Toxic Substances Control Act
Inspection Manual

Volume One:
TSCA Base Manual

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Volume One: TSCA Base Manual

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Foreword

The Toxic Substances Control Act Inspection Manual has been developed to support inspection personnel in conducting the complex field inspections that are fundamental to TSCA enforcement. The manual has been designed as a series of separate, coordinated volumes to reflect the complexity and diversity of the TSCA mandate and to accommodate expansion as new rules and enforcement programs are developed. This format was created to provide a base manual for general TSCA inspection information and a complementary series of volumes relating to the specific substances or rules developed under TSCA.

- Volume One: TSCA Base Manual introduces TSCA and provides general information relating to the Act. Inspector authorities and responsibilities are discussed along with the elements and scope of TSCA inspections. Procedures which are common to all TSCA inspections are outlined in detail: Pre-Inspection Preparation, Entry, Opening Conference, Records Inspection, Documentary Support, Sampling, Chain of Custody, Safety, Closing Conference, and Report Preparation. Special procedures are listed, and all TSCA forms are presented and explained. Information is also included on data systems, warrants, shipping samples, and testifying in court.

- Volume Two: PCB Inspection Manual supplements Volume One and provides the specific information necessary for conducting a comprehensive inspection for PCBs. An Enforcement Strategy details EPA plans for PCB inspection and provides an overview of the regulation. Inspecting, sampling, and reporting procedures for PCBs in specific industries is provided. This Volume is designed for portability and easy on-site reference.

- Volume Three and Ensuing Volumes will be developed as rules are promulgated and will follow a format similar to Volume Two. Each will deal with information relating to specific rules or substances and will complement Volume One.

Objectives of Volume One

The overall aim of the TSCA Inspection Manual is to provide clear, straightforward information in support of field inspection activities. The specific objectives incorporated into Volume One are:

- To provide a synopsis of the purpose, scope, and contents of the Act, and to provide a general overview of the elements of TSCA inspections, and inspector authorities and responsibilities.

- To provide detailed, standard procedures for inspecting under TSCA.

- To provide easily accessible inspection information which, in combination with any of the substance-specific Volumes, will form a complete, comprehensive inspection manual.

- To provide a basis for general training of new inspection personnel on TSCA inspection procedures and policies.

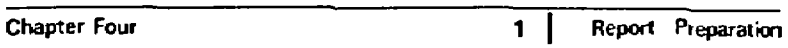
Using the Manual

The Manual format has been designed to present the material clearly and concisely and to allow the user to quickly locate specific information.

Volume One is organized into seven chapters, each of which contains several sections. (Chapter Three is further divided into subsections because of the large amount of material presented.) Divider tabs separate each chapter; following each tab is a detailed listing of the chapter contents.

Chapter and Section Numbers

The chapter number is printed at the top left of each page. Section numbers and titles are located at the top right of each page.



Page Numbers

Page numbering is organized by chapter. The first digit of the page number refers to the chapter, the second to the specific page within that chapter (e.g., page 3-12 refers to page 12 in Chapter Three).

Headings

The pages in the manual are designed to be easily read. Double-lined main headings are used instead of cumbersome outline numbers to allow a clean, clear page with space for notations. Subheadings are underlined, and listed items are identified by bullets.

Appendix

The Appendix, which provides supplementary details on information discussed in the chapters, is designed to be expanded as needed. Clear references to Appendix materials are made at appropriate places in the chapters.

Index

The detailed, cross-referenced Index is provided to help locate specific material throughout each Volume of the manual.

The Update System

As revised or additional material is developed for the manual, it will be distributed to all manual holders. A transmittal form will accompany and explain these changes. The revised or additional pages will be identical to the original page, but with added identification at the foot.

TSCA Inspection Manual Volume One	Page	Revised (Date)

When revisions entail the addition of pages into the manual (i.e., when 3 pages in the manual are replaced by 5 pages), the additional pages will be numbered as follows:

Original numbering: 3-3, 3-4, 3-5, 3-6, etc.
Addition of pages: 3-3, 3-4, 3-5a, 3-5b, 3-5c, 3-6, etc.

This system will allow updates to be made quickly and easily and will avoid disruption of the chapters. New material will be numbered sequentially by chapter.

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Chapter One

TSCA Overview

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1

Introduction

The Toxic Substances Control Act, Public Law 94-469, was passed by Congress in 1976 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." The Act, referred to as "TSCA," is codified at 15 USC et seq. A copy of the Act is provided in this section of the manual.

Purpose

TSCA was designed to correct the lack of health and safety information on chemical substances and mixtures and to prevent unreasonable risk of injury to health or the environment. Under TSCA the term "chemical substance" means any organic or inorganic substance of a particular molecular identity, with certain specific exemptions such as pesticides and tobacco. The Act states that it is the policy of the United States that:

- Manufacturers must develop adequate data on the health and environmental effects of chemical substances;
- Chemical substances presenting health and environmental risks should be regulated; and
- Regulation should not create unnecessary barriers to technological innovation.

Scope

TSCA authorizes EPA to obtain from industry data on the production, use, health and environmental effects, and other matters concerning chemical substances and mixtures. If warranted, EPA may regulate the manufacture, processing, distribution in commerce, use, and disposal of a chemical substance.

Relationship to Other Laws

The Act directs the Administrator to use other laws administered by EPA, such as the Federal Water Pollution Control Act or the Clean Air Act, to protect against unreasonable risks unless the Administrator determines that it is in the public interest to protect against such risks under TSCA. The Administrator may also determine that an unreasonable risk presented by a chemical may be prevented or sufficiently reduced by action under a Federal law not administered by EPA.

EPA Authority and Responsibility

The Administrator of EPA is authorized to administer the Act in a reasonable and prudent manner and to consider the environmental, economic, and social impact of actions taken under TSCA. Within EPA, the Pesticides and Toxic Substances Enforcement Division (PTSED) of the Office of Enforcement is responsible for TSCA enforcement activities.

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TSCA Synopsis

TSCA Provisions

The principal sections of the Act authorize testing of chemicals, premanufacture notification for new substances or for significant new uses of existing substances, regulation of chemicals which pose unreasonable risk, and requirements for recordkeeping and reporting. The Act also defines TSCA's relationship with other Federal laws; authorizes research and development; and provides specific authorities for inspections and subpoenas, regulation of exports and imports, and imposition of prohibitions, penalties, and injunctive relief. It also provides for protection of confidential business information. These sections are briefly reviewed below. (A complete copy of the Act is provided in the Appendix to this Section.)

Testing of Chemicals (Section 4)

The Administrator may by regulation require testing of substances or mixtures suspected to be harmful. Testing and evaluation of such substances may be required to determine health and environmental effects such as carcinogenesis, mutagenesis, teratogenesis, chronic toxicity or behavioral disorders causing cumulative effects, or synergistic effects. The Agency sets and reviews standards for these tests. Manufacturers and processors may be required to conduct these tests and/or submit existing data.

Manufacturing and Processing Notices (Section 5)

Manufacturers must submit premanufacture notices to EPA 90 days before manufacturing any new chemical substance or beginning a significant new use of an existing substance that is not exempt. Any chemical not listed in the Inventory of Chemicals is considered "new" under this requirement. The Agency may limit the production or even ban a substance which EPA feels presents an unreasonable risk or for which there is not sufficient information to base a decision regarding environmental and/or health effects.

Regulation of Hazardous Chemicals (Section 6)

In cases of potential unreasonable risk of injury to health or the environment from chemical substances, the Administrator is required to apply by rule one or more of the following controls:

- Prohibit or limit manufacture and/or processing;
- Impose quality control procedures;
- Prohibit or limit distribution in commerce;
- Prohibit or limit use;
- Require warnings and instructions by labeling or other means;
- Regulate manner of disposal.

Imminent Hazards (Section 7)

EPA may ask the appropriate U.S. district court for a seizure and/or other immediate relief when a chemical substance is found to pose an imminent danger.

Reporting and Retention of Information (Section 8)

The Agency may require submission of records and maintenance of records and reports necessary for the effective implementation of the Act. Under the Act, EPA is required to compile and maintain an inventory of each chemical substance manufactured or processed in the United States. The initial Inventory of Chemical Substances was published June 1, 1979.

Section 8 also requires immediate reporting of any information indicating that a chemical poses a substantial risk to human health or the environment.

Relationship to Other Federal Laws (Section 9)

Environmental or health risks identified by EPA, but which may be prevented or reduced by action under a law not administered by EPA, are referred by report to the appropriate agency. Actions under TSCA are to be coordinated with other laws administered by EPA. The Agency is required to coordinate with other Federal agencies for purposes of TSCA enforcement.

Research and Development (Section 10)

EPA may, in consultation with other agencies, conduct or support research, development, and monitoring to carry out the purposes of the Act.

Inspections and Subpoenas (Section 11)

TSCA authorizes, upon presentation of proper credentials and notice, inspection of establishments, facilities, and premises where chemical substances are manufactured, processed, stored, held, or conveyed. Inspection extends to all things within the premises that bear on the Act. Financial, sales, pricing, personnel, or research data may not be inspected unless specified in the Notice of Inspection. EPA may subpoena witnesses and documents.

Exports and Imports (Sections 12 and 13)

TSCA authorizes the regulation of a chemical intended for export only if it presents an unreasonable risk to health or the environment of the United States. Records and reports requirements of Section 8 apply to exports. EPA is responsible for notifying the governments of importing countries of any regulatory restrictions.

Imported chemical substances are subject to all requirements of TSCA. The U.S. Treasury Department (U.S. Customs Service) is responsible for establishing, in cooperation with EPA, procedures to ensure compliance.

Disclosure of Data (Section 14)

Section 14 of TSCA provides for protection of any confidential business information obtained under the Act, including data obtained during an inspection. The manufacturer, processor, or distributor may designate information meeting specified criteria. Willful disclosure of confidential business information by EPA employees is subject to criminal penalty.

Prohibited Acts (Section 15)

It is unlawful to:

- Fail or refuse to comply with rules, orders, and/or requirements under Sections 4, 5, or 6.
- Use for commercial purposes substances manufactured in violation of Sections 5, 6, or 7.
- Fail or refuse to establish or maintain records or submit reports.

Civil and Criminal Penalties (Section 16)

Any person who violates Section 15 is subject to a civil penalty of up to $25,000 per day per violation. Any person who knowingly or willfully violates Section 15 may receive a criminal fine of up to $25,000 per day per violation and/or be imprisoned for up to one year.

Specific Enforcement and Seizure (Section 17)

EPA can request the U.S. district court to take action to compel compliance with or restrain a violation of any provision of the Act or rules under the Act.

EPA may also ask for seizure or condemnation of a chemical substance which has been manufactured, processed, or distributed in commerce in violation of the Act or rule or order under the Act.

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Glossary

Act	When used in this manual the word Act means the Toxic Substances Control Act (TSCA).
Administrator	This term means the Administrator of the Environmental Protection Agency, or any representative to whom the Administrator may delegate his authority to carry out his functions.
Agency	Unless otherwise specified, Agency means the United States Environmental Protection Agency (EPA).
Byproduct	A byproduct is a chemical substance produced without separate commercial intent during the manufacture or processing of another substance or mixture.
Chemical Substance	Under the Act, a chemical substance is any organic or inorganic substance or any combination of such substances occurring as a result of a chemical reaction or occurring in nature. The term does not include: • Any mixture; • Any pesticide (as defined in the Federal Insecticide, Fungicide, and Rodenticide Act) 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 such terms are defined in the Atomic Energy Act of 1954 and regulations issued under such Act);

- Any article the sale of which is subject to the tax imposed by Section 4181 of the Internal Revenue Code of 1954 (determined without regard to any exemptions from such tax provided by Section 4182 or 4221 or any other provision of such Code); and

- Any food, food additive, drug, cosmetic, or device (as such terms are defined in Section 201 of the Federal Food, Drug, and Cosmetic Act) when manufactured, processed, or distributed in commerce for use as a food, additive, drug, cosmetic, or device.

Commerce	In the Act, commerce refers to trade, traffic, transportation, or other commerce (1) between a place in a State and any place outside of such State, or (2) which affects trade, traffic, transportation, or commerce.
Complainant	In this manual, complainant refers to the Agency acting through any person authorized by the Administrator to issue a complaint to persons alleged to be in violation of the Act.
Disposal	In this manual, disposal means to intentionally or accidentally discard, throw away, eliminate, or otherwise complete or terminate the useful life of chemical substances.
Distribute in Commerce	This term refers to the sale, introduction into commerce, delivery, or holding of a substance, mixture, or article.
Documentary Sample	This term refers to documents which substantiate a suspected violation relating to a chemical substance. A documentary sample does not include a sample of the substance itself.
Duplicate Sample	In this manual, a duplicate sample is a sample taken at the request of a facility official that is in every respect the same as the official sample taken by the inspector.
Environment	The environment includes water, air, and land and the interrelationship which exists among and between water, air, and land, and all living things.

Facility — As defined in the manual, facility means any establishment, site, or other premises subject to TSCA enforcement activity.

Health Effects — Terms referring to the health effects of chemical substances are defined as follows:

- Behavioral Disorder refers to a disturbance of personal function resulting from exposure to a toxic substance.
- Carcinogenesis is the property of a substance which causes cancer.
- Cumulative Effect refers to the accumulation of a substance within a living organism and the increasingly pronounced effects with each exposure.
- Mutagenesis refers to the property of a substance that causes changes in the genetic structure of subsequent generations.
- Synergistic Effect refers to the coordination in action of the effects of a toxic substance.
- Teratogenesis refers to the property of a substance that causes malformations or serious deviations from the normal type in embryos or fetuses.

Injunction — In this manual, an injunction is a court order requiring a person to perform or to refrain from a specific action.

Inspector — An inspector is a representative of the Environmental Protection Agency authorized by the Administrator to conduct inspections, make investigations, collect documents and samples, and otherwise monitor compliance and enforce the Act.

Impurity — In the Act, impurity refers to a substance which is unintentionally present with another chemical substance.

Manufacture — Manufacture means to produce, manufacture, or import into the customs territory of the United States.

Mixture — A mixture is any combination of two or more chemical substances if the combination does not occur in nature and is not, in whole or in part, the result of a chemical reaction.

Person	In this manual, a person is defined as any natural or judicial person including any individual, corporation, partnership, or association; any State or political subdivision thereof; any interstate body; and any department, agency, or instrumentality of the Federal Government.
Physical Sample	Physical samples are samples that are representative of a chemical substance as drawn from a container or as contained in a medium such as soil or solvent. They are used to confirm the presence and concentration of a chemical substance.
Process	Process refers to the preparation of a chemical substance or mixture, after its maufacture, for distribution in commerce: • In the same or in a different physical state than that in which it was received by the processor; or • As part of an article containing the chemical substance or mixture.
Process for Commercial Purposes	As defined in the Act, this means to process (1) for distribution in commerce, including for test marketing purposes, or (2) for use as an intermediate.
Processor	A processor is any person who processes a chemical substance or mixture.
Respondant	In the Act, respondant refers to the person or company responding to a complaint issued by the Agency.
Seizure	In the Act, seizure is the condemnation and taking of any substance, mixture, or article manufactured, processed, or distributed in commerce in violation of the Act.
State	This term refers to any State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Canal Zone, American Samoa, the Northern Mariana Islands, or any other territory or possession of the United States.
Toxicity	Toxicity is the property of a chemical substance or mixture to cause any adverse physiological effects.
United States	When used in the geographic sense, this term means all of the States, territories, and possessions of the United States.
Viscosity	In this manual, viscosity refers to the thickness of a liquid as measured by its ability to flow freely.

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Toxic Substances Control Act

TOXIC SUBSTANCES CONTROL ACT, 1976: PUBLIC LAW 94-469

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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE AND TABLE OF CONTENTS.

This Act may be cited as the "Toxic Substances Control Act".

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SEC. 2. FINDINGS, POLICY, AND INTENT.

(a) FINDINGS.—The Congress finds that—

(1) human beings and the environment are being exposed each year to a large number of chemical substances and mixtures;

(2) among the many chemical substances and mixtures which are constantly being developed and produced, there are some whose manufacture, processing, distribution in commerce, use, or disposal may present an unreasonable risk of injury to health or the environment, and

(3) the effective regulation of interstate commerce in such chemical substances and mixtures also necessitates the regulation of intrastate commerce in such chemical substances and mixtures.

(b) POLICY.—It is the policy of the United States that—

(1) adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment and that the development of such data should be the responsibility of those who manufacture and those who process such chemical substances and mixtures,

(2) adequate authority should exist to regulate chemical substances and mixtures which present an unreasonable risk of injury to health or the environment, and to take action with respect to chemical substances and mixtures which are imminent hazards; and

(3) authority over chemical substances and mixtures should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation while fulfilling the primary purpose of this Act to assure that such innovation and commerce in such chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment.

(c) INTENT OF CONGRESS.—It is the intent of Congress that the Administrator shall carry out this Act in a reasonable and prudent manner, and that the Administrator shall consider the environmental, economic, and social impact of any action the Administrator takes or proposes to take under this Act.

SEC. 3. DEFINITIONS.

As used in this Act—

(1) the term "Administrator" means the Administrator of the Environmental Protection Agency.

(2)(A) Except as provided in subparagraph (B), the term "chemical substance" means any organic or inorganic substance of a particular molecular identity, including—

(i) any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and

(ii) any element or uncombined radical.

(B) Such term does not include—

(i) any mixture,

(ii) any pesticide (as defined in the Federal Insecticide, Fungicide, and Rodenticide Act) when manufactured, processed, or distributed in commerce for use as a pesticide,

(iii) tobacco or any tobacco product,

(iv) any source material, special nuclear material, or byproduct material (as such terms are defined in the Atomic Energy Act of 1954 and regulations issued under such Act),

(v) any article the sale of which is subject to the tax imposed by section 4181 of the Internal Revenue Code of 1954 (determined without regard to any exemptions from such tax provided by section 4182 or 4221 or any other provision of such Code), and

(vi) any food, food additive, drug, cosmetic, or device (as such terms are 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.

The term "food" as used in clause (vi) of this subparagraph includes poultry and poultry products (as defined in sections 4(e) and 4(f) of the Poultry Products Inspection Act), meat and meat food products (as defined in section 1(j) of the Federal Meat Inspection Act), and eggs and egg products (as defined in section 4 of the Egg Products Inspection Act).

(3) The term "commerce" means trade, traffic, transportation, or other commerce (A) between a place in a State and any place outside

of such State, or (B) which affects trade, traffic, transportation, or commerce described in clause (A).

(4) The terms "distribute in commerce" and "distribution in commerce" when used to describe an action taken with respect to a chemical substance or mixture or article containing a substance or mixture mean to sell, or the sale of, the substance, mixture, or article in commerce; to introduce or deliver for introduction into commerce, or the introduction or delivery for introduction into commerce of, the substance, mixture, or article; or to hold, or the holding of, the substance, mixture, or article after its introduction into commerce.

(5) The term "environment" includes water, air, and land and the interrelationship which exists among and between water, air, and land and all living things.

(6) The term "health and safety study" means any study of any effect of a chemical substance or mixture on health or the environment or on both, including underlying data and epidemiological studies, studies of occupational exposure to a chemical substance or mixture, toxicological, clinical, and ecological studies of a chemical substance or mixture, and any test performed pursuant to this Act.

(7) The term "manufacture" means to import into the customs territory of the United States (as defined in general headnote 2 of the Tariff Schedules of the United States), produce, or manufacture.

(8) The term "mixture" means any combination of two or more chemical substances if the combination does not occur in nature and is not, in whole or in part, the result of a chemical reaction; except that such term does include any combination which occurs, in whole or in part, as a result of a chemical reaction if none of the chemical substances comprising the combination is a new chemical substance and if the combination could have been manufactured for commercial purposes without a chemical reaction at the time the chemical substances comprising the combination were combined.

(9) The term "new chemical substance" means any chemical substance which is not included in the chemical substance list compiled and published under section 8(b)

(10) The term "process" means the preparation of a chemical substance or mixture, after its manufacture, for distribution in commerce—

(A) in the same form or physical state as, or in a different form or physical state from, that in which it was received by the person so preparing such substance or mixture, or

(B) as part of an article containing the chemical substance or mixture.

(11) The term "processor" means any person who processes a chemical substance or mixture.

(12) The term "standards for the development of test data" means a prescription of—

(A) the—

(i) health and environmental effects, and

(ii) information relating to toxicity, persistence, and other characteristics which affect health and the environment,

for which test data for a chemical substance or mixture are to be developed and any analysis that is to be performed on such data, and

(B) to the extent necessary to assure that data respecting such effects and characteristics are reliable and adequate—

(i) the manner in which such data are to be developed,

(ii) the specification of any test protocol or methodology to be employed in the development of such data, and

(iii) such other requirements as are necessary to provide such assurance.

(13) The term "State" means any State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Canal Zone, American Samoa, the Northern Mariana Islands, or any other territory or possession of the United States.

(14) The term "United States", when used in the geographic sense, means all of the States.

SEC. 4. TESTING OF CHEMICAL SUBSTANCES AND MIXTURES.

(a) TESTING REQUIREMENTS.—If the Administrator finds that—

(1)(A)(i) the manufacture, distribution in commerce, processing, use, or disposal of a chemical substance or mixture, or that any combination of such activities, may present an unreasonable risk of injury to health or the environment,

(ii) there are insufficient data and experience upon which the effects of such manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and

(iii) testing of such substance or mixture with respect to such effects is necessary to develop such data; or

(B)(i) a chemical substance or mixture is or will be produced in substantial quantities, and (I) it enters or may reasonably be anticipated to enter the environment in substantial quantities or (II) there is or may be significant or substantial human exposure to such substance or mixture,

(ii) there are insufficient data and experience upon which the effects of the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and

(iii) testing of such substance or mixture with respect to such effects is necessary to develop such data; and

(2) in the case of a mixture, the effects which the mixture's manufacture, distribution in commerce, processing, use, or disposal or any combination of such activities may have on health or the environment may not be reasonably and more efficiently determined or predicted by testing the chemical substances which comprise the mixture;

the Administrator shall by rule require that testing be conducted on such substance or mixture to develop data with respect to the health and environmental effects for which there is an insufficiency of data and experience and which are relevant to a determination that the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture, or that any combination of such activities, does or does not present an unreasonable risk of injury to health or the environment

(b)(1) TESTING REQUIREMENT RULE.—A rule under subsection (a) shall include—

(A) identification of the chemical substance or mixture for which testing is required under the rule,

(B) standards for the development of test data for such substance or mixture, and

(C) with respect to chemical substances which are not new chemical substances and to mixtures, a specification of the period (which period may not be of unreasonable duration) within which the persons required to conduct the testing shall submit to the Administrator data developed in accordance with the standards referred to in subparagraph (B).

In determining the standards and period to be included, pursuant to subparagraphs (B) and (C), in a rule under subsection (a), the Administrator's considerations shall include the relative costs of the various test protocols and methodologies which may be required under the rule and the reasonably foreseeable availability of the facilities and personnel needed to perform the testing required under the rule. Any such rule may require the submission to the Administrator of preliminary data during the period prescribed under subparagraph (C).

(2)(A) The health and environmental effects for which standards for the development of test data may be prescribed include carcinogenesis, mutagenesis, teratogenesis, behavioral disorders, cumulative or synergistic effects, and any other effect which may present an unreasonable risk of injury to health or the environment. The characteristics of chemical substances and mixtures for which such standards may be prescribed include persistence, acute toxicity, subacute toxicity, chronic toxicity, and any other characteristic which may present such a risk. The methodologies that may be prescribed in such standards include epidemiologic studies, serial or hierarchical tests, in vitro tests, and whole animal tests, except that before prescribing epidemiologic studies of employees, the Administrator shall consult with the Director of the National Institute for Occupational Safety and Health.

(B) From time to time, but not less than once each 12 months, the Administrator shall review the adequacy of the standards for development of data prescribed in rules under subsection (a) and shall, if necessary, institute proceedings to make appropriate revisions of such standards.

(3)(A) A rule under subsection (a) respecting a chemical substance or mixture shall require the persons described in subparagraph (B) to conduct tests and submit data to the Administrator on such substance or mixture, except that the Administrator may permit two or more of such persons to designate one such person or a qualified third party to conduct such tests and submit such data on behalf of the persons making the designation.

(B) The following persons shall be required to conduct tests and submit data on a chemical substance or mixture subject to a rule under subsection (a):

(i) Each person who manufactures or intends to manufacture such substance or mixture if the Administrator makes a finding

described in subsection (a)(1)(A)(ii) or (a)(1)(B)(ii) with respect to the manufacture of such substance or mixture.

(ii) Each person who processes or intends to process such substance or mixture if the Administrator makes a finding described in subsection (a)(1)(A)(ii) or (a)(1)(B)(ii) with respect to the processing of such substance or mixture.

(iii) Each person who manufactures or processes or intends to manufacture or process such substance or mixture if the Administrator makes a finding described in subsection (a)(1)(A)(ii) or (a)(1)(B)(ii) with respect to the distribution in commerce, use, or disposal of such substance or mixture

(4) Any rule under subsection (a) requiring the testing of and submission of data for a particular chemical substance or mixture shall expire at the end of the reimbursement period (as defined in subsection (c)(3)(B)) which is applicable to test data for such substance or mixture unless the Administrator repeals the rule before such date; and a rule under subsection (a) requiring the testing of and submission of data for a category of chemical substances or mixtures shall expire with respect to a chemical substance or mixture included in the category at the end of the reimbursement period (as so defined) which is applicable to test data for such substance or mixture unless the Administrator before such date repeals the application of the rule to such substance or mixture or repeals the rule.

(5) Rules issued under subsection (a) (and any substantive amendment thereto or repeal thereof) shall be promulgated pursuant to section 553 of title 5, United States Code, except that (A) the Administrator shall give interested persons an opportunity for the oral presentation of data, views, or arguments, in addition to an opportunity to make written submissions, (B) a transcript shall be made of any oral presentation, and (C) the Administrator shall make and publish with the rule the findings described in paragraph (1)(A) or (1)(B) of subsection (a) and, in the case of a rule respecting a mixture, the finding described in paragraph (2) of such subsection.

(c) EXEMPTION.—(1) Any person required by a rule under subsection (a) to conduct tests and submit data on a chemical substance or mixture may apply to the Administrator (in such form and manner as the Administrator shall prescribe) for an exemption from such requirement.

(2) If, upon receipt of an application under paragraph (1), the Administrator determines that—

(A) the chemical substance or mixture with respect to which such application was submitted is equivalent to a chemical substance or mixture for which data has been submitted to the Administrator in accordance with a rule under subsection (a) or for which data is being developed pursuant to such a rule, and

(B) submission of data by the applicant on such substance or mixture would be duplicative of data which has been submitted to the Administrator in accordance with such rule or which is being developed pursuant to such rule,

the Administrator shall exempt, in accordance with paragraph (3) or (4), the applicant from conducting tests and submitting data on such substance or mixture under the rule with respect to which such application was submitted.

(3)(A) If the exemption under paragraph (2) of any person from the requirement to conduct tests and submit test data on a chemical substance or mixture is granted on the basis of the existence of previously submitted test data and if such exemption is granted during the reimbursement period for such test data (as prescribed by subparagraph (B)), then (unless such person and the persons referred to in clauses (i) and (ii) agree on the amount and method of reimbursement) the Administrator shall order the person granted the exemption to provide fair and equitable reimbursement (in an amount determined under rules of the Administrator)—

(i) to the person who previously submitted such test data, for a portion of the costs incurred by such person in complying with the requirement to submit such data, and

(ii) to any other person who has been required under this subparagraph to contribute with respect to such costs, for a portion of the amount such person was required to contribute.

In promulgating rules for the determination of fair and equitable reimbursement to the persons described in clauses (i) and (ii) for costs incurred with respect to a chemical substance or mixture, the Administrator shall, after consultation with the Attorney General and the Federal Trade Commission, consider all relevant factors, including the effect on the competitive position of the person required to provide reimbursement in relation to the person to be reimbursed and the share of the market for such substance or mixture of the person required to provide reimbursement in relation to the share of such market of the persons to be reimbursed. An order under this subparagraph shall, for purposes of judicial review, be considered final agency action.

(B) For purposes of subparagraph (A), the reimbursement period for any test data for a chemical substance or mixture is a period—

(i) beginning on the date such data is submitted in accordance with a rule promulgated under subsection (a), and

(ii) ending—

(I) five years after the date referred to in clause (i), or

(II) at the expiration of a period which begins on the date referred to in clause (i) and which is equal to the period which the Administrator determines was necessary to develop such data,

whichever is later.

(4)(A) If the exemption under paragraph (2) of any person from the requirement to conduct tests and submit test data on a chemical substance or mixture is granted on the basis of the fact that test data is being developed by one or more persons pursuant to a rule promulgated under subsection (a), then (unless such person and the persons referred to in clauses (i) and (ii) agree on the amount and method of reimbursement) the Administrator shall order the person granted the exemption to provide fair and equitable reimbursement (in an amount determined under rules of the Administrator)—

(i) to each such person who is developing such test data, for a portion of the costs incurred by each such person in complying with such rule, and

(ii) to any other person who has been required under this subparagraph to contribute with respect to the costs of complying with such rule, for a portion of the amount such person was required to contribute.

In promulgating rules for the determination of fair and equitable reimbursement to the persons described in clauses (i) and (ii) for costs incurred with respect to a chemical substance or mixture, the Administrator shall, after consultation with the Attorney General and the Federal Trade Commission, consider the factors described in the second sentence of paragraph (3)(A). An order under this subparagraph shall, for purposes of judicial review, be considered final agency action.

(B) If any exemption is granted under paragraph (2) on the basis of the fact that one or more persons are developing test data pursuant to a rule promulgated under subsection (a) and if after such exemption is granted the Administrator determines that no such person has complied with such rule, the Administrator shall (i) after providing written notice to the person who holds such exemption and an opportunity for a hearing, by order terminate such exemption, and (ii) notify in writing such person of the requirements of the rule with respect to which such exemption was granted.

(d) NOTICE.—Upon the receipt of any test data pursuant to a rule under subsection (a), the Administrator shall publish a notice of the receipt of such data in the Federal Register within 15 days of its receipt. Subject to section 14, each such notice shall (1) identify the chemical substance or mixture for which data have been received, (2) list the uses or intended uses of such substance or mixture and the information required by the applicable standards for the development of test data; and (3) describe the nature of the test data developed Except as otherwise provided in section 14, such data shall be made available by the Administrator for examination by any person

(e) PRIORITY LIST.—(1)(A) There is established a committee to make recommendations to the Administrator respecting the chemical substances and mixtures to which the Administrator should give priority consideration for the promulgation of a rule under subsection (a) In making such a recommendation with respect to any chemical substance or mixture, the committee shall consider all relevant factors, including—

(i) the quantities in which the substance or mixture is or will be manufactured,

(ii) the quantities in which the substance or mixture enters or will enter the environment,

(iii) the number of individuals who are or will be exposed to the substance or mixture in their places of employment and the duration of such exposure,

(iv) the extent to which human beings are or will be exposed to the substance or mixture,

(v) the extent to which the substance or mixture is closely related to a chemical substance or mixture which is known to present an unreasonable risk of injury to health or the environment,

(vi) the existence of data concerning the effects of the substance

or mixture on health or the environment,

(vii) the extent to which testing of the substance or mixture may result in the development of data upon which the effects of the substance or mixture on health or the environment can reasonably be determined or predicted, and

(viii) the reasonably foreseeable availability of facilities and personnel for performing testing on the substance or mixture.

The recommendations of the committee shall be in the form of a list of chemical substances and mixtures which shall be set forth, either by individual substance or mixture or by groups of substances or mixtures, in the order in which the committee determines the Administrator should take action under subsection (a) with respect to the substances and mixtures. In establishing such list, the committee shall give priority attention to those chemical substances and mixtures which are known to cause or contribute to or which are suspected of causing or contributing to cancer, gene mutations, or birth defects. The committee shall designate chemical substances and mixtures on the list with respect to which the committee determines the Administrator should, within 12 months of the date on which such substances and mixtures are first designated, initiate a proceeding under subsection (a) The total number of chemical substances and mixtures on the list which are designated under the preceding sentence may not, at any time, exceed 50.

(B) As soon as practicable but not later than nine months after the effective date of this Act, the committee shall publish in the Federal Register and transmit to the Administrator the list and designations required by subparagraph (A) together with the reasons for the committee's inclusion of each chemical substance or mixture on the list. At least every six months after the date of the transmission to the Administrator of the list pursuant to the preceeding sentence, the committee shall make such revisions in the list as it determines to be necessary and shall transmit them to the Administrator together with the committee's reasons for the revisions Upon receipt of any such revision, the Administrator shall publish in the Federal Register the list with such revision, the reasons for such revision, and the designations made under subparagraph (A). The Administrator shall provide reasonable opportunity to any interested person to file with the Administrator written comments on the committee's list, any revision of such list by the committee, and designations made by the committee, and shall make such comments available to the public. Within the 12-month period beginning on the date of the first inclusion on the list of a chemical substance or mixture designated by the committee under subparagraph (A) the Administrator shall with respect to such chemical substance or mixture either initiate a rulemaking proceeding under subsection (a) or if such a proceeding is not initiated within such period, publish in the Federal Register the Administrator's reason for not initiating such a proceeding.

(2)(A) The committee established by paragraph (1)(A) shall consist of eight members as follows.

(i) One member appointed by the Administrator from the Environmental Protection Agency.

(ii) One member appointed by the Secretary of Labor from officers or employees of the Department of Labor engaged in the Secretary's activities under the Occupational Safety and Health Act of 1970

(iii) One member appointed by the Chairman of the Council on Environmental Quality from the Council or its officers or employees.

(iv) One member appointed by the Director of the National Institute for Occupational Safety and Health from officers or employees of the Institute.

(v) One member appointed by the Director of the National Institute of Environmental Health Sciences from officers or employees of the Institute.

(vi) One member appointed by the Director of the National Cancer Institute from officers or employees of the Institute.

(vii) One member appointed by the Director of the National Science Foundation from officers or employees of the Foundation

(viii) One member appointed by the Secretary of Commerce from officers or employees of the Department of Commerce.

(B)(i) An appointed member may designate an individual to serve on the committee on the member's behalf Such a designation may be made only with the approval of the applicable appointing authority and only if the individual is from the entity from which the member was appointed.

(ii) No individual may serve as a member of the committee for more than four years in the aggregate. If any member of the committee leaves the entity from which the member was appointed, such member may not continue as a member of the committee, and the member's position shall be considered to be vacant. A vacancy in the committee shall be filled in the same manner in which the original appointment was made

(iii) Initial appointments to the committee shall be made not later than the 60th day after the effective date of this Act. Not later than the 90th day after such date the members of the committee shall hold a meeting for the selection of a chairperson from among their number.

(C)(i) No member of the committee, or designee of such member, shall accept employment or compensation from any person subject to any requirement of this Act or of any rule promulgated or order issued thereunder, for a period of at least 12 months after termination of service on the committee.

(ii) No person, while serving as a member of the committee, or designee of such member, may own any stocks or bonds, or have any pecuniary interest, of substantial value in any person engaged in the manufacture, processing, or distribution in commerce of any chemical substance or mixture subject to any requirement of this Act or of any rule promulgated or order issued thereunder.

(iii) The Administrator, acting through attorneys of the Environmental Protection Agency, or the Attorney General may bring an action in the appropriate district court of the United States to restrain any violation of this subparagraph.

(D) The Administrator shall provide the committee such administrative support services as may be necessary to enable the committee to carry out its function under this subsection.

(f) REQUIRED ACTIONS.—Upon the receipt of—

(1) any test data required to be submitted under this Act, or

(2) any other information available to the Administrator,

which indicates to the Administrator that there may be a reasonable basis to conclude that a chemical substance or mixture presents or will present a significant risk of serious or widespread harm to human beings from cancer, gene mutations, or birth defects, the Administrator shall, within the 180-day period beginning on the date of the receipt of such data or information, initiate appropriate action under section 5, 6, or 7 to prevent or reduce to a sufficient extent such risk or publish in the Federal Register a finding that such risk is not unreasonable. For good cause shown the Administrator may extend such period for an additional period of not more than 90 days. The Administrator shall publish in the Federal Register notice of any such extension and the reasons therefor. A finding by the Administrator that a risk is not unreasonable shall be considered agency action for purposes of judicial review under chapter 7 of title 5, United States Code. This subsection shall not take effect until two years after the effective date of this Act.

(g) PETITION FOR STANDARDS FOR THE DEVELOPMENT OF TEST DATA.—A person intending to manufacture or process a chemical substance for which notice is required under section 5(a) and who is not required under a rule under subsection (a) to conduct tests and submit data on such substance may petition the Administrator to prescribe standards for the development of test data for such substance. The Administrator shall by order either grant or deny any such petition within 60 days of its receipt. If the petition is granted, the Administrator shall prescribe such standards for such substance within 75 days of the date the petition is granted. If the petition is denied, the Administrator shall publish, subject to section 14, in the Federal Register the reasons for such denial

SEC. 5. MANUFACTURING AND PROCESSING NOTICES.

(a) IN GENERAL.—(1) Except as provided in subsection (h), no person may—

(A) manufacture a new chemical substance on or after the 30th day after the date on which the Administrator first publishes the list required by section 8(b), or

(B) manufacture or process any chemical substance for a use which the Administrator has determined, in accordance with paragraph (2), is a significant new use,

unless such person submits to the Administrator, at least 90 days before such manufacture or processing, a notice, in accordance with subsection (d), of such person's intention to manufacture or process such substance and such person complies with any applicable requirement of subsection (b).

(2) A determination by the Administrator that a use of a chemical substance is a significant new use with respect to which notification is required under paragraph (1) shall be made by a rule promulgated after a consideration of all relevant factors, including—

(A) the projected volume of manufacturing and processing of a chemical substance,

(B) the extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance,

(C) the extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance, and

(D) the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

(b) SUBMISSION OF TEST DATA.—(1)(A) If (i) a person is required by subsection (a)(1) to submit a notice to the Administrator before beginning the manufacture or processing of a chemical substance, and (ii) such person is required to submit test data for such substance pursuant to a rule promulgated under section 4 before the submission of such notice, such person shall submit to the Administrator such data in accordance with such rule at the time notice is submitted in accordance with subsection (a)(1).

(B) If—

(i) a person is required by subsection (a)(1) to submit a notice to the Administrator, and

(ii) such person has been granted an exemption under section 4(c) from the requirements of a rule promulgated under section 4 before the submission of such notice,

such person may not, before the expiration of the 90 day period which begins on the date of the submission in accordance with such rule of the test data the submission or development of which was the basis for the exemption, manufacture such substance if such person is subject to subsection (a)(1)(A) or manufacture or process such substance for a significant new use if the person is subject to subsection (a)(1)(B).

(2)(A) If a person—

(i) is required by subsection (a)(1) to submit a notice to the Administrator before beginning the manufacture or processing of a chemical substance listed under paragraph (4), and

(ii) is not required by a rule promulgated under section 4 before the submission of such notice to submit test data for such substance,

such person shall submit to the Administrator data prescribed by subparagraph (B) at the time notice is submitted in accordance with subsection (a)(1).

(B) Data submitted pursuant to subparagraph (A) shall be data which the person submitting the data believes show that—

(i) in the case of a substance with respect to which notice is required under subsection (a)(1)(A), the manufacture, processing, distribution in commerce, use, and disposal of the chemical substance or any combination of such activities will not present an unreasonable risk of injury to health or the environment, or

(ii) in the case of a chemical substance with respect to which notice is required under subsection (a)(1)(B), the intended significant new use of the chemical substance will not present an unreasonable risk of injury to health or the environment.

(3) Data submitted under paragraph (1) or (2) shall be made available, subject to section 14, for examination by interested persons.

(4)(A)(i) The Administrator may, by rule, compile and keep current a list of chemical substances with respect to which the Administrator finds that the manufacture, processing, distribution in commerce, use, or disposal, or any combination of such activities, presents or may present an unreasonable risk of injury to health or the environment.

(ii) In making a finding under clause (i) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or any combination of such activities presents or may present an unreasonable risk of injury to health or the environment, the Administrator shall consider all relevant factors, including—

(I) the effects of the chemical substance on health and the magnitude of human exposure to such substance; and

(II) the effects of the chemical substance on the environment and the magnitude of environmental exposure to such substance.

(B) The Administrator shall, in prescribing a rule under subparagraph (A) which lists any chemical substance, identify those uses, if any, which the Administrator determines, by rule under subsection (a)(2), would constitute a significant new use of such substance.

(C) Any rule under subparagraph (A), and any substantive amendment or repeal of such a rule, shall be promulgated pursuant to the procedures specified in section 553 of title 5, United States Code, except that (i) the Administrator shall give interested persons an opportunity for the oral presentation of data, views, or arguments, in addition to an opportunity to make written submissions, (ii) a transcript shall be kept of any oral presentation, and (iii) the Administrator shall make and publish with the rule the finding described in subparagraph (A).

(c) EXTENSION OF NOTICE PERIOD.—The Administrator may for good cause extend for additional periods (not to exceed in the aggregate 90 days) the period, prescribed by subsection (a) or (b) before which the manufacturing or processing of a chemical substance subject to such subsection may begin. Subject to section 14, such an extension and the reasons therefor shall be published in the Federal Register and shall constitute a final agency action subject to judicial review.

(d) CONTENT OF NOTICE, PUBLICATIONS IN THE FEDERAL REGISTER.—(1) The notice required by subsection (a) shall include—

(A) insofar as known to the person submitting the notice or insofar as reasonably ascertainable, the information described in subparagraphs (A), (B), (C), (D), (F), and (G) of section 8(a)(2), and

(B) in such form and manner as the Administrator may prescribe, any test data in the possession or control of the person giving such notice which are related to the effect of any manufacture, processing, distribution in commerce, use, or disposal of such substance or any article containing such substance, or of any combination of such activities, on health or the environment, and

(C) a description of any other data concerning the environmental and health effects of such substance, insofar as known to the person making the notice or insofar as reasonably ascertainable.

Such a notice shall be made available, subject to section 14, for examination by interested persons.

(2) Subject to section 14, not later than five days (excluding Saturdays, Sundays and legal holidays) after the date of the receipt of a notice under subsection (a) or of data under subsection (b), the Administrator shall publish in the Federal Register a notice which—

(A) identifies the chemical substance for which notice or data has been received;

(B) lists the uses or intended uses of such substance; and

(C) in the case of the receipt of data under subsection (b), describes the nature of the tests performed on such substance and any data which was developed pursuant to subsection (b) or a rule under section 4.

A notice under this paragraph respecting a chemical substance shall identify the chemical substance by generic class unless the Administrator determines that more specific identification is required in the public interest.

(3) At the beginning of each month the Administrator shall publish a list in the Federal Register of (A) each chemical substance for which notice has been received under subsection (a) and for which the notification period prescribed by subsection (a), (b), or (c) has not expired, and (B) each chemical substance for which such notification period has expired since the last publication in the Federal Register of such list.

(e) REGULATION PENDING DEVELOPMENT OF INFORMATION.—(1)(A) If the Administrator determines that—

(i) the information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of a chemical substance with respect to which notice is required by subsection (a); and

(ii)(I) in the absence of sufficient information to permit the Administrator to make such an evaluation, the manufacture, processing, distribution in commerce, use, or disposal of such substance, or any combination of such activities, may present an unreasonable risk of injury to health or the environment, or

(II) such substance is or will be produced in substantial quantities, and such substance either enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the substance,

the Administrator may issue a proposed order, to take effect on the expiration of the notification period applicable to the manufacturing or processing of such substance under subsection (a), (b), or (c), to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of such substance or to prohibit or limit any combination of such activities.

(B) A proposed order may not be issued under subparagraph (A) respecting a chemical substance (i) later than 45 days before the expiration of the notification period applicable to the manufacture or processing of such substance under subsection (a), (b), or (c), and (ii) unless the Administrator has, on or before the issuance of the

proposed order, notified, in writing, each manufacturer or processor, as the case may be, of such substance of the determination which underlies such order.

(C) If a manufacturer or processor of a chemical substance to be subject to a proposed order issued under subparagraph (A) files with the Administrator (within the 30-day period beginning on the date such manufacturer or processor received the notice required by subparagraph (B)(ii)) objections specifying with particularity the provisions of the order deemed objectionable and stating the grounds therefor, the proposed order shall not take effect

(2)(A)(i) Except as provided in clause (ii), if with respect to a chemical substance with respect to which notice is required by subsection (a), the Administrator makes the determination described in paragraph (1)(A) and if—

(I) the Administrator does not issue a proposed order under paragraph (1) respecting such substance, or

(II) the Administrator issues such an order respecting such substance but such order does not take effect because objections were filed under paragraph (1)(C) with respect to it,

the Administrator, through attorneys of the Environmental Protection Agency, shall apply to the United States District Court for the District of Columbia or the United States district court for the judicial district in which the manufacturer or processor, as the case may be, of such substance is found, resides, or transacts business for an injunction to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of such substance (or to prohibit or limit any combination of such activities).

(ii) If the Administrator issues a proposed order under paragraph (1)(A) respecting a chemical substance but such order does not take effect because objections have been filed under paragraph (1)(C) with respect to it, the Administrator is not required to apply for an injunction under clause (i) respecting such substance if the Administrator determines, on the basis of such objections, that the determinations under paragraph (1)(A) may not be made

(B) A district court of the United States which receives an application under subparagraph (A)(i) for an injunction respecting a chemical substance shall issue such injunction if the court finds that—

(i) the information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of a chemical substance with respect to which notice is required by subsection (a), and

(ii)(I) in the absence of sufficient information to permit the Administrator to make such an evaluation, the manufacture, processing, distribution in commerce, use, or disposal of such substance, or any combination of such activities, may present an unreasonable risk of injury to health or the environment, or

(II) such substance is or will be produced in substantial quantities, and such substance either enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the substance

(C) Pending the completion of a proceeding for the issuance of an injunction under subparagraph (B) respecting a chemical substance, the court may, upon application of the Administrator made through attorneys of the Environmental Protection Agency, issue a temporary restraining order or a preliminary injunction to prohibit the manufacture, processing, distribution in commerce, use, or disposal of such a substance (or any combination of such activities) if the court finds that the notification period applicable under subsection (a), (b), or (c) to the manufacturing or processing of such substance may expire before such proceeding can be completed

(D) After the submission to the Administrator of test data sufficient to evaluate the health and environmental effects of a chemical substance subject to an injunction issued under subparagraph (B) and the evaluation of such data by the Administrator, the district court of the United States which issued such injunction shall, upon petition, dissolve the injunction unless the Administrator has initiated a proceeding for the issuance of a rule under section 6(a) respecting the substance. If such a proceeding has been initiated, such court shall continue the injunction in effect until the effective date of the rule promulgated in such proceeding or, if such proceeding is terminated without the promulgation of a rule, upon the termination of the proceeding, whichever occurs first.

(f) PROTECTION AGAINST UNREASONABLE RISKS.—(1) If the Administrator finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance with respect to which notice is required by subsection (a), or that any combination of such activities, presents or will present an unreasonable risk of injury to health or environment before a rule promulgated under section 6 can protect against such risk, the Administrator shall, before the expiration of the notification period applicable under subsection (a), (b), or (c) to the manufacturing or processing of such substance, take the action authorized by paragraph (2) or (3) to the extent necessary to protect against such risk.

(2) The Administrator may issue a proposed rule under section 6(a) to apply to a chemical substance with respect to which a finding was made under paragraph (1)—

(A) a requirement limiting the amount of such substance which may be manufactured, processed, or distributed in commerce,

(B) a requirement described in paragraph (2), (3), (4), (5), (6), or (7) of section 6(a), or

(C) any combination of the requirements referred to in subparagraph (B).

Such a proposed rule shall be effective upon its publication in the Federal Register Section 6(d)(2)(B) shall apply with respect to such rule.

(3)(A) The Administrator may—

(i) issue a proposed order to prohibit the manufacture, processing, or distribution in commerce of a substance with respect to which a finding was made under paragraph (1), or

(ii) apply, through attorneys of the Environmental Protection Agency, to the United States District Court for the District of Columbia or the United States district court for the judicial district in which the manufacturer, or processor, as the case may be, of such substance, is found, resides, or transacts business for an injunction to prohibit the manufacture, processing, or distribution in commerce of such substance

A proposed order issued under clause (i) respecting a chemical substance shall take effect on the expiration of the notification period applicable under subsection (a), (b), or (c) to the manufacture or processing of such substance

(B) If the district court of the United States to which an application has been made under subparagraph (A)(ii) finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance with respect to which such application was made, or that any combination of such activities, presents or will present an unreasonable risk of injury to health or the environment before a rule promulgated under section 6 can protect against such risk, the court shall issue an injunction to prohibit the manufacture, processing, or distribution in commerce of such substance or to prohibit any combination of such activities

(C) The provisions of subparagraphs (B) and (C) of subsection (e)(1) shall apply with respect to an order issued under clause (i) of subparagraph (A), and the provisions of subparagraph (C) of subsection (e)(2) shall apply with respect to an injunction issued under subparagraph (B)

(D) If the Administrator issues an order pursuant to subparagraph (A)(i) respecting a chemical substance and objections are filed in accordance with subsection (e)(1)(C), the Administrator shall seek an injunction under subparagraph (A)(ii) respecting such substance unless the Administrator determines, on the basis of such objections, that such substance does not or will not present an unreasonable risk of injury to health or the environment

(g) STATEMENT OF REASONS FOR NOT TAKING ACTION.—If the Administrator has not initiated any action under this section or section 6 or 7 to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance, with respect to which notification or data is required by subsection (a)(1)(B) or (b), before the expiration of the notification period applicable to the manufacturing or processing of such substance, the Administrator shall publish a statement of the Administrator's reasons for not initiating such action. Such a statement shall be published in the Federal Register before the expiration of such period. Publication of such statement in accordance with the preceding sentence is not a prerequisite to the manufacturing or processing of the substance with respect to which the statement is to be published

(h) EXEMPTIONS.—(1) The Administrator may, upon application, exempt any person from any requirement of subsection (a) or (b) to permit such person to manufacture or process a chemical substance for test marketing purposes—

(A) upon a showing by such person satisfactory to the Administrator that the manufacture, processing, distribution in commerce, use, and disposal of such substance, and that any combination of such activities, for such purposes will not present any

unreasonable risk of injury to health or the environment, and

(B) under such restrictions as the Administrator considers appropriate.

(2)(A) The Administrator may, upon application, exempt any person from the requirement of subsection (b)(2) to submit data for a chemical substance If, upon receipt of an application under the preceding sentence, the Administrator determines that—

(i) the chemical substance with respect to which such application was submitted is equivalent to a chemical substance for which data has been submitted to the Administrator as required by subsection (b)(2), and

(ii) submission of data by the applicant on such substance would be duplicative of data which has been submitted to the Administrator in accordance with such subsection.

the Administrator shall exempt the applicant from the requirement to submit such data on such substance No exemption which is granted under this subparagraph with respect to the submission of data for a chemical substance may take effect before the beginning of the reimbursement period applicable to such data.

(B) If the Administrator exempts any person, under subparagraph (A), from submitting data required under subsection (b)(2) for a chemical substance because of the existence of previously submitted data and if such exemption is granted during the reimbursement period for such data, then (unless such person and the persons referred to in clauses (i) and (ii) agree on the amount and method of reimbursement) the Administrator shall order the person granted the exemption to provide fair and equitable reimbursement (in an amount determined under rules of the Administrator)—

(i) to the person who previously submitted the data on which the exemption was based, for a portion of the costs incurred by such person in complying with the requirement under subsection (b)(2) to submit such data, and

(ii) to any other person who has been required under this subparagraph to contribute with respect to such costs, for a portion of the amount such person was required to contribute

In promulgating rules for the determination of fair and equitable reimbursement to the persons described in clauses (i) and (ii) for costs incurred with respect to a chemical substance, the Administrator shall, after consultation with the Attorney General and the Federal Trade Commission, consider all relevant factors, including the effect on the competitive position of the person required to provide reimbursement in relation to the persons to be reimbursed and the share of the market for such substance of the person required to provide reimbursement in relation to the share of such market of the persons to be reimbursed For purposes of judicial review, an order under this subparagraph shall be considered final agency action.

(C) For purposes of this paragraph, the reimbursement period for any previously submitted data for a chemical substance is a period—

(i) beginning on the date of the termination of the prohibition, imposed under this section, on the manufacture or processing of such substance by the person who submitted such data to the Administrator, and

(ii) ending—

(I) five years after the date referred to in clause (i), or

(II) at the expiration of a period which begins on the date referred to in clause (i) and is equal to the period which the Administrator determines was necessary to develop such data,

whichever is later

(3) The requirements of subsections (a) and (b) do not apply with respect to the manufacturing or processing of any chemical substance which is manufactured or processed, or proposed to be manufactured or processed, only in small quantities (as defined by the Administrator by rule) solely for purposes of—

(A) scientific experimentation or analysis, or

(B) chemical research on, or analysis of such substance or another substance, including such research or analysis for the development of a product,

if all persons engaged in such experimentation, research, or analysis for a manufacturer or processor are notified (in such form and manner as the Administrator may prescribe) of any risk to health which the manufacturer, processor, or the Administrator has reason to believe may be associated with such chemical substance.

(4) The Administrator may, upon application and by rule, exempt the manufacturer of any new chemical substance from all or part of the requirements of this section if the Administrator determines that the manufacture, processing, distribution in commerce, use, or disposal of such chemical substance, or that any combination of such activities, will not present an unreasonable risk of injury to health or the environment. A rule promulgated under this paragraph (and any substantive amendment to, or repeal of, such a rule) shall be promulgated in accordance with paragraphs (2) and (3) of section 6(c).

(5) The Administrator may, upon application, make the requirements of subsections (a) and (b) inapplicable with respect to the manufacturing or processing of any chemical substance (A) which 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

(6) Immediately upon receipt of an application under paragraph (1) or (5) the Administrator shall publish in the Federal Register notice of the receipt of such application The Administrator shall give interested persons an opportunity to comment upon any such application and shall, within 45 days of its receipt, either approve or deny the application The Administrator shall publish in the Federal Register notice of the approval or denial of such an application.

(i) DEFINITION.—For purposes of this section, the terms "manufacture" and "process" mean manufacturing or processing for commercial purposes

SEC. 6. REGULATION OF HAZARDOUS CHEMICAL SUBSTANCES AND MIXTURES.

(a) SCOPE OF REGULATION.—If the Administrator finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents or will present an unreasonable risk of injury to health or the environment, the Administrator shall by rule apply one or more of the following requirements to such substance or mixture to the extent necessary to protect adequately against such risk using the least burdensome requirements

(1) A requirement (A) prohibiting the manufacturing, processing, or distribution in commerce of such substance or mixture, or (B) limiting the amount of such substance or mixture which may be manufactured, processed, or distributed in commerce.

(2) A requirement—

(A) prohibiting the manufacture, processing, or distribution in commerce of such substance or mixture for (i) a particular use or (ii) a particular use in a concentration in excess of a level specified by the Administrator in the rule imposing the requirement, or

(B) limiting the amount of such substance or mixture which may be manufactured, processed, or distributed in commerce for (i) a particular use or (ii) a particular use in a concentration in excess of a level specified by the Administrator in the rule imposing the requirement

(3) A requirement that such substance or mixture or any article containing such substance or mixture be marked with or accompanied by clear and adequate warnings and instructions with respect to its use, distribution in commerce, or disposal or with respect to any combination of such activities. The form and content of such warnings and instructions shall be prescribed by the Administrator.

(4) A requirement that manufacturers and processors of such substance or mixture make and retain records of the processes used to manufacture or process such substance or mixture and monitor or conduct tests which are reasonable and necessary to assure compliance with the requirements of any rule applicable under this subsection.

(5) A requirement prohibiting or otherwise regulating any manner or method of commercial use of such substance or mixture

(6)(A) A requirement prohibiting or otherwise regulating any manner or method of disposal of such substance or mixture, or of any article containing such substance or mixture, by its manufacturer or processor or by any other person who uses, or disposes of, it for commercial purposes.

(B) A requirement under subparagraph (A) may not require any person to take any action which would be in violation of any law or requirement of, or in effect for, a State or political subdivision, and shall require each person subject to it to notify each State and political subdivision in which a required disposal may occur of such disposal

(7) A requirement directing manufacturers or processors of such substance or mixture (A) to give notice of such unreasonable

risk of injury to distributors in commerce of such substance or mixture and, to the extent reasonably ascertainable, to other persons in possession of such substance or mixture or exposed to such substance or mixture, (B) to give public notice of such risk of injury, and (C) to replace or repurchase such substance or mixture as elected by the person to which the requirement is directed.

Any requirement (or combination of requirements) imposed under this subsection may be limited in application to specified geographic areas.

(b) QUALITY CONTROL.—If the Administrator has a reasonable basis to conclude that a particular manufacturer or processor is manufacturing or processing a chemical substance or mixture in a manner which unintentionally causes the chemical substance or mixture to present or which will cause it to present an unreasonable risk of injury to health or the environment—

(1) the Administrator may by order require such manufacturer or processor to submit a description of the relevant quality control procedures followed in the manufacturing or processing of such chemical substance or mixture; and

(2) if the Administrator determines—

(A) that such quality control procedures are inadequate to prevent the chemical substance or mixture from presenting such risk of injury, the Administrator may order the manufacturer or processor to revise such quality control procedures to the extent necessary to remedy such inadequacy; or

(B) that the use of such quality control procedures has resulted in the distribution in commerce of chemical substances or mixtures which present an unreasonable risk of injury to health or the environment, the Administrator may order the manufacturer or processor to (i) give notice of such risk to processors or distributors in commerce of any such substance or mixture, or to both, and, to the extent reasonably ascertainable, *to any other person in possession of or exposed* to any such substance, (ii) to give public notice of such risk, and (iii) to provide such replacement or repurchase of any such substance or mixture as is necessary to adequately protect health or the environment.

A determination under subparagraph (A) or (B) of paragraph (2) shall be made on the record after opportunity for hearing in accordance with section 554 of title 5, United States Code. Any manufacturer or processor subject to a requirement to replace or repurchase a chemical substance or mixture may elect either to replace or repurchase the substance or mixture and shall take either such action in the manner prescribed by the Administrator

(c) PROMULGATION OF SUBSECTION (a) RULES.—(1) In promulgating any rule under subsection (a) with respect to a chemical substance or mixture, the Administrator shall consider and publish a statement with respect to—

(A) the effects of such substance or mixture on health and the magnitude of the exposure of human beings to such substance or mixture,

(B) the effects of such substance or mixture on the environment and the magnitude of the exposure of the environment to such substance or mixture,

(C) the benefits of such substance or mixture for various uses and the availability of substitutes for such uses, and

(D) the reasonably ascertainable economic consequences of the rule, after consideration of the effect on the national economy, small business, technological innovation, the environment, and public health.

If the Administrator determines that a risk of injury to health or the environment could be eliminated or reduced to a sufficient extent by actions taken under another Federal law (or laws) administered in whole or in part by the Administrator, the Administrator may not promulgate a rule under subsection (a) to protect against such risk of injury unless the Administrator finds, in the Administrator's discretion, that it is in the public interest to protect against such risk *under this Act. In making such a finding the Administrator shall consider* (i) all relevant aspects of the risk, as determined by the Administrator in the Administrator's discretion, (ii) a comparison of the estimated costs of complying with actions taken under this Act and under such law (or laws), and (iii) the relative efficiency of actions under this Act and under such law (or laws) to protect against such risk of injury.

(2) When prescribing a rule under subsection (a) the Administrator shall proceed in accordance with section 553 of title 5, United States Code (*without regard to any reference in such section to sections 556 and 557 of such title*), and shall also (A) publish a notice of proposed rulemaking stating with particularity the reason for the proposed rule; (B) allow interested persons to submit written data, views, and arguments, and make all such submissions publicly available; (C) provide an opportunity for an informal hearing in accordance with paragraph (3); (D) promulgate, if appropriate, a final rule based on the matter in the rulemaking record (as defined in section 19(a)), and (E) make and publish with the rule the finding described in subsection (a).

(3) Informal hearings required by paragraph (2)(C) shall be conducted by the Administrator in accordance with the following requirements:

(A) Subject to subparagraph (B), an interested person is entitled—

(i) to present such person's position orally or by documentary submissions (or both), and

(ii) *if the Administrator determines* that there are disputed issues of material fact it is necessary to resolve, to present such rebuttal submissions and to conduct (or have conducted under subparagraph (B)(ii)) such cross-examination of persons as the Administrator determines (I) to be appropriate, and (II) to be required for a full and true disclosure with respect to such issues.

(B) The Administrator may prescribe such rules and make such rulings concerning procedures in such hearings to avoid unnecessary costs or delay. Such rules or rulings may include (i) the imposition of reasonable time limits on each interested person's oral presentations, and (ii) requirements that any cross-examination to which a person may be entitled under subparagraph (A) be conducted by the Administrator on behalf of that person in such manner as the Administrator determines (I) to be appropriate, and (II) to be required for a full and true disclosure with respect to disputed issues of material fact.

(C)(i) Except as provided in clause (ii), if a group of persons each of whom under subparagraphs (A) and (B) would be entitled to conduct (or have conducted) cross-examination and who are determined by the Administrator to have the same or similar interests in the proceeding cannot agree upon a single *representative of such interests for purposes of cross-examination*, the Administrator may make rules and rulings (I) limiting the representation of such interest for such purposes, and (II) governing the manner in which such cross-examination shall be limited.

(ii) When any person who is a member of a group with respect to which the Administrator has made a determination under clause (i) is unable to agree upon group representation with the other members of the group, then such person shall not be denied under the authority of clause (i) the opportunity to conduct (or have conducted) cross-examination as to issues affecting the person's particular interests if (I) the person satisfies the Administrator that the person has made a reasonable and good faith effort to reach agreement upon group representation with the other members of the group and (II) the Administrator determines that there are substantial and relevant issues which are not adequately presented by the group representative.

(D) A verbatim transcript shall be taken of any oral presentation made, and cross-examination conducted in any informal hearing under this subsection. Such transcript shall be available to the public.

(4)(A) The Administrator may, pursuant to rules prescribed by the *Administrator, provide compensation for reasonable attorneys' fees*, expert witness fees, and other costs of participating in a rulemaking proceeding for the promulgation of a rule under subsection (a) to any person—

(i) who represents an interest which would substantially contribute to a fair determination of the issues to be resolved in the proceeding, and

(ii) if—

(I) the economic interest of such person is small in comparison to the costs of effective participation in the proceeding by such person, or

(II) such person demonstrates to the satisfaction of the Administrator that such person does not have sufficient resources adequately to participate in the proceeding without compensation under this subparagraph.

In determining for purposes of clause (i) if an interest will substantially contribute to a fair determination of the issues to be resolved in a proceeding, the Administrator shall take into account the number

and complexity of such issues and the extent to which representation of such interest will contribute to widespread public participation in the proceeding and representation of a fair balance of interests for the resolution of such issues.

(B) In determining whether compensation should be provided to a person under subparagraph (A) and the amount of such compensation, the Administrator shall take into account the financial burden which will be incurred by such person in participating in the rulemaking proceeding. The Administrator shall take such action as may be necessary to ensure that the aggregate amount of compensation paid under this paragraph in any fiscal year to all persons who, in rulemaking proceedings in which they receive compensation, are persons who either—

(i) would be regulated by the proposed rule, or

(ii) represent persons who would be so regulated,

may not exceed 25 per centum of the aggregate amount paid as compensation under this paragraph to all persons in such fiscal year.

(5) Paragraph (1), (2), (3), and (4) of this subsection apply to the promulgation of a rule repealing, or making a substantive amendment to, a rule promulgated under subsection (a)

(d) EFFECTIVE DATE.—(1) The Administrator shall specify in any rule under subsection (a) the date on which it shall take effect, which date shall be as soon as feasible.

(2)(A) The Administrator may declare a proposed rule under subsection (a) to be effective upon its publication in the Federal Register and until the effective date of final action taken, in accordance with subparagraph (B), respecting such rule if—

(i) the Administrator determines that—

(I) the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance or mixture subject to such proposed rule or any combination of such activities is likely to result in an unreasonable risk of serious or widespread injury to health or the environment before such effective date; and

(II) making such proposed rule so effective is necessary to protect the public interest; and

(ii) in the case of a proposed rule to prohibit the manufacture, processing, or distribution of a chemical substance or mixture because of the risk determined under clause (i)(I), a court has in an action under section 7 granted relief with respect to such risk associated with such substance or mixture.

Such a proposed rule which is made so effective shall not, for purposes of judicial review, be considered final agency action.

(B) If the Administrator makes a proposed rule effective upon its publication in the Federal Register, the Administrator shall, as expeditiously as possible, give interested persons prompt notice of such action, provide reasonable opportunity, in accordance with paragraphs (2) and (3) of subsection (c), for a hearing on such rule, and either promulgate such rule (as proposed or with modifications) or revoke it; and if such a hearing is requested, the Administrator shall commence the hearing within five days from the date such request is made unless the Administrator and the person making the request agree upon a later date for the hearing to begin, and after the hearing is concluded the Administrator shall, within ten days of the conclusion of the hearing, either promulgate such rule (as proposed or with modifications) or revoke it.

(e) POLYCHLORINATED BIPHENYLS.—(1) Within six months after the effective date of this Act the Administrator shall promulgate rules to—

(A) prescribe methods for the disposal of polychlorinated biphenyls, and

(B) require polychlorinated biphenyls to be marked with clear and adequate warnings, and instructions with respect to their processing, distribution in commerce, use, or disposal or with respect to any combination of such activities.

Requirements prescribed by rules under this paragraph shall be consistent with the requirements of paragraphs (2) and (3).

(2)(A) Except as provided under subparagraph (B), effective one year after the effective date of this Act no person may manufacture, process, or distribute in commerce or use any polychlorinated biphenyl in any manner other than in a totally enclosed manner.

(B) The Administrator may by rule authorize the manufacture, processing, distribution in commerce or use (or any combination of such activities) of any polychlorinated biphenyl in a manner other than in a totally enclosed manner if the Administrator finds that such manufacture, processing, distribution in commerce, or use (or combination of such activities) will not present an unreasonable risk of injury to health or the environment.

(C) For the purposes of this paragraph, the term "totally enclosed manner" means any manner which will ensure that any exposure of human beings or the environment to a polychlorinated biphenyl will be insignificant as determined by the Administrator by rule.

(3)(A) Except as provided in subparagraphs (B) and (C)—

(i) no person may manufacture any polychlorinated biphenyl after two years after the effective date of this Act, and

(ii) no person may process or distribute in commerce any polychlorinated biphenyl after two and one-half years after such date.

(B) Any person may petition the Administrator for an exemption from the requirements of subparagraph (A), and the Administrator may grant by rule such an exemption if the Administrator finds that—

(i) an unreasonable risk of injury to health or environment would not result, and

(ii) good faith efforts have been made to develop a chemical substance which does not present an unreasonable risk of injury to health or the environment and which may be substituted for such polychlorinated biphenyl.

An exemption granted under this subparagraph shall be subject to such terms and conditions as the Administrator may prescribe and shall be in effect for such period (but not more than one year from the date it is granted) as the Administrator may prescribe.

(C) Subparagraph (A) shall not apply to the distribution in commerce of any polychlorinated biphenyl if such polychlorinated biphenyl was sold for purposes other than resale before two and one half years after the date of enactment of this Act

(4) Any rule under paragraph (1), (2)(B), or (3)(B) shall be promulgated in accordance with paragraphs (2), (3), and (4) of subsection (c).

(5) This subsection does not limit the authority of the Administrator, under any other provision of this Act or any other Federal law, to take action respecting any polychlorinated biphenyl.

SEC. 7. IMMINENT HAZARDS.

(a) ACTIONS AUTHORIZED AND REQUIRED.—(1) The Administrator may commence a civil action in an appropriate district court of the United States—

(A) for seizure of an imminently hazardous chemical substance or mixture or any article containing such a substance or mixture,

(B) for relief (as authorized by subsection (b)) against any person who manufactures, processes, distributes in commerce, or uses, or disposes of, an imminently hazardous chemical substance or mixture or any article containing such a substance or mixture, or

(C) for both such seizure and relief.

A civil action may be commenced under this paragraph notwithstanding the existence of a rule under section 4, 5, or 6 or an order under section 5, and notwithstanding the pendency of any administrative or judicial proceeding under any provision of this Act.

(2) If the Administrator has not made a rule under section 6(a) immediately effective (as authorized by subsection 6(d)(2)(A)(i)) with respect to an imminently hazardous chemical substance or mixture, the Administrator shall commence in a district court of the United States with respect to such substance or mixture or article containing such substance or mixture a civil action described in subparagraph (A), (B), or (C) of paragraph (1).

(b) RELIEF AUTHORIZED.—(1) The district court of the United States in which an action under subsection (a) is brought shall have jurisdiction to grant such temporary or permanent relief as may be necessary to protect health or the environment from the unreasonable risk associated with the chemical substance, mixture, or article involved in such action.

(2) In the case of an action under subsection (a) brought against a person who manufactures, processes, or distributes in commerce a chemical substance or mixture or an article containing a chemical substance or mixture, the relief authorized by paragraph (1) may include the issuance of a mandatory order requiring (A) in the case of purchasers of such substance, mixture, or article known to the defendant, notification to such purchasers of the risk associated with it; (B) public notice of such risk; (C) recall, (D) the replacement or repurchase of such substance, mixture, or article; or (E) any combination of the actions described in the preceding clauses.

(3) In the case of an action under subsection (a) against a chemical substance, mixture, or article, such substance, mixture, or article may be proceeded against by process of libel for its seizure and con-

demnation. Proceedings in such an action shall conform as nearly as possible to proceedings in rem in admiralty.

(c) VENUE AND CONSOLIDATION.—(1)(A) An action under subsection (a) against a person who manufactures, processes, or distributes a chemical substance or mixture or an article containing a chemical substance or mixture may be brought in the United States District Court for the District of Columbia or for any judicial district in which any of the defendants is found, resides, or transacts business; and process in such an action may be served on a defendant in any other district in which such defendant resides or may be found. An action under subsection (a) against a chemical substance, mixture, or article may be brought in any United States district court within the jurisdiction of which the substance, mixture, or article is found.

(B) In determining the judicial district in which an action may be brought under subsection (a) in instances in which such action may be brought in more than one judicial district, the Administrator shall take into account the convenience of the parties.

(C) Subpeonas requiring attendance of witnesses in an action brought under subsection (a) may be served in any judicial district.

(2) Whenever proceedings under subsection (a) involving identical chemical substances, mixtures, or articles are pending in courts in two or more judicial districts, they shall be consolidated for trial by order of any such court upon application reasonably made by any party in interest, upon notice to all parties in interest

(d) ACTION UNDER SECTION 6.—Where appropriate, concurrently with the filing of an action under subsection (a) or as soon thereafter as may be practicable, the Administrator shall initiate a proceeding for the promulgation of a rule under section 6(a).

(e) REPRESENTATION.—Notwithstanding any other provision of law, in any action under subsection (a), the Administrator may direct attorneys of the Environmental Protection Agency to appear and represent the Administrator in such an action

(f) DEFINITION.—For the purposes of subsection (a), the term "imminently hazardous chemical substance or mixture" means a chemical substance or mixture which presents an imminent and unreasonable risk of serious or widespread injury to health or the environment. Such a risk to health or the environment shall be considered imminent if it is shown that the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance or mixture, or that any combination of such activities, is likely to result in such injury to health or the environment before a final rule under section 6 can protect against such risk.

SEC. 8. REPORTING AND RETENTION OF INFORMATION.

(a) REPORTS.—(1) The Administrator shall promulgate rules under which—

(A) each person (other than a small manufacturer or processor) who manufactures or processes or proposes to manufacture or process a chemical substance (other than a chemical substance described in subparagraph (B)(ii)) shall maintain such records, and shall submit to the Administrator such reports, as the Administrator may reasonably require, and

(B) each person (other than a small manufacturer or processor) who manufactures or processes or proposes to manufacture or process—

(i) a mixture, or

(ii) a chemical substance in small quantities (as defined by the Administrator by rule) solely for purposes of scientific experimentation or analysis or chemical research on, or analysis of, such substance or another substance, including any such research or analysis for the development of a product,

shall maintain records and submit to the Administrator reports but only to the extent the Administrator determines the maintenance of records or submission of reports, or both, is necessary for the effective enforcement of this Act.

The Administrator may not require in a rule promulgated under this paragraph the maintenance of records or the submission of reports with respect to changes in the proportions of the components of a mixture unless the Administrator finds that the maintenance of such records or the submission of such reports, or both, is necessary for the effective enforcement of this Act. For purposes of the compilation of the list of chemical substances required under subsection (b), the Administrator shall promulgate rules pursuant to this subsection not later than 180 days after the effective date of this Act.

(2) The Administrator may require under paragraph (1) maintenance of records and reporting with respect to the following insofar as known to the person making the report or insofar as reasonably ascertainable:

(A) The common or trade name, the chemical identity, and the molecular structure of each chemical substance or mixture for which such a report is required.

(B) The categories or proposed categories of use of each such substance or mixture.

(C) The total amount of each such substance and mixture manufactured or processed, reasonable estimates of the total amount to be manufactured or processed, the amount manufactured or processed for each of its categories of use, and reasonable estimates of the amount to be manufactured or processed for each of its categories of use or proposed categories of use.

(D) A description of the byproducts resulting from the manufacture, processing, use, or disposal of each such substance or mixture.

(E) All existing data concerning the environmental and health effects of such substance or mixture.

(F) The number of individuals exposed, and reasonable estimates of the number who will be exposed, to such substance or mixture in their places of employment and the duration of such exposure.

(G) In the initial report under paragraph (1) on such substance or mixture, the manner or method of its disposal, and in any subsequent report on such substance or mixture, any change in such manner or method.

To the extent feasible, the Administrator shall not require under paragraph (1), any reporting which is unnecessary or duplicative.

(3)(A)(i) The Administrator may by rule require a small manufacturer or processor of a chemical substance to submit to the Administrator such information respecting the chemical substance as the Administrator may require for publication of the first list of chemical substances required by subsection (b).

(ii) The Administrator may by rule require a small manufacturer or processor of a chemical substance or mixture—

(I) subject to a rule proposed or promulgated under section 4, 5(b)(4), or 6, or an order in effect under section 5(c), or

(II) with respect to which relief has been granted pursuant to a civil action brought under section 5 or 7,

to maintain such records on such substance or mixture, and to submit to the Administrator such reports on such substance or mixture, as the Administrator may reasonably require. A rule under this clause requiring reporting may require reporting with respect to the matters referred to in paragraph (2).

(B) The Administrator, after consultation with the Administrator of the Small Business Administration, shall by rule prescribe standards for determining the manufacturers and processors which qualify as small manufacturers and processors for purposes of this paragraph and paragraph (1).

(b) INVENTORY.—(1) The Administrator shall compile, keep current, and publish a list of each chemical substance which is manufactured or processed in the United States. Such list shall at least include each chemical substance which any person reports, under section 5 or subsection (a) of this section, is manufactured or processed in the United States. Such list may not include any chemical substance which was not manufactured or processed in the United States within three years before the effective date of the rules promulgated pursuant to the last sentence of subsection (a)(1). In the case of a chemical substance for which a notice is submitted in accordance with section 5, such chemical substance shall be included in such list as of the earliest date (as determined by the Administrator) on which such substance was manufactured or processed in the United States. The Administrator shall first publish such a list not later than 315 days after the effective date of this Act. The Administrator shall not include in such list any chemical substance which is manufactured or processed only in small quantities (as defined by the Administrator by rule) solely for purposes of scientific experimentation or analysis or chemical research on, or analysis of, such substance or another substance, including such research or analysis for the development of a product

(2) To the extent consistent with the purposes of this Act, the Administrator may, in lieu of listing, pursuant to paragraph (1), a chemical substance individually, list a category of chemical substances in which such substance is included.

(c) RECORDS.—Any person who manufactures, processes, or distributes in commerce any chemical substance or mixture shall maintain records of significant adverse reactions to health or the environment, as determined by the Administrator by rule, alleged to have been

caused by the substance or mixture. Records of such adverse reactions to the health of employees shall be retained for a period of 30 years from the date such reactions were first reported to or known by the person maintaining such records. Any other record of such adverse reactions shall be retained for a period of five years from the date the information contained in the record was first reported to or known by the person maintaining the record. Records required to be maintained under this subsection shall include records of consumer allegations of personal injury or harm to health, reports of occupational disease or injury, and reports or complaints of injury to the environment submitted to the manufacturer, processor, or distributor in commerce from any source. Upon request of any duly designated representative of the Administrator, each person who is required to maintain records under this subsection shall permit the inspection of such records and shall submit copies of such records.

(d) HEALTH AND SAFETY STUDIES.—The Administrator shall promulgate rules under which the Administrator shall require any person who manufactures, processes, or distributes in commerce or who proposes to manufacture, process, or distribute in commerce any chemical substance or mixture (or with respect to paragraph (2), any person who has possession of a study) to submit to the Administrator—

(1) lists of health and safety studies (A) conducted or initiated by or for such person with respect to such substance or mixture at any time, (B) known to such person, or (C) reasonably ascertainable by such person, except that the Administrator may exclude certain types or categories of studies from the requirements of this subsection if the Administrator finds that submission of lists of such studies are unnecessary to carry out the purposes of this Act; and

(2) copies of any study contained on a list submitted pursuant to paragraph (1) or otherwise known by such person.

(e) NOTICE TO ADMINISTRATOR OF SUBSTANTIAL RISKS.—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.

(f) DEFINITIONS.—For purposes of this section, the terms "manufacture" and "process" mean manufacture or process for commercial purposes.

SEC. 9. RELATIONSHIP TO OTHER FEDERAL LAWS.

(a) LAWS NOT ADMINISTERED BY THE ADMINISTRATOR.—(1) If the Administrator has reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents or will present an unreasonable risk of injury to health or the environment and determines, in the Administrator's discretion, that such risk may be prevented or reduced to a sufficient extent by action taken under a Federal law not administered by the Administrator, the Administrator shall submit to the agency which administers such law a report which describes such risk and includes in such description a specification of the activity or combination of activities which the Administrator has reason to believe so presents such risk. Such report shall also request such agency—

(A)(i) to determine if the risk described in such report may be prevented or reduced to a sufficient extent by action taken under such law, and

(ii) if the agency determines that such risk may be so prevented or reduced, to issue an order declaring whether or not the activity or combination of activities specified in the description of such risk presents such risk, and

(B) to respond to the Administrator with respect to the matters described in subparagraph (A)

Any report of the Administrator shall include a detailed statement of the information on which it is based and shall be published in the Federal Register. The agency receiving a request under such a report shall make the requested determination, issue the requested order, and make the requested response within such time as the Administrator specifies in the request, but such time specified may not be less than 90 days from the date the request was made The response of an agency shall be accompanied by a detailed statement of the findings and conclusions of the agency and shall be published in the Federal Register

(2) If the Administrator makes a report under paragraph (1) with respect to a chemical substance or mixture and the agency to which such report was made either—

(A) issues an order declaring that the activity or combination of activities specified in the description of the risk described in the report does not present the risk described in the report, or

(B) initiates, within 90 days of the publication in the Federal Register of the response of the agency under paragraph (1), action under the law (or laws) administered by such agency to protect against such risk associated with such activity or combination of activities,

the Administrator may not take any action under section 6 or 7 with respect to such risk.

(3) If the Administrator has initiated action under section 6 or 7 with respect to a risk associated with a chemical substance or mixture which was the subject of a report made to an agency under paragraph (1), such agency shall before taking action under the law (or laws) administered by it to protect against such risk consult with the Administrator for the purpose of avoiding duplication of Federal action against such risk.

(b) LAWS ADMINISTERED BY THE ADMINISTRATOR.—The Administrator shall coordinate actions taken under this Act with actions taken under other Federal laws administered in whole or in part by the Administrator. If the Administrator determines that a risk to health or the environment associated with a chemical substance or mixture could be eliminated or reduced to a sufficient extent by actions taken under the authorities contained in such other Federal laws, the Administrator shall use such authorities to protect against such risk unless the Administrator determines, in the Administrator's discretion, that it is in the public interest to protect against such risk by actions taken under this Act. This subsection shall not be construed to relieve the Administrator of any requirement imposed on the Administrator by such other Federal laws.

(c) OCCUPATIONAL SAFETY AND HEALTH.—In exercising any authority under this Act, the Administrator shall not, for purposes of section 4(b)(1) of the Occupational Safety and Health Act of 1970, be deemed to be exercising statutory authority to prescribe or enforce standards or regulations affecting occupational safety and health

(d) COORDINATION.—In administering this Act, the Administrator shall consult and coordinate with the Secretary of Health, Education, and Welfare and the heads of any other appropriate Federal executive department or agency, any relevant independent regulatory agency, and any other appropriate instrumentality of the Federal Government for the purpose of achieving the maximum enforcement of this Act while imposing the least burdens of duplicative requirements on those subject to the Act and for other purposes. The Administrator shall, in the report required by section 30, report annually to the Congress on actions taken to coordinate with such other Federal departments, agencies, or instrumentalities, and on actions taken to coordinate the authority under this Act with the authority granted under other Acts referred to in subsection (b).

SEC. 10. RESEARCH, DEVELOPMENT, COLLECTION, DISSEMINATION, AND UTILIZATION OF DATA.

(a) AUTHORITY.—The Administrator shall, in consultation and cooperation with the Secretary of Health, Education, and Welfare and with other heads of appropriate departments and agencies, conduct such research, development, and monitoring as is necessary to carry out the purposes of this Act. The Administrator may enter into contracts and may make grants for research, development, and monitoring under this subsection. Contracts may be entered into under this subsection without regard to sections 3648 and 3709 of the Revised Statutes (31 U.S.C. 529, 14 U.S.C. 5).

(b) DATA SYSTEMS.—(1) The Administrator shall establish, administer, and be responsible for the continuing activities of an interagency committee which shall design, establish, and coordinate an efficient and effective system, within the Environmental Protection Agency, for the collection, dissemination to other Federal departments and agencies, and use of data submitted to the Administrator under this Act.

(2)(A) The Administrator shall, in consultation and cooperation with the Secretary of Health, Education, and Welfare and other heads of appropriate departments and agencies design, establish, and coordinate an efficient and effective system for the retrieval of toxicological and other scientific data which could be useful to the Administrator in carrying out the purposes of this Act. Systematized retrieval shall be developed for use by all Federal and other departments and agencies with responsibilities in the area of regulation or study of chemical substances and mixtures and their effect on health or the environment.

(B) The Administrator, in consultation and cooperation with the Secretary of Health, Education, and Welfare, may make grants and enter into contracts for the development of a data retrieval system described in subparagraph (A). Contracts may be entered into under

this subparagraph without regard to sections 3648 and 3709 of the Revised Statutes (31 U.S C 529, 41 U.S.C. 5).

(c) SCREENING TECHNIQUES.—The Administrator shall coordinate, with the Assistant Secretary for Health of the Department of Health, Education, and Welfare, research undertaken by the Administrator and directed toward the development of rapid, reliable, and economical screening techniques for carcinogenic, mutagenic, teratogenic, and ecological effects of chemical substances and mixtures.

(d) MONITORING.—The Administrator shall, in consultation and cooperation with the Secretary of Health, Education, and Welfare, establish and be responsible for research aimed at the development, in cooperation with local, State, and Federal agencies, of monitoring techniques and instruments which may be used in the detection of toxic chemical substances and mixtures and which are reliable, economical, and capable of being implemented under a wide variety of conditions.

(e) BASIC RESEARCH.—The Administrator shall, in consultation and cooperation with the Secretary of Health, Education, and Welfare, establish research programs to develop the fundamental scientific basis of the screening and monitoring techniques described in subsections (c) and (d), the bounds of the reliability of such techniques, and the opportunities for their improvement.

(f) TRAINING.—The Administrator shall establish and promote programs and workshops to train or facilitate the training of Federal laboratory and technical personnel in existing or newly developed screening and monitoring techniques.

(g) EXCHANGE OF RESEARCH AND DEVELOPMENT RESULTS.—The Administrator shall, in consultation with the Secretary of Health, Education, and Welfare and other heads of appropriate departments and agencies, establish and coordinate a system for exchange among Federal, State, and local authorities of research and development results respecting toxic chemical substances and mixtures, including a system to facilitate and promote the development of standard data format and analysis and consistent testing procedures.

SEC. 11. INSPECTIONS AND SUBPOENAS.

(a) IN GENERAL.—For purposes of administering this Act, the Administrator, and any duly designated representative of the Administrator, may inspect 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 and any conveyance being used to transport chemical substances, mixtures, or such articles in connection with distribution in commerce Such an inspection may only be made upon the presentation of appropriate credentials and of a written notice to the owner, operator, or agent in charge of the premises or conveyance to be inspected. A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness and shall be conducted at reasonable times, within reasonable limits, and in a reasonable manner

(b) SCOPE.—(1) Except as provided in paragraph (2), an inspection conducted under subsection (a) shall extend to all things within the premises or conveyance inspected (including records, files, papers, processes, controls, and facilities) bearing on whether the requirements of this Act applicable to the chemical substances or mixtures within such premises or conveyance have been complied with.

(2) No inspection under subsection (a) shall extend to—

(A) financial data,

(B) sales data (other than shipment data),

(C) pricing data,

(D) personnel data, or

(E) research data (other than data required by this Act or under a rule promulgated thereunder),

unless the nature and extent of such data are described with reasonable specificity in the written notice required by subsection (a) for such inspection.

(c) SUBPOENAS.—In carrying out this Act, the Administrator may by subpoena require the attendance and testimony of witnesses and the production of reports, papers, documents, answers to questions, and other information that the Administrator deems necessary. Witnesses shall be paid the same fees and mileage that are paid witnesses in the courts of the United States In the event of contumacy, failure, or refusal of any person to obey any such subpoena, any district court of the United States in which venue is proper shall have jurisdiction to order any such person to comply with such subpoena. Any failure to obey such an order of the court is punishable by the court as a contempt thereof.

SEC. 12. EXPORTS.

(a) IN GENERAL.—(1) Except as provided in paragraph (2) and subsection (b), this Act (other than section 8) shall not apply to any chemical substance, mixture, or to an article containing a chemical substance or mixture, if—

(A) it can be shown that such substance, mixture, or article is being manufactured, processed, or distributed in commerce for export from the United States, unless such substance, mixture, or article was, in fact, manufactured, processed, or distributed in commerce, for use in the United States, and

(B) such substance, mixture, or article (when distributed in commerce), or any container in which it is enclosed (when so distributed), bears a stamp or label stating that such substance, mixture, or article is intended for export.

(2) Paragraph (1) shall not apply to any chemical substance, mixture, or article if the Administrator finds that the substance, mixture, or article will present an unreasonable risk of injury to health within the United States or to the environment of the United States. The Administrator may require, under section 4, testing of any chemical substance or mixture exempted from this Act by paragraph (1) for the purpose of determining whether or not such substance or mixture presents an unreasonable risk of injury to health within the United States or to the environment of the United States.

(b) NOTICE.—(1) If any person exports or intends to export to a foreign country a chemical substance or mixture for which the submission of data is required under section 4 or 5(b), such person shall notify the Administrator of such exportation or intent to export and the Administrator shall furnish to the government of such country notice of the availability of the data submitted to the Administrator under such section for such substance or mixture.

(2) If any person exports or intends to export to a foreign country a chemical substance or mixture for which an order has been issued under section 5 or a rule has been proposed or promulgated under section 5 or 6, or with respect to which an action is pending, or relief has been granted under section 5 or 7, such person shall notify the Administrator of such exportation or intent to export and the Administrator shall furnish to the government of such country notice of such rule, order, action, or relief

SEC. 13. ENTRY INTO CUSTOMS TERRITORY OF THE UNITED STATES.

(a) IN GENERAL.—(1) The Secretary of the Treasury shall refuse entry into the customs territory of the United States (as defined in general headnote 2 to the Tariff Schedules of the United States) of any chemical substance, mixture, or article containing a chemical substance or mixture offered for such entry if—

(A) it fails to comply with any rule in effect under this Act, or

(B) it is offered for entry in violation of section 5 or 6, a rule or order under section 5 or 6, or an order issued in a civil action brought under section 5 or 7.

(2) If a chemical substance, mixture, or article is refused entry under paragraph (1), the Secretary of the Treasury shall notify the consignee of such entry refusal, shall not release it to the consignee, and shall cause its disposal or storage (under such rules as the Secretary of the Treasury may prescribe) if it has not been exported by the consignee within 90 days from the date of receipt of notice of such refusal, except that the Secretary of the Treasury may, pending a review by the Administrator of the entry refusal, release to the consignee such substance, mixture, or article on execution of bond for the amount of the full invoice of such substance, mixture, or article (as such value is set forth in the customs entry), together with the duty thereon. On failure to return such substance, mixture, or article for any cause to the custody of the Secretary of the Treasury when demanded, such consignee shall be liable to the United States for liquidated damages equal to the full amount of such bond. All charges for storage, cartage, and labor on and for disposal of substances, mixtures, or articles which are refused entry or release under this section shall be paid by the owner or consignee, and in default of such payment shall constitute a lien against any future entry made by such owner or consignee.

(b) RULES.—The Secretary of the Treasury, after consultation with the Administrator, shall issue rules for the administration of subsection (a) of this section.

SEC. 14. DISCLOSURE OF DATA.

(a) IN GENERAL.—Except as provided by subsection (b), any information reported to, or otherwise obtained by, the Administrator (or any representative of the Administrator) under this Act, which is exempt from disclosure pursuant to subsection (a) of section 552 of

title 5, United States Code, by reason of subsection (b)(4) of such section, shall, notwithstanding the provisions of any other section of this Act, not be disclosed by the Administrator or by any officer or employee of the United States, except that such information—

(1) shall be disclosed to any officer or employee of the United States—

(A) in connection with the official duties of such officer or employee under any law for the protection of health or the environment, or

(B) for specific law enforcement purposes;

(2) shall be disclosed to contractors with the United States and employees of such contractors if in the opinion of the Administrator such disclosure is necessary for the satisfactory performance by the contractor of a contract with the United States entered into on or after the date of enactment of this Act for the performance of work in connection with this Act and under such conditions as the Administrator may specify;

(3) shall be disclosed if the Administrator determines it necessary to protect health or the environment against an unreasonable risk of injury to health or the environment; or

(4) may be disclosed when relevant in any proceeding under this Act, except that disclosure in such a proceeding shall be made in such manner as to preserve confidentiality to the extent practicable without impairing the proceeding.

In any proceeding under section 552(a) of title 5, United States Code, to obtain information the disclosure of which has been denied because of the provisions of this subsection, the Administrator may not rely on section 552(b)(3) of such title to sustain the Administrator's action.

(b) DATA FROM HEALTH AND SAFETY STUDIES.—(1) Subsection (a) does not prohibit the disclosure of—

(A) any health and safety study which is submitted under this Act with respect to—

(i) any chemical substance or mixture which, on the date on which such study is to be disclosed has been offered for commercial distribution, or

(ii) any chemical substance or mixture for which testing is required under section 4 or for which notification is required under section 5, and

(B) any data reported to, or otherwise obtained by, the Administrator from a health and safety study which relates to a chemical substance or mixture described in clause (i) or (ii) of subparagraph (A).

This paragraph does not authorize the release of any data which discloses processes used in the manufacturing or processing of a chemical substance or mixture or, in the case of a mixture, the release of data disclosing the portion of the mixture comprised by any of the chemical substances in the mixture.

(2) If a request is made to the Administrator under subsection (a) of section 552 of title 5, United States Code, for information which is described in the first sentence of paragraph (1) and which is not information described in the second sentence of such paragraph, the Administrator may not deny such request on the basis of subsection (b)(4) of such section.

(c) DESIGNATION AND RELEASE OF CONFIDENTIAL DATA.—(1) In submitting data under this Act, a manufacturer, processor, or distributor in commerce may (A) designate the data which such person believes is entitled to confidential treatment under subsection (a), and (B) submit such designated data separately from other data submitted under this Act. A designation under this paragraph shall be made in writing and in such manner as the Administrator may prescribe.

(2)(A) Except as provided by subparagraph (B), if the Administrator proposes to release for inspection data which has been designated under paragraph (1)(A), the Administrator shall notify, in writing and by certified mail, the manufacturer, processor, or distributor in commerce who submitted such data of the intent to release such data. If the release of such data is to be made pursuant to a request made under section 552(a) of title 5, United States Code, such notice shall be given immediately upon approval of such request by the Administrator. The Administrator may not release such data until the expiration of 30 days after the manufacturer, processor, or distributor in commerce submitting such data has received the notice required by this subparagraph.

(B)(i) Subparagraph (A) shall not apply to the release of information under paragraph (1), (2), (3), or (4) of subsection (a), except that the Administrator may not release data under paragraph (3) of subsection (a) unless the Administrator has notified each manufacturer, processor, and distributor in commerce who submitted such data of such release. Such notice shall be made in writing by certified mail at least 15 days before the release of such data, except that if the Administrator determines that the release of such data is necessary to protect against an imminent, unreasonable risk of injury to health or the environment, such notice may be made by such means as the Administrator determines will provide notice at least 24 hours before such release is made.

(ii) Subparagraph (A) shall not apply to the release of information described in subsection (b)(1) other than information described in *the second sentence of such subsection.*

(d) CRIMINAL PENALTY FOR WRONGFUL DISCLOSURE.—(1) Any officer or employee of the United States or former officer or employee of the United States, who by virtue of such employment or official position has obtained possession of, or has access to, material the disclosure of which is prohibited by subsection (a), and who knowing that disclosure of such material is prohibited by such subsection, willfully discloses the material in any manner to any person not entitled to receive it, shall be guilty of a misdemeanor and fined not more than $5,000 or imprisoned for not more than one year, or both. Section 1905 of title 18, United States Code, does not apply with respect to the publishing, divulging, disclosure, or making known of, or making available, information reported or otherwise obtained under this Act.

(2) For the purposes of paragraph (1), any contractor with the United States who is furnished information as authorized by subsection (a)(2), and any employee of any such contractor, shall be considered to be an employee of the United States.

(e) ACCESS BY CONGRESS.—Notwithstanding any limitation contained in this section or any other provision of law, all information reported to or otherwise obtained by the Administrator (or any representative of the Administrator) under this Act shall be made available, upon written request of any duly authorized committee of the Congress, to such committee.

SEC. 15. PROHIBITED ACTS.

It shall be unlawful for any person to—

(1) fail or refuse to comply with (A) any rule promulgated or *order issued under section 4, (B) any requirement prescribed by* section 5 or 6, or (C) any rule promulgated or order issued under section 5 or 6;

(2) use for commercial purposes a chemical substance or mixture which such person knew or had reason to know was manufactured, processed, or distributed in commerce in violation of section 5 or 6, a rule or order under section 5 or 6, or an order issued in action brought under section 5 or 7;

(3) fail or refuse to (A) establish or maintain records, (B) submit reports, notices, or other information, or (C) permit access to or copying of records, as required by this Act or a rule thereunder; or

(4) fail or refuse to permit entry or inspection as required by section 11.

SEC. 16. PENALTIES.

(a) CIVIL.—(1) Any person who violates a provision of section 15 shall be liable to the United States for a civil penalty in an amount not to exceed $25,000 for each such violation. Each day such a violation continues shall, for purposes of this subsection, constitute a separate violation of section 15.

(2)(A) A civil penalty for a violation of section 15 shall be assessed by the Administrator by an order made on the record after opportunity (provided in accordance with this subparagraph) for a hearing in accordance with section 554 of title 5, United States Code. Before issuing such an order, the Administrator shall give written notice to the person to be assessed a civil penalty under such order of the Administrator's proposal to issue such order and provide such person an opportunity to request, within 15 days of the date the notice is received by such person, such a hearing on the order.

(B) In determining the amount of a civil penalty, the Administrator shall take into account the nature, circumstances, extent, and gravity of the violation or violations and, with respect to the violator, ability to pay, effect on ability to continue to do business, any history of prior such violations, the degree of culpability, and such other matters as justice may require.

(C) The Administrator may compromise, modify, or remit, with or without conditions, any civil penalty which may be imposed under this subsection. The amount of such penalty, when finally determined, or the amount agreed upon in compromise, may be deducted from any sums owing by the United States to the person charged.

(3) Any person who requested in accordance with paragraph (2)(A) a hearing respecting the assessment of a civil penalty and who is aggrieved by an order assessing a civil penalty may file a petition for judicial review of such order with the United States Court of Appeals for the District of Columbia Circuit or for any other circuit in which such person resides or transacts business. Such a petition may only be filed within the 30-day period beginning on the date the order making such assessment was issued.

(4) If any person fails to pay an assessment of a civil penalty—

(A) after the order making the assessment has become a final order and if such person does not file a petition for judicial review of the order in accordance with paragraph (3), or

(B) after a court in an action brought under paragraph (3) has entered a final judgment in favor of the Administrator,

the Attorney General shall recover the amount assessed (plus interest at currently prevailing rates from the date of the expiration of the 30-day period referred to in paragraph (3) or the date of such final judgment, as the case may be) in an action brought in any appropriate district court of the United States. In such an action, the validity, amount, and appropriateness of such penalty shall not be subject to review.

(b) CRIMINAL.—Any person who knowingly or willfully violates any provision of section 15 shall, in addition to or in lieu of any civil penalty which may be imposed under subsection (a) of this section for such violation, be subject, upon conviction, to a fine of not more than $25,000 for each day of violation, or to imprisonment for not more than one year, or both.

SEC. 17. SPECIFIC ENFORCEMENT AND SEIZURE.

(a) SPECIFIC ENFORCEMENT.—(1) The district courts of the United States shall have jurisdiction over civil actions to—

(A) restrain any violation of section 15,

(B) restrain any person from taking any action prohibited by section 5 or 6 or by a rule or order under section 5 or 6,

(C) compel the taking of any action required by or under this Act, or

(D) direct any manufacturer or processor of a chemical substance or mixture manufactured or processed in violation of section 5 or 6 or a rule or order under section 5 or 6 and distributed in commerce, (i) to give notice of such fact to distributors in commerce of such substance or mixture and, to the extent reasonably ascertainable, to other persons in possession of such substance or mixture or exposed to such substance or mixture, (ii) to give public notice of such risk of injury, and (iii) to either replace or repurchase such substance or mixture, whichever the person to which the requirement is directed elects.

(2) A civil action described in paragraph (1) may be brought—

(A) in the case of a civil action described in subparagraph (A) of such paragraph, in the United States district court for the judicial district wherein any act, omission, or transaction constituting a violation of section 15 occurred or wherein the defendant is found or transacts business, or

(B) in the case of any other civil action described in such paragraph, in the United States district court for the judicial district wherein the defendant is found or transacts business.

In any such civil action process may be served on a defendant in any judicial district in which a defendant resides or may be found. Subpoenas requiring attendance of witnesses in any such action may be served in any judicial district.

(b) SEIZURE.—Any chemical substance or mixture which was manufactured, processed, or distributed in commerce in violation of this Act or any rule promulgated or order issued under this Act or any article containing such a substance or mixture shall be liable to be proceeded against, by process of libel for the seizure and condemnation of such substance, mixture, or article, in any district court of the United States within the jurisdiction of which such substance, mixture, or article is found. Such proceedings shall conform as nearly as possible to proceedings in rem in admiralty.

SEC. 18. PREEMPTION.

(a) EFFECT ON STATE LAW.—(1) Except as provided in paragraph (2), nothing in this Act shall affect the authority of any State or political subdivision of a State to establish or continue in effect regulation of any chemical substance, mixture, or article containing a chemical substance or mixture.

(2) Except as provided in subsection (b)—

(A) if the Administrator requires by a rule promulgated under section 4 the testing of a chemical substance or mixture, no State or political subdivision may, after the effective date of such rule, establish or continue in effect a requirement for the testing of such substance or mixture for purposes similar to those for which testing is required under such rule; and

(B) if the Administrator prescribes a rule or order under section 5 or 6 (other than a rule imposing a requirement described in subsection (a)(6) of section 6) which is applicable to a chemical substance or mixture, and which is designed to protect against a risk of injury to health or the environment associated with such substance or mixture, no State or political subdivision of a State may, after the effective date of such requirement, establish or continue in effect, any requirement which is applicable to such substance or mixture, or an article containing such substance or mixture, and which is designed to protect against such risk unless such requirement (i) is identical to the requirement prescribed by the Administrator, (ii) is adopted under the authority of the Clean Air Act or any other Federal law, or (iii) prohibits the use of such substance or mixture in such State or political subdivision (other than its use in the manufacture or processing of other substances or mixtures).

(b) EXEMPTION.—Upon application of a State or political subdivision of a State the Administrator may by rule exempt from subsection (a)(2), under such conditions as may be prescribed in such rule, a requirement of such State or political subdivision designed to protect against a risk of injury to health or the environment associated with a chemical substance, mixture, or article containing a chemical substance or mixture if—

(1) compliance with the requirement would not cause the manufacturing, processing, distribution in commerce, or use of the substance, mixture, or article to be in violation of the applicable requirement under this Act described in subsection (a)(2), and

(2) the State or political subdivision requirement (A) provides a significantly higher degree of protection from such risk than the requirement under this Act described in subsection (a)(2) and (B) does not, through difficulties in marketing, distribution, or other factors, unduly burden interstate commerce.

SEC. 19. JUDICIAL REVIEW.

(a) IN GENERAL.—(1)(A) Not later than 60 days after the date of the promulgation of a rule under section 4(a), 5(a)(2), 5(b)(4), 6(a), 6(e), or 8, any person may file a petition for judicial review of such rule with the United States Court of Appeals for the District of Columbia Circuit or for the circuit in which such person resides or in which such person's principal place of business is located. Courts of appeals of the United States shall have exclusive jurisdiction of any action to obtain judicial review (other than in an enforcement proceeding) of such a rule if any district court of the United States would have had jurisdiction of such action but for this subparagraph.

(B) Courts of appeals of the United States shall have exclusive jurisdiction of any action to obtain judicial review (other than in an enforcement proceeding) of an order issued under subparagraph (A) or (B) of section 6(b)(1) if any district court of the United States would have had jurisdiction of such action but for this subparagraph.

(2) Copies of any petition filed under paragraph (1)(A) shall be transmitted forthwith to the Administrator and to the Attorney General by the clerk of the court with which such petition was filed. The provisions of section 2112 of title 28, United States Code, shall apply to the filing of the rulemaking record of proceedings on which the Administrator based the rule being reviewed under this section and to the transfer of proceedings between United States courts of appeals.

(3) For purposes of this section, the term "rulemaking record" means—

(A) the rule being reviewed under this section;

(B) in the case of a rule under section 4(a), the finding required by such section, in the case of a rule under section 5(b)(4), the finding required by such section, in the case of a rule under section 6(a) the finding required by section 5(f) or 6(a), as the case may be, in the case of a rule under section 6(a), the statement required by section 6(c)(1), and in the case of a rule under section 6(e), the findings required by paragraph (2)(B) or (3)(B) of such section, as the case may be;

(C) any transcript required to be made of oral presentations made in proceedings for the promulgation of such rule;

(D) any written submission of interested parties respecting the promulgation of such rule; and

(E) any other information which the Administrator considers to be relevant to such rule and which the Administrator identified, on or before the date of the promulgation of such rule, in a notice published in the Federal Register.

(b) ADDITIONAL SUBMISSIONS AND PRESENTATIONS; MODIFICATIONS.—If in an action under this section to review a rule the petitioner or the Administrator applies to the court for leave to make additional oral submissions or written presentations respecting such rule and shows to the satisfaction of the court that such submissions and presentations would be material and that there were reasonable grounds for the submissions and failure to make such submissions and presentations in the proceeding before the Administrator, the court may order the Administrator to provide additional opportunity to make such submissions and presentations. The Administrator may modify or set aside the rule being reviewed or make a new rule by reason of the additional submissions and presentations and shall file such modified or new rule with the return of such submissions and presentations. The court shall thereafter review such new or modified rule

(c) STANDARD OF REVIEW.—(1)(A) Upon the filing of a petition under subsection (a)(1) for judicial review of a rule, the court shall have jurisdiction (i) to grant appropriate relief, including interim relief, as provided in chapter 7 of title 5, United States Code, and (ii) except as otherwise provided in subparagraph (B), to review such rule in accordance with chapter 7 of title 5, United States Code.

(B) Section 706 of title 5, United States Code, shall apply to review of a rule under this section, except that—

(i) in the case of review of a rule under section 4(a), 5(b)(4), 6(a), or 6(e), the standard for review prescribed by paragraph (2)(E) of such section 706 shall not apply and the court shall hold unlawful and set aside such rule if the court finds that the rule is not supported by substantial evidence in the rulemaking record (as defined in subsection (a)(3)) taken as a whole,

(ii) in the case of review of a rule under section 6(a), the court shall hold unlawful and set aside such rule if it finds that—

(I) a determination by the Administrator under section 6(c)(3) that the petitioner seeking review of such rule is not entitled to conduct (or have conducted) cross-examination or to present rebuttal submissions, or

(II) a rule of, or ruling by, the Administrator under section 6(c)(3) limiting such petitioner's cross-examination or oral presentations,

has precluded disclosure of disputed material facts which was necessary to a fair determination by the Administrator of the rulemaking proceeding taken as a whole, and section 706(2)(D) shall not apply with respect to a determination, rule, or ruling referred to in subclause (I) or (II); and

(iii) the court may not review the contents and adequacy of—

(I) any statement required to be made pursuant to section 6(c)(1), or

(II) any statement of basis and purpose required by section 553(c) of title 5, United States Code, to be incorporated in the rule

except as part of a review of the rulemaking record taken as a whole.

The term "evidence" as used in clause (i) means any matter in the rulemaking record

(C) A determination, rule, or ruling of the Administrator described in subparagraph (B)(ii) may be reviewed only in an action under this section and only in accordance with such subparagraph

(2) The judgment of the court affirming or setting aside, in whole or in part, any rule reviewed in accordance with this section shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification, as provided in section 1254 of title 28, United States Code.

(d) FEES AND COSTS.—The decision of the court in an action commenced under subsection (a), or of the Supreme Court of the United States on review of such a decision, may include an award of costs of suit and reasonable fees for attorneys and expert witnesses if the court determines that such an award is appropriate

(e) OTHER REMEDIES.—The remedies as provided in this section shall be in addition to and not in lieu of any other remedies provided by law

SEC. 20. CITIZENS' CIVIL ACTIONS.

(a) IN GENERAL.—Except as provided in subsection (b), any person may commence a civil action—

(1) against any person (including (A) the United States, and (B) any other governmental instrumentality or agency to the extent permitted by the eleventh amendment to the Constitution) who is alleged to be in violation of this Act or any rule promulgated under section 4, 5, or 6 or order issued under section 5 to restrain such violation, or

(2) against the Administrator to compel the Administrator to perform any act or duty under this Act which is not discretionary

Any civil action under paragraph (1) shall be brought in the United States district court for the district in which the alleged violation occurred or in which the defendant resides or in which the defendant's principal place of business is located. Any action brought under paragraph (2) shall be brought in the United States District Court for the District of Columbia, or the United States district court for the judicial district in which the plaintiff is domiciled. The district courts of the United States shall have jurisdiction over suits brought under this section, without regard to the amount in controversy or the citizenship of the parties. In any civil action under this subsection process may be served on a defendant in any judicial district in which the defendant resides or may be found and subpoenas for witnesses may be served in any judicial district.

(b) LIMITATION.—No civil action may be commenced—

(1) under subsection (a)(1) to restrain a violation of this Act or rule or order under this Act—

(A) before the expiration of 60 days after the plaintiff has given notice of such violation (i) to the Administrator, and (ii) to the person who is alleged to have committed such violation, or

(B) if the Administrator has commenced and is diligently prosecuting a proceeding for the issuance of an order under section 16(a)(2) to require compliance with this Act or with such rule or order or if the Attorney General has commenced and is diligently prosecuting a civil action in a court of the United States to require compliance with this Act or with such rule or order, but if such proceeding or civil action is commenced after the giving of notice, any person giving such notice may intervene as a matter of right in such proceeding or action; or

(2) under subsection (a)(2) before the expiration of 60 days after the plaintiff has given notice to the Administrator of the alleged failure of the Administrator to perform an act or duty which is the basis for such action or, in the case of an action under such subsection for the failure of the Administrator to file an action under section 7, before the expiration of ten days after such notification

Notice under this subsection shall be given in such manner as the Administrator shall prescribe by rule

(c) GENERAL.—(1) In any action under this section, the Administrator, if not a party, may intervene as a matter of right

(2) The court, in issuing any final order in any action brought pursuant to subsection (a), may award costs of suit and reasonable fees for attorneys and expert witnesses if the court determines that such an award is appropriate. Any court, in issuing its decision in an action brought to review such an order, may award costs of suit and reasonable fees for attorneys if the court determines that such an award is appropriate

(3) Nothing in this section shall restrict any right which any person (or class of persons) may have under any statute or common law to seek enforcement of this Act or any rule or order under this Act or to seek any other relief.

(d) CONSOLIDATION.—When two or more civil actions brought under subsection (a) involving the same defendant and the same issues or violations are pending in two or more judicial districts, such pending actions, upon application of such defendants to such actions which is made to a court in which any such action is brought, may, if such court in its discretion so decides, be consolidated for trial by order (issued after giving all parties reasonable notice and opportunity to be heard) of such court and tried in—

(1) any district which is selected by such defendant and in which one of such actions is pending,

(2) a district which is agreed upon by stipulation between all the parties to such actions and in which one of such actions is pending, or

(3) a district which is selected by the court and in which one of such actions is pending

The court issuing such an order shall give prompt notification of the order to the other courts in which the civil actions consolidated under the order are pending

SEC. 21. CITIZENS' PETITIONS.

(a) IN GENERAL.—Any person may petition the Administrator to initiate a proceeding for the issuance, amendment, or repeal of a rule under section 4, 6, or 8 or an order under section 5(e) or (6)(b)(2)

(b) PROCEDURES.—(1) Such petition shall be filed in the principal office of the Administrator and shall set forth the facts which it is claimed establish that it is necessary to issue, amend, or repeal a rule under section 4, 6, or 8 or an order under section 5(e), 6(b)(1)(A), or 6(b)(1)(B).

(2) The Administrator may hold a public hearing or may conduct such investigation or proceeding as the Administrator deems appropriate in order to determine whether or not such petition should be granted

(3) Within 90 days after filing of a petition described in paragraph (1), the Administrator shall either grant or deny the petition. If the Administrator grants such petition, the Administrator shall promptly commence an appropriate proceeding in accordance with section 4, 5, 6, or 8. If the Administrator denies such petition, the Administrator shall publish in the Federal Register the Administrator's reasons for such denial.

(4)(A) If the Administrator denies a petition filed under this section (or if the Administrator fails to grant or deny such petition within the 90-day period) the petitioner may commence a civil action in a district court of the United States to compel the Administrator to initiate a rulemaking proceeding as requested in the petition. Any such action shall be filed within 60 days after the Administrator's denial of the petition or, if the Administrator fails to grant or deny the petition within 90 days after filing the petition, within 60 days after the expiration of the 90-day period

(B) In an action under subparagraph (A) respecting a petition to initiate a proceeding to issue a rule under section 4, 6, or 8 or an order under section 5(e) or 6(b)(2), the petitioner shall be provided an opportunity to have such petition considered by the court in a de novo proceeding. If the petitioner demonstrates to the satisfaction of the court by a preponderance of the evidence that—

(i) in the case of a petition to initiate a proceeding for the issuance of a rule under section 4 or an order under section 5(e)—

(I) information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of the chemical substance to be subject to such rule or order, and

(II) in the absence of such information, the substance may present an unreasonable risk to health or the environment, or the substance is or will be produced in substantial quantities and it enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to it; or

(ii) in the case of a petition to initiate a proceeding for the issuance of a rule under section 6 or 8 or an order under section 6(b)(2), there is a reasonable basis to conclude that the issuance of such a rule or order is necessary to protect health or the environment against an unreasonable risk of injury to health or the environment.

the court shall order the Administrator to initiate the action requested by the petitioner If the court finds that the extent of the risk to health or the environment alleged by the petitioner is less than the extent of risks to health or the environment with respect to which the Administrator is taking action under this Act and there are insufficient resources available to the Administrator to take the action requested by the petitioner the court may permit the Administrator to defer initiating the action requested by the petitioner until such time as the court prescribes.

(C) The court in issuing any final order in any action brought pursuant to subparagraph (A) may award costs of suit and reasonable fees for attorneys and expert witnesses if the court determines that such an award is appropriate. Any court, in issuing its decision in an action brought to review such an order, may award costs of suit and reasonable fees for attorneys if the court determines that such an award is appropriate

(5) The remedies under this section shall be in addition to, and not in lieu of, other remedies provided by law.

SEC. 22. NATIONAL DEFENSE WAIVER.

The Administrator shall waive compliance with any provision of this Act upon a request and determination by the President that the requested waiver is necessary in the interest of national defense. The Administrator shall maintain a written record of the basis upon which such waiver was granted and make such record available for in camera examination when relevant in a judicial proceeding under this Act. Upon the issuance of such a waiver, the Administrator shall publish in the Federal Register a notice that the waiver was granted for national defense purposes, unless, upon the request of the President, the Administrator determines to omit such publication because the publication itself would be contrary to the interests of national defense, in which event the Administrator shall submit notice thereof to the Armed Services Committees of the Senate and the House of Representatives.

SEC. 23. EMPLOYEE PROTECTION.

(a) IN GENERAL.—No employer may discharge any employee or otherwise discriminate against any employee with respect to the employee's compensation, terms, conditions, or privileges of employment because the employee (or any person acting pursuant to a request of the employee) has—

(1) commenced, caused to be commenced, or is about to commence or cause to be commenced a proceeding under this Act;

(2) testified or is about to testify in any such proceeding; or

(3) assisted or participated or is about to assist or participate in any manner in such a proceeding or in any other action to carry out the purposes of this Act.

(b) REMEDY.—(1) Any employee who believes that the employee has been discharged or otherwise discriminated against by any person in violation of subsection (a) of this section may, within 30 days after such alleged violation occurs, file (or have any person file on the employee's behalf) a complaint with the Secretary of Labor (hereinafter in this section referred to as the "Secretary") alleging such discharge or discrimination. Upon receipt of such a complaint, the Secretary shall notify the person named in the complaint of the filing of the complaint.

(2)(A) Upon receipt of a complaint filed under paragraph (1), the Secretary shall conduct an investigation of the violation alleged in the complaint. Within 30 days of the receipt of such complaint, the Secretary shall complete such investigation and shall notify in writing the complainant (and any person acting on behalf of the complainant) and the person alleged to have committed such violation of the results of the investigation conducted pursuant to this paragraph. Within ninety days of the receipt of such complaint the Secretary shall, unless the proceeding on the complaint is terminated by the Secretary on the basis of a settlement entered into by the Secretary and the person alleged to have committed such violation, issue an order either providing the relief prescribed by subparagraph (B) or denying the complaint. An order of the Secretary shall be made on the record after notice and opportunity for agency hearing. The Secretary may not enter into a settlement terminating a proceeding on a complaint without the participation and consent of the complainant.

(B) If in response to a complaint filed under paragraph (1) the Secretary determines that a violation of subsection (a) of this section has occurred, the Secretary shall order (i) the person who committed such violation to take affirmative action to abate the violation, (ii) such person to reinstate the complainant to the complainant's former position together with the compensation (including back pay), terms, conditions, and privileges of the complainant's employment, (iii) compensatory damages, and (iv) where appropriate, exemplary damages. If such an order issued, the Secretary, at the request of the complainant, shall assess against the person against whom the order is issued a sum equal to the aggregate amount of all costs and expenses (including attorney's fees) reasonably incurred, as determined by the Secretary, by the complainant for, or in connection with, the bringing of the complaint upon which the order was issued.

(c) REVIEW.—(1) Any employee or employer adversely affected or aggrieved by an order issued under subsection (b) may obtain review of the order in the United States Court of Appeals for the circuit in which the violation, with respect to which the order was issued, allegedly occurred The petition for review must be filed within sixty days from the issuance of the Secretary's order. Review shall conform to chapter 7 of title 5 of the United States Code.

(2) An order of the Secretary, with respect to which review could have been obtained under paragraph (1), shall not be subject to judicial review in any criminal or other civil proceeding

(d) ENFORCEMENT.—Whenever a person has failed to comply with an order issued under subsection (b)(2), the Secretary shall file a civil action in the United States district court for the district in which the violation was found to occur to enforce such order In actions brought under this subsection, the district courts shall have jurisdiction to grant all appropriate relief, including injunctive relief and compensatory and exemplary damages Civil actions brought under this subsection shall be heard and decided expeditiously.

(e) EXCLUSION.—Subsection (a) of this section shall not apply with respect to any employee who, acting without direction from the

employee's employer (or any agent of the employer), deliberately causes a violation of any requirement of this Act.

SEC. 24. EMPLOYMENT EFFECTS.

(a) IN GENERAL.—The Administrator shall evaluate on a continuing basis the potential effects on employment (including reductions in employment or loss of employment from threatened plant closures) of—

(1) the issuance of a rule or order under section 4, 5, or 6, or

(2) a requirement of section 5 or 6.

(b)(1) INVESTIGATIONS.—Any employee (or any representative of an employee) may request the Administrator to make an investigation of—

(A) a discharge or layoff or threatened discharge or layoff of the employee, or

(B) adverse or threatened adverse effects on the employee's employment,

allegedly resulting from a rule or order under section 4, 5, or 6 or a requirement of section 5 or 6. Any such request shall be made in writing, shall set forth with reasonable particularity the grounds for the request, and shall be signed by the employee, or representative of such employee, making the request.

(2)(A) Upon receipt of a request made in accordance with paragraph (1) the Administrator shall (i) conduct the investigation requested, and (ii) if requested by any interested person hold public hearings on any matter involved in the investigation unless the Administrator, by order issued within 45 days of the date such hearings are requested, denies the request for the hearings because the Administrator determines there are no reasonable grounds for holding such hearings. If the Administrator makes such a determination, the Administrator shall notify in writing the person requesting the hearing of the determination and the reasons therefor and shall publish the determination and the reasons therefor in the Federal Register.

(B) If public hearings are to be held on any matter involved in an investigation conducted under this subsection—

(i) at least five days' notice shall be provided the person making the request for the investigation and any person identified in such request,

(ii) such hearings shall be held in accordance with section 6(c)(3), and

(iii) each employee who made or for whom was made a request for such hearings and the employer of such employee shall be required to present information respecting the applicable matter referred to in paragraph (1)(A) or (1)(B) together with the basis for such information.

(3) Upon completion of an investigation under paragraph (2), the Administrator shall make findings of fact, shall make such recommendations as the Administrator deems appropriate, and shall make available to the public such findings and recommendations.

(4) This section shall not be construed to require the Administrator to amend or repeal any rule or order in effect under this Act.

SEC. 25. STUDIES.

(a) INDEMNIFICATION STUDY.—The Administrator shall conduct a study of all Federal laws administered by the Administrator for the purpose of determining whether and under what conditions, if any, indemnification should be accorded any person as a result of any action taken by the Administrator under any such law. The study shall—

(1) include an estimate of the probable cost of any indemnification programs which may be recommended;

(2) include an examination of all viable means of financing the cost of any recommended indemnification; and

(3) *be completed and submitted to Congress within two years* from the effective date of enactment of this Act.

The General Accounting Office shall review the adequacy of the study submitted to Congress pursuant to paragraph (3) and shall report the results of its review to the Congress within six months of the date such study is submitted to Congress.

(b) CLASSIFICATION, STORAGE, AND RETRIEVAL STUDY.—The Council on Environmental Quality, in consultation with the Administrator, the Secretary of Health, Education, and Welfare, the Secretary of Commerce, and the heads of other appropriate Federal departments or agencies, shall coordinate a study of the feasibility of establishing (1) a standard classification system for chemical substances and related substances, and (2) a standard means for storing and for obtaining rapid access to information respecting such substances. A report on such study shall be completed and submitted to Congress not later than 18 months after the effective date of enactment of this Act.

SEC. 26. ADMINISTRATION OF THE ACT.

(a) COOPERATION OF FEDERAL AGENCIES.—Upon request by the Administrator, each Federal department and agency is authorized—

(1) to make its services, personnel, and facilities available (with or without reimbursement) to the Administrator to assist the Administrator in the administration of this Act; and

(2) to furnish to the Administrator such information, data, estimates, and statistics, and to allow the Administrator access to all information in its possession as the Administrator may reasonably determine to be necessary for the administration of this Act.

(b) FEES.—(1) The Administrator may, by rule, require the payment of a reasonable fee from any person required to submit data under section 4 or 5 to defray the cost of administering this Act. Such rules shall not provide for any fee in excess of $2,500 or, in the case of a small business concern, any fee in excess of $100. In setting a fee under this paragraph, the Administrator shall take into account the ability to pay of the person required to submit the data and the cost to the Administrator of reviewing such data. Such rules may provide for sharing such a fee in any case in which the expenses of testing are shared under section 4 or 5.

(2) The Administrator, after consultation with the Administrator of the Small Business Administration, shall by rule prescribe standards for determining the persons which qualify as small business concerns for purposes of paragraph (1).

(c) ACTION WITH RESPECT TO CATEGORIES.—(1) Any action authorized or required to be taken by the Administrator under any provision of this Act with respect to a chemical substance or mixture may be taken by the Administrator in accordance with that provision with respect to a category of chemical substances or mixtures. Whenever the Administrator takes action under a provision of this Act with respect to a category of chemical substances or mixtures, any reference in this Act to a chemical substance or mixture (insofar as it relates to such action) shall be deemed to be a reference to each chemical substance or mixture in such category.

(2) For purposes of paragraph (1)

(A) The term "category of chemical substances" means a group of chemical substances the members of which are similar in molecular structure, in physical, chemical, or biological properties, in use, or in mode of entrance into the human body or into the environment, or the members of which are in some other way suitable for classification as such for purposes of this Act, except that such term does not mean a group of chemical substances which are grouped together solely on the basis of their being new chemical substances.

(B) The term "category of mixtures" means a group of mixtures the members of which are similar in molecular structure, in physical, chemical, or biological properties, in use, or in the mode of entrance into the human body or into the environment, or the members of which are in some other way suitable for classification as such for purposes of this Act.

(d) ASSISTANCE OFFICE.—The Administrator shall establish in the Environmental Protection Agency an identifiable office to provide technical and other nonfinancial assistance to manufacturers and processors of chemical substances and mixtures respecting the requirements of this Act applicable to such manufacturers and processors, the policy of the Agency respecting the application of such requirements to such manufacturers and processors, and the means and methods by which such manufacturers and processors may comply with such requirements.

(e) FINANCIAL DISCLOSURES.—(1) Except as provided under paragraph (3), each officer or employee of the Environmental Protection Agency and the Department of Health, Education, and Welfare who—

(A) performs any function or duty under this Act, and

(B) has any known financial interest (i) in any person subject to this Act or any rule or order in effect under this Act, or (ii) in any person who applies for or receives any grant or contract under this Act,

shall, on February 1, 1978, and on February 1 of each year thereafter, file with the Administrator or the Secretary of Health, Education, and Welfare (hereinafter in this subsection referred to as the "Secretary"), as appropriate, a written statement concerning all such interests held by such officer or employee during the preceding calendar year. Such statement shall be made available to the public.

(2) The Administrator and the Secretary shall—

(A) act within 90 days of the effective date of this Act—

(i) to define the term "known financial interests" for purposes of paragraph (1), and

(ii) to establish the methods by which the requirement to file written statements specified in paragraph (1) will be monitored and enforced, including appropriate provisions for review by the Administrator and the Secretary of such statements, and

(B) report to the Congress on June 1, 1978, and on June 1 of each year thereafter with respect to such statements and the actions taken in regard thereto during the preceding calendar year.

(3) The Administrator may by rule identify specific positions with the Environmental Protection Agency, and the Secretary may by rule identify specific positions with the Department of Health, Education, and Welfare, which are of a nonregulatory or nonpolicy making nature, and the Administrator and the Secretary may by rule provide that officers or employees occupying such positions shall be exempt from the requirements of paragraph (1).

(4) This subsection does not supersede any requirement of chapter 11 of title 18, United States Code.

(5) Any officer or employee who is subject to, and knowingly violates, this subsection or any rule issued thereunder, shall be fined not more than $2,500 or imprisoned not more than one year, or both.

(f) STATEMENT OF BASIS AND PURPOSE.—Any final order issued under this Act shall be accompanied by a statement of its basis and purpose. The contents and adequacy of any such statement shall not be subject to judicial review in any respect.

(g) ASSISTANT ADMINISTRATOR.—(1) The President, by and with the advice and consent of the Senate, shall appoint an Assistant Administrator for Toxic Substances of the Environmental Protection Agency. Such Assistant Administrator shall be a qualified individual who is, by reason of background and experience, especially qualified to direct a program concerning the effects of chemicals on human health and the environment. Such Assistant Administrator shall be responsible for (A) the collection of data, (B) the preparation of studies, (C) the making of recommendations to the Administrator for regulatory and other actions to carry out the purposes and to facilitate the administration of this Act, and (D) such other functions as the Administrator may assign or delegate.

(2) The Assistant Administrator to be appointed under paragraph (1) shall (A) be in addition to the Assistant Administrators of the Environmental Protection Agency authorized by section 1(d) of Reorganization Plan No. 3 of 1970, and (B) be compensated at the rate of pay authorized for such Assistant Administrators.

SEC. 27. DEVELOPMENT AND EVALUATION OF TEST METHODS.

(a) IN GENERAL.—The Secretary of Health, Education, and Welfare, in consultation with the Administrator and acting through the Assistant Secretary for Health, may conduct, and make grants to public and nonprofit private entities and enter into contracts with public and private entities for, projects for the development and evaluation of inexpensive and efficient methods (1) for determining and evaluating the health and environmental effects of chemical substances and mixtures, and their toxicity, persistence, and other characteristics which affect health and the environment, and (2) which may be used for the development of test data to meet the requirements of rules promulgated under section 4. The Administrator shall consider such methods in prescribing under section 4 standards for the development of test data.

(b) APPROVAL BY SECRETARY.—No grant may be made or contract entered into under subsection (a) unless an application therefor has been submitted to and approved by the Secretary. Such an application shall be submitted in such form and manner and contain such information as the Secretary may require. The Secretary may apply such conditions to grants and contracts under subsection (a) as the Secretary determines are necessary to carry out the purposes of such subsection. Contracts may be entered into under such subsection without regard to sections 3648 and 3709 of the Revised Statutes (31 U.S.C. 529; 41 U.S.C. 5).

(c) ANNUAL REPORTS.—(1) The Secretary shall prepare and submit to the President and the Congress on or before January 1 of each year a report of the number of grants made and contracts entered into under this section and the results of such grants and contracts.

(2) The Secretary shall periodically publish in the Federal Register reports describing the progress and results of any contract entered into or grant made under this section.

SEC. 28. STATE PROGRAMS.

(a) IN GENERAL.—For the purpose of complementing (but not reducing) the authority of, or actions taken by, the Administrator under this Act, the Administrator may make grants to States for the establishment and operation of programs to prevent or eliminate unreasonable risks within the States to health or the environment which are associated with a chemical substance or mixture and with respect to which the Administrator is unable or is not likely to take action under this Act for their prevention or elimination. The amount of a grant under this subsection shall be determined by the Administrator, except that no grant for any State program may exceed 75 per centum of the establishment and operation costs (as determined by the Administrator) of such program during the period for which the grant is made.

(b) APPROVAL BY ADMINISTRATOR.—(1) No grant may be made under subsection (a) unless an application therefor is submitted to and approved by the Administrator. Such an application shall be submitted in such form and manner as the Administrator may require and shall—

(A) set forth the need of the applicant for a grant under subsection (a),

(B) identify the agency or agencies of the State which shall establish or operate, or both, the program for which the application is submitted,

(C) describe the actions proposed to be taken under such program,

(D) contain or be supported by assurances satisfactory to the Administrator that such program shall, to the extent feasible, be integrated with other programs of the applicant for environmental and public health protection,

(E) provide for the making of such reports and evaluations as the Administrator may require, and

(F) contain such other information as the Administrator may prescribe.

(2) The Administrator may approve an application submitted in accordance with paragraph (1) only if the applicant has established to the satisfaction of the Administrator a priority need, as determined under rules of the Administrator, for the grant for which the application has been submitted. Such rules shall take into consideration the seriousness of the health effects in a State which are associated with chemical substances or mixtures, including cancer, birth defects, and gene mutations, the extent of the exposure in a State of human beings and the environment to chemical substances and mixtures, and the extent to which chemical substances and mixtures are manufactured, processed, used, and disposed of in a State.

(c) ANNUAL REPORTS.—Not later than six months after the end of each of the fiscal years 1979, 1980, and 1981, the Administrator shall submit to the Congress a report respecting the programs assisted by grants under subsection (a) in the preceding fiscal year and the extent to which the Administrator has disseminated information respecting such programs.

(d) AUTHORIZATION.—For the purpose of making grants under subsection (a) there are authorized to be appropriated $1,500,000 for the fiscal year ending September 30, 1977, $1,500,000 for the fiscal year ending September 30, 1978, and $1,500,000 for the fiscal year ending September 30, 1979. Sums appropriated under this subsection shall remain available until expended.

SEC. 29. AUTHORIZATION FOR APPROPRIATIONS.

There are authorized to be appropriated to the Administrator for purposes of carrying out this Act (other than sections 27 and 28 and subsections (a) and (c) through (g) of section 10 thereof) $10,100,000 for the fiscal year ending September 30, 1977, $12,625,000 for the fiscal year ending September 30, 1978, $16,200,000 for the fiscal year ending September 30, 1979. No part of the funds appropriated under this section may be used to construct any research laboratories.

SEC. 30. ANNUAL REPORT.

The Administrator shall prepare and submit to the President and the Congress on or before January 1, 1978, and on or before January 1 of each succeeding year a comprehensive report on the administration of this Act during the preceding fiscal year. Such report shall include—

(1) a list of the testing required under section 4 during the year for which the report is made and an estimate of the costs incurred during such year by the persons required to perform such tests;

(2) the number of notices received during such year under section 5, the number of such notices received during such year under such section for chemical substances subject to a section 4 rule, and a summary of any action taken during such year under section 5(g),

(3) a list of rules issued during such year under section 6,

(4) a list, with a brief statement of the issues, of completed or pending judicial actions under this Act and administrative actions under section 16 during such year;

(5) a summary of major problems encountered in the administration of this Act, and

(6) such recommendations for additional legislation as the Administrator deems necessary to carry out the purposes of this Act.

SEC. 31. EFFECTIVE DATE.

Except as provided in section 4(f), this Act shall take effect on January 1, 1977.

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Chapter Two

The TSCA Inspector

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1

Inspection Overview

Inspections may be necessary for the enforcement of several of the provisions of TSCA. Compliance inspection is the enforcement mechanism for detection and verification of violations. Facilities are selected for inspection under a neutral administrative inspection scheme or may be selected "for cause." Selection may be made, depending on the circumstances, by headquarters or regional offices.

Evidence obtained during an inspection may result in the Agency taking any of the following enforcement actions:

- Issue a notice on noncompliance;
- Issue a notice to show cause;
- Assess an administrative civil penalty;
- Institute a civil court action; or
- Institute a criminal court action.

The government's case in a formal hearing or criminal prosecution depends on the accuracy and quality of the evidence gathered by the inspector.

Authority

Sections 11(a) and (b) provide the authority for conducting inspections to monitor compliance with the provisions of, and rules under, TSCA. Any establishment, facility, or other premises in which chemical substances or mixtures are manufactured, processed, stored, or held before or after distribution in commerce and any conveyance used to transport chemical substances is subject to inspection under TSCA.

Scope

Inspections conducted under Section 11 extend to all things relating to compliance with the requirements of TSCA which are within the premises or conveyance being inspected. This includes:

- Records;
- Files;
- Papers;
- Chemical substances;
- Processes
- Controls; and
- Facilities.

To carry out the inspection, samples may be taken and photographs may be made.

Limitations

Certain types of data can only be inspected if the nature and extent of such data are described specifically in the written Notice of Inspection presented to the owner, operator, or agent in charge of the premises or conveyance. These include:

- Financial data;
- Sales data (other than shipment data);
- Pricing data;
- Personnel data; or
- Research data (other than research data required by the provisions of TSCA).

Purpose

The purpose of inspection is to ensure compliance with TSCA and with the rules under TSCA. The inspector's role is

- To inform the regulated industry of the requirements of the law, and
- To document suspected violations.

Confidentiality

During the course of TSCA inspections, inspectors will encounter information which may be entitled to confidential treatment under Section 14 of TSCA and EPA regulations (40 CFR Part 2). This Section of the statute and the regulations are designed to protect confidential business information from urauthorized 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.

Because of the sensitivity of some of the information that will be submitted or collected under TSCA, very stringent procedures for handling confidential information have been established for TSCA-Confidential Business Information (TSCA-CBI). These procedures are contained in the TSCA-CBI Manual which governs access to and control of documents by EPA personnel. There are special procedures for access to TSCA-CBI by contractors and other Federal agencies.

Because conducting TSCA inspections presents some special considerations with regard to declaration and handling of confidential business information, additional procedures concerning confidentiality have been incorporated into each section of this manual. These procedures are designed to provide adequate notification to companies of their right to declare inspection data confidential and to ensure secure handling of this information at each stage of the inspection.

NOTE: It should be clearly understood that the confidential business information as referenced throughout this manual does not in any manner refer to classified National Security Information as defined in Executive Order 12065 nor do these procedures imply authorization to classified information. All materials claimed confidential business information must be marked with the words "Confidential business information does not include National Security Information (EO 12065)."

Elements of an Inspection

The elements of TSCA facility inspections can be grouped into the following five procedural categories: (1) pre-inspection preparation, (2) entry, (3) opening conference, (4) sampling and documentation, and (5) the closing conference. These elements are common to all inspections, but the emphasis given to the separate elements will vary with the needs of the individual inspection. Each of the procedural categories is discussed in detail in Chapter Three of this manual. Refer to later Volumes for substance specific details.

Pre-Inspection Preparation

To ensure effective use of the inspector's time, the following procedures are undertaken before beginning the inspection of a selected facility:

- Establishing inspection objectives
- Establishing the scope of the inspection
- Conducting a review of Agency records
- Preparing necessary documents and equipment

Entry

Entry procedures are those which relate to obtaining actual physical entry of the facility. Entry involves the following steps.

- Introduction
- Presenting credentials
- Presenting Notice of Inspection
- Managing denial of entry when necessary

Opening Conference

After entry, the inspector conducts an opening conference with the facility management. During the opening conference, the inspector is responsible for the following activities:

- Discussing the objectives and scope of the inspection
- Presenting the TSCA Inspection Confidentiality Notice
- Advising of the availability of duplicate samples
- Providing information on TSCA and its rules

Sampling and Documentation

Reviewing facility records, taking physical samples, and preparing documentation are the basic inspection activities. It is these activities which provide the evidentiary support the Agency uses in enforcement actions. The inspector's responsibilities include:

- Targeting and locating facility records
- Assessing facility records
- Preparing documentation of all inspection activities
- Assessing conditions and taking necessary samples
- Operating in a safe and efficient manner

Closing Conference

The closing conference with facility officials enables the inspector to prepare receipts, answer questions, and provide information about TSCA. At the closing conference, the inspector "wraps up" the inspection by

- Writing necessary receipts
- Reviewing confidentiality claims
- Discussing inspectional findings

Other Inspection Activities

Inspectors may be called upon to participate in special inspectional operations. Such inspections are conducted under TSCA authority and usually contain the same elements as scheduled TSCA inspections. Inspections may be undertaken as a result of the need for emergency response, or as a result of citizen, labor, or industry complaints.

Emergencies

The nature of the substances regulated under TSCA may involve inspectors in responding to potentially dangerous emergency situations. Inspectors may be called upon to undertake inspections in cases of possible imminent hazard or other unforeseeable circumstances that are violations of TSCA. The usual requirements and procedures for inspection apply in such cases. Although it may not be possible to plan or conduct pre-inspection procedures with *customary thoroughness, the elements of the inspection remain* essentially the same. The importance of safety procedures and precautions should be stressed in such situations.

Complaints and Citizen Referrals

EPA inspectors may conduct inspections which are being undertaken as a result of complaints or other information submitted to the Agency by workers, industry, individual citizens, or citizen groups. For the goals of TSCA to be achieved, this kind of public participation in the detection of discrepancies and potential violations is of great value and should be encouraged by inspectors. Referrals and tips given to an inspector should be thoroughly investigated, and whenever possible, substantiating evidence should be obtained to aid in followup inspections.

Section 23 of TSCA protects from discrimination any employee who reports a violation to EPA or who testifies or otherwise participates in a proceeding against a firm.

Referral Inspection Program

The IRLG referral inspection program was created so that inspectors from the member agencies -- Consumer Product Safety Commission (CPSC), Food and Drug Administration (FDA), Occupational Safety and Health Administration (OSHA), Food Safety and Quality Service (FSQS), and EPA -- could recognize and make referrals of potential violations of another agency's laws or regulations. Inspectors from the member agencies are trained to recognize and refer such potential violations to the appropriate agency for followup inspection. EPA inspectors may be called upon to make such referrals or to handle followup investigations and inspections resulting from another agency's activities. (For details and guidance on IRLG programs consult with your supervisor.)

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Inspector Authority

Inspectors are skilled professionals who represent the Agency in dealing with regulated industry and the public. Inspectors are responsible for conducting inspections in a professional manner that reflects credit on themselves and the Agency. The primary responsibility of inspectors is to inspect facilities for compliance with TSCA requirements.

Inspector Authority

Delegation

Authority to inspect under TSCA is granted to the EPA Administrator who, in turn, has redelegated his authority to the Regional Administrators and Headquarters enforcement personnel.

The individual inspector is granted the authority to inspect under TSCA through the issuance of a multi-media inspection credential which identifies the inspector as a duly designated representative of the Administrator.

An inspector is, then, a specially appointed representative of the Administrator, charged with enforcement of TSCA.

Credentials

Official EPA inspection credentials are issued to each inspector and empower the inspector to conduct Agency inspections.

Only persons with multi-media inspection credentials have the right to conduct facility inspections. The Act requires that these credentials be presented to appropriate facility personnel at each inspection.

Credentials are valuable documents which should never leave the sight of the inspector; they must never be permitted to be photocopied.

Applicable Laws. To carry out their duties effectively, inspectors must be thoroughly familiar with the legal basis for their actions. An inspector must be thoroughly knowledgeable about:

- Toxic Substances Control Act
- Regulations promulgated under TSCA

In addition, an inspector should be familiar with other EPA-administered laws relating to toxics, including

- Federal Water Pollution Control Act
- Clean Air Act
- Federal Insecticide, Fungicide, and Rodenticide Act
- Resource Conservation and Recovery Act
- Safe Drinking Water Act

Confidential Business Information Access Authorization

An inspector who conducts TSCA inspections is likely to encounter TSCA Confidential Business Information (TSCA-CBI). Since such information may only be viewed by individuals who have been cleared for access, each TSCA inspector will be required to have a TSCA-CBI access authorization.

Following is a brief summary of the specific procedures that have been developed for obtaining access authorization to TSCA-CBI. Check with the Document Control Officer for complete instructions and necessary forms.

The form "Authorization for Access to TSCA Confidential Business Information" outlines the three basic steps of the authorization process:

1. The inspector must obtain written authorization from the Division Director or other appropriate authorizing official. (Part I of the form.)

2. The inspector must sign the Confidentiality Agreement for EPA Employees. (Part II of the form.)

3. The local Document Control Officer must certify that appropriate investigative forms have been filed with the Headquarters Security Branch. (Part III of the form.)

Upon completion of this process, the local Document Control Officer will place the inspector's name on the Authorized Access List and will notify the inspector of the authorization.

A letter certifying that the inspector is authorized for access will be issued by the Deputy Administrator for General Enforcement. This letter may be used to prove authorization upon entry into a facility.

Special Category

Some TSCA Confidential Business Information, considered particularly sensitive, has been designated Special Category TSCA-CBI. This subset includes: (1) specific chemical identities, (2) information about product formulations, and (3) information about specific processes used in manufacturing or processing.

Inspectors who perform TSCA inspections under Sections 5 and 8 or certain kinds of inspections under Section 6 rules should request Special Category clearance. An inspector who has Special Category also has general access. See the Document Control Officer for details.

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Inspector Responsibilities

A high level of professional skills and work ethics standards is required of all inspectors. Inspectors are required to have a working knowledge of all applicable laws and regulations, to be familiar with Agency legal and procedural requirements, and to develop appropriate communications and interpersonal skills. In the execution of their duties inspectors are expected to collect samples, review records, and prepare the appropriate documents associated with the inspection.

Confidential Business Information Procedures

The Agency recognizes the obligation of trust placed upon it by the reporters of confidential business information. For this reason, EPA employees are prohibited under penalty of law from disclosing, in any manner and to any extent not authorized by law, any TSCA Confidential Business Information (TSCA-CBI) coming to them in the course of their employment or official duties. Unauthorized disclosure of such information may subject the employee to criminal penalties of up to $5,000 and/or imprisonment for up to one year.

Inspectors will be required to abide by the terms of the "Confidentiality Agreement for EPA Employees" they have signed. In addition, inspectors must be familiar with and carefully follow the procedures for handling TSCA-CBI as prescribed in the TSCA-CBI Security Manual as well as the additional confidentiality procedures discussed throughout this manual.

When practical circumstances in the field prohibit strict adherence to these procedures, inspectors are expected to take all measures necessary to ensure protection of the information.

Professional Skills

Procedural Requirements

Effective inspections are based upon experience, and upon knowledge and observance of correct procedures. Inspectors are required to be familiar with legal requirements, procedures for effective evidence gathering, and safety practices.

- Legal Requirements

Because the inspector directly represents the Agency to regulated industry, it is essential that he carefully abide by the legal and regulatory requirements of the Act.

Inspection Requirements. Inspectors must be familiar with and observe specific legal requirements that have been established for inspection, including:

- Presentation of proper credentials
- Presentation of required notices and receipts
- Proper handling of confidential business information

Regulatory Requirements. Inspectors must be familiar with and observe all of the regulations regarding the handling of chemical substances controlled under TSCA.

- Evidence Gathering

Inspectors must be familiar with general evidence gathering techniques, including collecting samples and obtaining statements from witnesses.

The specific information collected during a TSCA inspection will depend on the nature of the regulatory requirement being monitored. The objective of inspections is to document suspected violations of the law. Because the Government's case in a civil or criminal prosecution depends on the evidence gathered by the inspector, it is imperative that each inspector keep detailed records of each inspection and describe all photographs taken during an inspection. This data will serve as an aid in preparing the inspection report, in determining the appropriate enforcement response, and in giving testimony in an enforcement case.

- Safety

The handling and sampling of any chemical substance regulated under TSCA always poses a certain degree of risk. To avoid unnecessary health and safety risks it is the responsibility of each inspector

- To be thoroughly familiar with all safety guidance and practices for TSCA substances;
- To use safety equipment in accordance with guidance received and labeling instructions;
- To maintain safety equipment in good condition and proper working order;
- To dress appropriately for the activity in which he is engaged, and wear appropriate protective clothing; and
- To wear any safety equipment customary in the establishment being inspected, e.g., hard hat or safety glasses.

NOTE: See Chapter Three, Section 4f for detailed information on Health and Safety.

Communications and Interpersonal Skills

TSCA inspectors must know how to effectively apply and communicate information relating to inspection operations. Inspectors should develop and maintain expertise in relevant communications and interpersonal areas. Inspectors should know:

- How to substantiate all facts with statements of witnesses or items of evidence.
- How to evaluate what evidence is necessary to obtain successful civil actions, criminal prosecution, or seizure.
- How to obtain respect, inspire confidence, and maintain the good will of the public, industry, and consumers.
- How to detect discrepancies or lack of good faith during interviews.
- How to testify in court and administrative hearings.

- How to conduct sampling procedures in a professional and safe manner.

- How to write clear and informative reports.

Work Ethics

As officers of the Federal government, inspectors are expected to perform their duties as responsible law enforcement officers with the highest degree of honesty. Procedures and requirements ensuring ethical actions have been worked out through many years of EPA and Federal government inspectional experience. These procedures and standards of conduct have evolved for the protection of the individual and the Agency, as well as industry, so that the rights of neither are jeopardized. The inspector has an opportunity to set an example for private industry in encouraging concern over health and safety in the environment and to reinforce attitudes encouraging compliance with laws that protect the environment.

- All investigations are to be conducted within the framework of the United States Constitution and with due regard for individual rights regardless of race, sex, creed, or national origin.

- Inspectors are to conduct themselves at all times in accordance with the regulations prescribing EPA Employee Responsibilities and Conduct, which are codified at 40 CFR Part 3 and available in the EPA handbook "Responsibilities and Conduct for EPA Employees."

- The facts of an investigation are to be developed and reported completely, accurately, and objectively.

- In the course of an investigation, any act or failure to act motivated by reason of private gain is illegal. Actions which could be construed as such should be scrupulously avoided.

- A continuing effort to improve professional knowledge and technical skill in the investigative field should be made.

Professional Attitude. The inspector is a representative of EPA and is often the initial or only contact between the Agency and the regulated industries. In dealing with industry representatives and employees, inspectors must be dignified, tactful, courteous, and diplomatic. A firm but responsive attitude will help establish an atmosphere of cooperation and will initiate good working relations.

Attire. Inspectors should dress appropriately, including wearing protective clothing or equipment, for the activity in which they are engaged.

Industry, Public, and Consumer Relations. All information acquired in the course of an inspector's duties is for official use only. Inspectors should not speak of any product, manufacturer, or person in a derogatory manner.

Gifts, Favors, Luncheons. Inspectors should avoid accepting favors or benefits under circumstances that might be construed as influencing the performance of government duties. EPA regulations provide an exemption whereby an inspector could accept food and refreshments of nominal value on infrequent occasions in the ordinary course of a luncheon or dinner meeting or other meeting, or during an inspection tour. Inspectors should use this exemption only when absolutely necessary.

Requests for Information. EPA has an "open-door" policy on releasing information to the public. This policy aims at making information about EPA and its work freely and equally available to all interested individuals, groups, and organizations. In fact, EPA employees have both a legal and traditional responsibility for making useful educational and safety information available to the public. This policy, however, does not extend to information relating to the suspicion of a violation, evidence of possible misconduct, or confidential business information.

3 TSCA Inspection Procedures

Chapter Three

Inspection Procedures

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Pre-Inspection Preparation

Preplanning is necessary to ensure that the inspection is properly focused, and that the inspection is conducted both smoothly and efficiently. During the preplanning process, documents, forms, equipment, and educational material necessary to the inspection should be prepared.

Agency Records Review

A thorough review of records in Agency files relating to a facility to be inspected is essential in pre-inspection preparation. This review will save time and minimize inconvenience during an inspection by not requiring examination of information that has previously been made available. The review will also give the inspector important background information on the facility's operations and compliance history.

Review Considerations

The following documents and types of information may be reviewed in preparing for an inspection:

- General facility information, including type, size, and location of the facility to be inspected. This information will be helpful in planning time and resource allocation and in preparing documents and equipment.

- Previous inspection records and reports on enforcement proceedings that resulted from other inspections. Special note should be made of any violations observed in previous inspections so the facility can be checked to ensure current compliance.

- Special exemptions from requirements that may have been granted by EPA. Additional requirements may have been placed on the facility in granting the exemption.

- Reports prepared by the facility that were obtained during previous inspections. Inspectors should review these reports and note any discrepancies previously observed in the facility records. If information is not clearly presented in the annual facility report, an inspector should note that deficiency in order to pay particular attention during the inspection and thus clarify the information.

- Documents, correspondence, and permits concerning current wastewater discharge, solid waste disposal, and on-going construction.

- Additional information may be requested from the facility when obvious inadequacies, inconsistencies, or voids are discovered in the facility files.

Confidential Business Information

An inspector may need access to confidential business information in the course of preparing for an inspection. This information may consist of confidential business data a firm has previously reported to the Agency or which was collected during a prior inspection. The inspector will request access to the information from the appropriate Document Control Officer (DCO), who will:

- Verify the inspector's listing on the authorized access list.

- Secure a copy for the inspector.

- Determine if the inspector has secure storage approved by the Security Branch. Confidential business data may be checked out for 30 days if storage provisions are adequate according to Chapter III 3.b. of the TSCA-CBI Security Manual. Otherwise, data must be returned to the DCO that same day.

Safeguards During Use

Confidential business information, when in actual use by an authorized person, is to be protected in the following manner:

- Kept under the constant surveillance of an authorized person who can exercise direct security control over the material.
- Covered, turned face down, placed in approved storage containers, or otherwise protected, when unauthorized persons are present.
- Returned to approved storage containers when not in use or to the DCO at close of business when not checked out.
- Discussed only with other authorized persons. (Check with the DCO to determine if the person is authorized.)
- Transferred to one authorized person within a division by means of a Loan Receipt for TSCA-CBI available from the DCO. A copy of the Receipt is to be furnished to the DCO. The secondary recipient must also sign the cover sheet.

Document Preparation

Documents and forms necessary for the inspection should be prepared in advance of the inspection whenever possible. (Document and form samples and instructions for completion can be found in Chapter Six. Discussions of their use appear at the appropriate places in the text.)

Inspection Documents

- Notice of Inspection. Written notice must be presented upon the inspector's arrival at the facility. Portions of this form can be filled out in advance; but the time of inspection and name(s) of facility official(s) are entered at the time of inspection.
- Compliance Report Form. Substance-specific inspection Volumes will provide a detailed compliance form which will guide inspectors in gathering relevant information.

- TSCA Inspection Confidentiality Notice. This form is used to inform facility officials of their right to claim inspection data confidential business information.

- Sampling Documents. The following forms relate to physical samples and are used to record and control sample identification and custody. These forms are discussed in detail in Chapter Three, Sections 4d and 4e, and include:

    - Custody Seal(s)
    - Chain of Custody Record

- Receipt of Samples and Documents. All samples and documents taken during an inspection are listed on this form.

- Declaration of Confidential Business Information. This form is used to list all documents and samples taken during an inspection that have been claimed confidential business information.

- Copies of TSCA and of Specific Regulations. Some facility officials may not have copies of the Act or of applicable rules and regulations. Inspectors should have these available for distribution.

- Agency Outreach Materials. Inspectors should provide current, relevant educational information to facility officials relating to voluntary compliance efforts.

Equipment Preparation

The kinds of equipment that an inspector carries should be specifically related to the kind of inspection to be undertaken. For example, a PCB inspection will require several kinds of sampling devices and containers, while a CFC inspection may only require packaging materials for samples. The inspector is expected to use sound judgment and rely on training and past experience in deciding what equipment is necessary for a particular inspection.

Checklists are provided as guidelines for inspectors. The requirements of the inspection, the availability of certain equipment, and regional policies and conditions are, of course, to be considered during this pre-inspection phase.

Form and Equipment Checklist

- All equipment should be well-maintained and checked to see that it is in good condition prior to each inspection.

- Special circumstances may require equipment such as fireproof clothing or self-contained breathing units. Check with your supervisor for guidance and availability if the situation may warrant such extra safety measures.

General Equipment

- Camera
- Film and flash equipment
- Pocket calculator
- Tape measure
- Clipboard
- Waterproof pens, pencils, markers
- Locking brief case
- "Confidential Business Information" stamp
- Stamp pad
- Envelopes pre-addressed to Document Control Officer
- Plain envelopes
- Polyethylene bags
- Disposable towels or rags
- Portable typewriter
- Portable copying machine
- Flashlight and batteries
- Pocket knife

Sampling Equipment

The use of quality disposable equipment can be very helpful in eliminating or minimizing sample contamination. If the use of disposable equipment is not feasible or not possible, sampling equipment should be thoroughly decontaminated by a qualified laboratory.

- 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 and containers (certified clean bottles with teflon-lined lids)
- Labeling tags, tape
- Storage and shipping containers with lids
- Ice chest
- Container for contaminated material

Safety Equipment (See Chapter Three, Section 4F for details)

- 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

Emergency Equipment (See Chapter Three, Section 4F for details)

- 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

Forms

- Notice of Inspection
- TSCA Inspection Confidentiality Notice
- Declaration of Confidential Business Information
- Receipt for Samples and Documents
- Chain of Custody Record
- Official Seal

2

Entry

Authority

Section 11 of TSCA provides authority for an EPA inspector to enter "any establishment or facility in which chemical substances are manufactured, processed, stored, or held before or after their distribution in commerce."

Under Section 11, the inspector is required to present the owner, operator, or agent in charge of the facility with:

- Proper credentials identifying the holder as a duly authorized representative of the EPA Administrator; and
- A written notice of inspection.

In addition, Section 11 requires inspections to be:

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

Arrival

Arrival at the facility must be during normal working hours. The facility owner or agent in charge should be located as soon as the inspector arrives on the premises.

Locating the proper officials may take some time and require contact with several receptionists and secretaries. Inspectors should be careful to keep official credentials in sight at all times during

the process. Business cards (available at inspector cost through the Regional Offices) may be used for introductory purposes but do not replace official credentials for identification.

Credentials

When the proper facility officials have been located, the inspector should introduce himself as an EPA inspector and present the proper EPA credentials as required in Section 11. These credentials indicate that the holder is a lawful representative of the Administrator of EPA and is authorized to perform inspections under TSCA regulations. The credentials must be presented whether or not identification is requested.

After facility officials have scrutinized the credentials, they may telephone the EPA regional office for verification of the inspector's identification.

Credentials should never leave the sight of the inspector.

Notice of Inspection

Once inspector identification has been established, the written Notice of Inspection is to be presented to the facility officials as required by Section 11. The Notice should be dated, and the time of inspection should be entered as proof that entry was requested at a reasonable hour.

If records ordinarily exempt from inspection (financial, sales, pricing, personnel, or research data) are specifically listed on the Notice, facility officials should be informed verbally of the intent to inspect these records.

(See Sample Notice of Inspection in Chapter 6: Forms)

Consent

Consent to inspect the premises must be given by the owner or by the agent-in-charge at the time of the inspection. As long as the inspector is allowed to enter, entry is considered voluntary and consensual, unless the inspector is expressly told to leave the premises. Express consent is not necessary; absence of an express denial constitutes consent.

Reluctance to Give Consent

The receptiveness of facility officials toward inspectors is likely to vary from firm to firm. Most inspections will proceed without difficulty. If consent to enter is flatly denied, the inspector should follow Denial of Entry procedures. In other cases, officials may be reluctant to give entry consent because of misunderstandings of responsibilities, inconvenience to a firm's schedule, or other reasons that may be overcome by diplomacy and discussion.

Whenever there is difficulty in gaining consent to enter, inspectors should tactfully probe the reasons and work with officials to overcome the obstacles. Care should be taken, however, to avoid threats of any kind, inflammatory discussions, or deepening of misunderstandings. If the situation is beyond the authority or ability of the inspector, the Regional Office should be contacted for guidance.

Uncredentialed Persons Accompanying an Inspector

The consent of the owner or agent in charge must be obtained for the entry of persons accompanying an inspector to a site if they do not have specific authorization. If consent is not given voluntarily, these persons may not enter the premises. If consent is given, these persons may not view confidential business information unless officially authorized for access.

Denial of Entry

If an inspector is refused entry into a facility for the purpose of an inspection under TSCA, certain procedural steps must be followed. The procedures have been developed in accordance with the 1978 U.S. Supreme Court decision in Marshal v. Barlow's, Inc.

Denial of Entry Procedures

1. Make certain that all credentials and notices have been properly presented to the facility owner or agent in charge.

2. If entry is not granted, ask why. Tactfully probe the reason for the denial to see if obstacles (such as misunderstandings) can be cleared. If resolution is beyond the authority of the inspector, he may suggest that the officials seek advice from their attorneys on clarification of the scope of EPA's inspectional authority under Section 11 of TSCA.

3. If entry is still denied, the inspector should withdraw from the premises and contact his supervisor. The supervisor will confer with attorneys to discuss the desirability of obtaining an administrative warrant, and will contact the Headquarters Pesticides and Toxic Substances Enforcement Division.

4. All observations pertaining to the denial are to be carefully noted in the field notebook. Include facility name and exact address, name and title of person(s) approached, authority of person who refused entry, time of denial, reason for denial, facility appearance, any reasonable suspicions that refusal was based on a desire to cover up regulatory violations, etc. All such information will be important should a warrant be sought.

Important Considerations

- Under no circumstances should the inspector discuss potential penalties under Section 15 of TSCA or do anything that may be construed as coercive or threatening.

- Inspectors should avoid any situations that may be potentially threatening or inflammatory.

- Inspectors should leave a copy of the written Notice of Inspection with facility officials to show that proper procedures were followed.

Withdrawal of Consent During Inspection

If the agent in charge asks the inspector to leave the premises after the inspection has begun, the inspector should follow the procedures above for denial of entry. All activities and evidence obtained prior to the withdrawal of consent are valid.

Denial of Access to Some Areas of the Facility

If, during the course of the inspection, access to some parts of the facility is denied, the inspector should make a notation of the circumstances surrounding the denial of access and of the portion of the inspection that could not be completed. He should proceed with the rest of the inspection. After leaving the facility, the inspector should contact the regional office to determine whether a warrant should be obtained to complete the inspection.

Administrative Warrants

An administrative warrant can be used to gain entry into a facility when facility officials have denied entry to an inspector or when consent to inspect has been withdrawn during an inspection. A warrant is a judicial authorization for an appropriate official (EPA inspector, U.S. Marshal, or other Federal officer) to enter a specifically described location and perform specifically described inspection functions.

Policy

Denied Entry

It is the policy of EPA to obtain a warrant when all other efforts to gain lawful entry have been exhausted, and the inspector has carefully followed established entry/denial of entry procedures. Determination to secure a warrant will be made by the Regional Office in consultation with the Headquarters Pesticides and Toxic Substances Enforcement Division.

In Advance of Inspection

A warrant may be obtained before the inspector sets forth to conduct the inspection. A pre-inspection warrant may be obtained at the discretion of the Regional Office in consultation with the Headquarters Pesticides and Toxic Substances Enforcement Division if:

- A violation is suspected which could be covered up during the time needed to secure a warrant;

- Prior correspondence or other contact with the facility to be inspected provides reason to believe that entry will be denied when the inspector arrives; or

- The facility is unusually remote from the Regional Office or a U.S. District court and obtaining a warrant would be inconvenient to the government.

Securing and Serving a Warrant

The procedures for obtaining and serving a warrant involve a number of people, and are as follows:

1. Contact the Regional Office. The inspector should discuss the facts regarding the denial or withdrawal of consent or the circumstances which give rise to the need for a pre-inspection warrant. The determination will then be made whether or not to seek a warrant, and who should contact the U.S. Attorney.

2. Contact the Headquarters Pesticides and Toxic Substances Enforcement Division. The Regional Office will consult with Headquarters in accordance with established policy.

3. Contact the U.S. Attorney. After a decision has been made to obtain the warrant, the designated regional official should contact the U.S. Attorney of the district in which the property is located. The Agency should assist the Attorney in the preparation of the warrant and necessary affidavits.

4. Apply for the Warrant. The application for a warrant should identify the statutes and regulations under the Agency is seeking the warrant. The name and location of the site or establishment to be inspected should be clearly identified, and, if possible, the owner and/or operator should be named. The application can be a one- or two-page document if all factual background for seeking the warrant is stated in the affidavit, and the application so states. The application is to be signed by the U.S. Attorney or by his assistant. (See the model warrant in the Appendix.)

5. Prepare the Affidavits. The affidavits in support of the warrant application are crucial documents. Each affidavit should consist of consecutively numbered paragraphs that describe all of the facts in support of warrant issuance. Each affidavit should be signed by a person with first-hand knowledge of all the facts stated, most likely the inspector. An affidavit is a sworn statement that must be notarized or sworn to before the magistrate. (See the model affidavit in the Appendix.)

6. Prepare the Warrant for Signature. The draft warrant should be ready for the magistrate's signature. Once signed, the warrant is an enforceable document. The warrant should contain a "return of service" or "certificate of service" which will indicate upon whom the warrant was served. This part of the warrant is to be dated and signed by the inspector after the warrant is served. (See the model warrant in the Appendix.)

7. Serve the Warrant. The warrant is served on the facility owner or his agent in charge and the inspection will normally commence or continue. Where there is probability that entry will still be refused, or where there are threats of violence, the inspector should be accompanied by a U.S. Marshal. In this case, the Marshal is principally charged with executing the warrant, and the inspector should abide by the Marshal's decisions.

8. Inspecting with the Warrant. The inspection should be conducted strictly in accordance with the warrant. If sampling is authorized, all procedures must be followed carefully, including presentation of receipts for all samples taken. If records or other property are authorized to be taken, the inspector must issue a receipt for the property and maintain an inventory of anything removed from the premises. This inventory will be examined by the magistrate to assure that the warrant's authority has not been exceeded.

9. Return the Warrant. After the inspection has been completed, the warrant must be returned to the magistrate. Whoever executes the warrant (i.e., the U.S. Marshal or whoever performs the inspection), must sign the return of service form indicating to whom the warrant was served and the date of service. The executed warrant is then returned to the U.S. Attorney who will formally return it to the issuing magistrate or judge. If anything has been 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.

10. Important Considerations

- The application for a warrant should be made as soon as possible after the denial of entry or withdrawl of consent.
- The warrant must be served without undue delay and within the number of days stated (standard is 10 days). The warrant will usually direct that it be served during daylight hours.
- Since the inspection is limited by the terms of the warrant, it is very important to specify to the greatest extent possible the areas intended for inspection, records to be inspected, samples to be taken, etc. A vague, overly broad warrant, however, will probably not be signed by the magistrate.

3

Opening Conference

Once credentials and required notices have been presented the inspector can proceed to outline inspection plans with facility officials.

The Inspector as Educator

The opening conference provides an ideal opportunity for the inspector to strengthen Agency-Industry relations. The inspector's role of educator and public relations liaison is important in establishing a sound spirit of cooperation. The inspector is regarded as a source of regulatory information, and should provide tactful help before, during, and after the inspection. Areas of particular concern include:

- Voluntary compliance
- Overview of the law
- Specific regulation requirements
- Help with specific problems
- Agency outreach efforts
- Other resources for Agency assistance

Meeting Considerations

- Inspection Objectives. An outline of inspection objectives will inform facility officials of the purpose and scope of the inspection and may help avoid misunderstandings.

- Order of Inspection. A discussion of the order in which operations will be inspected will help eliminate wasted time by allowing officials time to make records available and start up intermittent operations.

- Meeting Schedules. A schedule of meetings with key personnel will allow them to clear time to meet with the inspector.

- Organizational Directory. A telephone directory or a chart showing how the facility is organized would be helpful.

- List of Records. A list of records to be inspected will allow officials to gather and make them available for the inspector.

- Accompaniment. It would be beneficial to encourage a facility official to accompany the inspector during the inspection to describe the plant and its principal operating characteristics and to indicate which processes, records, etc., should be claimed as confidential business information. (See below.)

- Safety Requirements. The inspector should determine what OSHA and facility safety regulations will be involved in the inspection, and should be prepared to meet these requirements.

- Closing Conference. A "wrap-up" meeting should be scheduled with appropriate officials to provide a final opportunity to gather information, answer questions, and complete administrative duties.

- New Requirements. The inspector should discuss any new rules and regulations which might affect the facility, and answer questions pertaining to them. If the inspector is aware of proposed rules which might affect the facility, he may wish to encourage facility officials to obtain a copy.

- General Information. Any necessary general information such as the name and address of the chief executive officer should be obtained during the meeting.

Confidentiality Notice and Discussions

The TSCA Inspection Confidentiality Notice (see Chapter Six: Forms) is presented to the facility owner or agent in charge during the opening conference. This Notice informs facility officials of their right to claim as confidential business information any information (documents, physical samples, or other material) collected by the inspector. The inspector should also show the facility officials his letter from the Deputy Administrator for General Enforcement certifying that he is authorized for access to confidential business information.

Authority to Make Confidentiality Claims

The inspector must ascertain whether the facility official to whom the Notice was given has the authority to make business confidentiality claims for the company. The facility official's signature must be obtained at the appropriate place on the Notice certifying that he does or does not have such authority.

- The facility owner is assumed to always have the authority to make business confidentiality claims. In most cases, it is expected that the agent in charge will also have such authority. It is possible that the officials will want to consult with their attorneys (or superiors in the case of agents in charge) regarding this issue.

- If no one at the site has the authority to make business confidentiality claims, the Notice and accompanying forms (see Section 5: Closing Conference) are to be sent to the chief executive officer of the firm within two days of the inspection. He will then have seven calendar days in which to make confidentiality claims.

- The facility official may designate a company official in addition to the chief executive officer who should also receive a copy of the Notice and accompanying forms. Space is provided on the Notice form to make such a designation.

Confidentiality Discussion

Officials should be informed of the procedures and requirements that EPA must follow in handling TSCA confidential business information. The inspector should explain that these procedures were established to protect the companies subject to TSCA and cover the following points during the disucssion:

- Data may be claimed confidential business information during the closing conference if a person authorized to make such claims is on-site at the facility.

- It is suggested that a company official accompany the inspector during the inspection to facilitate designation (or avoidance, if possible) of confidential business data.

- A detailed receipt for all documents, photographs, physical samples, and other materials collected during the inspection will be issued at the closing conference.

- An authorized person may make immediate declarations that some or all of the information is confidential business information. This is done by completing the Declaration of Confidential Business Information form. Each item claimed must meet all four of the criteria shown on the Notice and Declaration forms.

- If no authorized person is available on-site, a copy of the Notice along with the Receipt for Samples and Documents will be sent by certified, return-receipt-requested mail to the chief executive officer of the firm, and to another company official, if one has been designated.

  --Claims of confidentiality must be sent by registered return-receipt-requested mail to the appropriate EPA office within seven calendar days of receipt of the Notice. (The inspector will insert the name and address of the Regional Document Control Office in the appropriate place on the Notice.)

- All data claimed confidential will be turned to the Document Control Officer and treated in accordance with procedures described in the TSCA-CBI Security Manual. Only authorized persons will have access to the information.

- Data not immediately claimed confidential business information because no authorized person is available on-site will be kept in locked storage and otherwise accorded confidential treatment (routine security measures) until the seven-day period has expired. The information will not be logged in by the Document Control Officer until an actual business confidentiality claim has been made.

Preparation/Distribution of Confidentiality Forms

When the TSCA Confidentiality Notice is completed, four or five copies are made and distributed as follows:

- Facility owner or agent-in-charge
- Company chief executive officer* (if no authorized person is available)
- Other company official* (if designated)
- Inspection report
- Inspector's files

*If the Notice is to be sent to the chief executive officer (and other company official, if designated), attach a copy of the completed Receipt for Samples and Documents and a partially completed Declaration form. Mail within two days of the inspection. (See Section 5: Closing Conference, for a complete discussion.)

Three or four copies are made of the Declaration of Confidential Information form and distributed as follows:

- Facility owner or agent in charge
- Other company official (if designated)
- Document Control Officer
- Inspection report

Other Considerations

Duplicate Samples

Facility officials should be informed during the opening conference of their right to receive a duplicate of any physical sample (liquid or solid) collected for laboratory analysis. Officials should indicate at this point the desire to receive duplicate samples so arrangements can be made to secure the samples during the inspection.

Photographs

The inspector may take photographs during the inspection. If officials object to the use of cameras in their facilities, it should be explained in a tactful manner that the photographs will result in a more thorough and accurate inspection report. Officials may declare as confidential business information any photographs taken during the inspection. If polaroid/instant photographs are taken, they can be reviewed during the closing conference.

4a

Sampling and Documentation

Reviewing facility records, taking physical samples, and preparing documentation are the basic elements of a compliance inspection. These activities provide the evidentiary support the Agency uses to initiate enforcement actions.

In the overall enforcement process, the inspector plays the key role of providing reports and evidence that will withstand legal scrutiny.

Authority

Section 11(a) of the Act establishes the authority to inspect for TSCA compliance. Included within the scope of TSCA inspections are samples, records, files, papers, and photographs. In carrying out these functions, the inspector acts as the duly designated representative of the EPA Administrator.

Objectives

The primary objective of sampling and documentation is to provide the Agency with accurate and complete substantiation of violations that can be admitted as evidence in a legal proceeding.

Development of admissible evidence is a complex process with many interrelated facets. Evidence must be factual and objective; it must be relevant and comprehensive; and it must be developed within the scope of the law.

The inspector's primary responsibility is to ensure that all evidence is prepared so as to be admissible in court. The procedures outlined in this Section will guide the inspector through this process.

In the evidence-gathering process, two considerations are of vital importance:

- Observance of Policy and Procedures. Specific procedures and policies have been developed to ensure efficient and effective evidence gathering. These procedures, which encompass the many individual components of sampling and documentation activities, are detailed to help ensure that evidence generated by inspectors will be admissible in court. Inspectors are expected to follow these procedures.

- Inspecting within the Scope of the Law. Specific requirements have been established to protect all parties involved in an inspection--facility, Agency, and inspector. It is imperative that inspectors operate within these requirements to avoid endangering a case on procedural or legal grounds.

4b

Records Inspection

The Toxic Substances Control Act requires that manufacturers, processors, and distributors of chemical substances maintain specific records relating to data that would aid EPA in identifying and monitoring toxic substances.

These requirements include reports of adverse reactions to health or to the environment, and the creation and retention of records relating to rules and regulations promulgated under the Act. Details of these requirements are listed in specific Volumes of this manual.

Objectives

The basic purpose for inspecting facility records is to determine compliance with TSCA requirements. The primary objectives of records inspection are:

- To determine whether records required by the Act, or by rules promulgated under the Act, are being adequately maintained.
- To aid in determining the scope and objectives of the facility inspection and to coordinate documentation of on-site observations and sampling activities

Industry maintains various systems to document the procedures, methods of manufacture, distribution, quality control, and other functions undertaken in the manufacture or handling of toxic substances. Although records are required, no specific recordkeeping system or formats are detailed under TSCA. An effective facility inspection must be planned to consider what kinds of recorded information are necessary to aid in establishing compliance with TSCA requirements.

Inspectors should clearly establish the objectives of the inspection to avoid a cumbersome review of irrelevant materials. Records inspection should be clearly tied to the overall goals of the particular inspection being undertaken.

Types of Records

The inspector may need to examine the following types of records:

- Annual reports
- Production records
- Shipping records
- Inventory records
- Sales records (invoices, receiving records, etc.)
- Process records
- Quality control records
- Disposal records
- Label and literature
- Permits--state, local, and federal
- Correspondence
- Exemptions

Information Retrieval Systems. Inspectors will encounter many electronic and visual systems for storing information needed for an inspection. Computers, microfilm, microfiche, and other systems will not pose retrieval problems if the inspector has carefully established inspection objectives and knows the type of information he is looking for.

Details of copying and handling these types of information are outlined below.

Procedures and Considerations

Accurate and complete records inspection entails a number of procedural steps, including targeting, locating, copying, and handling.

When reviewing records, inspectors should enter into the field notebook the kinds of records examined, and the reasons for examining them. Particular attention should be paid to the quality of information being reviewed. When reviewing records, the following questions should be kept in mind:

- Is the information complete?
- What are alternative sources for the same information?
- Has the facility made an honest attempt to meet TSCA record-keeping requirements?

In addition, inspectors should look at records in terms of the following general considerations:

- Compare current with past reports for possible discrepancies or false reports.
- Check for completeness and accuracy of required records and reports.
- Ascertain compliance with record retention requirements.
- Compare information contained in the records with first-hand observations.

Guidelines for inspecting records under substance-specific regulations are provided in the other Volumes of this Manual.

Targeting and Locating Records

The specific inspection objectives will help determine exactly what records and/or information the inspector will need to examine. In this process, the inspector should:

- List the kinds of records needed for compliance, and their retention requirements. (Refer to the substance specific Volumes of this manual and to the related regulations for guidance.)
- Become familiar with the firm's record-keeping system. (A field report entry about the system may help with future inspections.)

- Establish priorities for the material to be reviewed.
- Request that records personnel point out pertinent files and sources.
- Check back-up systems and cross-filing systems which may make retrieval more efficient.

There is often more than one route to the information needed for an inspection. Different firms may organize data in different ways. Inspectors should be aware of alternative approaches to data retrieval. For example, a firm may consider disposal records to be a subcategory of its shipping or transportation file system.

Copying Records

Records and files may be stored in a variety of information retrieval systems, including written or printed materials, computer or electronic systems, or visual systems such as microfilm and microfiche.

When copies of records are necessary for an inspection report, storage and retrieval methods must be taken into consideration:

- Written or printed records can generally be photocopied on-site. Portable photocopy machines may be available to inspectors through the Regional Office. When necessary, however, inspectors are authorized to pay a facility a "reasonable" price for the use of facility copying equipment.
  - At a minimum, all copies made for or by the inspector should be initialed and dated for identification purposes. (See Identification details below.)
  - When photocopying is impossible or impracticable, close-up photographs may be taken to provide suitable copies.
- Computer or electronic records may require the generation of "hard" copies for inspection purposes.
  - Arrangements should be made during the opening conference, if possible, for these copies.
  - Photographs of computer screens may possibly provide adequate copies of records if other means are impossible.

- Visual systems (microfilm, microfiche) usually have photocopying capacity built into the viewing machine which can be used to generate copies.

    - Photographs of the viewing screen may provide adequate copies if "hard" copies cannot be generated.

Identification Procedures

Immediate and adequate identification of records reviewed is essential to ensure the ability to identify records throughout the Agency custody process and to ensure their admissibility in court. When inspectors are called to testify in court, it is imperative that they be able to positively identify each particular document and state its source and the reason for its collection.

Initial, date, number, and write in the facility's name on each record, and log these items in the field notebook.

- Initialing Dating. Each inspector should develop a unique system for initialing (or coding) and dating records and copies of records so that he can easily verify their validity. This can be done by initialing each document in a similar position, or by another method, at the time of collection. Both the original and copy should be initialed. All record identification notations should be made on the back of the document.

  The inspector must be able to positively identify that he so marked the document.

- Numbering. Each document or set of documents substantiating a suspected violation or violations should be assigned an identifying number unique to that document. The number should be recorded on each document and in the field notebook.

- Logging. Documents obtained during the inspection should be entered in the field notebook by a logging or coding system. The system should include the identifying number, date, and other relevant information:

    - The reason for copying the material (i.e., the nature of the suspected violation or discrepancy).

    - The source of the record (i.e., type of file, individual who supplied record).

- The physical location of the record (i.e., address of the facility, building number, room number).
- The manner of collection (i.e., photocopy, other arrangements).

General Considerations

- Return originals to the proper personnel or to their correct location.
- Keep related records grouped together.
- Confidential business records should be handled according to the special confidential provisions discussed below.
- All copies of records are to be delivered to the case proceedings file after completion of the inspection.
- All records are to be kept under lock when not in actual use by the inspector.

Confidentiality Considerations and Procedures

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 completion of the inspection.

Preliminary Indications of Confidentiality

Under ideal circumstances, a facility official will accompany the inspector and make preliminary indications of the business information considered confidential.

Such information should not be entered into field notebooks; a non-confidential reference should be made to the information and the information should be placed on separate sheets which are then to be considered documents. When the facility official is unwilling or unable to make such preliminary indications, the inspector must exercise judgment in deciding which information should not be entered into the field notebook.

Manual Copying of Records

Only that information essential to the inspection should be copied manually from facility records. If it is known or suspected that a business confidentiality claim might be made, a reference only should be made in the field notebook and the information placed on separate sheets of paper. This treatment of the information will permit it to be placed on the Receipt for Samples and Documents, just as photocopies are listed.

Photocopying Documents

If only some information is needed from facility records to be photocopied, it is suggested that potentially confidential portions not necessary to the inspection be shielded.

To ensure that such shielded copies will be admissable as evidence if needed, the inspector should obtain the signature of the facility official on the back of the photocopy under a statement which reads:

"I hereby acknowledge that this is a photocopy of a page from our (kind of record). A portion of the page was shielded and not photocopied at the company's request."

Facility Official Signature

Date

For long documents, one statement listing the relevant pages may be substituted.

Identification of Confidential Documents

Each page of each document copied either manually or by photocopy should by stamped "Confidential Business Information" as soon as confidentiality is claimed.

The document(s) should be placed inside an envelope also marked "Confidential Business Information." This envelope should be placed inside a plain envelope and mailed immediately to the Document Control Officer in the Regional Office. See Section 6: Security Procedures, for a detailed discussion of the treatment of confidential business information.

4c

Documentary Support

Objective

Providing strong documentary support of discrepancies uncovered in an inspection is a basic responsibility of an inspector. Documentation serves to "freeze" the actual conditions existing at the time of the inspection so that evidence may be examined objectively at a later date by case proceedings personnel.

Documentation is a general term referring to all print and mechnical media produced, copied, or taken by an inspector to provide evidence of suspected violations. Types of documentation include the Field Notebook, Statements, Copies of Records, Photographs, Drawings and Maps, Printed Matter, and Mechnical Recordings.

Inspector's Field Notebook

The core of all documentation relating to an inspection is the field notebook, which provides accurate and inclusive documentation of all inspection activities. The notebook will form the basis for written reports and should contain only facts and pertinent observations.

Language should be objective, factual, and free of personal feelings or terminology which might later prove embarrassing. Notebooks become an important part of case proceedings evidence and can be entered in court as evidentiary material.

Confidentiality Considerations and Procedures

Some of the information that an inspector would ordinarily include in the field notebook may be considered confidential business information by the company. During discussions with facility officials, the inspector should avoid topics involving potentially confidential information not needed for completion of the inspection.

If information claimed or suspected to be claimed confidential is obtained (either orally or copied from facility records), such information should be referenced in a non-confidential statement in the field notebook and placed on separate sheets of paper that are then treated as documents. Photocopied documents should be referenced in the same manner.

- The non-confidential statement should state generally what information has been collected (i.e., "information about the firm's process for making x chemical").

- The separate sheets should be headed by the reference statement in the field notebook and identified by the name of the facility, date of inspection, and inspector's signature. The sheets should contain data only; no observations of extraneous notes should appear since the sheets will be reviewed by facility officials.

- The sheets are described as documents on the Receipt for Samples and Documents which is given to facility officials at the closing conference.

- The sheets are described as documents on the Receipt for Samples and Documents given to facility officials at the closing conference.

- The sheets can be reviewed by the facility officials during the closing conference and declared confidential, as appropriate.

It is recognized that the inspector will not always be able to make a prior determination about confidential business information before making entries into the field notebook, and that potentially confidential data may be included in the regular field notes. The intent here is to reduce, to the extent possible, such entries so that later difficulties regarding the field notes can be avoided. (See Section 5: Closing Conference, and Chapter Four, Section 1: Report Preparation, for discussions of confidential information contained in field notes.)

Inspection Entries

Since an inspector may be called to testify in an enforcement proceeding, it is imperative that each inspector keep detailed records of inspections, investigations, samples collected, etc. Types of information that should be entered into the field notebook include:

- Observations. All conditions, practices, and other observations that will be useful in preparing the inspection report or will contribute to valid evidence, should be recorded.

- Procedures. Inspectors should list all procedures followed involving entry, sampling, records inspection, and document preparation. Such information will help avoid damage to case proceedings on procedural grounds.

- Documents. All documents taken or prepared by the inspector should be noted and related to specific inspection activities. (For example, photographs taken at a sampling site should be listed, described, and related to the specific sample number.)

- Unusual Conditions and Problems. Unusual conditions and problems should be noted and described in detail.

- General Information. Names and titles of facility personnel and the activities they perform should be listed along with statements they may have made and other general information. Information about a facility's recordkeeping procedures may be useful in later inspections.

Administrative Entries

These entries provide documentation relating to travel and other fiscal data. All information requested by the Travel Voucher (SF 1012) should be listed in the notebook.

The field notebook is a part of the Agency's files and are not to be considered the inspector's personal record. Notebooks are held indefinitely pending disposition instructions.

Statements

Inspectors can obtain statements from persons who have personal, first-hand knowledge of facts pertinent to a potential violation. This statement of facts is signed by the person who can testify to those facts in court, and it may be admissible as evidence.

Objective

The principal objective of obtaining a statement is to record in writing, clearly and concisely, relevant factual information so that it can be used to document an alleged violation.

Procedures and Considerations

- Determine the need for a statement. Will it provide useful information? Is the person making the statement qualified to do so by personal knowledge?
- Ascertain all the facts and record those which are relevant and which the person can verify in court. Make sure all information is factual and first-hand. Avoid taking statements that can not be personally verified.
- In preparing a statement:
    - Use a simple narrative style; avoid stilted language.
    - Narrate the facts in the words of the person making the statement.
    - Use the first-person singular ("I am manager of...").
    - Present the facts in chronological order (unless the situation calls for other arrangement).
- Positively identify the person (name, address, position).
- Show why the person is qualified to make the statement.
- Present the pertinent facts.
- Have the person read the statement and make any necessary corrections before signing. If necessary, read the statement to the person in the presence of a witness.
    - All mistakes that are corrected must be initialed by the person making the statement.
- Ask the person making the statement to write a brief concluding paragraph indicating that he read and understood the statement. (This safeguard will counter a later claim that the person did not know what he was signing.)

- Have the person making the statement sign it.
- If he refuses to sign the statement, elicit an acknowledgement that it is true and correct. Ask for a statement in his own hand ("I have read this statement and it is true, but I am not signing it because..."). Failing that, declare at the bottom of the statement that the facts were recorded as revealed and that the person read the statement and avowed it to be true. Attempt to have any witness to the statement sign the statement with his name and address.
- Provide a copy of the statement to the signer if requested.

Photographs

The documentary value of photographs ranks high as admissible evidence. Clear photos of relevant subjects, taken in proper light and at proper lens settings provide an objective record of conditions at the time of inspection.

Inspectors should make certain that all equipment is in good working order prior to an inspection, and that supplies are adequate. Film is adversely affected by temperature extremes and care should be taken to avoid unsuitable storage conditions (e.g., an overheated auto).

Polaroid-type instant photos should be identified immediately with location, purpose, date, time, inspector's initials, and related sample number (if applicable). Identification should be recorded on the photo and in the field notebook. Photographs taken on film requiring developing should be identified in the field notebook in the order they are taken. Once developed, identification should be transferred to the photo itself.

Scale, Location, and Direction

It is sometimes useful to photograph a subject from a point that will indicate the location and direction of the subject. The addition of an object of known size (e.g., a person, an auto) will help indicate the approximate size of the subject.

Safety

In areas where there is a danger of explosion, flash photographs should not be taken. If there is a danger of electrical shock, photographs should be taken from a distance known to be safe.

Confidentiality Considerations

To avoid difficulties arising from confidential 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 be used. If not, and a confidentiality claim is made, the film must be processed by a contractor authorized for access to confidential business information.

Drawings and Maps

Schematic drawings, maps, charts, and other graphic records can be useful in supporting violation documentation. They can provide graphic clarification of site location relative to the overall facility, spill or contamination parameters, relative height and size of objects, and other information which, in combination with samples, photographs, and other documentation, can produce an accurate, complete, evidence package.

Drawings and maps should be simple and free of extraneous details. Basic measurements should be included to provide a scale for interpretation and compass points should be included.

Printed Matter

Brochures, literature, labels, and other printed matter may provide important information regarding a firm's conditions and operations. These materials may be collected as documentation, if in the inspector's judgment, they are relevant.

All printed matter should be identified with date, inspector's initials, and related sample numbers

Mechanical Recordings

Records produced electronic or by mechanical apparatus can be entered as evidence. Charts, graphs, and other "hard copy" documents should be treated as documentation, and handled accordingly.

4d

Physical Samples

Samples play a fundamental role in the TSCA enforcement process. It is upon the analysis of samples that most enforcement actions are based.

Samples should be obtained when an inspector needs to establish that a violation exists. There are two classifications of samples:

Physical Samples

Physical samples represent a substance as drawn from a container. Physical samples also include environmental samples such as soil, water, air, or sediment, or biological samples including animals and vegetation. They are used to confirm the presence and concentration of a chemical substance.

This classification involves the majority of samples taken during an inspection. The procedures for proper physical sampling are discussed in detail in this section. Instructions for sampling to document specific violations are contained in subsequent volumes.

Documentary Samples

There will be occasions during inspections when taking physical samples is impossible or is not feasible. (For example: substances stored in bulk, pressurized containers, or in containers which can not be opened, such as capacitors.) In such cases, documentary samples can be prepared.

A documentary sample differs from a physical sample in that the substance itself is not collected. Thorough documentation of conditions and observations surrounding the substance thus becomes even more crucial.

Preparation of documentary samples involves the procedures detailed in the preceding section on Documentary Support.

Sampling Program

An inspector must be able to identify the sample examined in the laboratory as the same sample he collected. The inspector must also be able to explain and justify his sampling procedures. Mistakes or deficiencies in procedures may damage an enforcement action. An organized, well-planned sampling program will be of crucial importance in meeting this objective.

The substance-specific inspection Volumes provide details on how to sample. However, an effective program will contain the following general elements:

- Definite Purpose.
- Representative Sample.
- Proper Equipment and Technique.
- Sufficient Volume.
- Controlled Identification.
- Proper Handling.
- Adequate Documentation.

Definite Purpose

The inspector should have a clear, definable purpose for taking a particular sample and should note this purpose in the field notebook. This information will help in determining the types of documentation and sampling techniques required. It will also prove invaluable in the preparation for testimony at a future date.

Representative Sample

Proper sampling procedures demand selection of a site or a number of samples that will produce a representative sample. Specific techniques will vary with particular requirements and are discussed in the specific inspection Volumes. Notes should be made regarding site selection, and further documentation (e.g., photos or drawings) would be used to support the physical samples.

Proper Equipment and Technique

The use of proper equipment is essential in the collection of valid physical samples. The various substances and sample types will require different types of equipment. A list of frequently used equipment appears on page 3-5; the specific inspection Volumes will provide lists of equipment and tools that are compatible with the substance being sampled.

Care should be taken to prepare the equipment so that contamination is avoided. The use of disposable sampling equipment, when practical, will help minimize this risk. If disposable equipment is not used, care should be taken to assure that sampling equipment is properly decontaminated.

All steps followed in sampling should be noted in the field notebook.

Sufficient Sample Volume

The amount of volume of the sample taken should be sufficient to perform all required laboratory analyses plus an additional amount for quality control and repeat testing. Specific volumes will vary with the type of sample and the substance involved. The specific inspection volumes will provide details.

If duplicate samples were requested during the opening conference, they should be collected and handled in the same manner as official samples.

Controlled Identification

To maintain validity throughout the evidence gathering process, samples must be accurately and completely identified. A sample passes through a number of steps in this process, and there must be no question as to its source or integrity when a sample is entered as evidence.

The following steps are important aspects of the sample identification process:

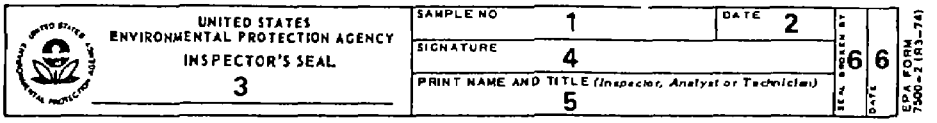
1. Identifying the Sample. The following information should be entered in the field notebook:

   - Sample number
   - Date of collection
   - Collection method
   - Description of sample, including color, texture, viscosity, etc.
   - Duplicate samples, if provided

   A tag or label should be affixed immediately to the sample container showing:

   - Sample number
   - Date of collection
   - Inspector's initials
   - Sub-sample number, if appropriate

2. Sealing the Sample. Once the sample has been collected and labeled, its container should be placed inside a plastic bag on which the inspector has written his name or initials, and the date. The bag is to be turned inside out to prevent any means of tampering with the contents. The bag is then taped closed in a secure manner with the Official Sample Seal (EP Form 7500-2). The seal should be completed as follows:



(1) Insert sample number.

(2) Insert date sealed.

(3) Print location of c ..ector's station.

(4) Signature of person sealing the sample.

(5) Print name (same as signature) and title of sealer.

(6) When a seal is broken for any purpose, initial here and enter the date broken. Submit broken seal with sample records.

The sample container or wrapper should be sealed so that it may not be opened at any point without breaking the seal and/or the original unit package. No more than one sample should be sealed under one seal.

Confidential Samples. If the company declares a physical sample confidential business information, the inspector should mark the seal "Confidential Business Information." (See Section 6: Security Measures for a discussion of the control of confidential samples between collection and shipping or delivery to the laboratory.)

Resealing a Sample. If it becomes necessary to break a seal, it should be mounted on a piece of paper properly initialed and dated and submitted with sample records to provide a continuous history. The sample should be resealed with a new seal.

3. Initiating Chain of Custody Record. Preparation of 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 which accompanies the sample throughout the stages of processing. Chain of Custody procedures and requirements are discussed in Section 4e.

Identification Considerations

- One sample number is used for each sample. One sample consisting of several subsamples or units is assigned only one number.
- Subsamples may be sealed in a single bag if they are part of one sample and if adequate packaging protection is provided.
- Sample numbers should appear on all documentation relating to a sample: Seals, Chain of Custody Record, drawings, photographs, etc.

Proper Handling

Samples must be handled, stored, and shipped properly to avoid loss, contamination, danger to handlers, and tampering. Requirements for handling specific substance samples are contained in the substance specific Volumes. General considerations include:

- Samples should always be handled in accordance with safety procedures that relate to the specific substance.
- Provisions for sample preservation (refrigeration, chemical preservatives, proper packaging materials, etc.) should be planned in advance of actual sampling.
- Recommended holding times for specific samples should be determined and care taken to avoid delays in transit.
- Highly toxic substances may require special handling and such arrangements should be made in advance, if possible.
- Security provisions should be adequate to protect both samples and documents.
- Samples can be delivered to the laboratory by the inspector. When this is not feasible, they should be shipped by the most economical means commensurate with the need for rapid handling. All shipments are to be in accordance with U.S. 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 should be obtained (e.g., bills of lading, return receipts, etc.).

Adequate Documentation

Sufficient and valid documentation of physical samples is as important as the sample itself. The inspector's field notebook should serve as the core of documentation with notations of all sampling activities clearly listed.

4e

Chain of Custody

As in any activity that may be used to support litigation, regulatory agencies must be able to prove that any analytical data offered into evidence in a court accurately represents conditions at the time of collection. Case proceedings personnel must be able to demonstrate that none of the samples involved have been tampered 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 its introduction into evidence.

Elements of Custody

A sample is in "custody" if:

- It is in one's actual physical possession.
- It is in one's view.
- It was in one's physical possession and it was secured so it couldn't be tampered with.
- It is kept in a secured area with access restricted to authorized personnel only.
- It is placed in a container sealed with an Official Seal (Form 7500-2) that will be broken when the container is opened.

Chain of Custody Procedures

The concept of custody requires the maintenance of several procedures to ensure the integrity of the sample. These procedures begin with the identification of the sample and continue through the laboratory analysis process.

1. Establishing Custody. Sample custody is initialed at the time of collection by sealing the sample with the Official Seal. The process is described in Section 4d.

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 and lab personnel. Properly maintained, this documentation will serve as a clear and complete account indicating the sample has remained intact from collection to introduction as evidence.

   The documentation includes the entries in the inspector's field notebook, the Official Seal, and the Chain of Custody Record.

3. Coordinating Sample and Documentation. The inspector must assure that the relationship between the physical sample the related documentation is clear, complete, and accurate. The sample number, date, and inspector's initials should appear on all documents, and the forms should be completed accurately and completely.

4. Ensuring Custody during Transit. Shipment of sample 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.

The forms described in these procedures can be found in Chapter Six: Forms. Detailed instructions for completion are included.

Confidential Samples

If a sample has been declared confidential business information, the seal is marked "Confidential Business Information." The chain of custody form is also marked "Confidential Business Information," and any analysis reports are also to be marked and held confidential.

It is essential that the inspector deliver or ship the confidential sample to an individual in the laboratory who has been cleared for access to confidential information. Each person who handles the sample and analysis report from that point must also have confidentiality clearance.

The forms described in these procedures can be found in Chapter Six: Forms - detailed instructions for completion are included.

Safety

4f

Health and Safety

The handling and sampling of toxic chemical substances always poses a certain degree of hazard. The objective of this section is to assure the safety of persons handling hazardous materials by the use of proper safety equipment and proper working habits. Most of the equipment listed here is available from scientific supply houses listed in the telephone directory.

Inspector Responsibilities

It is the responsibility of each inspector:

- To be thoroughly familiar with all safety guidance and practices, and to make the appropriate choice of safety equipment.
- To maintain safety equipment in good condition and proper working order.
- To use safety equipment in accordance with guidance received, labeling instructions, and as dictated by common sense.

Personal Protective Equipment

Inspectors should have the following safety equipment and use it for protection when handling chemical substances:

- Safety glasses (prescription if required), goggles, and face shield.

- Rubber-soled, non-skid, metal-toed shoes.
- High-top shoes or boots for field work.
- Gloves: liquid-proof, natural rubber or synthetic rubber, disposable, if possible. The gloves should be long enough to protect the wrist and be worn under the sleeves to prevent chemicals from running into the gloves from the sleeves.
- Coveralls should be of closely woven fabric and be spill-resistant; disposable if possible. If they are not, a liquid-proof apron should be worn over them.
- Rubber apron, long enough to provide adequate protection.
- Hard hat: plastic with a plastic sweatband. (Cloth and leather sweatbands are more comfortable, but are harder to clean.)
- Shoe covers: plastic, disposable.
- Respiratory protective devices should be used whenever a toxic contaminant is present or whenever there is an oxygen deficiency. When using these devices, care should be taken to follow device instructions carefully. In all cases, the equipment must be of the type approved by either the National Institute of Occupational Safety and Health (NIOSH) or by the Mine Safety and Health Administration (MSHA).
    - Self-Contained Breathing Apparatus (SCBA). This type of unit can be used in most cases when respiratory protection is needed. Since this unit has its own supply of oxygen, it has more flexibility in use than other types. If SCBA is too expensive for regular use, it should be available for use in emergencies.
    - Chemcial Cartridge Respirators. This type covers the mouth and nose. Some are available with goggles to protect the eyes. If they are not, separate goggles should be worn. Inhaled air comes through a filter pad and a cartridge made to absorb vapors. Most harmful vapors, gasses, and particles are removed.
    - Chemical Canister Respirators (Gas Masks). This type usually covers more of the face than the cartridge respirator and has longer-lasting absorbent material and filters. Neither kind will protect when oxygen supply is low.

The respirator must fit the face well. A beard, heavy sideburns, or glasses may prevent a good seal. Check the seal by covering the air intake and breathing in. If no air enters, there is a good seal. Tanks, cartridges, and filter units should be checked and maintained in accordance with manufacturer instructions. The face piece should be washed regularly.

The table which follows this section provides more information on respiratory protective devices.

General Safety Equipment

The following safety equipment should be in each inspector's car for use when needed. All equipment should be checked periodically to ensure that it is in proper condition.

- First-aid kit
- Fire extinguisher (ABC all purpose dry chemical)
- Airtight containers for storage of highly toxic samples
- Hand cleaner and towels
- Clean water for washing in case of an accident
- Emergency phone numbers (See Table following this Section)

Handling of Chemical Substances: General Guidelines

The following guidelines should be followed when handling or sampling chemical substances. When extraordinary circumstances exists, such as handling of spills or highly toxic substances, guidance and direction must be sought from your supervisor.

- Before entering any facility, ask the appropriate representative if there are any special safety precautions that should be taken or if there is any special safety equipment needed.

- Check all labels, manifests, and other sources of information before sampling a chemical in an effort to identify the substance and learn of potential hazards.

- Determine what routes of exposure to avoid for the chemical substance being sampled, and the proper sampling and protective equipment to be used.

- Use only proper tools for opening containers (e.g. non-sparking bung wrench) and be careful when opening and closing them.
- Exercise caution; the substance may be mislabeled.
- Open and sample substances in areas where spills can be cleaned up easily and properly.
- Make use of all appropriate protective clothing and equipment.
- Be careful not to spill toxic substances on the skin or clothing. If it happens, disrobe completely in a manner that keeps contact with the substance to a minimum, and wash the skin thoroughly for at least 15 minutes. A change of clean clothing should always be available.
- After exposure, remove all protective gear and dispose of it properly. Wash hands immediately after sampling, before eating, smoking, drinking, or using toilet facilities.
- Never use your mouth to siphon or put your hands near your eyes or mouth. Use an automatic syphon.
- A supply of detergent soap, clean water, and waterless hand cleaner should be readily available.
- Know the limitations of your protective equipment, especially respirators.
- Transport and store samples in an airtight storage box.
- Be alert for spilled materials, improperly stacked materials, moving equipment (fork lifts, conveyor belts, etc.), poor ventilation, bad lighting, etc.

Emergency Treatment

The purpose of emergency treatment is to give immediate and temporary care to a victim of an accident or sudden illness until the services of a physician can be obtained. In the case of poisoning, emergency treatment helps to remove, dilute, or slow up the movement of the poison. Knowledge of the poison combined with prompt treatment is essential in reducing the poison's concentration. Medical attention should be sought when appropriate.

The following tables provide emergency treatment guidelines for the four major routes of entry.

INHALATION

Breathing a gas, vapor, mist, fumes, or dust is the most common form of accidental exposure.

Inhalation affects the lining of the air passages of the nose, throat, and lungs, and usually results in an irritation and may cause mild burns. The chemical may enter the bloodstream through the lungs and be distributed throughout the body tissue, causing a systemic effect.

Sampling should always be done in a well-ventilated area and respirators should be used.

EMERGENCY TREATMENT

- If still conscious, get out of the contaminated air space immediately.
- If the victim is unconscious, he should be removed at once from the contaminated area. All rescuers should make sure they have proper respiratory equipment operational before attempting rescue.
- If the victim is no longer breathing, mouth-to-mouth resuscitation, artifical respiration, or cardio-pulmonary resuscitation (CPR) should be begun immediately.
- Medical attention should be sought immediately.

SKIN EXPOSURE

Some substances have the capacity to penetrate the unbroken skin and enter the bloodstream.

Precautions to be used in sampling include:

- Wipe all residue off the containers after filling them with the sample.
- Use proper procedures for removing contaminated clothing.
- Skin should be washed immediately after removal of contaminated clothing. Clothing should not be worn again unless decontaminated.

EMERGENCY TREATMENT

- Wash skin with plenty of soap and water for a minimum of 15 minutes.
- If clothing is contaminated, it should be removed in such a way as to minimize further contact with the substance.
- Get under a shower immediately and remove clothing while showering. Certain substances are rapidly absorbed through the skin. WASTE NO TIME.
- All contaminated parts of the body, including hair, should be thoroughly decontaminated. It may be necessary to wash repeatedly.

EYE CONTACT

Eyes may be harmed by substances in either liquid or vapor form.

Precautions to protect the eyes include:

- Wear goggles or face shield.
- Do not rub eyes at any time.

EMERGENCY TREATMENT

- Eye(s) should be washed immediately with plenty of water. The eye should be held open and flooded with water so that all surfaces are thoroughly washed.
- Washing should continue for 15 minutes.
- Seek medical aid.

INGESTION

Toxic amounts of a substance may be carried to the mouth by hand when drinking, eating, or smoking.

Precautions include:

- Wash hands thoroughly before eating, drinking, or smoking.
- NEVER pipette or siphon liquids by mouth.
- Do not bring hands into contact with the mouth until hands have been thoroughly washed.

EMERGENCY TREATMENT

- Call Poison Control Center.
- Follow directions on label of susbstance container.
- When petroleum products are involved, get medical advice immediately.
- Induce vomiting unless an aspiration hazard (as with petroleum products) is a predominant factor.
  - Take an emetic to induce vomiting. A table spoon of salt or powdered mustard in a glass of warm water may be used.
  - Drink plenty of water. Placing your finger in your throat may also be effective in inducing vomiting.
  - Treatment should be continued until vomitus is clear.
- Seek medical advice immediately.

Decontamination of Protective Clothing

After use of protective clothing to prevent contact with toxic substances, head coverings, coveralls, aprons, and gloves should be folded or turned inside-out, then placed in a plastic bag, and sealed. Subsequently, these items should be disposed of or washed. Face shields, goggles, respirators, rubber gloves, and boots should be washed thoroughly with soap and water between uses. Protective clothing which has been contaminated should be disposed of by appropriate methods.

Long Term Risk

The possibilities for long term risk inevitably exist with the handling of toxic substances. Although there are no defined measures to avoid these risks, handlers of toxic substances should be warned of their dangers. Among the many chemical substances and mixtures which are constantly being developed and produced, there are some whose manufacture or use may present an unreasonable risk of injury to health or to the environment. For this reason the inspector should vigorously follow the long term medical surveillance procedures of the Agency.

INDUSTRIAL AND MUTUAL AID EMERGENCY CONTACTS

Organization	Division	Hours	Telephone
Association of American Railroads	Emergency Response	24-hour	(202) 293-4048
CHEMTREC	Chemical Emergencies	24-hour	(800) 424-9300
Dow Chemical	Emergencies	24-hour	(517) 636-4400
Du Pont	Emergency Response	24-hour	(302) 774-1000
Monsanto	Safety Office	24-hour	(618) 271-5835
National Foam Center	Emergency Response	24-hour	(215) 363-1400
Poison Control Center		24-hour	Consult White Pages of Local Telephone Directory Under "Poison Control"

RESPIRATORY PROTECTIVE EQUIPMENT

Atmosphere	Respirator Type	Applications and Limitations	Precautions
All particulates gases, vapors, oxygen deficiency.	Self-contained. Recirculating compressed oxygen. Demand compressed air or oxygen. Self-generating oxygen.	Use in any atmosphere. Allows freedom of movement, allows worker to leave atmosphere by any route. Limited time of use. Careful training required for proper use.	Wearer should be in good physical condition and thoroughly trained. Assure plentiful supply of air or oxygen in tank. Check for proper and tight fit, use with life line. Leave at once if an odor is detected. Do not remove until out in respirable air.
	Supply air. Hose mask with blower Hose mask without blower. Air line respirator.	Unlimited time of use, use in any atmosphere (except air line not to be used in oxygen deficient or immediately dangerous atmosphere). Not to be used where worker cannot escape unharmed without protection. Must exit by entrance route. 150 ft. maximum from exit (75 ft hose mask without blower). Limits freedom of movement.	Place inlet in respirable air location, adjust fit and air lines properly. Test before entering dangerous atmosphere. Use life line, protect air line or hose from sharp edges or falling objects. Leave at once if air flow is interrupted Do not remove until in respirable air. Air line respirators must have a clean supply of air free from dust, oil and carbon monoxide.
Particulates alone	Mechanical Filter. Special filter respirators.	Allow freedom of movement. Not to be used in excessively dusty atmospheres, in oxygen deficient atmospheres, or in atmospheres containing gases or vapors. Not to be used for abrasive blasting. Relatively difficult to breathe. Limited time of use.	Use clean filter and change when plugged. Ensure good fit and good operating condition. Leave at once if difficulty in breathing increases significantly.
Gases and Vapors alone	Chemical Absorbers. Universal gas mask. Special canister gas mask. Special cartridge respirator	Allows freedom of movement. Do not use in atmospheres deficient in oxygen or containing excessive contaminants (above 2% with gas masks, above 1000 ppm with cartridge type). Used for limited time and specific contaminant only. (Cartridge respirators not to be used in atmospheres immediately dangerous to life.) Relatively difficult to breathe. Limited time of use.	Adjust properly, ensure good tight fit. Check operating condition. Always use fresh canister or cartridge at start of use if possible. Enter atmosphere cautiously. Whenever odor is detected leave at once. Leave if difficulty in breathing increases significantly.
Combination of particulates and gases and vapors	Chemical/Mechanical Filters. Gas mask with filter. Filter respirator with chemical cartridge.	See mechanical filters and chemical absorbers.	See mechanical filters and chemical absorbers.

Source: Sax, N. Irving, Dangerous Properties of Industrial Materials, 1968.

Bibliography

The following is a partial listing of works on safety and a brief summary of the information contained therein.

- "Occupational Safety and Health for the Federal Employee", U.S. Department of Labor, Occupational Safety and Health Administration," January 1, 1979 A booklet outlining Federal Government policy concerning occupational safety and health protection provided for government employees.

- "NEIC Safety Manual," Environmental Protection Agency, Office of Enforcement, National Enforcement Investigation Center, EPA-330/9-74-002-B, Denver, Colorado, February, 1977. Provides general guidelines on safety for NEIC personnel, consistent with OSHA requirements.

- "Hygienic Guide Series," American Industrial Hygiene Association, Akron, Ohio 44313, March, 1977. Contains an alphabetical list of chemicals, with the following information for each. hygienic standards, significant properties, industrial hygiene practice, specific procedures for safe handling and literature references.

- Handling Guide for Potentially Hazardous Commodities," ed David Baskin, Ph D., Commodity Safety System of the Railway Systems and Management Association. Contains the following relevant information chemical synonym directory, medical digest, pollution control, references, priority risk worksheet, and emergency equipment.

- "Matheson Gas Data Book," The Matheson Company, Inc., East Rutherford, New Jersey; Joilet, Illinois, Newark, California. Matheson of Canada, Ltd., Whitby, Ontario, 1961. Contains information on handling, use and recommended controls for gases. Includes description, specification, toxicity, first aid, precautions in handling and storage, container construction materials, cylinder and valve description, safety devices, recommended controls, shipping regulations, commercial preparation, chemical properties, and physical data.

- "CHRIS, A Condensed Guide to Chemical Hazards," Department of Transportation, Coast Guard, October, 1978. Contains a directory of chemical names and the following information for each: common synonyms, appearance, and general response information outlining basic preventive and precautionary actions to be taken.

- "Patty's Industrial Hygiene and Toxicology, 3rd Revised Ed., Volume I· General Principles," ed. George D. Clayton and Florence E. Clayton, 1978. Twenty-seven authorities in their respective fields discuss such facets of the profession as air pollution; agricultural hazards, odors, heat stress; fire and explosion hazards, atmospheric contaminants, pulmonary effects of inhaled dusts, noise and conservation of hearing, and more. The book also includes methods of evaluation of the various problems likely to be encountered, samples of methods of record keeping, and hazard control methods.

- "Dangerous Properties of Industrial Materials," Newton Irving Sax, Reinhold Publishing Corporation, New York, 1963, Third Edition Contains information covering over 12,000 hazardous materials. Areas of hazard covered include: radiation hazards, industrial fire protection, storage and handling of hazardous materials, respiratory protection, and personal hygiene.

- "Condensed Chemical Dictionary," Arthur and Elizabeth Rose, Reinhold Publishing Corporation, New York. Contains useful information on chemical materials including shipping instructions and safety regulations.

- "Threshold Limit Values of Airborne Contaminants," adopted by ACGIH for 1969, American Conference of Governmental Industrial Hygienists, 1014 Broadway, Cincinnati, Ohio 45202.

- "American Red Cross First Aid Textbook," American National Red Cross, Doubleday and Company, Garden City, New York, 1957.

- "Clinical Toxicology of Commercial Products," Marion N Gleason, ed , Williams and Wilkins Company, Baltimore, 1957.

- "Alphabetical Index Industrial Safety Data Sheets," National Safety Council, 425 North Michigan Avenue, Chicago, Illinois 60611. Lists bulletins available on characteristics of over 200 chemicals.

- Chemical Manufacturers Association, 1825 Connecticut Avenue, N.W., Washington, D C. 20009. The CWA has many publications which give complete information on health and fire hazards, handling, storage, labeling, packaging and transportation. A list of publications is available.

- "Fire Protection Guide on Hazardous Materials," National Fire Protection Association, 60 Batterymarch Street, Boston, Massachusetts 02110. This recent publication is a complete volume on fire, explosion, and health characteristics of many chemicals and materials. It combines five previous NFPA texts (49, 491M, 325A, 325M, and 704M).

5

Closing Conference

A final meeting with facility cfficials will enable the inspector to "wrap up" an inspection. Necessary receipts can be prepared, questions can be answered, and information gaps can be resolved.

Required Receipts

Receipt for Samples and Documents

A written receipt for all samples and documents taken should be issued to the facility officials. The receipt should describe each item and its point of origin and be signed and dated by the inspector. To be included on the receipt are:

- A description of all physical samples taken.
- A description of all records, photographs, or other property taken. This is particularly crucial when inspecting with a warrant.
- A description of all separate sheets containing sensitive information taken in lieu of entries in the field notebook.

The purpose of this detailed receipt is twofold:

- To protect the Agency by showing that facility officials knew exactly what was taken.
- To allow full review by the facility officials of the material and information collected so that confidentiality claims can be made.

Declaration of Confidential Business Information

The Declaration of Confidential Business Information should include a list of all items declared confidential by an authorized facility official. Each item declared must meet the four criteria shown on the form.

- Some information may have been declared confidential during the inspection itself. These items should be reviewed and confirmed with facility officials and each item then listed on the Declaration form.

- Facility officials then review the completed Receipt for Samples and Documentation and make any further entries on the Declaration form.

No Authorized Claimant. If no on-site facility official is authorized to make confidentiality claims, the following steps should be followed:

- A copy of the completed Receipt for Samples and Documents should be made.

- A copy of the TSCA Notice of Confidentiality that was signed by the facility official should be made. The Notice should include the name and address of the Regional Document Control Officer in the place provided.

- A Declaration of Confidential Business Information form should be partially completed (top portion and inspector's name and title only).

- The three forms should be mailed by certified, return-receipt-requested mail to the chief executive officer of the firm within two days of the inspection. (The chief executive officer will have seven calendar days to make confidentiality claims.)

- If another company official has also been designated to make business confidentiality claims, the three forms should be sent to him in addition to the chief executive officer.

- No additional measures beyond the routine security procedures normally followed for inspection data need be taken with regard to this information during the seven-day period.

- TSCA-CBI procedures will commence immediately upon notification of the Document Control Officer of a confidentiality claim. If a confidentiality claim is made, it is the responsibility of the Document Control Officer to notify all parties (inspector, laboratory, case preparation staff, and any others who may be handling the information) and log in the material as required.

Industry Outreach

Since the inspector is often the only contact between the Agency and the regulated industries, he should be acutely aware of opportunities to maintain and improve Agency-Industry relations. 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 ways to help overcome them. Considerations include:

- Answering all questions within the ability and authority of the inspector.
- Referral of questions and problems to other EPA personnel when necessary. Follow-up with those personnel when practical.
- Discussion of problems with facility officials, tactfully offering help and suggestions.
- Tactful probing of problem areas uncovered during the inspection which facility officials may not be aware of.
- Offering or suggesting available resources to facility officials to help overcome problems (i.e., Agency outreach materials, technical publications, special services available to industry, etc.)

It is very important for the inspector--as an industry relations representative--to follow up all referrals and offers for help. A letter, phone call, or repeat visit will indicate to facility officials a genuine interest on the part of the Agency. Such expression of interest will immeasurably aid the Agency's industry relations and voluntary compliance programs.

6

Security Measures

Overview

Security measures must be taken to protect all inspection data (including documents, samples, field notes, and other documentation) collected by the inspector. The information must be protected because:

- The very nature of an enforcement investigation assumes the possibility that some legal action might result.
- Any inspection involves the collection of information that a firm would not ordinarily make available to outsiders.

In addition to the routine security measures, which are always taken with regard to inspection data, the declaration of certain information as TSCA Confidential Business Information (TSCA-CBI) imposes a further layer of security procedures designed to control access to the information within the Agency.

Routine security measures and the additional procedures for TSCA Confidential Business Information are discussed below.

Routine Security Measures

The main objective of the routine security measures is to ensure that reasonable precautions are taken to prevent unauthorized persons from viewing the information. When practical circumstances prohibit the inspector from following the procedures exactly, the inspector is expected to take steps for protection of the information that will achieve this objective.

While Traveling

The inspector may be on the road for several days while doing inspections. It is his responsibility to ensure that the information he collects is handled securely.

- Documents and field notes are considered secure if they are in the physical possession of the inspector and not visible to others while in use. For example, it is permissible to review documents in the privacy of a motel room or motor vehicle, but not acceptable to review them in a public place such as a restaurant.

- Inspection documents contain sensitive information and should be kept in a locked briefcase. If it is impractical to carry the briefcase into a given situation, the briefcase may be stored in a locked area such as a motel room or trunk of a motor vehicle.

- Physical samples should be placed in locked containers and stored in a locked portion of the motor vehicle. The chain of custody procedures provide further protection for ensuring the integrity of the sample.

In the Office

Documents and field notes must be kept in a locked filing cabinet when not in actual use.

TSCA-CBI Security Procedures

In addition to all of the routine security measures that must be taken for any inspection data, the further procedures discussed below must be followed with regard to information declared TSCA Confidential Business Information.

While Traveling

Because of the difficulties in protecting TSCA-CBI while traveling, it is recommended that such information be mailed, shipped, or hand delivered to an authorized person as soon as possible after the inspection.

- Documents and other "paper" data should be mailed or hand carried to the Regional Document Control Officer.

- Physical samples should be shipped or hand carried to an individual in the laboratory who is cleared for access to confidential information.

Handling of Documents

- As soon as they are declared, confidential documents or papers should be marked "Confidential Business Information" and placed inside an envelope also marked "Confidential Business Information." This envelope is placed inside a plastic envelope addressed to the Regional Document Control Officer and mailed immediately.

- If mailing is not feasible immediately, the double envelope should be placed inside a locking briefcase. The double envelope is required during this interim period to prevent others from seeing that the inspector is carrying "Confidential Business Information" should he open his briefcase.

- The locked briefcase must be kept in the sight of the inspector at all times. If it is totally impractical to carry the briefcase into a given situation, the briefcase may be stored in a key-locked area for which the inspector has control of the only key. The inspector would be expected to take the briefcase into a restaurant, but not into another facility inspection. Briefcases should not be left unattended in a motel room.

- If it is necessary for the inspector to review the document, this can only be done in absolute privacy because the "Confidential Business Information" marking is likely to arouse curiosity. If privacy is violated, the documents must be shielded from view immediately.

Handling of Physical Samples

- Physical samples declared confidential should be marked "Confidential Business Information" on the seal and the same mark should be placed on the chain of custody report. The sample and chain of custody report should be shipped or delivered immediately to an individual in the laboratory who is known by the inspector to be cleared for confidential business information.

- If shipping is not feasible immediately, the samples should be stored in a locked container inside a locking portion of the motor vehicle.

In the Office

- If the inspector has confidential business information in his possession from an inspection when he returns to the office, he should check it in with the Document Control Officer (DCO) immediately upon his arrival.

- The Document Control Officer should be informed of any physical samples that were declared confidential. It is the responsibility of the DCO to notify the laboratory of the Document Control Number (DCN) assigned to the sample which should appear on the sample chain of custody and laboratory analysis reports. If a copy of the laboratory analysis is sent to the firm, it must be sent by registered mail in a double envelope.

- After the documents have been logged in by the DCO, they must then be handled in accordance with the procedures detailed in the TSCA-CBI Security Manual.

4 Post-Inspection Activities

Chapter Four

Post-Inspection Activities

Chapter Contents — Page

1

Report Preparation

The adequacy of an enforcement case depends on the evidence package prepared by the inspector. The preceding chapter details the procedures for collecting and substantiating this evidence. Once collected, however, this evidence must be organized and arranged in a manner that will allow case proceedings personnel to make maximum use of the information.

The information presented in this section provides general guidelines for organizing evidence and preparing an inspection report.

Objective of an Inspection Report

The objective of an inspection report is to organize and coordinate all evidence gathered in an inspection in a comprehensive useable manner. In order to meet this objective, information in an inspection report must be:

- Accurate. All information must be factual and based on sound inspection practices. *Observations should be the verifiable* result of first-hand knowledge. Case proceedings personnel must be able to depend on the accuracy of all information.

- Relevant. Information in an inspection report should be pertinent to the subject of the report. Irrelevant facts and data will clutter a report and may reduce its clarity and usefulness.

- Comprehensive. The subject of the report (i.e., suspected violation(s) should be substantiated by as much factual, relevant information as is feasible. The more comprehensive the evidence, the better and easier the prosecution task.

- Coordinated. All information pertinent to the subject should be organized into a complete package. Documentary support (photographs, statements, sample documentation, etc.) accompanying the report should be clearly referenced so that anyone reading the report will get a complete, clear overview of the subject.

- Objective. Information should be objective and factual; the report should not draw conclusions.

- Clear. The information in the report should be presented in a clear, well-organized manner.

- Neat and Legible. Adequate time should be taken to allow the preparation of a neat, legible report.

Confidentiality Considerations and Procedures

All documents and other materials that have been claimed confidential business information are stored with the Document Control Officer as prescribed in the TSCA-CBI Security Manual. The inspector may review these documents when preparing the inspection report, but they must be handled under the strict security measures imposed for TSCA Confidential Business Information.

Preparation of Inspection Report

In preparing the inspection report, it is recommended that confidential business information be referenced in a non-confidential manner (i.e., by Document Control Number and a general description of the information contained in the document). An alternative would be to include the information, but to treat the entire inspection report as a confidential document. If the latter alternative is selected, the report would be logged in with the Document Control Officer, ensuring that only persons cleared for access are permitted to review it.

Field Notes

The procedures for taking field notes (see Chapter Three, Section 4d) require that potentially confidential information be referenced only in the field notes, and that the information itself be placed on separate sheets of paper. The purpose of these procedures was to reduce confidentiality problems associated with the field notebook.

In the event that confidential business information does appear in the field notes, those pages should be photocopied and the photocopied pages logged in with the Document Control Officer. The confidential business information in the notebook should then be obliterated in such a manner as to make them unreadable.

To ensure that the photocopies of the obliterated pages can be used in an enforcement proceeding, they must be carefully identified in the following manner:

- The inspector and a witness should initial and date a spot on the page that will not need to be obliterated.
- A photocopy of the notebook page should be made. This photocopy should be logged in by the Document Control Officer along with a statement by the inspector which reads:

  "The undersigned certifies that this is a true copy of a page from my field notebook from the inspection of (facility, address) on (date). The original notebook pages were obliterated by me to protect confidential business information."

  Inspector's Signature Date
  Witness Signature Date

- Confidential business information on the notebook pages should be obliterated; the identifying initials and date should remain.

Elements of a Report

Although each substance and rule will differ in specific information requirements for an inspection report, most reports will contain the same basic elements:

- Inspection Report Forms
- Narrative Report
- Documentary Support

Inspection Report Forms

Individual inspection report forms, developed for most substances and rules, are designed to collect standard, reviewable information

about an inspection. They function as guides to ensure that all basic data is being collected, and are generally completed as the inspection progresses.

Inspection report forms are only one aspect of a complete report and should by no means be considered to be sufficient in themselves.

Individual items on these forms will often need clarification and elaboration; inspectors should use the field notebook for this information.

In cases where inspection report forms are either unavailable or inappropriate, pertinent information should be entered in the field notebook.

Narrative Report

The narrative portion of an inspection report should be a concise, factual summary of observations and activities, organized in a logical, legible manner, and supported by specific references to accompanying evidence (documentary support).

A work plan will simplify preparation and will help ensure that information is organized in a useable form. Basic steps involved in writing the narrative report include:

- Reviewing the information
- Organizing the material
- Referencing accompanying material
- Writing the narrative

Reviewing the Information. The first step in preparing the narrative is to collect all information gathered during the inspection. The inspector's field notebook should be reviewed in detail. All evidence should be reviewed for relevancy and completeness. Gaps may need to be filled by a phone call or, in unusual circumstances, a follow-up visit.

Organizing the Material. Organization of the information can take many forms, depending on the case, but should present the material in a logical, comprehensive manner. The narrative should be organized so that it will be understood easily by the reader.

Referencing Accompanying Material. All documentary support that accompanies a narrative report should be clearly referenced so that the reader will be able to locate these documents easily. The Documentary Support section in Chapter Three provides details on document identification. All documentary support should be checked for clarity prior to writing the report.

Writing the Narrative Report. Once the material has been reviewed, organized, and referenced, the narrative can be written. The purpose of the narrative report is to record factually the procedures used in, and findings resulting from, the evidence-gathering process. In this report, the inspector should refer to routine procedures and practices used during the inspection, but should describe in detail facts relating to potential violations and discrepancies. The field notebook is a guide for preparing the narrative report.

If the inspector has followed the steps presented in this manual, the report can develop logically from the organizational framework of the inspection. In preparing the narrative, simplicity should be a prime consideration:

- Use a simple writing style; avoid stilted language.
- Use an active, rather than passive approach: (e.g., "He said that... rather than "It was said that...")
- Keep paragraphs brief and to the point.
- Avoid repetition.
- Proofread the narrative carefully.

A basic format which can be adapted for most narrative reports is outlined below.

Narrative Report Format

Introduction

General Information

- State the purpose of the inspection and how the facility came to be inspected (i.e., neutral scheme, follow-up, for cause).
- State the facts of the inspection (i.e., date, time, location, name of the agent-in-charge, etc.).

Summary of Findings

- Give a brief, factual summary of the inspection findings.

History of Facility

- List the status of the facility (i.e., corporation, proprietorship, partnership, state agency, non-profit organization, etc., and where incorporated).
- Give the size of the organization based on inspector observations or agency records.
- List any related firms, subsidiaries, branches, etc.
- List the type of operations performed at the facility under inspection.
- List names and titles of facility officials interviewed. List the name(s) of officials(s) responsible for day-to-day operations at the facility.

Inspection Activities

Entry/Opening Conference

- Describe the procedures used at arrival, including presentation of credentials and written Notice of Inspection, and to whom they were presented.
- Describe any special problems or observations if there was reluctance on the part of facility officials to give consent, or if consent was withdrawn or denied.
- If special procedures were necessary, such as obtaining a warrant, describe the procedures.
- Summarize the topics discussed during the opening conference.
- Note presentation of the TSCA Inspection Confidentiality Notice and the official to whom it was presented.
- Note if duplicate samples were requested.

The remainder of the report should be prepared in the same order that the inspection was conducted. Be certain to insert all observations when appropriate and to cover the following topics when appropriate.

Records

- List the types of records reviewed, noting the reasons for their review, and referencing documents that were borrowed or copied.
- Describe any inadequacies in recordkeeping procedures, or if any required information was unavailable or incomplete.
- Note if recordkeeping requirements are being met.

Documents

- Note and reference any statements taken during the inspection.
- Describe and reference photographs taken during the inspection if they are relevant to possible discrepancies.
- Reference any drawings, maps, charts, or other documents made or taken during the inspection.

Physical Samples

- Describe the purpose for which samples were obtained.
- Describe sampling techniques used.
- Reference controlled identification procedures.
- Describe the physical aspects of the sample (color, texture, viscosity, etc.).
- Describe chain of custody procedures used in sample handling.

Closing Conference

- Note and reference receipts for samples and documents given to facility officials.
- Note procedures taken to confirm claims of confidentiality and Receipts for Confidential Business Information.
- Note any recommendations, referrals, etc., made to facility officials.

Attachments

List of Attachments

- Prepare a list of all documentary support attached to the report. A general index list, rather than detailed descriptions will aid case proceedings personnel in locating specific documents.

Documents

- Attach copies of all documentary support collected during the inspection. All documents should be clearly identified.

- In cases where documentary support items can not be included easily with the report, it may be possible to substitute descriptive information. Consult supervisory personnel about this.

2

Appearing as a Witness

Vigorous enforcement programs will increase the probability that an inspector will be called on to testify in court. By the time a case has entered the judicial system, inspectors and case proceedings personnel will have invested many hours in developing a sound program for prosecution. When an inspector is called to testify, it is imperative that quality testimony is provided and a professional image is projected in the courtroom.

A witness, to be effective, must make statements that are understandable, and must have them accepted as truth by the judge or jury. In addition to being truthful and honest, a witness' principal aim should be to make a favorable impression on the court. The guidelines presented in this section will help prepare the inspector to be an effective and credible witness.

Personal Appearance and Conduct

- Dress is important. A well-groomed, neatly attired witness makes a more favorable impression in the courtroom.
- Conduct should reflect the solemn nature of the judicial proceedings.
    - Do nothing that may attract attention to you. Make yourself as inconspicuous as possible.
    - Do not sit in groups with more than 2 or 3 colleagues. Spread out in the courtroom.
    - Do not whisper or talk to another person, or cause any disturbance in courtroom.

  - Show no incredulity or surprise at any testimony given from the witness stand or at statements made by the defense attorney. Avoid expressing approval or disapproval of any testimony by nod, glance, or other gesture.

  - Do not have anything in your mouth, including gum, toothpick, tobacco, candy, or food.

- Do not sit within the enclosure unless instructed to do so.

- Do not discuss the case with the defendant or his attorney.

- Do not talk to the jurors or discuss the case within their hearing.

- Unless directed to do so, do not attempt to consult with case personnel while court is in session.

- Avoid conversations with principals or witnesses for the opposing side. If conversation are unavoidable, confine remarks to matters other than the trial.

- Come into the courtroom prepared. Be thoroughly familiar with your facts. Pertinent time and dates should be checked. Order all documents and exhibits so that testimony will be presented without fumbling.

- Be on time when court opens and be available immediately when called to testify.

Witness Stand Technique

- When called to the witness stand, unless previously sworn, go directly to the desk of the clerk of the court to be sworn.

- Take the oath in a solemn manner. Then proceed to the witness chair. If you have a long or difficult name, give a card or paper with the correct spelling to the court stenographer.

- Assume and maintain proper posture, bearing, and demeanor. Sit erect, but don't appear stiff or tense. Attempt to project an image of poise and self-control.

Speaking

- Speak in a clear, distinct, and well-modulated voice. When addressing a jury, look at and speak distinctly to them. Speak plainly enough so that the farthest juror can hear you.

- Use simple language. If the subject is technical or scientific, reduce the terminology to an understandable level or give definitions of terms used. Avoid idioms or language particular to your profession or to the Agency.

Notes

- You may bring notes to the witness stand with you. However, do not bring your field notebook or any other documents you do not want the opposing side to examine. They have a right to see them.

- Do not hesitate to ask permission to refer to your notes when testifying, provided your notes were made at the time of, or immediately after, the event about which you are testifying.

- Do not be embarrassed if you can not recall exact details without referring to your notes.

- Do not read long passages verbatim from your notes.

Answering Questions

- Wait until a question is asked in its entirety before beginning to answer.

- Never attempt to answer a question you do not fully understand.

  - Ask that the question be repeated or rephrased if its meaning is not clear.

  - If you do not know the answer to a question, say so. Don't try to cover up a lack of knowledge of a particular subject.

- Answer each question with spoken words. Don't nod assent or shake your head.

- Don't volunteer information. Answer only the question asked, but answer it fully and to the point.

- Don't spar with the questioning attorney or attempt to match wits with him. Answer all questions frankly, factually, and confidently.

- Be truthful. Remember that you are sworn to tell the truth.

- Be factual. Limit your testimony to those facts about which you have first-hand knowledge. Anything else may be hearsay.

  - Don't express opinions or conclusions unless you are testifying as an expert witness. State only facts.

  - Don't assume expert knowledge in a field unless you are an expert by reason of your training and experience.

  - If questioned on a subject beyond your soope, admit that the subject is outside your field or knowledge.

  - Don't exaggerate. State the facts accurately, don't embellish them.

General Guidelines

- Don't be afraid to admit that you discussed your testimony with Government attorneys. There is nothing improper in a practical discussion of your testimony with the attorneys.

- In your effort to appear impartial and unbiased, do not become listless or "dead pan." Be natural, candid, frank, and "alive."

- Do not appear impatient or overly anxious to testify.

- Do not speak to the judge unless he asks you a question.

- Attempt to minimize nervous tendencies, such as arranging clothes, notes, etc.

Testifying under Cross-Examination

Cross examination is the questioning of witnesses by attorneys representing the opposing side. Under cross examination you may be subjected to vigorous questioning.

- The opposing counsel may attempt to intimidate you by attacking your veracity and integrity, by making uncomplimentary references to your qualifications or length of service, or by empahsizing errors you have made. Remain calm and answer any question asked unless an objection is raised and sustained.

- If the cross-examiner attempts to confuse you with rapid questions, answer him deliberately and at a comfortable pace. Ask him to repeat or rephrase any question that is unclear or confusing.

    - If asked a double or "two-pronged" question, ask the cross-examiner to restate it, or carefully answer each part separately.

- Wait several seconds before you answer a question put to you in cross examination in order to give the U.S. Attorney an opportunity to object. Avoid, however, undue delays in answering.

    - If an objection has been raised, do not answer any questions until a ruling on the objection has been made.

- Don't lose your patience or temper while testifying. A cross-examining attorney often deliberately baits an irascible witness to anger him. Remain calm and unruffled.

    - Do not become argumentative with the cross-examiner if he interrupts your testimony or for any other reason.

- Beware of questions to which the cross-examiner demands a "Yes" or "No" answer if such an answer will not reveal the entire truth. These are often leading questions. If a simple yes or no does not properly answer the question, inform the cross-examiner that the question can not be so answered.

- If the cross examiner should misquote any of your earlier testimony, you may correct the misquote before answering the question.

- If you make an error while testifying, correct it at the first opportunity. If you discover the error after you have completed your testimony and have been dismissed, discuss the matter with the U.S. Attorney.

- You may be asked whether you regard certain persons in the field about which you are testifying as recognized authorities. This is often preparatory to asking you whether you agree with certain statements which those authorities made in writings, etc. If your answer is no, that you don't recognize them as authorities, that line of cross-examination cannot be pursued. Unless you definitely have heard of the named persons and are familiar with their works and do recognize them as authorities, don't expose yourself by saying that you so recognize them.

Proper Conduct During Recess and After the Trial

- During recess, continue to maintain the same demeanor as in the courtroom.
  - Don't engage in loud conversation or joking, especially about the proceedings.
  - Be as discreet as possible when making any comments that might be overheard.
- After the trial, continue to conduct yourself in a manner that will bring credit to you and to the Agency.
  - Make no public display of elation or disappointment over the outcome of the trial.
  - If there is occasion to speak to the defendants, be courteous regardless of their demeanor.

5 Special Procedures

Chapter Five

Special Procedures

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1

Subpoenas

In the general sense, a subpoena is an order to a witness to appear at a specified time and place to give testimony before a court or a magistrate. In a civil context, a subpoena is used to require a person to deliver documents in his possession to a court or authorized agency. Such documents will be pertinent to a particular inspection or investigation.

Section 11(c) of TSCA authorizes the EPA Administrator to require, by subpoena:

- The attendance and testimony of witnesses; and
- The production of reports, papers, documents, answers to questions, and other information that is deemed necessary by the Administrator.

The TSCA subpoena is enforceable by United States District Court. Failure to respond to the subpoena carries contempt of court penalties.

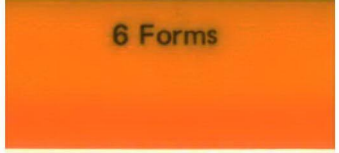
The Inspector's Role in the Subpoena Process

The effectiveness of a subpoena lies in part in its flexibility. It's purpose and content will depend upon the matter under investigation, as will the method used to serve the subpoena.

Specific procedures regarding the role of the inspector have not been developed. Instructions and directions for inspector involvement will come from enforcement supervisors.

Reference to subpoena authority or to contempt penalties should never be made during an inspection. Any difficulties relating to the collection of information during an inspection should be referred to a supervisor immediately. Case proceedings personnel will evaluate the situation and determine a suitable response.

Should an inspector be called upon to serve a subpoena, detailed instructions will be provided by the appropriate case proceedings personnel.


6 Forms

Chapter Six

Forms

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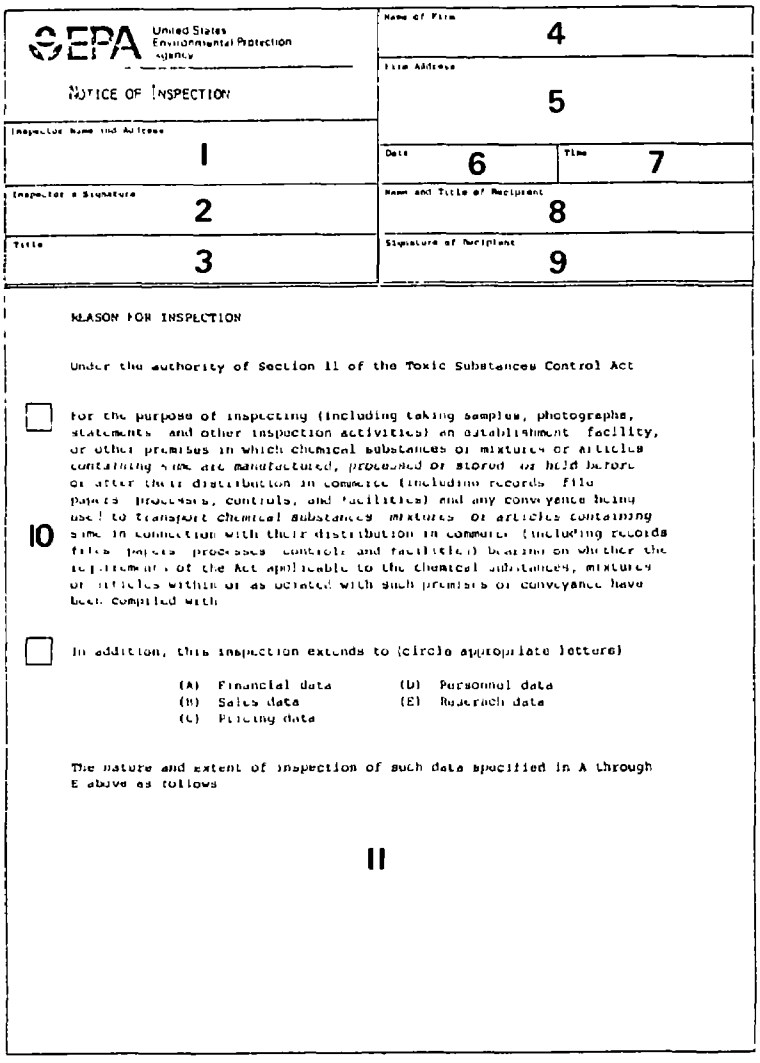
Instructions and comments are located on the pages facing each of the forms listed below.

Notice of Inspection

1. Enter Inspector's name and EPA office address.
2. Sign the Notice of Inspection.
3. Enter the Inspector's official title.
4. Enter the complete, official name of the firm to be inspected.
5. Enter the complete street address of the firm to be inspected.
6. Enter the date of inspection.
7. Enter the time of entry.
8. Enter the name and title of the person receiving the Notice of Inspection.
9. Have the recipient sign the Notice of Inspection.
10. Check the appropriate boxes concerning the scope of the inspection.
11. If the inspection will include any data listed in items A through E on the form, specify the nature and extent of inspection of this data.



EPA United States Environmental Protection Agency

NOTICE OF INSPECTION

Inspector Name and Address: 1

Inspector's Signature: 2

Title: 3

Name of Firm: 4

Firm Address: 5

Date: 6 Time: 7

Name and Title of Recipient: 8

Signature of Recipient: 9

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

10

☐ In addition, this inspection extends to (circle appropriate letters)

(A) Financial data (D) Personnel data
(B) Sales data (E) Research data
(C) Pricing data

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

11

EPA United States Environmental Protection Agency

NOTICE OF INSPECTION

Inspector Name and Address	Name of Firm Firm Address Date / Time
Inspector's Signature	Name and Title of Recipient
Title	Signature of Recipient

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 compiled with.

☐ In addition, this inspection extends to (circle appropriate letters):

(A) Financial data
(B) Sales data
(C) Pricing data
(D) Personnel data
(E) Reserach data

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

TSCA Inspection Confidentiality Notice

1. Enter Inspector's name (1) and EPA office address (2)

2. Enter the complete, official name of the facility being inspected (3) and its complete street address (4).

5. Enter the name (5), title (6), and complete address (7) of the chief executive officer of the firm.

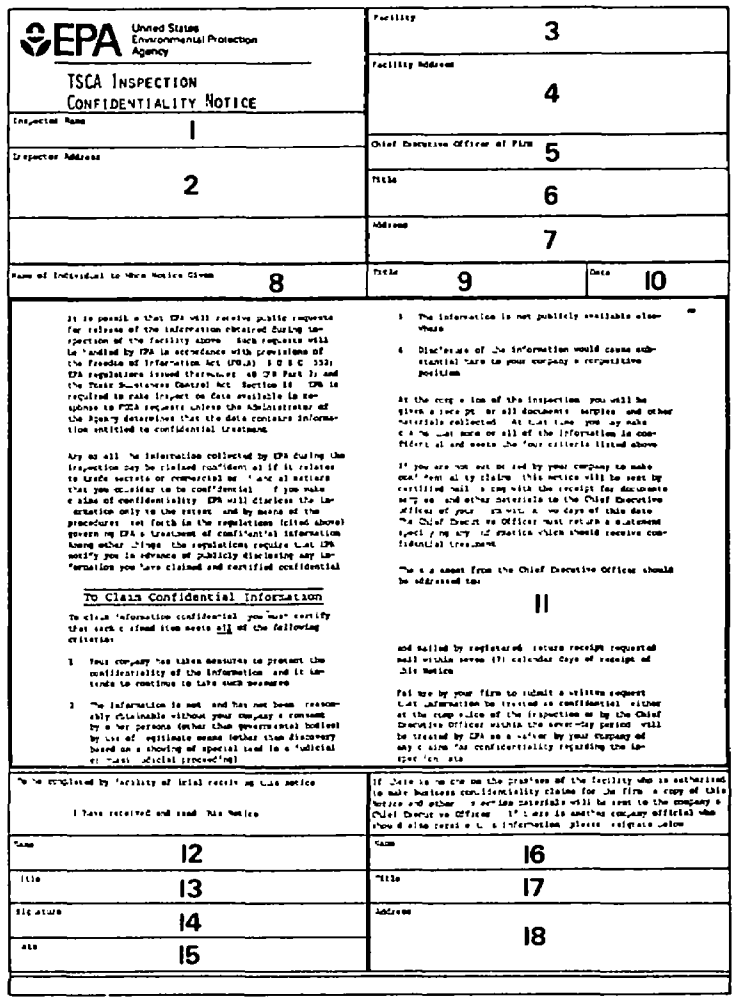
8. Enter the name (8) and title (9) of the person receiving the Notice.

10. Enter the date of the Notice.

11. Enter the complete address of the Regional Document Control Officer authorized to receive the statement from the chief executive officer.

12. Enter the name (12) and title (13) of the person receiving the Notice. Have this person sign (14) and date (15) the Notice.

16. Enter the name (16), title (17), and complete address (18) of the company official who, in addition to the chief executive officer, should receive a copy of the Notice.



EPA United States Environmental Protection Agency

TSCA INSPECTION CONFIDENTIALITY NOTICE

Inspector Name 1

Inspector Address 2

Facility 3

Facility Address 4

Chief Executive Officer of Firm 5

Title 6

Address 7

Name of Individual to Whom Notice Given 8

Title 9

Date 10

It is possible that EPA will receive public requests for release of the information obtained during the inspection of the facility above. Such requests will be handled by EPA in accordance with provisions of the Freedom of Information Act (FOIA) 5 U.S.C. 552; EPA regulations issued thereunder (40 CFR Part 2) and the Toxic Substances Control Act Section 14. EPA is required to make its part on data available in response to FOIA requests unless the Administrator of the Agency determines that the data contains information entitled to confidential treatment.

Any or all the information collected by EPA during the inspection may be claimed confident al if it relates to trade secrets or commercial or financial matters that you consider to be confidential. If you make a claim of confidentiality 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 information. Among other things the regulations require that EPA notify you in advance of publicly disclosing any information you have claimed and certified confidential.

To Claim Confidential Information

To claim information confidential you must certify that each specified item meets all of the following criteria:

1. Your company has taken measures to prevent 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 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 your company's competitive position.

At the conclusion of the inspection you will be given a receipt for all documents samples and other materials collected. At that time you may make a claim that some or all of the information is confidential and meets the four criteria listed above.

If you are not notified by your company to make such a 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 seven days of this date. The Chief Executive Officer must return a statement specifying any claim of confidentiality which should receive confidential treatment.

The statement from the Chief Executive Officer should be addressed to:

11

and mailed by registered return receipt requested mail within seven (7) calendar days of receipt of this Notice.

Failure by your firm to submit a written request that information be treated as confidential either at the conclusion of the inspection or by the Chief Executive Officer within the seven-day period will be treated by EPA as a waiver by your company of any claim for confidentiality regarding the information sub

To be completed by facility at time notice

I have received and read this Notice

Name 12

Title 13

Signature 14

Date 15

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 previous materials will be sent to the company's Chief Executive Officer. If there is another company official who should also receive a copy of the information please designate below

Name 16

Title 17

Address 18

United States Environmental Protection Agency

TSCA Inspection Confidentiality Notice

Inspector Name	Facility
Inspector Address	Facility Address
	Chief Executive Officer of Firm
	Title
Name of Individual to Whom Notice Given	Title

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 U S C 552, EPA regulations issued thereunder, 40 CFR Part 2, and the Toxic Substances Control Act, 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 contains information entitled to confidential treatment

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 If you make claims of confidentiality, 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 information Among other things, the regulations require that EPA notify you in advance of publicly disclosing any information you have claimed and certified confidential

To Claim Confidential Information

To claim information confidential, you must certify that each claimed item meets all of 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 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 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 and meets the four criteria listed above

If you are not authorized by your company to make confidentiality claims, 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 two 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

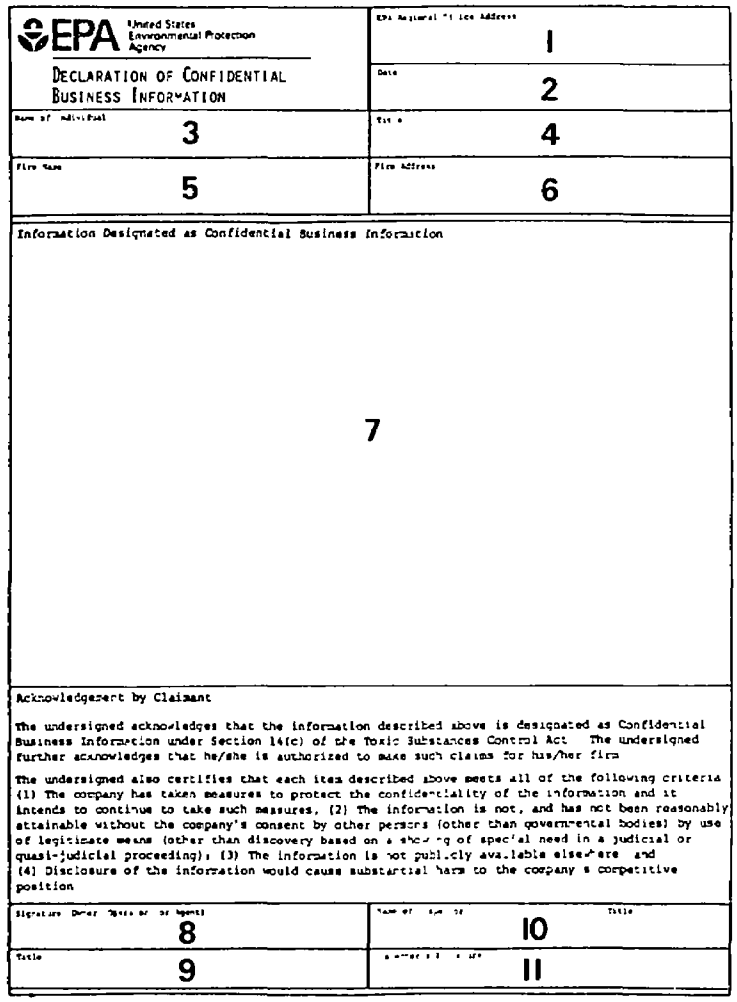
and mailed by registered, return-receipt-requested mail within seven (7) calendar days of receipt of this Notice

Failure by your firm to submit a written request that information be treated as confidential, either at the completion of the inspection or by the Chief Executive Officer within the seven-day period, will be treated by EPA as a waiver by your company of any claims for confidentiality regarding the inspection data

To be completed by facility official receiving this notice I have received and read 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.
Name	Name
Title	Title
Signature	Address
Date	

Declaration of Confidential Business Information

1. Enter the complete EPA Regional Office address.
2. Enter the date of this declaration.
3. Enter the name(3), title (4), official firm name (5), and complete firm address (6) of the individual making this declaration.
7. List by title or description all information begin designated as confidential business information.
8. Have the individual making the declaration sign (8) and list his/her title (9).
10. Enter the name and title of the Inspector
11. Sign the Declaration (*Inspector*).



EPA United States Environmental Protection Agency

DECLARATION OF CONFIDENTIAL BUSINESS INFORMATION

EPA Regional Office Address: 1

Date: 2

Name of Individual: 3

Title: 4

Firm Name: 5

Firm Address: 6

Information Designated as Confidential Business Information

7

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 also certifies that each item described above meets all of the following criteria (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

Signature Owner Agent or Agent: 8

Name of Title Title: 10

Title: 9

11

United States Environmental Protection Agency

DECLARATION OF CONFIDENTIAL BUSINESS INFORMATION

	EPA Regional Office Address
	Date
Name of Individual	Title
Firm Name	Firm Address

Information Designated as Confidential Business Information

Acknowledgment 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 also certifies that each item described above meets all of the following criteria: (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.

Signature (Owner, Operator, Agent)	Name of Inspector Title
Title	Inspector's Signature

Receipt for Samples and Documents

1. Enter Inspector's name (1) and EPA office address (2).

3. Enter name (3) and complete address (4) of the firm being inspected.

5. Enter the name (5) and title (6) of the individual receiving this Receipt.

7. Enter the date of collection of the samples and documents listed on the Receipt.

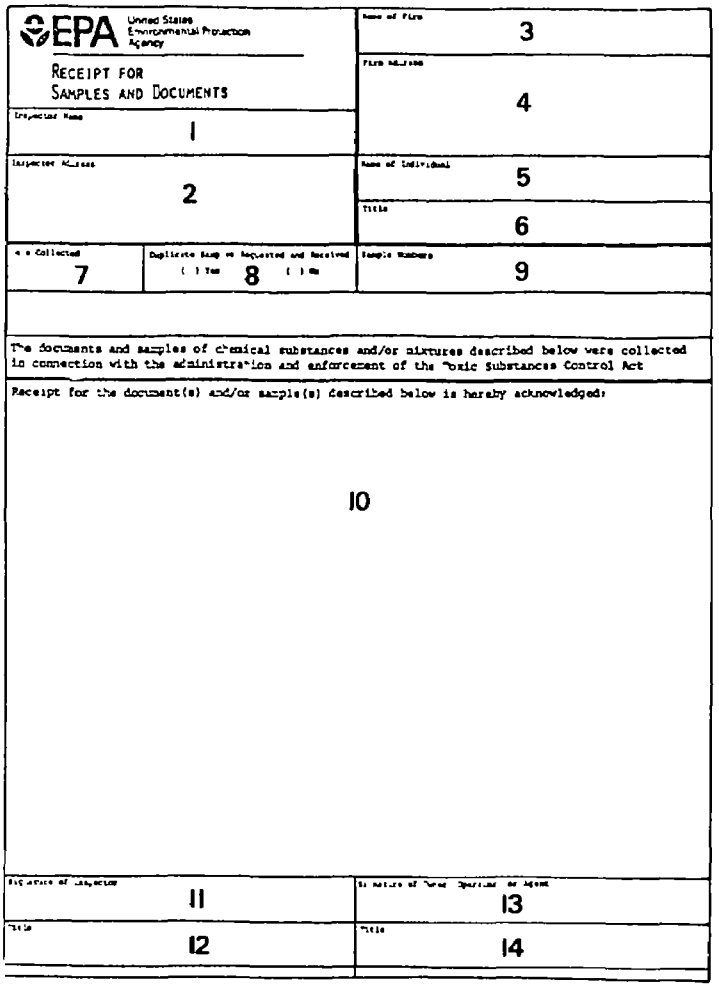
8. Check the appropriate column if duplicate samples were requested and received.

9. List the sample numbers of all samples taken.

10. List by title or description all samples and documents taken during the inspection.

11. Sign (11) and date (12) the Receipt.

13. Have the facility official named in (5) sign (13) the Receipt and list his/her title (14).



EPA United States Environmental Protection Agency

RECEIPT FOR SAMPLES AND DOCUMENTS

1

2

3

4

5

6

7

( ) Yes 8 ( ) No

9

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 for the document(s) and/or sample(s) described below is hereby acknowledged:

10

11

12

13

14

EPA United States Environmental Protection Agency

RECEIPT FOR SAMPLES AND DOCUMENTS

Inspector Name	Name of Firm
	Firm Address
Inspector Address	Name of Individual
	Title

Date Collected	Duplicate Samples Requested and Received ( ) Yes ( ) No	Sample Numbers

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 for the document(s) and/or sample(s) described is hereby acknowedged:

Signature of Inspector	Signature of Owner, Operator, or Agent
Title	Title

Chain of Custody Record

1. Enter Inspector's name and EPA office address.

2. Sign the Chain of Custody Record.

3-4. Sample and Inspection numbering program is currently under development. Information regarding these spaces will be provided at a later date.

5. Task numbers refer to EPA contractors. Inspectors may disregard.

6. Describe the sample, including size, container, and contents. (e.g. 8 oz. bottle of PCB transformer oil.) List brand names if any.

7-8. List date (7) and time (8) sample was collected.

9. Indicate if duplicate sample was requested by facility officials.

10. Enter name and address of firm.

11. List testing required for samples collected. (e.g. test for PCB concentration.

The remaining parts of the Record will be completed by personnel other than the inspector.

EPA United States Environmental Protection Agency

Chain of Custody Record

Inspector Name and Address: 1		Sample Number: 3	Task Number: 5
		Inspection Number: 4	
		Sample Name: 6	
		Date Sample: 7	Time: 8
		Duplicate Requested ( ) Yes ( ) No: 9	
Inspector Signature: 2		Location of Sampling: 10	
Analysis/Testing Required: 11			
Laboratory			
Date Received			
Received By			
Sent Via			
Sample Condition			
Condition of Seals			
Units Received			
Storage Location			
Assigned By			
Assigned To			
Delivered By			
Date Delivered			
Number of Units Received			
Units Analyzed			
Date Seal Broken			
Date Resealed			
Resealed By			
Storage Location			
Date Results of Analysis Issued to EPA		Date Results of Analysis Issued to Facility	
Remarks			

EPA United States Environmental Protection Agency

Chain of Custody Record

Sample Number		Task Number
Inspection Number		
Sample Name		
Inspector Name and Address	Date Sample / Time / Duplicate Requested ( ) Yes ( ) No	
Inspector Signature	Location of Sampling	
Analysis/Testing Required		

Laboratory			
Date Received			
Received By			
Sent Via			
Sample Condition			
Condition of Seals			
Units Received			
Storage Location			
Assigned By			
Assigned To			
Delivered By			
Date Delivered			
Number of Units Received			
Units Analyzed			
Date Seal Broken			
Date Resealed			
Resealed By			
Storage Location			
Date Results of Analysis Issued to EPA		Date Results of Analysis Issued to Facility	

Remarks

7 Data Systems

Chapter Seven

Data Systems

This chapter is reserved for future development.

TSCA Appendix

Appendix A

Shipping Samples

This Appendix outlines considerations for preparing samples for shipment to a laboratory for analysis.

When it is not feasible to personally deliver a sample to the examining laboratory, it should be shipped by the most economical means commensurate with the need for rapid handling. Sample documentation should be forwarded under separate cover.

Shipping Hazardous Substances

Shipments of hazardous or toxic substances via postal service or common carrier are subject to regulations developed by the Department of Transportation (DOT) and the U.S. Postal Service (USPS). These substances are generally classified into three independent hazard categories:

- Toxicity
- Flammability
- Corrosiveness

Specific definitions and requirements can be found in USPS Publication 52 and in the Department of Transportation Hazardous Materials Regulation, Title 49, Code of Federal Regulations, Sections 170-179 (49 CFR 170-179). The sources should be consulted for guidance when preparing samples for shipment.

DOT and USPS do not list specific shipping requirements for chemical substances currently regulated under TSCA jurisdiction. However, samples taken during an inspection will often contain other substances

that may be subject to DOT regulations. For example, a PCB sample may be partly composed of a solvent that is highly flammable. The total composition of the sample should be taken into account for shipping purposes.

It is the responsibility of the inspector to observe shipping regulations to ensure safe and efficient shipping of samples.

Packing Samples for Shipment

Security Considerations

All samples must be securely packaged in a manner that prevents mixing of the substances within the package or their release into the environment.

- Fragile Containers

  Fragile containers should be packed in cushioning material to prevent shifting and breaking while in transit.

- Liquids

  Liquid samples should be packed in sufficient cushioning or absorbent material to absorb and retain any leakage which might occur.

  Liquid and dry samples should not be packed in the same shipping case as leakage might contaminate all samples.

  Containers of liquid samples should have effective closure mechanisms: screw caps, soldering, clips, or other means to prevent leakage. Friction closures (i.e., lids of the type found on paint cans) are not generally acceptable for transit unless an additional method of security is provided.

- Aerosols

  Aerosol containers are accepted for shipment by both parcel post and common carriers if packaged in accordance with DOT regulations concerning the limit of quantities of compressed gases (49 CFR §173.306).

Aerosol containers must have a positive means to prevent accidental discharge of contents. This may be accomplished through the use of recessed valves, screw thread caps, tape closures, or other effective means of preventing discharge.

Markings

Packages containing samples of toxic or hazardous substances must be properly and clearly marked. The following information should be included:

- Name and address of both shipper and addressee.
- "Shipping name" of the article (i.e., the generic name as listed at 49 CFR 172.101)
- Hazardous materials warning label(s), if appropriate (e.g., "Flammable", "Poison", etc.) Aerosol containers when shipped by air must bear the label "Compressed Gases".
- Handling cautions: "Glass", "Handle with Care", "This End Up", etc., as appropriate.

Parcel Post Shipment

Shipment of Samples

Samples within parcel post size and weight limits should be shipped by this means.

Gallon-size glass bottles should not be shipped by parcel post.

Payment of Charges

Parcel post is mailed under the Government frank on the address label reading: "Postage and Feed Paid" and showing a Government department as shipped, over words: "Official Business". EPA Form 1820 - Mailing Label should be used for this purpose.

Postal Regulations

USPS Publication 52 and the USPS Domestic Mail Manual should be used as a guide when making shipments by mail.

Government Bill of Lading

The U.S. Government Bill of Lading (GBL) is the primary document used to request freight and express transportation and related services from commercial carriers. It is used for transportation of property when freight charges are to be paid by the Government directly to commercial carriers regardless of the mode of transportation or the amount of transportation charges.

A GBL should be prepared for all shipments made by common carrier. Small shipments, however may move on commercial bills of lading as authorized by the General Accounting Office (5 GAO 3). Refer to the GSA publication "How to Prepare and Process U.S. Government Bills of Lading (7610-00-682-6740) for specific details.

General Guidelines Concerning Mailability

- Substances that may kill or injure, or damage mail or other property are considered non-mailable unless specifically provided for in the postal regulations or guidelines.
- All parcels containing hazardous materials must have the nature of the contents stated clearly on the outside of the package.
- The mailer is ultimately responsible for determining beforehand whether an item is mailable or not. Inspectors should keep abreast of current regulations concerning shipment of hazardous materials.

Common Carrier Shipment

Motor freight or United Parcel Service should normally be used for larger shipments and for shipments of more fragile and toxic samples.

- Buses should only be used when another means of transportation is not available and only for less toxic substances.
- Air freight should be used if rapid handling is imperative. Certain restrictions apply to the type of substance shipped, and specific marking and labeling requirements may apply.

DOT Regulations

The Department of Transportation regulates the transportation of all hazardous materials within the United States, and all shipments made by common carrier are subject to DOT regulations and requirements.

49 CFR 170-179 provides details of DOT regulations concerning classification, packaging, marking, labeling, and other shipping requirements. This source should be consulted to ensure compliance when shipping samples.

- Certification

  The shipping papers must contain the shipper's certification that the materials are properly classified, described, packaged, marked, and labeled, and are in proper condition for transportation in accordance with all applicable government regulations.

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