreement to read as follows:

3. The following provisions shall govern the list required to be submitted under Unit II.B.1.c of this CAP Agreement:

a. For each study or report listed, the listing must comply with the requirements of Unit II.C of this CAP Agreement, must describe the date of the submission and (i) the mandatory reporting requirement of TSCA or another EPA-administered statute under which the study or report was submitted, or (ii) the Office of Toxic Substances "FYI" filing system number for the submission. Within 360 days after submission of the list, EPA may request the Regulatee to submit any of the listed information in order to determine if the Regulatee correctly listed rather than submitted the study or report.

b. The Regulatee agrees to pay the following stipulated civil penalty for information listed under this audit as data that would have been reportable under TSCA Section 8(e) when initially obtained by the Regulatee, and that subsequent to the section 8(e) reporting deadline as specified in Part IV of the TSCA Section 8(e) Policy Statement (and before June 18, 1991), were (i) submitted in writing to and received by EPA pursuant to a mandatory reporting requirement under TSCA or another statute administered by EPA, or (ii) received by the Office of Toxic Substances (OTS) on an "FYI" basis and included in the formal OTS "FYI" filing system: $5,000 per study or report.

C. Additions to the TSCA Section 8(e) Reporting Guide

In response to a written request from the Chemical Manufacturers Association (CMA) for additional guidance on the section 8(e) reportability of certain types of health effects and environmental effects/release information, EPA agreed to perform an expedited review of a limited number of case studies submitted by CMA. The Office of Pesticides and Toxic Substances (OPTS) established a panel of EPA toxicologists, biologists, chemists, medical and public health experts, environmental scientists, TSCA policy staff, and legal and enforcement staff to perform an expedited review of the case studies which were submitted by CMA. EPA reviewed the case studies involving reportability of health effects information, and provides an analysis of the toxicologic significance and TSCA section 8(e)-reportability of the health effects case studies in the TSCA section 8(e) reporting guide described above and referenced in the CAP Agreement.

D. Reporting of Information Referenced in Parts V(b)(1) and V(c) of EPA's Section 8(e) Policy Statement

TSCA section 8(e) requires reporting of information which reasonably supports the conclusion that a chemical substance or mixture presents a substantial risk of injury to the environment. EPA provided guidance on how persons could fulfill their section 8(e) reporting obligations in the TSCA Section 8(e) Policy Statement. However, in reviewing this guidance in connection with the TSCA Section 8(e) Compliance Audit Program, EPA has determined that Part V(b)(1) ("widespread and previously unsuspected distribution in environmental media") and Part V(c) ("emergency incidents of environmental contamination") of the TSCA Section 8(e) Policy Statement need additional clarification and that possible misinterpretation with regard to the guidance in these sections could lead to overreporting under the TSCA Section 8(e) Compliance Audit Program.

Therefore, EPA plans to initiate a review of the reporting of information on widespread environmental distribution and emergency incidents of environmental contamination under TSCA section 8(e) and other Federal statutes in order to determine what information of these types should continue to be considered for submittal under section 8(e). The review may involve discussions with other EPA program offices, EPA Regional offices, other Federal Agencies, State Governments, members of the regulated industry, environmental interest groups, and others. All interested persons will have the opportunity to comment on any proposed revisions to Parts V(b)(1) and V(c) of the TSCA Section 8(e) Policy Statement that result from this review.

In the interim, regulatees auditing their files for reportable environmental risk information under the TSCA Section 8(e) Compliance Audit Program should be guided by the statutory language of section 8(e) and Part V(b)(2) through (b)(5) of EPA's TSCA Section 8(e) Policy Statement. In assessing whether information or studies involving widespread and previous unsuspected environmental distribution, emergency incidents of environmental contamination, or other previously unknown situations involving significant environmental contamination should be submitted under the TSCA Section 8(e) Compliance Audit Program, or under section 8(e) in general, regulatees should make a reasonable judgement whether such information meets the statutory standards of TSCA section 8(e) instead of relying on Parts V(b)(1) or V(c) of the TSCA Section 8(e) Policy Statement. Even though EPA is suspending the applicability of Parts V(b)(1) and V(c) of the TSCA Section 8(e) Policy Statement, persons are still responsible under TSCA section 8(e) to report information that reasonably supports a conclusion of substantial risk of injury to the environment. This is a continuing statutory obligation. Thus, to reflect this change, Unit II.B.1 of the CAP Agreement has been modified to read as follows:

1. In conducting the TSCA Section 8(e) Compliance Audit Program, the Regulatee shall follow the statutory language of TSCA section 8(e) and EPA's guidance on section 8(e) in the March 16, 1978, "Statement of Interpretation and Enforcement Policy; Notification of Substantial Risk" (43 FR 11110) ("TSCA Section 8(e) Policy Statement"), with the exception of Parts V(b)(1) and V(c) of the TSCA Section 8(e) Policy Statement, to determine whether the reviewed study or report is:....

No other modifications to the "Terms of Agreement" provisions of the CAP Agreement have been made.

IV. Conclusion

EPA believes that the actions described above emphasize the Agency's strong commitment to making the TSCA Section 8(e) Compliance Audit Program a successful initiative. EPA believes that providing the section 8(e) reporting guide as well as the results of the Agency's review of several toxicologic case studies will enhance understanding of the TSCA section 8(e) program, and assist the regulated community as they participate in the TSCA Section 8(e) Compliance Audit Program. Any further information regarding this Compliance Audit Program or the CAP Agreement may be obtained from the contact person noted above.

Dated: June 18, 1991.

Victor J. Kimm,

Acting Assistant Administrator for Pesticides and Toxic Substances.

[FR Doc. 91-????? Filed ??-??-91; 8:45 am]

BILLING CODE 6560-50-F

Support Information for Confidentiality Claims

Information submitted under specific reporting requirements of the Toxic Substances Control Act (TSCA) or in support of TSCA is subject to the provisions of Section 14 of TSCA and to EPA's Regulations on the Confidentiality of Business Information (see 40 CFR Part 2). You must comply with the following procedures to assert a claim of confidentiality for the information solicited in the attached letter. Failure to follow these procedures fully at the time you submit the information to EPA will be interpreted by the Agency as a waiver of your claim of confidentiality.

Asserting a Claim

Information claimed as confidential must be clearly marked by boxing, circling or underlining. All pages containing such information should also be stamped "**CONFIDENTIAL**". Care should be taken to ensure that these markings do not obscure the submission's text.

Sanitized Copy

Two copies must be submitted of any documents containing information claimed as confidential. One copy should be complete, with the information being claimed as confidential marked in the manner described in the preceding paragraph. The other copy should have all of the information claimed as confidential excised. This version will be placed in EPA's Public Files.

Substantiating Claims of Confidentiality

Detailed written responses to the following questions must be provided at the time you submit information for any portion of the information you claim as confidential. Your responses should be as specific as possible, with examples as appropriate, and should provide substantiation arguments for all types of information (e.g., sales or production/importation volumes, chemical identity, company identity) you claim as confidential.

1. For what period of time do you assert this claim of confidentiality? If a claim is to extend until a certain event or point in time, please indicate that event or time period. Explain why the information should remain confidential until such event or time.

2. Have there been any confidentiality determinations made by EPA, other Federal agencies, or courts in connection with this information? If so, please enclose copies.

3. Has any of the information that you are claiming as confidential been disclosed to individuals outside your company? Will it be disclosed to such persons in the future? If so, what restrictions, if any, apply to use or further disclosure of the information?

4. Briefly describe any physical or procedural restrictions within your company relating to the use and storage of the information you are claiming as confidential. What other steps, if any, have you taken to prevent undesired disclosure of the information during its use or when an employee leaves your company?

5. Does the information claimed as confidential appear or is it referred to in any of items listed below:

   - advertising or promotional materials for the chemical or the end product containing it;

   - safety data sheets or other similar materials for the chemical or the end product containing it;

   - professional or trade publications; or

   - any other media available to the public or to your competitors.

   If you answered yes to any of the above questions, you must indicate where the information appears and explain why it should nonetheless be treated as confidential.

6. Would disclosure of this information be likely to result in substantial harm to your competitive position? If so, you must specifically describe the alleged harmful effects and indicate why they should be considered to be substantial. Also, you must describe how disclosure of the information would cause the harm.

7. If the information in question is "health and safety data" pursuant to 40 CFR Part 2.306(3)(i), do you assert that disclosure of the information you are claiming as confidential would reveal:

   a) confidential process information;

   b) confidential proportions of a mixture; or

   c) information unrelated to the effects of the substance on human health or the environment?

   If your answer to any of the above questions is yes, you must explain how such information would be revealed.

APPENDIX 13

FINAL RULE: CHEMICAL IMPORTS AND EXPORTS; GENERAL IMPORT REQUIREMENTS AND RESTRICTIONS POLICY FOR IMPORT OF CHEMICAL SUBSTANCES

48 FR 55462-65

federal register

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 707

[OPTS 13000A; TSH FRL 2444-6]

Chemical Imports and Exports; General Import Requirements and Restrictions Policy for Import of Chemical Substances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This policy explains how EPA will interpret and carry out its responsibilities under the Toxic Substances Control Act (TSCA) section 13 chemical substances import rule issued by the U.S. Customs Service (Customs), Treasury Department. The Customs rule was published in the Federal Register of August 1, 1983 (48 FR 34734), and is codified in 19 CFR 12.118 through 12.127, and 127.28 (amended). The effective date of the Customs rule was postponed to January 1, 1984, as published in the Federal Register of September 30, 1983 (48 FR 44771).

DATE: The effective date of this policy is December 13, 1983.

FOR FURTHER INFORMATION CONTACT: Jack P. McCarthy, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, Rm. E-543, 401 M St., SW., Washington, DC. 20460. Toll-free: (800-424-9065), in Washington, D.C. (554-1404); Outside the USA: (Operator-202-554-1404).

SUPPLEMENTARY INFORMATION:

Background

Customs issued a final rule concerning import of chemical substances under section 13 of the Toxic Substances Control Act (15 U.S.C. 2612), which was published in the Federal Register of August 1, 1983 (48 FR 34734). The Customs rule is codified in 19 CFR 12.118 through 12.127, and 127.28 (amended). The effective date of the Customs rule was postponed to January 1, 1984, as published in the Federal Register of September 30, 1983 (48 FR 44772).

When the Customs rule was proposed in the December 1, 1980, issue of the Federal Register (45 FR 79730), EPA simultaneously proposed and solicited comment on a policy concerning EPA responsibilities under TSCA section 13 (45 FR 79728). This is the final EPA policy explaining how EPA will carry out its responsibilities under the Customs chemical substances import rule. The EPA policy is codified in 40 CFR with other EPA rules. It cross-references the Customs rule at 19 CFR Part 12.

Comments that were received on the proposed Customs rule and proposed EPA policy are addressed in the preamble to the final Customs rule, which was published in the Federal Register of August 1, 1983 (48 FR 34734). The final rule and policy adopted several suggestions made by commenters.

Customs Rule Provisions

The Customs rule requires importers of chemical substances in bulk or as part of a mixture subject to TSCA to certify at the port of entry that the chemical substances and their import comply with TSCA. Because some chemicals (e.g., pesticides) are not "chemical substances" subject to TSCA, the Customs rule requires importers to certify that such chemicals are not subject to TSCA. The rule also describes entry and detention procedures that will be used to ensure compliance.

Customs has the responsibility to detain all shipments that fail to comply with TSCA or any applicable rule or order under TSCA. EPA's responsibilities under the rule are to determine whether detained shipments and their entries comply, to notify Customs which shipments should be detained, and to identify steps necessary to bring detained shipments into compliance, or to be taken when shipments are not brought into compliance. Because of its relevant knowledge and expertise, EPA is also responsible for storage and disposal of abandoned noncomplying shipments.

The Customs rule sets forth general certification requirements and detention procedures. It does not address how a chemical shipment and its import would comply with TSCA. The main purpose of the EPA policy statement is to describe what compliance with TSCA means.

TSCA'S Treatment of Imports

The policy of Congress toward regulation of imports under TSCA is expressed in the legislative history of TSCA:

> [I]mported chemical substances and mixtures will be subject to regulation in the same manner as domestically produced chemical substances and mixtures are. In addition, importers of chemical substances and mixtures will have the same responsibilities and obligations as domestic manufacturers. H.R. Rep. No. 94-1341, 94th Cong. 2d Session 13-17 (1976).

The Act recognizes the critical position of importers in protecting health and the environment from exposure to hazardous chemicals by defining "manufacture" to include importation in addition to domestic production and manufacture (section 3(7); 15 U.S.C. 2602(7)). Consequently, whenever TSCA places responsibilities on domestic manufacturers, the responsibilities also extend to importers.

The TSCA regulations that apply to importers, because they are defined as manufacturers, include among other things, section 5 rules for chemical substances not on the TSCA Inventory and for chemicals subject to notification for significant new uses, and other manufacture or use restrictions under section 6. Importers must comply with such rules under section 5 and section 6 before chemicals may be imported. Importers may also be subject to export notification requirements under section 12 when entry is denied for an intended import, and the importer chooses to export noncomplying shipments.

In addition, because TSCA defines importers as manufacturers, importers may be subject to rules such as testing requirements under section 4 and reporting requirements under section 8.

However, because such rules do not apply to individual chemical shipments and because compliance with such rules may be a lengthy procedure, importation would not depend on the importers' satisfaction of section 4 and section 8 requirements. However, if a section 4 or 8 rule requires notification of EPA prior to the import of a specified chemical, any importer of that chemical should ensure that the required notification has been completed before certifying that a shipment containing the chemical is in compliance with TSCA.

Importers are subject as manufacturers to sanctions for violations of TSCA. Section 16 of TSCA describes civil penalties and criminal penalties which may be invoked. Sections 7 and 17 provide for specific enforcement of TSCA by the district courts of the United States, and for seizure and condemnation of noncomplying chemical substances, mixtures, and articles by process of libel. If an imported shipment does not comply with TSCA, EPA will seek appropriate remedies under TSCA against persons responsible for the violations. The sanctions are in addition to those which may independently be prescribed for violation of the Customs rule.

Meaning of Certification

Certification that a chemical import complies with TSCA, and that an importer has discharged all the TSCA obligations related to the import, is accomplished by a brief statement typed or preprinted on an entry document, invoice, or attachment and be signed by the importer. The statement would read: "I certify that chemical substances in this shipment comply with all applicable rules under TSCA and that I am not offering a chemical substance for entry in viola

of TSCA or any applicable rule or order under TSCA."

The section 13 rule requires importers to certify that other appropriate TSCA requirements are satisfied; section 13 by itself does not impose additional substantive requirements. No more detailed information than is needed to comply with other TSCA rules is needed to comply with the section 13 certification requirement.

The final Customs rule requires importers of chemicals not subject to TSCA (e.g., pesticides) to sign the statement: "I certify that all chemicals in this shipment are not subject to TSCA." This was added to the rule at the request of commenters who were concerned about possible delays at entry ports.

Chemical Substances Subject to Certification

Under the Customs rule, certification of compliance with TSCA is required for chemical substances imported in bulk or as part of mixtures. The certification requirement becomes effective January 1, 1984.

The rule does not require certification for chemical substances imported as part of articles unless EPA requires reporting under a TSCA rule. The primary reason for not requiring certification of all articles at this time is the difficulty in identifying their component chemical substances and mixtures for purposes of determining whether they are on the TSCA Chemical Substance Inventory. At this time, there are no TSCA rules which apply to articles. However, future TSCA rules may apply to articles containing certain chemical substances. These future TSCA rules which apply to articles will specify that certification is required.

Who Must Certify

One commenter requested that the section 13 rule allow development of a corporate mechanism, similar to that of TSCA section 8(e), to end individual liability when the importing company institutes a corporate certification procedure. The rule does not adopt this suggestion. As discussed in the preamble to the Customs rule, the person who certifies is responsible for the truth of his statement. However, EPA would use its prosecutional discretion to determine appropriate liability for persons involved in specific cases.

In this policy, "importer" is defined by reference to the Customs section 13 rule. This adopts the general Customs definition at 19 CFR 101.1(k). The definition is repeated here for convenience.

"Importer" means the person primarily liable for the payment of any duties on the merchandise, or an authorized agent acting on his behalf. The importer may be: (1) The consignee, or (2) the importer of record, or (3) the actual owner of the merchandise if an actual owner's declaration and superseding bond has been filed in accordance with § 141.20 of this chapter, or (4) the transferee of the merchandise, if the right to withdraw merchandise in a bonded warehouse has been transferred in accordance with subpart C of Part 144 of Chapter I of 19 CFR.

TSCA Requirements Covered by Certification

The exact TSCA requirements concerning chemical imports will change as rules are developed and other actions taken under sections 5, 6, and 7 of TSCA. Consequently, it will be important for importers to remain informed of TSCA rules. Examples of current requirements are described below. To obtain additional information on TSCA rules, importers may request the TSCA Assistance Office to be placed on the mailing list for the Chemicals-in-Progress Bulletin. This is a bi-monthly publication that lists current rulemakings. EPA uses the Chemicals-in-Progress Bulletin mailing list when the Agency sends out other information about TSCA. Importers may request other information by writing or phoning the TSCA Assistance Office at the address given above under "FOR FURTHER INFORMATION CONTACT."

1. *Inventory and premanufacture notice requirements.* Section 5(a)(1) of TSCA imposes an important responsibility on persons who intend to import new chemical substances into the United States. Persons who import chemical substances not on the TSCA Inventory must submit premanufacture notices under section 5, 90 days prior to import. If a chemical substance is not on the inventory, its importation would comply with TSCA requirements only if (a) the chemical substance had completed EPA review under section 5, or (b) it were exempt from section 5 requirements.

A chemical substance is considered to be on the inventory if it is on the EPA Master Inventory File. This includes the most recently published chemical substances Inventory (including any supplements or revisions) and substances accepted for inclusion on the Inventory but not yet published. The most recently published Inventory is the Revised Inventory. This consists of the Initial Inventory published on June 1, 1979, together with the Cumulative Supplements published in July 1980, and May 1982.

The importer certification applies only to chemical substances intentionally present in the import. Importers are not generally subject to section 5 requirements. There are other specific exemptions from section 5 requirements. One exemption applies to chemical substances imported solely for research and development. Under section 5, the importer would himself determine whether an import were intended solely for research and development. Another exemption applies to chemical substances imported for test marketing purposes. Persons planning to import chemical substances for test marketing purposes must apply for an exemption from section 5 requirements if they do not submit a PMN. These section 5 requirements are described in detail in: Premanufacture Notification: Premanufacture Notice Requirements and Review Procedures, published in the Federal Register of May 13, 1983 (48 FR 21722).

2. *Other requirements.* Certification of compliance with TSCA also means that imported chemical substances and their importation comply with any applicable requirement in effect under sections 5, 6, or 7 of TSCA. These requirements may include, among others, significant new use notification requirements under section 5(a)(2); prohibitions or limitations on importation, processing, or distribution under sections 5(e), 5(f), or 6; and court orders under section 7. Importers will need to be aware of rules that apply to imports of chemical substances in bulk, in mixtures, or in articles in order to ensure that applicable rules have been observed.

A commenter pointed out that a chemical substance imported for purposes exempt from TSCA might later be used for TSCA-regulated purposes. The commenter asked if the importer would be responsible in this instance, and suggested that the situation be covered by a preprocessing notification similar to the one proposed on August 15, 1980.

This suggestion has not been adopted, because EPA considers the situation unlikely to occur.

Basis for Certification—Enforcement

Under this section 13 rule, the importer is required to place the certification of compliance on the appropriate entry document. The importer who certifies may, in a particular case, be the person primarily liable for payment of duties or one of his agents. In some cases, a domestic purchaser may cause the importation and handle the entire entry process himself, without employing agents. In other cases, brokers or other agents may be used. In any case, the person

certifying compliance must insure that the imported chemical substances comply with TSCA and any applicable regulations under TSCA.

Whenever the documents accompanying the imported shipment identify the chemical substances exactly, the person who is certifying compliance can check the identity against requirements under TSCA. When the chemical substance or mixture is imported under a name that does not identify it exactly, and the person certifying does not otherwise know the identity, he should attempt to discover the chemical constituents of the shipment by contacting another party to the transaction (e.g., his principal or the foreign manufacturer). This person may be able to identify the components of the substance or mixture, or at least state that the substance or mixture complies with TSCA. The greater the effort an importer makes to learn the identities of the imported substances, the smaller his chance of committing a violation by importing a noncomplying shipment. If a shipment were ultimately determined to have violated TSCA, the good faith efforts of the importer to verify compliance, as evidenced by documents contained in his files, may obviate or mitigate the assessment of a civil penalty under section 16 of TSCA.

International Cooperation

EPA recognizes its obligations under Title IV of the Trade Agreements Act of 1979 (Pub. L. 96-39). That law provides the legal framework for implementing trade agreements entered into by the United States: Title IV (Standards Code) sets forth principles and procedures for Federal agencies, including EPA, to follow in their rulemakings, to prevent the creation of unnecessary technical barriers to foreign trade.

The Standards Code is not intended to prevent Federal agencies from making rules or setting standards affecting international trade, for example, in chemical products, if such measures have a demonstrable purpose to achieve a legitimate domestic objective, such as protecting health, safety, and the environment within the United States, and do not serve to exclude imported products that fully meet the objectives of such measures. The Standards Code states, however, that agencies involved in such rulemaking shall consider the adoption of existing international standards, if they are appropriate, and insure that imported products are treated no less favorably than like domestic or other imported products. Although there are no existing international standards for control of imported chemicals, at such time as international agreement is reached, EPA would be prepared to modify this policy as needed. However, EPA considers that the TSCA section 13 policy complies with the principles of the international Standards Code. In addition, the certification required by the section 13 rule is designed to acknowledge compliance with TSCA requirements that are also in effect for domestically manufactured chemical substances.

Economic Impact

An analysis of the industry cost of importer certification was prepared in conjunction with development of the section 13 rule issued by the U.S. Customs Service (see 45 FR 54734, August 1, 1973). This policy statement imposes no costs beyond those considered in the promulgation of the section 13 rule.

Public Record

The EPA public record for development of this import policy is docket OPTS 130000. All documents, including the final Customs rule, are available to the public in the OTS Reading Room from 8:00 a.m. to 4:00 p.m. on working days in Rm. E-107, 401 M St., SW., Washington, D.C. 20460. This record includes basic information considered by EPA and Customs in developing the rule and policy. The EPA public record contains all comments submitted to EPA and copies of all comments submitted to Customs.

List of Subjects in 40 CFR Part 707

Chemicals, Environmental protection, Imports, Exports, Reporting and recordkeeping requirements.

(Sec. 13, Pub. L. 94-469, 90 Stat. 2034 (15 U.S.C. 2612))

Dated: December 6, 1983.

William D. Ruckelshaus,

Administrator.

Therefore, 40 CFR Part 707 is amended by adding a new Subpart B consisting of § 707.20 to read as follows:

PART 707—IMPORTS AND EXPORTS

Subpart A—[Reserved]

Subpart B—General Import Requirements and Restrictions

§ 707.20 Chemical substances import policy.

(a) *Scope.* (1) This statement addresses the policy of the Environmental Protection Agency (EPA) on importation of chemical substances, mixtures, and articles under section 13 of the Toxic Substances Control Act (TSCA; 15 U.S.C. 2601 et seq.). In particular, it addresses aspects of the regulation promulgated by the United States Customs Service (Customs), Department of the Treasury (19 CFR 12.118 through 12.127, and 127.28 [amended]) to implement section 13 of TSCA, 15 U.S.C. 2612. Section 13 requires the Secretary of the Treasury to refuse entry into the Customs territory of the United States of a chemical substance, mixture, or article if it does not comply with rules in effect under TSCA, or if it is offered for entry in violation of TSCA or rules or orders under TSCA.

(2) In addition to this statement of policy, EPA will continue, as necessary, to address problems associated with imports in rulemaking and other actions under individual sections of TSCA, i.e., sections 4, 5, 6, 7, 8, and 12. Sections 5, 6, and 7 apply directly to imports subject to the section 13 requirements. Section 12 may apply to export of a shipment that is refused entry under section 13. Importers may have obligations under sections 4 and 8; section 4 and 8 requirements for importers would not apply to individual chemical shipments and thus are not included under section 13 requirements. Interested persons should refer to the records of these individual rulemaking actions for specific information and guidance.

(b) *Objectives.* (1) TSCA is intended to be comprehensive, and assure protection of health and the environment from unreasonable risks associated with chemicals whether the chemicals are imported or produced domestically. This intent is manifested by the inclusion of importation in the Act's definition of the term "manufacture": "[M]anufacture means to import . . . produce, or manufacture" (15 U.S.C. 2602(7)). Thus, importers are responsible for insuring that chemical importation complies with TSCA just as domestic manufacturers are responsible for insuring that chemical manufacture complies with TSCA.

(2)(i) The section 13 rule requires importers to sign the following statement for each import of chemical substances subject to TSCA: "I certify that all chemical substances in this shipment comply with all applicable rules or orders under TSCA and that I am not offering a chemical substance for entry in violation of TSCA or any applicable rule or order under TSCA." The certification will document that, in accordance with TSCA, the importer has taken the necessary steps to insure compliance.

(ii) The section 13 rule requires importers of chemicals not subject to TSCA (e.g., pesticides) to certify that

compliance with TSCA is not required. Importers must certify this by signing the statement: "I certify that all chemicals in this shipment are not subject to TSCA." This is appropriate when a chemical import is not clearly identified as a pesticide or other chemical not subject to TSCA.

(3) The United States is involved in a major effort toward international harmonization in the control of chemicals. At such time as international agreement is reached on this issue, EPA would be prepared to modify its policy if necessary. EPA believes that its international harmonization efforts in the control of chemicals will protect health and the environment while fulfilling its obligations under the Trade Agreements Act of 1979.

(c) *The section 13 rule*—(1) *General certification.* (i) The rule promulgated under section 13 of TSCA by Customs, in consultation with EPA, implements the requirement of section 13 that chemical substances, mixtures, or articles not in compliance with TSCA, or whose importation is not in compliance with TSCA, shall be denied entry into the customs territory of the United States. The rule requires that importers certify by a statement, on the entry document or invoice, that any shipment of a chemical substance subject to TSCA, imported in bulk or as part of a mixture, complies with TSCA, and that it is not offered for entry in violation of TSCA or any rule or order under TSCA, or that the chemicals imported are not subject to TSCA.

(ii) The certification applies to TSCA sections 5, 6, and 7.

(iii) EPA expects that this certification will be based upon actual knowledge of the importer in most cases. However, EPA realizes that sometimes importers may not have actual knowledge of the chemical composition of imported mixtures. In these cases, the importer should attempt to discover the chemical constituents of the shipment by contacting another party to the transaction (e.g., his principal or the foreign manufacturer). This person may be able to identify the components of the mixture, or at least state that the substances comply with TSCA. The greater the effort an importer makes to learn the identities of the imported substances and their compliance with TSCA, the smaller his chance of committing a violation by importing a noncomplying shipment. If a shipment is ultimately determined to have violated TSCA, the good faith efforts of the importer to verify compliance, as evidenced by documents contained in his files, may obviate or mitigate the assessment of a civil penalty under section 16 of TSCA.

(2) *EPA enforcement.* (i) EPA and Customs will monitor chemical imports to determine if shipments and their import comply with the certification requirements and the substantive mandates of TSCA. Customs will refuse entry to any shipment until such time as the certification is properly submitted. Customs will also detain a shipment if there are reasonable grounds to believe that such shipment or its import violates TSCA or regulations or orders thereunder. A violative shipment must either be brought into compliance, exported, destroyed, or voluntarily abandoned within the time periods prescribed in 19 CFR 12.124 of the section 13 rule.

(ii) When EPA determines that a shipment should be detained, EPA will identify the reasons for the detention and the necessary actions for an importer to bring the shipment into compliance with TSCA. If EPA has given this information to Customs before the district director issues the detention notice, the information will become part of the detention notice. The importer should contact one of the following EPA regional offices for guidance as to the proper procedures to correct any deficiencies in the shipment.

Region I

John F. Kennedy Federal Building, Boston, MA 02203 (617-223-0585)

Region II

26 Federal Plaza, New York, NY 10278 (201-321-6668)

Region III

Curtis Building, 6th & Walnut Streets, Philadelphia, PA 19106 (215-597-7866)

Region IV

345 Courtland Street, N.E., Atlanta, GA 30365 (404-881-3004)

Region V

230 South Dearborn Street, Chicago, IL 60604 (312-353-2231)

Region VI

1201 Elm Street, Dallas, TX 75270 (214-767-2734)

Region VII

324 East 11th Street, Kansas City, MO 64106 (816-374-3238)

Region VIII

1860 Lincoln Street, Denver, CO 80295 (303-837-3926)

Region IX

215 Fremont Street, San Francisco, CA 94105 (415-974-8119)

Region X

1200 Sixth Avenue, Seattle, WA 98101 (206-442-1871)

(iii) If Customs detains or refuses entry of a shipment (other than for failure to make the general certification) and the importer takes measures necessary to bring the shipment into conformity with the requirements of TSCA, EPA officials will reassess the shipment to determine its current compliance status. When a shipment is no longer in violation, EPA will notify the district director and the importer. The district director will then release the shipment. This notice will also serve as a determination to permit entry under 19 CFR 12.123(c) if a shipment is brought into compliance before the 19 CFR 12.123(c) decision-making process has been completed. If compliance is achieved after a 19 CFR 12.123(c) determination (adverse to the importer) has been made, the EPA notice to the district director will serve as a reversal of the decision to refuse entry.

(3) *EPA assistance.* Assistance in determining whether a chemical shipment is in compliance with TSCA can be obtained from: TSCA Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, 401 M St., SW., Washington, D.C. 20460. Toll free (800-424-9065). In Washington, D.C. (554-1404). Outside the USA (Operator-202-554-1404).

[FR Doc. 83-33229 Filed 12-12-83; 8:45 am]
BILLING CODE 6560-50-M

APPENDIX 14

ANNOUNCEMENT OF POLICY AND NOTICE FOR PUBLIC COMMENT; COORDINATED FRAMEWORK FOR REGULATION OF BIOTECHNOLOGY
51 *FR* 23302-93

federal register

Thursday
June 26, 1986

Part II

Office of Science and Technology Policy

Coordinated Framework for Regulation of Biotechnology; Announcement of Policy and Notice for Public Comment

OFFICE OF SCIENCE AND TECHNOLOGY POLICY

Coordinated Framework for Regulation of Biotechnology

AGENCY: Executive Office of the President, Office of Science and Technology Policy.

ACTION: Announcement of policy; notice for public comment.

SUMMARY: This Federal Register notice announces the policy of the federal agencies involved with the review of biotechnology research and products. As certain concepts are new to this policy, and will be the subject of rulemaking, the public is invited to comment on these aspects which are specifically identified herein.

DATE: Comments must be received on or before August 25, 1986.

Public Participation: The Domestic Policy Council Working Group on Biotechnology through the Office of Science and Technology Policy, is seeking advice on certain refinements published herein to the previously published proposed coordinated framework for regulation of biotechnology. These new aspects include the Biotechnology Science Coordinating Committee's (BSCC's) definitions for an "intergeneric organism (new organism)" and for "pathogen." These definitions are critical to the coordinated framework for the regulation of biotechnology because they establish the types of the organisms subject to certain kinds of review.

It is the intention of the Domestic Policy Council Working Group on Biotechnology, the Biotechnology Science Coordinating Committee (BSCC), the Department of Agriculture (USDA), the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), the National Science Foundation (NSF), and the Occupational Safety and Health Administration (OSHA) that the policies contained herein be effective immediately. In consideration of comments, modifications, if any, may be published either in a separate notice or as part of proposed rulemaking by the involved agencies.

Information submitted to an agency that is trade secret information or confidential business information should be clearly marked so that it can be accorded the protection provided to such by each respective agency.

ADDRESS: Comments specific to the BSCC definitions or overall comments to the Coordinated Framework for the Regulation of Biotechnology statements, should be addressed to: BSCC: Docket #BSCC 0001, Office of Science and Technology Policy, Executive Office of the President, NEOB-Room 5005, Washington, DC 20506.

Comments relating to the policy statements of a particular agency should be sent directly to the agency contact identified at the beginning of the respective agency policy statement.

FOR FURTHER INFORMATION CONTACT: Dr. David T. Kingsbury, Assistant Director for Biological, Behavioral, and Social Sciences, National Science Foundation, 1800 G Street, N.W., Washington, D.C. 20550, (202-357-9854).

Jerry D. Jennings,

Executive Director, Office of Science and Technology Policy

June 18, 1986

Table of Contents

I. Preamble
- A. Introduction
- B. The Coordinated Framework for the Regulation of Biotechnology
- C. Interagency Coordination Mechanisms
- D. BSCC Definitions
- E. International Aspects

II. Statements of Policy
- A. Food and Drug Administration
- B. Environmental Protection Agency
- C. U.S. Department of Agriculture
- D. Occupational Safety and Health Administration
- E. National Institutes of Health

A. Introduction

This notice describes the comprehensive federal regulatory policy for ensuring the safety of biotechnology research and products. Specifically addressed are agency policies that formed part of the previously proposed Coordinated Framework for the Regulation of Biotechnology, published in the Federal Register December 31, 1984 (49 FR 50856, hereinafter "the December 84 Notice"). These agency policies build upon experience with agricultural, pharmaceutical, and other commercial products developed by traditional genetic modification techniques.

Existing statutes provide a basic network of agency jurisdiction over both research and products; this network forms the basis of this coordinated framework and helps assure reasonable safeguards for the public. This framework is expected to evolve in accord with the experiences of the industry and the agencies, and, thus, modifications may need to be made through administrative or legislative actions.

The application of traditional genetic modification techniques is relied upon broadly for enhancement of characteristics of food (e.g., hybrid corn, selective breeding), manufactured food (e.g., bread, cheese, yogurt), waste disposal (e.g., bacterial sewage treatment), medicine (e.g., vaccines, hormones), pesticides (e.g. *Bacillus thuringiensis*) and other uses. Federal agencies implement an array of laws which seek to ensure the safety of these products. A concise index of these U.S. laws was published in the Federal Register November 14, 1985 (50 FR 47174, hereinafter "the November 85 Notice"). These laws are product-specific because they regulate certain product uses, such as foods or pesticides. This approach provides the opportunity for similar products to be treated similarly by particular regulatory agencies.

Biotechnology also includes recently developed and newly emerging genetic manipulation technologies, such as recombinant DNA (rDNA), recombinant RNA (rRNA) and cell fusion, that are sometimes referred to as genetic engineering. While the recently developed methods are an extension of traditional manipulations that can produce similar or identical products, they enable more precise genetic modifications, and therefore hold the promise for exciting innovation and new areas of commercial opportunity.

Concerns were raised as to whether products resulting from the recently developed techniques would pose greater risks than those achieved through traditional manipulation techniques. For example, what might be the possible environmental consequences of the many anticipated agricultural and environmental applications that will take place outside the physical constraints of a contained facility? In particular, the environmental application of genetically engineered microorganisms may elicit concern because they are of microscopic size, and some may be able to reproduce, proliferate, and become established.

The underlying policy question was whether the regulatory framework that pertained to products developed by traditional genetic manipulation techniques was adequate for products obtained with the new techniques. A similar question arose regarding the sufficiency of the review process for research conducted for agricultural and environmental applications.

The Administration, recognizing its responsibility to confront these concerns, formed an interagency working group under the former White House Cabinet Council on Natural Resources and the Environment in the spring of 1984. The working group sought to achieve a balance between regu-

adequate to ensure health and environmental safety while maintaining sufficient regulatory flexibility to avoid impeding the growth of an infant industry.

Upon examination of the existing laws available for the regulation of products developed by traditional genetic manipulation techniques, the working group concluded that, for the most part, these laws as currently implemented would address regulatory needs adequately. For certain microbial products, however, additional regulatory requirements, available under existing statutory authority, needed to be established.

The existing health and safety laws had the advantage that they could provide more immediate regulatory protection and certainty for the industry than possible with the implementation of new legislation. Moreover, there did not appear to be an alternative, unitary, statutory approach since the very broad spectrum of products obtained with genetic engineering cut across many product uses regulated by different agencies.

Because of the rapid growth in the scientific knowledge base, the working group felt strongly that the federal agencies needed to have an interagency mechanism for sharing scientific information related to biotechnology, particularly information on research and product applications submitted to the agencies.

The December 1984 Notice described the regulatory framework envisioned by the working group, and recognizing the evolutionary nature of its development, asked for comments. In summary, the Notice stated that the Food and Drug Administration (FDA) would regulate genetic engineering products no differently that those achieved through traditional techniques. The Environmental Protection Agency (EPA) described existing and proposed new policies for regulating pesticidal and nonpesticidal microorganisms. The Department of Agriculture (USDA) stated that under its different legislative authorities it could broadly regulate genetically engineered plants and animals, and plant and animal pathogens. The Notice also proposed an interagency science coordinating mechanism.

Many comments were received in response to the Notice. These contributed to the refinement of both the regulatory requirements and the interagency science coordination mechanism.

The interagency coordination mechanism, the Biotechnology Science Coordinating Committee (BSCC), discussed in more detail in section C. of this Preamble, came into being while the agencies were still in process of refining their regulatory proposals. Consequently, the BSCC was able to play a helpful role in the formulation of two basic principles: (1) Agencies should seek to adopt consistent definitions of those genetically engineered organisms subject to review to the extent permitted by their respective statutory authorities; and, (2) agencies should utilize scientific reviews of comparable rigor.

The regulatory framework anticipates that future scientific developments will lead to further refinements. Experience with earlier basic scientific research has shown that as the science progressed and became better understood by the public, regulatory regimens could be modified to reflect more complete understanding of the potential risks involved. Similar evolution is anticipated in the regulation of commercial products as scientists and regulators learn to predict more precisely particular product use that require greater or lesser controls or even exemption from any federal review.

This framework has sought to distinguish between those organisms that require a certain level of federal review and those that do not. This follows a traditional approach to regulation. Within agriculture, for example, introductions of new plants, animals and microorganisms have long occurred routinely with only some of those that are not native or are pathogenic requiring regulatory approval. It should be noted that microorganisms play many essential and varied roles in agriculture and the environment and that for decades agricultrual scientists have endeavored to exploit their advantages through routine experimentation and introduction into the environment; and as a rule these agricultural and environmental introductions have taken place without harm to the environment.

B. The Coordinated Framework for the Regulation of Biotechnology

General Comments

This notice includes separate descriptions of the regulatory policies of FDA, EPA, OSHA and USDA and the research policies of the National institutes of Health (NIH), NSF, EPA and USDA. The agencies will seek to operate their programs in an integrated and coordinated fashion and together should cover the full range of plants, animals and microorganisms derived by the new genetic engineering techmques. To the extent possible, responsibility for a product use will lie with a single agency. Where regulatory oversight or review for a particular product is to be performed by more than one agency, the policy establishes a lead agency, and consolidated or coordinated reviews. While this preamble seeks to convey an overview of the coordinated framework, it must be noted that the regulatory requirements are highly technical; reliance only on the simplified summary statements herein could be misleading and, thus, the agency policy statements must be consulted for specific details. In the event that questions arise regarding which federal agency has jurisdiction, an information contact is provided at the beginning of this notice.

While in part certain USDA and EPA requirements are new, the underlying regulatory regimens are not new. Members of the agricultural and industrial communities are familiar with the general requirements under these laws which include the Federal Plant Pest Act, The Plant Quarantine Act, the Toxic Substances Control Act (TSCA), and the Federal insecticide, Fungicide, and Rodenticide Act (FIFRA).

Because this comprehensive regulatory framework uses a mosaic of existing federal law, some of the statutory nomenclature for certain actions may seem inconsistent. Certain laws, such as USDA's Federal Plant Pest Act, require a "permit" before a microorganism pathogenic to plants may be transported or imported. Under other laws such as FIFRA, the agencies "license" or "approve" the use of particular products. TSCA requires a "premanufacturing notification (PMN)" There are also some variations among the agencies in the use of the phrase "genetic enginering." Regardless of the nomenclature, the public should be aware that the reviews conducted by each of the regulatory agencies are intended to be of comparable rigor. Agencies have agreed to have scientists from each other's staff participate in reviews. Each regulatory review will require that the safety, or safety and efficacy, of a particular agricultural or industrial product be satisfactorily demonstrated to the regulatory agency prior to commercialization.

The National Environmental Policy Act (NEPA) imposes procedural requirements on all federal agencies to prepare an analysis prior to making a decision to take any action that may significantly affect the environment. Depending on the characteristics of a proposal, an environmental assessment or a broader environmental impact statement may need to be prepared in connection with the release of

genetically manipulated organisms. EPA's actions under most of its environmental statutes have been considered to be the functional equivalent of NEPA compliance.

For the handling of microorganisms, agencies of the Department of Health and Human Services have established recommendations for the safe use of infectious agents. The CDC/NIH publication, *Biosafety in Microbiological and Biomedical Laboratories*, describes combinations of standard and special microbiological practices, safety equipment and facilities which are recommended for working with a variety of infectious agents in research laboratories, academic and industrial. The USDA also has issued guidance on other infectious agents.

The NIH has published guidelines for the contained use of DNA organisms in the *NIH Guidelines for Research Involving Recombinant DNA Molecules*, **Federal Register**, May 7, 1986 (51 FR 16958, NIH guidelines). The guidelines recommend physical containment at specific levels for different experiments, and exempt other experiments from containment requirements. However, they recommend Biosafety Level 1, the least stringent level of physical containment, for some "exempt" experiments. For large-scale exempt experiments, the NIH guidelines recommend "Biosafety Level 1-Large-Scale" although following review by the Institutional Biosafety Committee, "some latitude" in the application of these requirements is permitted.

The appropriate large-scale containment requirements for many low risk DNA derived industrial microorganisms will be no greater than those appropriate for the unmodified parental organisms. This concept is discussed further in the Organization for Economic Cooperation and Development (OECD) document, described in the International Aspects section below.

OSHA in its **Federal Register** Notice of April 12, 1984 (50 FR 14468) stated that its authority under the Occupational Safety and Health Act of 1970 (29 U.S.C. et seq.) provides an adequate and enforceable basis for protecting the safety and health of employees in the field of biotechnology and that no additional regulation is necessary. After consideration of comments in the April 1984 notice, OSHA is publishing this policy statement in final form without change.

Product Regulation

Agencies involved with regulating agriculture, foods, medical devices, drugs, biologics and pesticides have had extensive experience with products that involve living organisms in their manufacture and/or ultimate use including releases into the environment for these purposes. By the time a genetically engineered product is ready for commercialization, it will have undergone substantial review and testing during the research phase, and thus, information regarding its safety should be available. The manufacture by the newer technologies of food, the development of new drugs, medical devices, biologics for humans and animals, and pesticides, will be reviewed by FDA, USDA and EPA in essentially the same manner for safety and efficacy as products obtained by other techniques. The new products that will be brought to market will generally fit within these agencies' review and approval regimens.

The regulatory scheme for products is described in Chart I *Coordinated Framework—Marketing Approval of Biotechnology Products.*

CHART I.—COORDINATED FRAMEWORK—APPROVAL OF COMMERCIAL BIOTECHNOLOGY PRODUCTS

Subject	Responsible agency(ies)
Foods/Food Additives	FDA,[a] FSIS[b]
Human Drugs, Medical Devices and Biologics	FDA.
Animal Drugs	FDA.
Animal Biologics	APHIS.
Other Contained Uses	EPA.
Plants and Animals	APHIS,[c] FSIS[b], FDA.[d]
Pesticide Microorganisms Released in the Environment All	EPA,[e] APHIS.[c]
Other Uses (Microorganisms):	
Intergeneric Combination	EPA,[e] APHIS.[c]
Intrageneric Combination:	
Pathogenic Source Organism:	
1. Agricultural Use	APHIS.
2. Non-Agricultural use	EPA,[e] APHIS.[c]
No Pathogenic Source Organisms	EPA Report.
Nonengineered Pathogens:	
1. Agricultural Use	APHIS.
2. Non-agricultural Use	EPA,[e] APHIS.[c]
Nonengineered Nonpathogens	EPA Report.

[a] Lead agency
[b] FSIS, Food Safety and Inspection Service, under the Assistant Secretary of Agriculture for Marketing and Inspection Services is responsible for food use.
[c] FDA is involved when in relation to a food use.
[d] APHIS, Animal and Plant Health Inspection Service, is involved when the microorganism is plant pest, animal pathogen or regulated article requiring a permit.
[e] EPA requirements will only apply to environmental release under a significant new use rule that EPA intends to propose.

Jurisdiction over the varied biotechnology products is determined by their use, as has been the case for traditional products. The detailed description of the products and their review are found in the individual agency policy statements contained in this **Federal Register** Notice. The following is a brief summary of jurisdiction as described in Chart I.

Foods, food additives, human drugs, biologics and devices, and animal drugs are reviewed or licensed by the FDA. Food products prepared from domestic livestock and poultry are under the jurisdiction of the USDA's Food Safety Inspection Service (FSIS).

Animal biologics are reviewed by the Animal and Plant Health Inspection Service, (APHIS). APHIS also reviews plants, seeds, animal biologics, plant pests, animal pathogens and "regulated articles", i.e., certain genetically engineered organisms containing genetic material from a plant pest. An APHIS permit is required prior to the shipment (movement) or release into the environment of regulated articles, or the shipment of a plant pest or animal pathogen.

"Other contained uses" refers to the closed system uses of those microorganisms, subject the TSCA, that are intergeneric combinations, i.e., deliberately formed microorganisms which contain genetic material from dissimilar source organisms. These are subject to EPA's PMN requirement. EPA is considering promulgating a rule to exempt certain classes of microorganisms from this requirement.

Microbial pesticides will be reviewed by EPA, with APHIS involvement in cases where the pesticide is also a plant pest, animal pathogen, or regulated article requiring a permit. (FDA may become involved in implementing pesticide tolerances for foods.)

"Other uses (microorganisms)" include uses involving release into the environment. For these, jurisdiction depends on the characteristics of the organism as well as its use. "Intergeneric combination"[1] microorganisms will be reported to EPA under PMN requirements, with APHIS involvement in cases where the microorganism is also a regulated article requiring a permit.

"Intrageneric combinations" are those microorganisms formed by genetic engineering other than intergeneric combinations. For these, when there is a pathogenic[1] source organism, and the microorganism is used for agricultural purposes, APHIS has jurisdiction. If microorganism is used for nonagricultural purposes, then EPA has jurisdiction, with APHIS involvement in cases where the microorganism is a

[1] "Intergeneric organisms (new organism-pathogen" are defined in section D of the preamble.

regulated article requiring a permit. Intragenenc combinations with no pathogenic source organisms are under EPA jurisdiction although EPA will only require an informational report.

Nonengineered pathogens ' that are used for an agricultural use will fall under APHIS jurisdiction. Those that are for a nonagricultural use come under EPA jurisdiction. with APHIS involvement in cases where the microorganism is also a plant pest or animal pathogen requiring a permit Nonengineered nonpathogenic microorganisms are under EPA jurisdiction which will require only an informational report.

Research

The coordinated framework for the regulation of biotechnology establishes requirements for the conduct of research.

Approximately ten years ago the NIH issued the NIH guidelines describing the manner in which research with organisms derived by rDNA techniques should be conducted. Since then the guidelines have been modified many times with gradual relaxation of these requirements. The guidelines prescribe the conditions under which institutions which receive NIH funds must conduct experiments. For a very small category of NIH funded experiments including environmental release. the guidelines require that the Director. NIH. approve each experiment on an individual basis. For each of these experiments. the RAC conducts a scientific review with an opportunity for public comment. and makes a recommendation to the NIH Director. As research experiments have expanded out of the biomedical area to environmental applications both agricultural and nonagricultural. other agencies have become involved. with shifting of responsibility for research approval to NSF (described in the November 85 Notice). USDA's S&E. and EPA. These other agencies' policies build. in part. on the NIH guidelines and NIH experience.

The S&E guidelines for agricultural research published separately for comment in this issue of the Federal Register have adopted the NIH guidelines with certain modifications including expansion of the scope to manipulation techniques other than rDNA. the table included with the S&E guidelines shows where particular elements of the NIH guidelines are used.

It should be noted that not all experiments involving the environmental release of genetically engineered organisms require prior federal approval. In plant applications there is a substantial body of research indicating that such experiments are of low risk. For certain categories of microorganisms modified by traditional genetic modification techniques. there is also a substantial body of research indicating low risk for environmental experiments.

Chart II—*Coordinated Framework—Biotechnology Research Jurisdiction* shows which agency has responsibility for a particular experiment. If more than one agency has potential jurisdiction. one agency has been designated as the lead agency and it is marked with an asterisk on Chart II. The lead agency designation depends on which research agency is funding the research (e.g., NIH S&E. or NSF) or which regulatory agency reviews specific purpose research (e g pesticides). In the chart and in this discussion. the authority refers to approval of the actual execution of experiments and not to their funding.

CHART II —COORDINATED FRAMEWORK—BIOTECHNOLOGY RESEARCH JURISDICTION

Subject	Responsible agency(ies)
Contained Research No Release in Environment:	
1 Federally Funded	Funding agency,[1] NIH or S&E voluntary review APHIS[3]
2 Non-Federally Funded	
Foods/Food Additives. Human Drugs. Medical Devices. Biologics. Animal Drugs.	
1 Federally Funded	FDA[4] NIH guidelines & review
2 Non-Federally Funded	FDA[4] NIH voluntary review
Plants. Animals and Animal Biologics:	
1 Federally Funded	Funding agency,[1] APHIS.[3]
2 Non-Federally Funded	APHIS[3]. S&E voluntary review.
Pesticide Microorganisms:	
Genetically Engineered:	
Intergeneric	EPA,[5] APHIS,[3] S&E voluntary review
Pathogenic Intrageneric	EPA,[5] APHIS,[3] S&E voluntary review
Intrageneric Nonpathogen	EPA,[5] S&E voluntary review
Nonengineered:	
Nonindigenous Pathogens	EPA,[5] APHIS
Indigenous Pathogens	EPA,[5][6] APHIS.
Nonindigenous Nonpathogen	EPA.[5]
Other Uses (Microorganisms) Released in the Environment:	
Genetically Engineered:	
Intergeneric Organisms:	
1 Federally Funded	Funding agency,[1] APHIS,[3] EPA.[5]

CHART II —COORDINATED FRAMEWORK—BIOTECHNOLOGY RESEARCH JURISDICTION—Continued

Subject	Responsible agency(ies)
2 Commercially Funded	EPA APHIS S&E voluntary review
Intragenenc Organisms	
Pathogenic Source Organism	
1 Federally Funded	Funding agency,[1] APHIS EPA.[5]
2 Commercially Funding	APHIS,[3] EPA,[5] non-[illegible] (SE)
Intragenenc Combination	
No Pathogenic Source Organisms	EPA Report
Nonengineered	EPA Report,[7] APHIS

[1] Lead Agency
[2] Review and approval of research protocols conducted by NIH S&E or NSF
[3] APHIS issues permits for the importation and domestic shipment of certain plants and animals plant pests and animal pathogens. and for the shipment or release in the environment of regulated articles.
[4] FDA jurisdiction for research on a plot greater than 10 acres
[5] EPA reviews federally funded environmental research only when it is for commercial purposes.

For contained federally funded research for biomedical and agricultural purposes. research approval will be granted by the funding agency The NIH guidelines relate primarily to biomedical experiments and only to those using rDNA techniques. Research on foods/food additives. human drugs. medical devices and biologics will continue to rely on the NIH guidelines. with NIH approval required for certain experiments such as human gene therapy. and FDA permission for clinical trials.

Fashioned after the NIH guidelines. the S&E guidelines apply to agricultural research on plants. animals. and microorganisms and provide guidance for laboratory and field testing of organisms derived using rDNA manipulation and other technologies Adherence to the appropriate set of guidelines is required for institutions receiving financial support from NIH S&E. or NSF These guidelines specify what type of review procedures are required for specific categories of experiments. Some experiments require individual approval by the respective agency providing institutional support. For those experiments that require agency approval. advisory committees at NIH: S&E. and NSF. composed primarily of nongovernment scientists may be asked to provide expert review. In addition. research on plants and animal biologics will come under APHIS permit requirements if a regulated article. plant pest and pathogen is involved. An APHIS

is required prior to the shipment (movement) or release of a regulated article, or the importation or shipment of a plant pest or regulated article used in any research experiment.

EPA has authority for all environmental research on microbial pesticides regardless of whether research is federally funded or not. EPA will regulate research under a two level review system based upon its evaluation of the potential risks posed by various types of microorganisms with lesser notification required for level I reporting and full review for level II.

For the "other uses" category from Chart II (research involving nonpesticide microorganisms released into the environment), jurisdiction for release may be under S&E, NSF, APHIS, or EPA depending primarily upon the source of the funding, but also upon the purpose of the research and the characteristics of the genetically engineered microorganism. Thus, federally funded research conducted for an agricultural use will require adherence to S&E guidelines and approval of certain experiments by S&E or NIH depending on which is the funding agency. EPA will review commercial research. APHIS's jurisdiction applies to issuing permits for regulated articles, plant pests, or animal pathogens. EPA will require an *informational report for nonengineered* microorganisms released into the environment, with APHIS involvement for the review of plant pests or animal pathogens.

There may be situations where one agency may choose to defer to, or ask advice from, another agency. If experiments requiring NIH, NSF or S&E review/approval are submitted for review to another agency, then NIH, NSF, or S&E may determine that such review serves the same purpose, and based upon that determination, notify the submitter that no NIH, NSF, or S&E review will take place, and the experiment may proceed upon approval from the other agency.

C. Interagency Coordination Mechanisms

The Domestic Policy Council Working Group on Biotechnology

The Domestic Policy Council Working Group on Biotechnology has been responsible for this coordinated framework for the regulation of biotechnology; it also considers policy matters related to agency jurisdiction, commercialization, and international biotechnology matters. The Working Group monitors developments in biotechnology and is ready to identify problems and make appropriate recommendations for their solution. The Domestic Policy Council Working Group on Biotechnology is a continuation of a similar group established under the former Cabinet Council on Natural Resources and the Environment.

Although at the present time existing statutes seem adequate to deal with the emerging processes and products of modern biotechnology, there always can be potential problems and deficiencies in the regulatory apparatus in a fast moving field. The Working Group will be alert to the implications these changes will have on regulation, and in a timely fashion will make appropriate recommendations for administrative or legislative action.

The Biotechnology Science Coordinating Committee (BSCC)

The BSCC is responsible for coordination and consistency of scientific policy and scientific reviews. The BSCC, established October 31, 1985 as part of the Federal Coordinating Council for Science, Engineering and Technology (FCCSET), consists of senior policy officials of agencies involved in the oversight of biotechnology research and products. FCCSET is a statutory interagency coordinating mechanism managed by the Office of Science and Technology Policy, Executive Office of the President, with a mission to coordinate federal science activities among federal agencies. The November 85 Notice described the structure and activities of the BSCC.

One of the primary activities of the BSCC has been the development of definitions because a common scientific approach is essential to a coordinated federal regulatory framework. The underlying scientific issue, therefore, was defining those organisms subject to certain types of agency review.

The definitions are included in the following section of this preamble and *have been incorporated, with* modification, into the individual policy notices of the involved agencies. Explanatory material is also included in the agency policy statements. As mentioned elsewhere, the BSCC is seeking comments on these definitions.

Research to develop genetically modified organisms for environmental and agricultural applications (as for research on traditionally modified organisms) generally proceeds in a stepwise manner from highly contained facilities to progressively lesser degrees of containment as the investigator determines the safety and efficacy of experimental applications; these are conducted sequentially under controlled laboratory conditions, greenhouse testing, small field trials, and full field trials. The BSCC recognizes the need for further work to define the nature and extent of physical and biological barriers that limit or manage environmental release of modified organisms during greenhouse testing and field research.

The BSCC is authorized to hold public meetings in order to discuss public concerns about scientific and other issues. Accordingly, the BSCC will hold its first public meeting shortly after publication of this notice for discussion of the scientific aspects of this notice and the receipt of comments from the public. The public meeting will be held in July 1986. Details regarding time and location will be separately announced in the Federal Register.

D. BSCC Definitions

Any proposal to regulate the research and products of genetic manipulation techniques quickly confronts the issue of what organisms should be considered appropriate for certain types of review. The BSCC formulated definitions are effective immediately but are open to comment; the text following the definition of "pathogen" contains details of the request for comments.

Organisms meeting two different sets of criteria are proposed. First are organisms formed by deliberate *combination of genetic material from* sources in different genera. It was recognized, however, that in certain precisely constructed "intergeneric organisms" the genetic material is not considered to pose an increased risk to human health or the environment; thus, such combinations are excluded from the definition. A detailed explanation of the scientific basis for these exclusions is found in the footnote after the definition of pathogen. The BSCC specifically requests comments on whether also to consider for exclusion those organisms that exchange DNA by known physiological processes, as explained in the text immediately following the definition of "intergeneric organism (new organism)."

The second definition is "pathogen." This includes microorganisms that belong to a pathogenic species or that contain genetic material from source organisms that are pathogenic. In certain precisely constructed modified organisms, the genetic material from a pathogenic donor is not considered to pose an increased risk to human health or the environment; and, therefore, *combinations are excluded from the* definition.

The BSCC definitions of "intergeneric organism (new organism)" and

"pathogen" describe the combinations genetic material that would cause a modified organism to come under review. This does not mean to suggest that the behavior of a genetically manipulated organism exempted from these definitions is wholly predictable (since any biological organism is never 100% predictable), but that the probability of any incremental hazard compared to the unmodified organism host is low Also. this does not mean that any product manufacture or research experiment using an organism exempted from the definition should be conducted without adherence to proper manufacturing standards or research guidelines.

Given the statutory differences in the laws that they administer. the agencies adopted the principles underlying the definitions in ways consistent with their legislation. EPA. APHIS. and S&E are using the definitions to identify levels of review for microbial products within their jurisdiction. EPA. APHIS. FDA. S&E. and NSF are using the definitions as factors to consider in the review of products or experiments.

The BSCC is attempting to define what constitutes "release into the environment." The BSCC is establishing a working group on greenhouse containment and small field trials in order to develop scientific recommendations. The concept of "containment" has traditionally been used to describe physical conditions which severely limit release (for example. a contained laboratory fermentation facility). Containment can also be "biologic" because the ability of an organism to reproduce. exchange genetic information. or become established can be effectively limited biologically. Thus. the BSCC's exploration of the conditions that constitute release into the environment will consider circumstances of both physical and biological containment for particular organisms and the circumstances of their release. While the concept of physical containment may imply the high containment conditions found in certain laboratories and greenhouses. in agricultural practice many simpler effective barriers are rountinely used: these include microplots for soil bacteria and fungi. paddocks for noninfective animals. and removing or covering the reproductive parts of plants and animals.

Release into the environment. for the time being. will have somewhat varying definitions for the regulatory and research review of the different agencies. There may be minor differences between agricultural and nonagricultural approaches and betweeen macro-and microorganisms.

Intergeneric Organism (New Organism)

Those organisms deliberately formed to contain an intergeneric combination of genetic material: excluded are organisms that have resulted from the addition of intergeneric materials that is well-characterized and contains only non-coding regulatory regions such as operators. promoters. origins of replication. terminators and ribosome binding regions.

"Well-characterized and contains only non-coding regulatory regions" means that the producer of the microorganism can document the following:

a The exact nucleotide base sequence of the regulatory region and any inserted flanking nucleotides:

b The regulatory region and any inserted flanking nucleotides do not code independently for a protein. peptide of functional RNA molecules:

c The regulatory region solely controls the activity of other sequences that code for protein or peptide molecules or act as recognition sites for the initiation of nucleic acid or protein synthesis.

Pathogen

A pathogen is a virus or microorganism (including its viruses and plasmids. if any) that has the ability to cause disease in other living organisms (i.e., humans. animals. plants. microorganisms).

A microorganism (including viruses) will be subject to regulatory policies regarding pathogens if:

a. The microorganism belongs to a pathogenic species. according to sources identified by the agency. or from information known to the producer that the organism is a pathogen: excepted are organisms belonging to a strain used for laboratory research or commercial purposes and generally recognized as non-pathogenic according to sources identified by a federal agency. or information known to the producer and the appropriate federal agency (an example of a nonpathogenic strain of a species which contains pathogenic strains is *Escherichia coli* K-12: examples of nonpathogenic species are *Bacillus subtilis. Lactobacillus acidohilus.* and *Saccharomyces* species); or

b. The microorganism has been derived form a pathogen or has been deliberately engineered such that it contains genetic material from a pathogenic organism as defined in item a. above. Excepted are genetically engineered organisms developed by transferring a well-characterized. non-coding regulatory region from a pathogenic donor to a non-pathogenic recipient.

"Well-characterized. non-coding regulatory region" means that the producer of the microorganism can document the following:

a. The exact nucleotide base sequence of the regulatory region and any inserted flanking nucleotides:

b. The regulatory region and any inserted flanking nucleotides do not code independently for a protein. peptide. or functional RNA molecules. and.

c. The regulatory region solely controls the activity of other sequences that code for protein or peptide moldecules or act as recognition sites for the initiation of nucleic acid or protein-aysthesis.

This definition excludes organisms such as competitors or colonizers of the same substrates. commensal or mutualistic microorganisms. or opportunistic pathogens

The footnote contains the scientific basis for exempting non-coding regulatory regions from the definitions of intergeneric organisms and pathogen.[2]

[2] The BSCC has based the exemption of intergeneric transfers of regulatory regions on their lack of coding capacity for the production of proteins peptides or functional RNA molecules. It has been recommended by other members of the scientific community that these should be included exemptions such as ribosomal proteins ribosomal RNAs and transfer RNAs The BSCC has chosen to examine these suggestions in more detail during the next few months. At the present the BSCC has excluded.

1 Origins of replications:
2 Ribosome binding sites
3 Promoters:
4 Operators. and.
5 Terminators.

The basis for these exemptions is as follows: Each of these regulatory elements has no coding capacity for the production of any gene product and therefore does not promote the production of any new material. What these elements are responsible for is the initiation and modulation of nucleic acid synthesis at the specific region where they appear in the chromosome.

Bacterial genes are precisely regulated. This regulation is based on a series of regulatory elements. The principal regulatory unit is the *operon.* Operons are controlled primarily exclusively. through the regulation of the initiation of messenger RNA synthesis. This regulation is based on the interaction nucleotide sequences in the DNA. the which is the site of RNA polymerase the *operator.* which follows closely the off-on switch for the movement of the into the structural gene which follows of the operator is to *bind* a cellular which is synthesized in response to nutritional stimuli. *Terminator* regions nucleotide sequences which signal of mRNA synthesis by the polymerase a signal for the dissociation of the the DNA

Replication of DNA in every bi that has been examined is initiated or group of sites in the chromosome have broad specificity and a DNA the appropriate site will not be r which are critical to the initiation known as *origins of replication* short nucleotide sequences which sites for specific enzyme action replication process For example mammalian DNA to replicate in associated with a bacterial origin vice versa

Ribosome binding sites are short segments at the beginning of me molecules which signal the attachment for the initiation of protein synthesis this role they are not translated peptide being processed.

The BSCC is requesting comments on these definitions during the period of sixty days following the date of this notice and specifically seeks comments addressing the following:

1. The suitability and applicability of these definitions to applications involving release into the environment, contained industrial large-scale applications, foods/food additives, drugs, medical devices, and other possible products.

2. Whether combinations of genetic material from organisms that exchange DNA by known physiological processes should be excluded from the definition of intergeneric organisms; i.e., should organisms be excluded which contain intergeneric combinations of certain specified rDNA molecules that consist entirely of DNA segments from different genera that exchange DNA by known physiological processes? As certain rDNA organisms are exempted under section III-D-4 of the NIH guidelines, the question was raised whether these organisms when used in the environment should be similarly exempted from federal product review. This exemption would not, however, exclude from review such "natural exchangers" that are also pathogens or plant pests. In the event that the exclusion of such different species that exchange DNA by known physiological processes is accepted as appropriate, a list of such species combinations that has been maintained and updated by the Office of Recombinant DNA Activities of the National Institutes of Health will be updated, in light of environmental use.

3. What are the most appropriate definitions of "release into the environment" for macro- and microorganisms.

E. International Aspects

The United States seeks to promote international scientific cooperation and understanding of scientific considerations in biotechnology on a range of technical matters. These activities add to scientific knowledge and ultimately contribute to protection of health and the environment.

The United States also seeks to reduce barriers to international trade. U.S. agencies apply the same regulation and approval procedures on domestic and foreign biotechnological products. We are seeking recognition among nations of the need to harmonize, to the maximum extent possible, national regulatory oversight activities concerning biotechnology. Barriers to trade in biotechnological products should be avoided as nations join together in working toward this mutual goal.

The U.S. agencies that have published separate policy statements as part of this notice are committed to the policy described in this section on international harmonization and have incorporated by reference the language in this International Aspects section as part of their respective agency policy statements.

Organization for Economic Cooperation and Development (OECD)

The approach of the comprehensive framework contained in this notice takes into account, *inter alia*, the broad goals described by an Ad Hoc Group of Government Experts convened by OECD in their recent report entitled, "*Recombinant DNA Safety Considerations. Safety Considerations for Industrial, Agricultural and Environmental Applications of Organisms Derived by Recombinant DNA Techniques.*" The United States is pleased to have had the opportunity for its experts to work with those of other governments in the preparation of this report. The report includes the following concepts:

Summary of Major Points

Recombinant DNA techniques have opened up new and promising possibilities in a wide range of applications and can be expected to bring considerable benefits to mankind. They contribute in several ways to the improvement of human health and the extent of this contribution is expected to increase significantly in the near future.

The vast majority of industrial rDNA large-scale applications will use organisms of intrinsically low risk which warrant only minimal containment, Good Industrial Large-Scale Practice (GILSP).

When it is necessary to use rDNA organisms of higher risk, additional criteria for risk assessment can be identified and furthermore, the technology of physical containment is well known to industry and has successfully been used to contain pathogenic organisms for years. Therefore, rDNA microorganisms of higher risks can also be handled safely under appropriate physical and/or biological containment.

Assessment of potential risks of organisms for environmental or agricultural applications is less developed than the assessment of potential risks for industrial applications. However, the means for assessing rDNA organisms can be approached by analogy with the existing data base gained from the extensive use of traditionally modified organisms in agriculture and the environment generally. With step-by-step assessment during the research and development process, the potential risk to the environment of the applications of rDNA organisms should be minimized.

I. General Recommendations

1. Harmonization of approaches to rDNA technology can be facilitated by exchanging: Principles or guidelines for national regulations; developments in risk analysis; and practical experience in risk management. Therefore, information should be shared as freely as possible.

2. There is no scientific basis for specific legislation for the implementation of rDNA technology and applications. Member countries should examine their existing oversight and review mechanisms to ensure that adequate review and control may be applied while avoiding any undue burdens that may hamper technological developments in this field.

3. Any approach to implementing guidelines should not impede future developments in rDNA technology. International harmonization should recognize this need.

4. To facilitate data exchange and minimize trade barriers between countries, further developments such as testing methods, equipment design, and knowledge of microbial taxonomy should be considered by both national and international levels. Due account should be taken of ongoing work on standards within international organizations such as: World Health Organization; Commission of the European Communities; International Standards Organization; Food and Agricultural Organization; and, Microbial Strains Data Network.

5. Special efforts should be made to improve public understanding of various aspects of rDNA technology.

6. For rDNA applications in industry, agriculture and the environment, it will be important for OECD Member countries to watch the development of these techniques. For certain industrial applications and for environmental and agricultural applications of rDNA organisms, some countries may wish to have a notification scheme.

7. Recognizing the need for innovation, it is important to consider appropriate means to protect intellectual property and confidentiality interests while assuring safety.

II. Recommendations Specific for Industry

1. The large-scale industrial application of rDNA technology should wherever possible utilize microorganisms that are intrinsically of low risk. Such microorganisms can be safely handled under conditions of Good Industrial Large-Scale Practice (GILSP).

2. If, following assessment using the criteria outlined in the document, a rDNA microorganism cannot be handled under GILSP, measures of containment corresponding to the risk assessment should be used in addition to GILSP.

3. Further research to improve techniques for monitoring and controlling non-intentional release of rDNA organisms should be encouraged in large-scale industrial applications requiring physical containment.

III. Recommendations Specific for Environmental and Agricultural Applications

1. Considerable data on the environmental and human health effects of living

exist and should be used to guide risk assessments

2 It is important to evaluate rDNA modified organisms for potential risk. prior to applications in agricultural and the environment However. the development of general international guidelines governing such applications is premature at this time An independent review of potential risks should be conducted on a case-by-case basis prior to application Case-by-case means an individual review of a proposal against assessment criteria which are relevant to the particular proposal. this is not intended to imply that every case will require review by a national or other authority since various classes of proposals may be excluded.

3 Development of organisms for agricultural or environmental applications should be conducted in a stepwise fashion. moving. where appropriate. from the laboratory to the growth chamber and greenhouse. to limited field testing and finally. to large-scale field testing.

4 Further research to improve the prediction. evaluation. and monitoring of the outcome of applications of rDNA organisms should be encouraged.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 84N-0431]

Statement of Policy for Regulating Biotechnology Products

AGENCY: Food and Drug Administration.

ACTION: Final policy statement for regulating biotechnology products.

SUMMARY: In the Federal Register of December 31. 1984 (43 FR 50878). the Food and Drug Administration (FDA) published a policy statement for regulating biotechnology products. The policy statement was part of a larger document that included an index of U.S. laws related to biotechnology. a description of the policies of the major regulatory agencies that are involved in reviewing the products of biotechnology. a description of a proposed scientific advisory mechanism for assessment of biotechnology issues. and an explanation of how the activities of the Federal agencies involving biotechnology will be coordinated. Of the comments FDA received on the policy statement. most favored the policy statement: some requested further clarification and guidance. The current action constitutes FDA's final policy statement which has been revised in response to the comments.

ADDRESS: Written comments should be submitted to the Dockets Management Branch (HFA-305). Food and Drug Administration. Room 4-62. 5600 Fishers Lane. Rockville. MD 20857.

FOR FURTHER INFORMATION CONTACT: Dr Mary Ann Danello (HF-5). Food and Drug Administration. Room 14-90. 5600 Fishers Lane. Rockville. MD 20857. 301-443-4650.

SUPPLEMENTARY INFORMATION: FDA's policy statement of December 31. 1984 stated the FDA regulation must be based on the rational and scientific evaluation of products. and not on *a priori* assumptions about certain processes. Accordingly. FDA's administrative review of products. including those that employ specialized biotechnological techniques. is conducted in the light of the intended use of a product on a case-by-case basis FDA believes the agency need not establish new administrative procedures to deal with generic concerns about biotechnology.

These views were supported by the majority of comments received in response to FDA's notice. Thirty-four comments were received. with 12 from manufacturers of regulated products. 16 from associations and universities. and 6 from individuals. A summary of the comments and the agency's response to them follow:

1. Many commenters urged the agency to publish additional "Points to Consider" documents to provide further guidance for biotechnology product applicants. These commenters specifically requested guidance in the area of animal drugs (especially protein drugs) and human foods and food additives.

FDA agrees that "Points to Consider" documents provide useful guidance. especially in areas involving new biotechnology. and will consider developing these documents where appropriate.

2. Related comments raised questions on FDA's general requirements for approving biotechnology products that are animal drugs. human foods. or food additives.

In response to these comments. FDA has amended the animal drug section ("General Requirements for Animal Food Additives and Drugs") to be more informative and has added a new section concerning its policies on human foods and food additives (see "General Requirements for Human Foods and Food Additives").

3. Many comments questioned the need for new or supplemental marketing applications for biotechnology products that are identical to products derived from conventional technology.

The agency has re-examined this issue and continues to believe that. as a general principle. new marketing applications will be required for most products manufactured using new biotechnology For example. use of recombinant DNA (rDNA) technology has the potential to lead to new structural features in the product. result in product micro-heterogeneity. or introduce new contaminants (e.g. associated with new cell substrates). each of which may affect the safety efficacy and stability of the product. Because of potential differences in the products resulting from use of recombinant DNA technology the resulting products may be new products requiring separate approval under the applicable statutory provisions However. each case will be examined separately to determine the appropriate information to be submitted In some instances complete new applications may not be required For example. the sponsor of a conventionally produced animal drug product who manufactures an identical or virtually identical product using biotechnology may be required to submit only a supplemental application. However. if the animal drug product manufactured using biotechnology differs significantly from the product manufactured by conventional processes. a complete original application would be required The agency believes that each product must undergo adequate and appropriate testing and review to ensure that it is safe and effective regardless of the technology employed. Sponsors are urged to communicate with FDA to establish the scope of information required for products of biotechnology

4. Many comments questioned the need for the proposed review mechanism by a Biotechnology Science Board (BSB). These comments stated that the additional layer of review would cause delays in the product approval process.

A notice published in the Federal Register of November 14 1985 (50 FR 47174) discussed the establishment of the Biotechnology Science Coordinating Committee (BSCC) within the Federal Coordinating Council for Science. Engineering and Technology That notice addressed various criticisms the BSB. FDA believes that the new BSCC will facilitate sharing of biotechnology information among agencies and will not delay agency reviews of product applications

In view of the foregoing. FDA's policy statement for regulating biotechnology products reads as follows:

APPENDIX 15

INSPECTION CHECKLIST

PMN AND PMN EXEMPTION CHECKLIST

N/A	Yes	No	
			PMN Submission
			90-day Review Date and Notice of Commencement
			Chemical Identification and Structure
			Impurities, byproducts
			Proposed Volume of production
			Proposed categories of use
			Process description
			Worker exposure
			Release and disposal information
			Health and environmental effects data
			Polltuion prevention and recycling
			Research & Development (R&D) Exemption
			Company Policy
			Technically qualified individual
			Recordkeeping and notification
			Test Marketing Exemption
			Period of applicability
			Health and environmental effects testing data
			Chemical identification and structure
			Maximum quantity of chemical substance and number of customers
			Maximum number of persons exposed and duration and routes of exposure
			Description of test-marketing activity
			Additional EPA-imposed restrictions

PMN AND PMN EXEMPTION (continued)

N/A	Yes	No	
			Low Volume Exemption (LVE)
			Manufacturer's name and technical contact
			Chemical identification and structure
			Description of use
			Site of manufacture
			Heal and environmental effects testing data
			Customer notification
			Exposure controls
			Polymer Exemption (PE)
			Manufacturer's name and technical contact
			Site of manufacture
			Chemical identification and structure
			Impurity information
			Production volume
			Category of use
			Health and environmental effects testing data
			Instant Film Chemical Exemption (IFCE)
			Condition of manufacture and processing in the special production area (SPA)
			Conditions of processing outside the SPA
			Environmental release and waste treatment
			Chemical identification and structure
			Physical-chemical properties
			Byproducts
			Production volume
			Health and environmental effects testing data
			Identity of the article
			Release to water

SECTION 5(e)/5(f) ORDER AND SNUN

N/A	Yes	No	
			Section 5(e)/5(f) Order
			Testing trigger
			Glove testing
			Protective clothing, devices, and controls
			Employee training
			Disposal
			Labeling
			Customer notification and compliance
			Significant New Use Notice (SNUN)
			Commercial production dates
			Chemical identification and structure
			Impurities and byproducts
			Proposed volume of production
			Proposed categories of use
			Process description
			Worker exposure
			Release information
			Health and environmental effects testing data

SECTION 8(a) PAIR AND IUR REPORTS

N/A	Yes	No	
			PAIR report
			Quantity of chemical manufactured or imported for sale or use
			Qauntity lost to the environment and in wastes
			Manufacturing processes and worker exposure
			On-site use of chemical as a reactant
			On-site nonreactant use of the chemical
			On-site preparation of products
			Manufacturer's products
			Customers' uses and products
			Trade names
			Customers' process categories
			Research & Development (R&D) exemption
			Small quantity exemption
			Small manufacturer exemption
			Chemical manufactured as non-isolated intermediate, an impurity, or byproduct
			Inventory Update Rule (IUR) report
			Production volume
			Plant site
			Site-limited status
			Manufactured or imported chemical is a polymer, inorganic substance, microorganism, or naturally-occurring substance
			Not manufactured in reportable quantities
			Small manufacturer exemption
			Research & Development (R&D) exemption
			Chemical imported as part of an article

SECTIONS 8(c), 8(d), and 8(e)

N/A	Yes	No	
			Section 8(c): Allegations of Significant Adverse Human Health or Environmental Effects
			Company awareness of requirements
			Allegation records not kept as required
			No allegations on file
			Records not retained for the required period of time
			Section 8(d): Health and Safety Studies
			Company awareness of requirements
			Health and safety studies information inaccurate or incomplete
			Reports not submitted
			Section 8(e): Notification of Substantial Risks
			Company awareness
			Substantial risk information inaccurate, incomplete, or late
			Substantial risk information not reported