Office of Enforcement and Compliance Assurance

INSPECTION MANUAL

Toxic Substances Control Act (TSCA) New and Existing Chemicals Inspection Manual

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Toxic Substances Control Act (TSCA) New and Existing Chemicals Inspection Manual

U.S. Environmental Protection Agency

Office of Enforcement and Compliance Assurance

Office of Compliance

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Disclaimer

This Inspection Manual is an inspection support tool provided by the U.S. Environmental Protection Agency (EPA), for use by EPA regions conducting federal inspections under the Toxic Substances Control Act. This Inspection Manual is not a regulation and, therefore, does not add, eliminate, or change any existing regulatory requirements. The statements in this document are intended solely as guidance. This document is not intended, nor can it be relied on, to create any rights enforceable by any party in litigation with the United States. EPA officials may decide to follow the guidance provided in this document, or to act at variance with the guidance, based on analysis of specific-site circumstances. This guidance may be revised without public notice to reflect changes in EPA's policy.

Foreword

The purpose of this Manual is to assist inspectors who conduct inspections pursuant to the Toxic Substances Control Act (TSCA). This Manual applies to all TSCA New and Existing Chemicals (Core TSCA) inspections. To help us update the Manual so that it remains a viable working tool, readers are encouraged to offer suggestions, amendments and constructive criticism generated by their field experience and use of the Manual. Comments should be forwarded to Valarie Franklyn at EPA Headquarters franklyn.valarie@epa.gov, 202-564-1596.

Revision History

History	Effective Date
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Toxic Substances Control Act (TSCA) New and Existing Chemicals Inspection Manual

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Chapter 1 Introduction

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Introduction

The purpose of the Toxic Substances Control Act (TSCA) New and Existing Chemicals Inspection Manual is to provide uniform guidance on the conduct of compliance monitoring inspections by EPA-credentialed inspectors pursuant to TSCA Title I: Control of Toxic Substances, sections 4-8 and 11-17 (40 C.F.R. Parts 700-799).
Inspection activities conducted pursuant to this Manual should be consistent with the most recent versions of:

- The Compliance Monitoring Strategy (CMS) for TSCA
- The National Program Guidance (NPG)
- The EPA Quality Assurance Field Activity Procedures (QAFAP)

Inspection activities conducted pursuant to this Manual should be consistent with the EPA (Agency) QAFAP, which represent the minimum requirements for establishing a quality management system to support field activities for EPA. The QAFAP Guidelines cover personnel/training, document control, records management, evidence and sample management and handling, field documentation, field equipment, field inspections, reports, internal audits, and corrective actions for all field activities. Procedures inspectors are required to follow when conducting on site civil inspections include, but are not limited to, the following:

- Establishing the inspection time and place.

- Establishing inspection protocol: i.e. presenting credentials, explaining the nature and scope of the inspection, etc.
- Conducting the inspection following appropriate procedures and standards: i.e. documenting observations, taking samples, photos, conducting interviews, etc.
- Preparing an inspection report to be provided to the facility.

Role of the Inspector

An inspector has several roles. The main role of the TSCA inspector is to gather information and document observations in support of statutory and regulatory compliance monitoring and enforcement efforts. If violations are suspected during an inspection, EPA may choose to initiate an enforcement action after the inspection is completed and documentation is reviewed by a case development officer. An enforcement proceeding typically rests on the observations, evidence and information gathering activities of the inspector. Therefore, the inspector must ensure that all data introduced into an inspection file are complete, accurate, and representative of the observed conditions. Furthermore, in the event of an enforcement proceeding, an inspector may be needed to prepare for settlement negotiations, hearings, or to serve as a witness. Finally, since the inspector will come into contact with the regulated community, as well as the public, he/she is an important EPA representative.

Standards of Professional Conduct

At all times, the inspector shall:

- Conduct investigations within the framework of the United States Constitution and with due consideration for individual rights, regardless of race, sex, creed, or national origin.
- Uphold the Constitution, laws and regulations of the United States and all governments therein and never be a party to their evasion.
- Never use any information obtained confidentially in the performance of governmental duties as a means of making private profit.
- Never commit any act (or fail to act) in a manner that might be construed as being motivated by personal or private gain (conflict of interest).
- Never discriminate by dispensing special favors or privileges to anyone, whether for remuneration or not; and never accept favors or benefits under any circumstances.
- Develop and report facts of an inspection completely, objectively, and accurately.
- Make no promises of any kind; government employees (inspectors) cannot bind government enforcement.

- Continually attempt to improve professional knowledge and technical skill in the field of conducting inspections.
- Comply with all applicable ethical requirements.

Inspector Requirements

Federally credentialed inspectors who conduct Core TSCA inspections must obtain federal inspection credentials issued by EPA. To obtain credentials the inspector is responsible for meeting knowledge requirements. Generally, the knowledge requirements for all inspectors include: (1) a basic curriculum designed for inspections in all media; (2) an occupational health and safety curriculum; and (3) a program specific curriculum. The requirements for obtaining TSCA inspection credentials are set forth in EPA Order 3500.1. Specific occupational health and safety requirements are described in EPA Order 1440.2. Further guidance for when credentials are required when conducting compliance monitoring activities can be found in the June 2019 Office of Compliance memo, "Compliance Monitoring Activities that Require a Civil Inspector Credential."

Relationships with the Public and the Regulated Community

If an inspector is approached by a member of the public, including the media, during an inspection, the inspector should respectfully refer these inquiries to the appropriate EPA Press/Communications Office. The inspector must not divulge any information about the inspection. If the media representative is persistent, it may be necessary to stop the inspection temporarily to allow time to consult with the EPA Press/Communications Office.

The Freedom of Information Act (FOIA) governs the disclosure of information to the public. Federal inspectors should not release any notes, documents, reports, etc., obtained or prepared in connection with a Core TSCA inspection until such time as authorized by EPA. Until this process occurs, all documents are considered "enforcement confidential" and protectable under FOIA. The "enforcement confidential" designation extends to all inspection data and material including documents, samples, field notes, photographs and other documentation collected by the inspector. Procedures governing disclosure of information under FOIA are available at 40 C.F.R. Part 2, Subpart A.

The Interim Policy on Inspection Report Timeliness and Standardization, June 29, 2018, and any subsequent final policy provides the Agency's policy on the release of the final inspection report. Inspectors are expected to adhere to EPA policy. The policy provides information on the appropriate and timely notification of EPA inspection results to facilities and the public, including any potential deficiencies or areas of concern observed during an on-site inspection and the timely completion and release of inspection reports.

When a member of the public, or a representative from a state, local, tribal or federal agency requests access to any information considered confidential, the person handling the request must comply with the procedures set forth in Subpart B of 40 C.F.R Part 2. All such requests must be referred to the appropriate EPA regional office. Information collected during an inspection is made available in response to a Freedom of Information Act (FOIA) request unless the information is determined to be exempt from release under strict FOIA criteria. If data have been claimed as CBI by a company, EPA follows certain procedures to release the information, and the data is not released at all if it is determined to be entitled to confidential treatment. For more information on the release of information claimed to be CBI, see section "TSCA Confidential Business Information (CBI)" below.

Compliance Assistance

During an inspection, an inspector may be asked to provide site specific advice that amounts to compliance assistance. An example of compliance assistance would be to provide links to the EPA TSCA website and copies of EPA published materials. Specifically, if available, the inspector may provide any EPA pre-approved compliance assistance material containing information pertinent to the federal requirements. The inspector also may provide information regarding upcoming workshops or seminars. If the inspector is unable to provide informational materials at the time of the inspection, it is appropriate to mail compliance assistance material to the firm or individual. Inspectors may also refer facilities to the TSCA Hotline at tsca-hotline@epa.gov or (202) 554-1404 for most general TSCA related inquiries. To avoid any confusion, however, the inspector should be clear that the informational mailing does not constitute EPA's inspection response. See The Role of the EPA Inspector in Providing Compliance Assistance During Inspections.

IMPORTANT: *The inspection team should* ***never*** *answer questions about or provide recommendations for implementing specific procedural, administrative, or process changes at the facility to address regulatory requirements under TSCA. Rather, assistance should focus on general EPA guidance and providing additional clarity to information described in EPA guidance materials.*

Small Businesses

EPA provides a variety of resources to help small businesses understand and comply with federal and state law, in part, due to the Small Business Regulatory Enforcement Fairness Act (SBREFA). The EPA Small Business Resources Information Sheet should be given out during every inspection. The flyer provides useful information on resources for small business that may be faced with environmental compliance issues.

TSCA Confidential Business Information (CBI)

TSCA section 14 as well as 40 C.F.R. § 2.306 address the protection of trade secrets and confidential business information (CBI). Only persons authorized by EPA are allowed access to CBI. CBI includes information considered to be a trade secret (including chemical identity, process, formulation, or production data) that could damage a company's competitive position if it became publicly known. Information received that is marked "trade secret" or "confidential" must not be copied unless authorized in writing by EPA.

All EPA inspectors conducting Core TSCA inspections must be TSCA CBI certified, which means that the Agency has approved the inspector to have access to TSCA CBI. It is critical that the inspector adhere to the CBI requirements set forth in the TSCA CBI Protection Manual since TSCA section 14(d) authorizes a criminal penalty for wrongful disclosure, i.e. willful disclosure of the material in any manner to any person not entitled to receive it.

CBI claims must be asserted and substantiated concurrently with the submission of the information. TSCA section 14(c)(2) identifies certain information that is generally not subject to substantiation requirements, including:

- Specific information describing the processes used in manufacture or processing of a chemical substance, mixture, or article;
- Marketing and sales information;
- Information identifying a supplier or customer;
- In the case of a mixture, details of the full composition of the mixture and the respective percentages of constituents;
- Specific information regarding the use, function, or application of a chemical substance or mixture in a process, mixture, or article;
- Specific production or import volumes of the manufacturer or processor; and
- Prior to the date on which a chemical substance is first offered for commercial distribution, the specific chemical identity of the chemical substance, including the chemical name, molecular formula, Chemical Abstracts Service number, and other information that would identify the specific chemical substance, if the specific chemical identity was claimed as confidential at the time it was submitted in a notice under TSCA section 5.

Additionally, the authorized official submitting CBI claims must certify that information submitted to substantiate a CBI claim is true and correct, as required by sections 14(c)(1)(B) and 14(c)(5) of TSCA.

IMPORTANT: *The inspection team should not answer questions about what is or is not an appropriate CBI substantiation. However, they can direct facility representatives to EPA's webpage related to TSCA CBI substantiations for more guidance:* https://www.epa.gov/tsca-cbi/what-include-cbi-substantiations*. The inspector's role is to: (1) give information to the facility about CBI and its protections, (2) collect the CBI necessary to monitor compliance (3) collect any substantiation and (4) protect any CBI provided in conformance with the CBI Protection Manual.*

Furthermore, some information may not be protected as CBI, such as:

- Health and safety studies where the chemical or mixture has been offered for commercial distribution or for which testing is required under TSCA section 4 or notification is required under TSCA section 5.
- General information describing manufacturing volumes
- General description of a process used in the manufacture or processing and industrial, commercial or consumer functions and uses of a chemical substance, including information specific to an industry or industry sector that customarily would be shared with the general public or within an industry or industry sector.

Amendments to TSCA in 2016 expanded the categories of people who may now access information claimed as confidential business information (CBI) under TSCA. Information that a business claims as CBI under TSCA is protected from disclosure until the business withdraws the CBI claim, until the CBI claim expires, until EPA determines that the claim is not entitled to confidential treatment, or as authorized under TSCA and EPA regulations. TSCA now allows EPA, under certain conditions, to disclose CBI to:

- state, tribal, and local governments (TSCA section 14(d)(4));
- environmental, health, and medical professionals (TSCA 14(d)(5)); and
- emergency responders (TSCA section 14(d)(6)).

EPA provides guidance for requesting access to CBI under those provisions at:
https://www.epa.gov/tsca-cbi/guidance-requesting-access-confidential-business-information

Chapter 2 TSCA New and Existing Chemicals Program Overview

Contents

Statutory Authority and Regulation

The Toxic Substances Control Act (TSCA or the Act) authorizes the U.S. Environmental Protection Agency (EPA or Agency) to regulate both new and existing chemical substances.

Regulation of chemical substances prior to their introduction into commerce (new chemicals) allows EPA to obtain data necessary to assess the potential risks of such chemicals early and to take regulatory action that may be necessary to protect human health and the environment before the substance enters commerce.

Assessment and regulation of the manufacture, processing, distribution in commerce, use or disposal of chemical substances and mixtures already in commerce (existing chemicals) assures that such chemicals substances and mixtures do not present an unreasonable risk of injury to health and the environment.

For TSCA regulatory purposes, therefore, chemical substances are divided into two categories: new chemicals and existing chemicals. The different sections of TSCA pertain to one or both categories. For example, section 5 requires that manufacturers and importers of new chemicals submit Premanufacture Notices (PMNs) and Significant New Use Notices (SNUNs) to EPA. Section 6 authorizes EPA to impose limitations and restrictions on existing chemicals in commerce. Section 8 authorizes information collection on both those chemicals that are manufactured, processed, or distributed, plus those chemicals proposed for manufacturing or processing, thereby new and existing chemicals are subject to section 8 requirements.

The primary purpose of TSCA is, therefore, to assure that such innovation and commerce in such chemical substances and mixtures (chemicals) do not present an unreasonable risk of injury to health or the environment.

TSCA (15 U.S.C. §§ 2601–97) was passed in 1976 and amended in 2016 by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Lautenberg Amendments). TSCA broadly defines the term "chemical substance," as "any organic or inorganic substance of a particular molecular identity, including any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and any element or uncombined radical." However, several exclusions from the definition of "chemical substance" are provided in section 3(2)(B), including (i) mixtures[1], (ii) pesticides, (iii) tobacco and tobacco products, (iv) nuclear materials and byproducts, (v) pistols, firearms, revolvers, shells, cartridges, certain ammunition (bullets and shot), (vi) food, food additives, drugs, cosmetics, and devices.[2,3] To access the U.S. Code version of TSCA as amended by the Lautenberg Amendments, visit the U.S. Code website. More information on key provisions of the Lautenberg Amendments is available on EPA's website here, here and here.

TSCA is comprised of the following subchapters:

- I-Control of Toxic Substances
- II-Asbestos Hazard Emergency Response
- III-Indoor Radon Abatement
- IV-Lead Exposure Reduction
- V-Healthy High-Performance Schools
- VI-Formaldehyde Standards

1 Although mixtures are excluded, the components of the mixture are not.

2 Note that some chemical substances regulated by the FDA of FIFRA may also have TSCA uses covered under the definition of chemical substance.

3 For specific definitions of each exclusion from the term "chemical substance" under TSCA, see section 3 of TSCA ("definitions").

This manual applies to "Core TSCA" (Core TSCA), generally represented in Subchapter I, which addresses the control and regulation of chemical substances and mixtures. While Subchapter VI Formaldehyde Standards for Composite Wood Products is a separate Subchapter under TSCA, it is considered to be part of the Core TSCA enforcement program. The sections that are relevant to Core TSCA (excluding PCBs, but including elemental mercury), include the following:

- Section 4-Testing of Chemical Substances and Mixtures
- Section 5-Manufacturing and Processing Notices
- Section 6-Prioritization, Risk Evaluation, and Regulation of Chemical Substances and Mixtures
- Section 7-Imminent Hazards
- Section 8-Reporting and Retention of Information
- Section 11-Inspections and Subpoenas
- Section 12-Exports
- Section 13-Entry into Customs Territory of the United States
- Section 14-Disclosure of Data
- Section 15-Prohibted Acts
- Section 16-Penalties
- Section 17-Specific Enforcement and Seizure
- Subchapter VI Section 601-Formaldehyde Standards

> ***Tip:*** *A Core TSCA inspection includes reviewing facility records related to TSCA Title 1, sections 4, 5, 6, 8, 12, and 13. These are the focus of this manual. TSCA Title 1, sections 14-17 are related to inspection activities as they outline requirements for claiming and handling of CBI and EPA's authority to conduct inspections, impose civil or criminal penalties, and use specific enforcement and seizure for violations of TSCA; however, there is no facility reporting or recordkeeping requirements under these sections that require review during an inspection. The Subchapter VI section 601—Formaldehyde Standards only apply to manufacturers of certain wood products and, therefore, only need to be considered when inspecting such sites.*

The EPA regulations implementing TSCA are codified in Title 40 of the Code of Federal Regulations (C.F.R.), Parts 700–799. The following is a list of many of the regulations relating to Core TSCA inspections:

- 40 C.F.R. Part 700 – General
- 40 C.F.R. Part 702 – General Practices and Procedures
- 40 C.F.R. Part 704 – Reporting and Recordkeeping Requirements

- 40 C.F.R. Part 707 – Chemical Imports and Exports
- 40 C.F.R. Part 710 – Compilation of the TSCA Chemical Substance Inventory
- 40 C.F.R. Part 711 – TSCA Chemical Data Reporting Requirements
- 40 C.F.R. Part 712 – Chemical Information Rules
- 40 C.F.R. Part 716 – Health and Safety Data Reporting
- 40 C.F.R. Part 717 – Records and Reports of Allegations that Chemical Substances Cause Significant Adverse Reactions to Health or the Environment
- 40 C.F.R. Part 720 – Premanufacture Notification
- 40 C.F.R. Part 721 – Significant New Uses of Chemical Substances
- 40 C.F.R. Part 723 – Premanufacture Notification Exemptions
- 40 C.F.R. Part 725 – Reporting Requirements and Review Processes for Microorganisms
- 40 C.F.R. Part 750 – Procedures for Rulemaking Under Section 6 of TSCA
- 40 C.F.R. Part 751 – Regulation of Certain Chemical Substances and Mixtures under Section 6 of TSCA
- 40 C.F.R. Part 770 – Formaldehyde Standards for Composite Wood Products
- 40 C.F.R. Part 790 – Procedures Governing Testing Consent Agreements and Test Rules
- 40 C.F.R. Part 799 – Identification of Specific Chemical Substance and Mixture Testing Requirements

A summary of many of these regulations can be found in Appendix 1.

Compliance and Enforcement Policies and Strategies

Core TSCA inspectors may find the following general policies and documents to be helpful.

- Office of Enforcement and Compliance Assurance (OECA) National Program Guidance
- The Role of Inspector in Providing Compliance Assistance During Inspections
- The EPA Quality Assurance Field Activity Procedures (QAFAP)
- Digital Image Guidance for EPA Civil Inspections and Investigations
- Policy on the Use of Mobile Field Inspection Tools
- EPA's Privacy Policy for Personally Identifiable Information and Privacy Act Information
- Final Revised Policy Reaffirming the U.S. EPA Authority to Access Facilities and Conduct Inspections without Providing Personally Identifiable Information with Limited Exceptions for Federal Facilities
- Interim Policy on Inspection Report Timeliness and Standardization
- Policy on Civil Penalties: EPA General Enforcement Policy #GM-21 & 22

- Amendments to the EPA's Civil Penalty Policies to Account for Inflation (effective January 15, 2020) and Transmittal of the 2020 Civil Monetary Penalty Inflation Adjustment Rule

The following documents are specific to Core TSCA:

- Compliance Monitoring Strategy for the Toxic Substances Control Act
- Enforcement Response Policy for TSCA Section 4 Test Rules
- Amended TSCA Section 5 Enforcement Response Policy
- Amended TSCA Section 5 Enforcement Response Policy – Penalty Limit for Untimely NOC Submissions
- Issuance of Revised Enforcement Response Policy for TSCA Sections 8, 12 & 13

Overview of Key Core TSCA Sections Covered by Inspections

Supplemental statutory and regulatory background information can be found in Appendix A

Section 4: Testing of Chemical Substances and Mixtures

TSCA section 4 gives EPA the authority to require chemical manufacturers (including importers) and processors to test chemical substances and mixtures and submit the results to EPA. The requirements may consist of testing related to health and environmental effects, such as chronic toxicity, carcinogenicity, and other effects. EPA may issue a rule, order, or consent agreement when there is insufficient data for EPA to determine whether the chemical substance or mixture presents an unreasonable risk to health or the environment. EPA may also issue a rule, order or consent agreement if the information is necessary to: review a notice under section 5; perform a risk evaluation for prioritizing a chemical substance under section 6(b); implement a requirement imposed in an order, rule or consent agreement under section 5 (e) or (f); or in a rule promulgated under section 6(a).

Test Rules

Test rule regulations are found at 40 C.F.R. §§ 790.1 through 790.7 (general provisions), 790.40 through 790.59 (implementation, enforcement, and modification), 790.65 (failure to comply with a consent agreement), and 790.80 through 790.99 (exemptions). If EPA determines that it is necessary to test a chemical substance or mixture under TSCA section 4, it can promulgate a test rule. *See* 40 C.F.R. Part 799. Each test rule will specify who is responsible for testing for its selected chemical(s): 1) each person who manufactures or imports or intends to manufacture or import the chemical; (2) each person who processes or intends to process the chemical; or (3) both manufacturers/importers and processors. Pursuant to 40 C.F.R. § 790.45, each person

subject to a test rule must submit a notice of intent to conduct testing, or an application for exemption. After notifying EPA of intent to conduct testing required by a test rule, a person must conduct the test with the test standards and schedules adopted in the test rule, or as modified. Failure to submit an application for exemption from testing is also a violation of the rule.

Consent Agreements and Orders

Under section 4(a)(1) of TSCA, EPA can also by an enforceable consent agreement (ECA) or order require testing after finding that there is insufficient information regarding the effects on health or the environment or if significant exposure to humans or the environment is reasonably determined or predicted. Consent agreement regulations are found at 40 C.F.R. §§ 790.1 through 790.7, and 790.60 through 790.68. In some situations, EPA and industry can conserve resources by utilizing consent agreements. Consent agreements are only enforceable against its signatories.

EPA may use consent agreements to accomplish testing when a consensus exists among EPA, affected manufacturers, importers, and/or processors. The chemicals subject to testing consent agreements can be found in 40 C.F.R. §§ 799.5000 and 799.5025. For more information, a copy of an ECA is available on EPA's website.

Under section 4(a)(2), EPA can by order require testing when there is a need for information and all reasonably available information has been assessed. For example, order authority can be used to efficiently obtain information to inform the TSCA section 6 prioritization and risk evaluation process.

In 2020, EPA issued its first order requiring testing under TSCA section 4(a)(2) when it required two companies to conduct solubility testing and occupational inhalation exposure monitoring for C.I. Pigment Violet 29 (PV29). PV29 was one of the first ten chemicals to undergo risk evaluation under the Lautenberg amendments. The basis of the testing is to reduce uncertainties in the final risk evaluation of PV29 under TSCA section 6(b).

Orders, similar to consent agreements, are enforceable against the parties listed in the order.

More information on section 4 orders is available on EPA's website.

Section 5: Manufacturing and Processing Notices

Under TSCA section 5, EPA reviews all "new chemical substances" subject to pre-manufacture notice (PMN) requirements prior to their being manufactured or imported for a commercial purpose. A new chemical substance is any chemical substance that is not included on the TSCA section 8(b) Inventory and that is not specifically excluded from regulation under TSCA (e.g., pesticides, drugs, cosmetics). TSCA section 5(a) establishes PMN requirements for new chemical substances and notice requirements for chemical substances with designated significant new use rules (SNURs). TSCA section 5 authorizes EPA to review chemical substances before they are manufactured (including import), and new uses of chemical substances before they are manufactured or processed. EPA will review the notices and may issue an order under TSCA section 5(e) or 5(f) to regulate the new chemical or significant new use of the existing chemical. Various exemptions to this process exist under section 5; however, many of these exemptions also require notification of / application to EPA.

PMNs

Section 5(a)(1)(A) of TSCA prohibits any person from manufacturing a new chemical substance without notifying EPA prior to commencing manufacture or importation. New chemical substances are chemicals that do not appear on the chemical substance list [or Inventory] of "existing" chemicals established under section 8(b).

Notification is accomplished through the submittal of a PMN, which EPA has 90 days to review. EPA may extend the review period if the submitter requests a suspension of the review period. The review period provides EPA with an opportunity to review and evaluate information pertaining to potential risk of the substance and to take appropriate risk management action before the new manufacture begins.

Before the Lautenberg Amendments in 2016, if EPA took no action to limit or ban manufacture or importation or to extend the review period, the submitter could commence manufacture or import on the 91st day, as long as a notice of commencement (NOC) was submitted within 30 days after doing so. After the Lautenberg Amendments, EPA must make a determination before the submitter may submit a notice of commencement. If a company submitted a notice after June 26, 2016, and commenced manufacture before EPA made a determination, they are in violation of section 5(a)(1) of TSCA.

The submitter may withdraw the PMN at any time during the review process without giving a reason. The submitter may also request a suspension of the review period. EPA may also extend the PMN review period for up to 90 days and will notify the submitter that EPA is extending the review period for a specified length of time and state the reason(s) for extension.

SNURs

Under TSCA section 5(a)(2), EPA may determine that a use of a chemical substance constitutes "a significant new use" (or SNU) and therefore, promulgate a Significant New Use Rule (SNUR), which requires that manufacturers and processors notify EPA prior to engaging in a SNU. As with PMNs, Significant New Use Notices (SNUNs) permit EPA an opportunity to review and evaluate information pertaining to potential risk of the SNU and to take appropriate risk management action before the new use begins in the form of an order and/or modification of the SNUR.

Exemptions to PMNs/SNURs

TSCA section 5(h) permits EPA to grant or establish exemptions from the PMN and SNUN requirements in certain situations. Some exemptions are described in section 5(h) and other exemptions are described in specific rules, which include:

- Low volume exemption (LVE), found at 40 C.F.R. 723.50
- Low human exposure and environmental release exemption (LoREX), found at 40 C.F.R. 723.50
- Research and development (R&D) exemption, found at 40 C.F.R. 720.36 and 720.78
- Test marketing exemption (TME), found at 40 C.F.R. 720.38
- Polymer exemption (PE), found at 40 C.F.R. 723.250

LVEs, LoREX, and TMEs require prior application to EPA and EPA approval. The polymer exemption requires meeting certain criteria and sending a report to EPA postmarked by January 31st of the year subsequent to initial manufacture. The research and development exemption requires meeting the criteria specified in the regulation. Also, chemicals not subject to notifications are found at 40 C.F.R. § 720.30. Finally, note the recordkeeping requirements at 40 C.F.R. § 720.78 for any person who submits a notice under 40 C.F.R. Part 720.

Section 5(e)/(f) Orders

Under TSCA section 5(e), if EPA determines that the information available is insufficient to permit a reasoned evaluation of the health and environmental effects of a chemical substance **and** that either:

1. the manufacture, processing, distribution in commerce, use, and disposal of such a substance may present an unreasonable risk to health or the environment, **or**
2. the substance is/or will be produced in substantial quantities and either

a. enters or is reasonably anticipated to enter the environment in substantial quantities, or
b. there is or will be significant or substantial human exposure to the substance,

EPA may issue a proposed order (i.e., section 5(e) order) prohibiting or limiting the manufacture, importation, processing, release, distribution in commerce, use, or disposal of such a substance. Such orders typically require testing before a particular production volume is met and include other requirements designed to minimize human and environmental exposure to the substance. Examples of such terms include limited or no release to water, personal protective equipment, testing before any manufacture or a certain production limit. Orders become effective upon the expiration of the PMN notification period. The notice period expires on the date EPA receives the signed order or the 91st day, whichever is later.

"Unilateral" section 5(e) orders are rare. In most cases in which EPA believes that a 5(e) order is necessary, EPA negotiates with the PMN submitter to formulate a section 5(e) order.

Under TSCA section 5(f), if the Administrator determines that there is a reasonable basis to conclude that the manufacture, processing, distribution, release, use, or disposal of a new chemical substance or significant new use presents or will present an unreasonable risk of injury to health or environment, EPA may:

(1) limit the amount manufactured, processed, or distributed in commerce or impose other restrictions on the substance by an immediately effective proposed rule under section 6 of TSCA, or
(2) issue an order to prohibit or limit the manufacture, processing, or distribution in commerce to take effect on the expiration of the applicable review period.

Section 6: Prioritization, Risk Evaluation, and Regulation of Chemical Substances and Mixtures

TSCA section 6 authorizes EPA to regulate substances that present an "unreasonable risk of injury" to human health or the environment. Section 6(a) identifies certain stages of a chemical's life cycle (i.e. manufacturing, processing, use, disposal) and the types of risk mitigation (banning or limiting the volume of manufacture, the particular use, preventing or mandating a type of disposal, etc.) that EPA can impose. If EPA determines that the use of a chemical substance or mixture "presents an unreasonable risk of injury to health or the environment, the Administrator shall by rule" impose authorized restrictions necessary so that the chemical or mixture no longer presents such risk. Section 6 does for chemicals currently in commerce what section 5 does for new chemicals.

> ***Tip:*** *Prior to the passing of the amended TSCA in 2016, very few section 6 rules existed. However, under the amended TSCA a much higher number of chemicals will be undergoing risk evaluation simultaneously covering a much broader scope of conditions of use. Therefore, the number of section 6 rules is likely to increase dramatically from pre-2016. The inspection team should check ChemView and the Federal Register for new rules prior to arriving at a facility to familiarize with any new, potentially relevant, section 6 rules.*

Before taking action under TSCA section 6, EPA must conduct section 6 Rulemaking Procedures with input from the regulated community and the general public. Procedures for rulemaking under section 6 are found at 40 C.F.R. Part 750. Possible actions the Agency may take to regulate an existing chemical include:

(1) Prohibiting or limiting the manufacture, processing, or distribution in commerce of a substance or mixture.
(2) Prohibiting or limiting the manufacture, processing, or distribution in commerce of a substance or mixture for a particular use.
(3) Requiring clear and adequate warnings and instructions on use, distribution, or disposal to accompany the substance by label or other means.
(4) Requiring manufacturers or processors to maintain records of the processes used and monitor or conduct those tests necessary to assure compliance.
(5) Prohibiting or otherwise regulating commercial use of the substance or mixture.
(6) Regulating the manner of disposal.
(7) Requiring manufacturers or processors to give notice of risk of injury and to replace or repurchase the substance or mixture.

Prioritization and Risk Evaluation of Chemical Substances and Mixtures

Section 6(b) sets forth the risk evaluation process (including prioritization of chemicals) that provides the basis for regulating specific chemicals that are already in commerce. Procedures

for Prioritization of Chemical Substances for Risk Evaluation found at 40 C.F.R. 702 Subpart A. Procedures for Chemical Substance Risk Evaluations can be found at 40 C.F.R. 702 Subpart B.

Pursuant to TSCA section 6(b), a risk-based screening prioritization process is required for categorizing chemical substances or mixtures as either high or low priority for risk evaluations.

EPA requires payment of fees from manufacturers, including importers, of high-priority chemical substances undergoing TSCA risk evaluation. Because the manufacturers and importers of the chemical may not be known, EPA has initiated a process to identify those entities subject to the TSCA fees. More information regarding TSCA fees for EPA-initiated risk evaluations is available on EPA's website.

More information is available on EPA's website for prioritization and existing chemical risk evaluations. The list of chemicals currently undergoing risk evaluation is available on EPA's website.

EPA will be constantly conducting new risk prioritizations and evaluations. Under the Lautenberg Amendments, EPA must be evaluating 20 chemical substances. It is important to check if a chemical substance or mixture has undergone such review and if there is a resulting TSCA section 6 rule that might need to be addressed during an inspection.

Section 6(f) prohibits the sale, distribution, or transfer of elemental mercury by Federal agencies with exceptions, exemptions, and conditions.

More information about the Mercury Export Ban Act (MEBA) is addressed in Section 12 and discussed later in the manual. Additional information is available on EPA's website here.

Section 6(h) requires EPA to promulgate rules for chemicals that are persistent, bioaccumulative, and toxic (PBT). Risk evaluations are not necessary to promulgate rules for PBT chemicals. When regulated, PBT chemicals could be addressed in inspections.

More information regarding proposed rules to address PBT chemicals is available on EPA's website.

Section 7: Imminent Hazards

Under TSCA section 7, EPA is authorized to: a) commence a civil action in an appropriate district court for seizure of an imminently hazardous chemical substance, mixture or any article containing such a substance or mixture, or b) provide emergency action authorized under section 7(b) against any person who manufactures, processes, distributes in commerce, uses, or disposes of a chemical substance, mixture or any article containing such a substance or mixture,

which EPA has determined is imminently hazardous. Under the statute, an "imminently hazardous chemical substance or mixture'' is defined as: a chemical substance or mixture which presents an imminent and unreasonable risk of serious or widespread injury to health or the environment, without consideration of costs or other nonrisk factors. 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.

Section 8: Reporting and Retention of Information

TSCA section 8 consists of five subsections that establish reporting and recordkeeping requirements for chemical manufacturers, importers, processors, and, in certain cases, distributors.

Section 8(a) Preliminary Assessment Information Requirements (PAIR)) and the Chemical Data Reporting Rule (formerly Inventory Update Reporting Rule (IUR))

TSCA section 8(a) grants EPA the authority to require companies to document their chemical manufacturing, importing, and processing activities. Under section 8(a), EPA may set recordkeeping and reporting requirements for specific chemicals. In addition to several chemical-specific rules, EPA has used 8(a) authority to promulgate the Chemical Data Reporting (CDR) Rule (formerly known as the Inventory Update Reporting (IUR) Rule) and the Preliminary Assessment Information Rule (PAIR).

The general reporting and recordkeeping requirements are in 40 C.F.R. 704, the Preliminary Assessment Information Requirements are in 40 C.F.R. 712, the original Inventory reporting requirements are in 40 C.F.R. 710, and the Chemical Data Reporting rule requirements are in 40 C.F.R. 711.

> ***Tip:*** *EPA has not issued a PAIR rule since 2006. As of writing this manual, all existing PAIR rules have been sunset, so inspectors need only check for newly promulgated rules that are potentially*

In 1986, EPA published the IUR rule (40 C.F.R. 710), which was subsequently updated in 2003 and 2005. IUR required manufacturers and importers of chemicals on the TSCA Chemical Substances Control Inventory to report current data on chemical identity, production volume, plant site, and site-limited status (unless exempt). The IUR rule was updated and renamed the Chemical Data Reporting (CDR) rule in 2011. The CDR rule is in 40 C.F.R. 711, and 40 C.F.R. 710 was amended to contain only the Original Inventory reporting regulations. The CDR rule requires manufacturers and importers of certain chemicals listed on the Inventory to report

information about those chemicals manufactured and/or imported in volumes of 25,000 pounds or more at their site during any calendar year since the last principal reporting year. The current reporting frequency is every four years. The CDR rule requires manufacturers (including importers) to periodically report, among other things, information including:

- Chemical or mixture identity
- Categories of use
- Quantity manufactured or processed
- Byproduct description
- Health and environmental effects information
- Number of individuals exposed
- Method(s) of disposal.

Tip: *The specific CDR reporting requirements can change with each reporting cycle so it is important the inspection team familiarize themselves with any changes to the reporting requirements for the most recent reporting cycle prior to arriving at the facility.*

The reporting threshold is 2,500 pounds (1,134 kilograms) for chemicals that are:

- Subject of a rule proposed or promulgated under TSCA sections 5(a)(2), 5(b)(4), or 6
- Subject of an order issued under TSCA sections 5(e) or 5(f)
- Subject of relief that has been granted under a civil action under TSCA sections 5 or 7 (40 C.F.R. 711.8(b)).

Full Exemptions

- Small manufacturers, as defined at 40 C.F.R. § 704.3, are exempt from CDR reporting.
- The following activities are exempt from CDR reporting (40 C.F.R. 711.10):
    - Production of a substance solely for R&D.
    - Import of a substance as part of an article.
    - Manufacturing a substance as an impurity[4], non-isolated intermediate, or under any other circumstances identified in 40 C.F.R. § 720.30(g) and (h).
- The following substances are exempt from reporting under the CDR (40 C.F.R. § 711.6):
    - Polymers, microorganisms, naturally occurring substances, certain forms of natural gas, and water.
- Note: A chemical substance that falls into one of the exempt categories must still be reported if it is the subject of a rule proposed or promulgated under section 4, 5(a)(2), 5(b)(4), or 6 of TSCA, of an order in effect under section 5(e) or 5(f) of TSCA, relief that has been granted under a civil action under section 5 or 7 or an enforceable consent

4 For specific definitions under TSCA, see section 3 of TSCA ("definitions").

agreement (ECA) under 40 C.F.R. Part 790. The inspector should verify the status of a chemical for these types of regulatory actions.

Partial Exemptions

Manufacturers and importers of certain petroleum process streams, regardless of production volume, do not need to report processing and use information (required by 40 C.F.R. 711.15(b)(4)) for these chemicals. The partially exempt chemicals termed "petroleum process streams" for purposes of CDR are listed by CAS Registry Number at 40 C.F.R. 711.6(b)(1).

EPA maintains a list of partially exempt chemicals for which the CDR processing and use information is of "low current interest" at 40 C.F.R. 711.6(b)(2)(iv). Manufacturers and importers of these listed chemicals are exempt from reporting the processing and use information required by 40 C.F.R. 711.15(b)(4). Chemicals are included on this list only if EPA has determined that there is low current interest in the processing and use information for that substance.

Submitting Form U to EPA

The CDR rule requires all companies to report data electronically using e-CDRweb, the CDR web-based reporting tool, and EPA's Central Data Exchange (CDX) system (40 C.F.R. 711.35).

Manufacturers and importers subject to the CDR rule must submit a Form U for each site manufacturing and/or importing one or more reportable chemicals. A separate Form U is required for each reporting site.

The elements of the Form U include:

- Chemical name and chemical identifying number;
- Parent company name and address;
- Site name and address;
- Name and address of person who will serve as technical contact for each reportable chemical at the site;
- Certification statement;
- Manufacturing information, such as production volume; and
- Processing and use information, such as industrial function or consumer/commercial product category.
- Revisions to CDR requirements are available on EPA's website.

Recordkeeping Requirements

Pursuant to 40 C.F.R. 711.25, companies need to keep all data submissions, and records that document the information in the CDR submission, for 5 years beginning on the last day of the submission period. Production or import records to verify a reporting exemption because the production or importation is less than 25,000 pounds (11,340 kilograms) or 2,500 pounds (1,134 kilograms) for certain chemicals must also be maintained for 5 years.

Section 8(b) TSCA Chemical Substances Control Inventory (TSCA Inventory)

TSCA section 8(b) requires EPA to identify, compile, keep current, and publish a list of all chemical substances manufactured, imported, or processed in the United States. Under section 8(b), EPA created the TSCA Inventory. The Inventory provides the basis for distinguishing between new and existing chemicals under TSCA. The TSCA Inventory is updated regularly to reflect the commencement of manufacture of each new chemical substance.

TSCA section 8(b) requires EPA to maintain and update the TSCA Inventory of existing chemical substances. The purpose of the TSCA Inventory is to index current existing chemicals in commerce. When a new chemical has successfully completed review under the TSCA section 5 PMN process and the PMN submitter issues a Notice of Commencement (NOC) of non-exempt commercial manufacture or import, EPA adds this chemical to the Inventory and the chemical becomes an existing chemical.

TSCA Inventory Notification Rule

The Lautenberg Amendments require EPA to designate chemical substances on the TSCA Inventory as either “active” or “inactive” in U.S. commerce. To accomplish that, EPA finalized a rule requiring industry reporting of chemicals manufactured (including imported) or processed in the U.S. over a 10-year period ending on June 21, 2016. This reporting was completed on October 5, 2018 and was used to identify chemical substances on the TSCA Inventory as active or inactive in U.S. commerce. Starting August 5, 2019, manufacturers and processors are required to notify EPA before reintroducing inactive substances into U.S. commerce. Manufacturers and processors can notify EPA via a Notice of Activity Form B, found in EPA's CDX. Upon receiving such notification, EPA will change the commercial activity designation of inactive substances to active.

Section 8(c): Allegations of Significant Adverse Human Health or Environmental Effects

Under TSCA section 8(c), companies are required to record and track allegations of previously unknown significant adverse reactions to any substance or mixture they manufacture, import, process, or distribute.

The section 8(c) rule provides a mechanism to identify previously unknown chemical hazards. It may reveal (to EPA or an individual recordkeeper) patterns of adverse effects that otherwise may not be noticed or detected. The rule describes the types of allegations to be recorded by any manufacturer, importer, or processor of a chemical substance or mixture subject to the rule. Records required to be maintained under 8(c) include employee and other allegations of personal injury or harm to health. In addition, the company is not required to record significant adverse reactions that are known human effects from exposure to a given chemical.

Allegations that are subject to the rule implicate a chemical in an adverse reaction by:

- Naming the specific substance,
- Naming a mixture or article that contains a specific substance,
- Naming a company process or operation in which a specific substance is involved, or
- Naming an effluent, emission, or other discharge from a site of manufacturing, processing, or distribution of a specific substance.

No automatic reporting provision exists under section 8(c). The rule states that when the reporting of records is required, firms will be notified by letter, or by a notice in the *Federal Register*, of what chemical, when, and where to report.

The following persons are exempt from maintaining allegation files (40 C.F.R. 717.7):

- Persons whose manufacturing activities consist of mining or other solely extractive functions.
- Persons who are solely distributors. If a distributor also repackages chemicals or mixtures, then the distributor is a processor and not exempt from the rule.
- Persons who are retailers of a chemical substance unless such persons are also manufacturers or processors who are subject to the rule.

Recordkeeping Requirements

Pursuant to 40 C.F.R. 717.15(d), allegations from employees need to be retained for 30 years; other allegations only need to be retained for 5 years.

Section 8(d): Health and Safety Studies

Under TSCA section 8(d), EPA is required to promulgate rules requiring manufacturers, importers, processors, and distributors (or prospective manufacturers, importers, and processors) to submit lists and/or copies of ongoing and completed health and safety studies. EPA promulgated a model health and safety data reporting rule (40 C.F.R. Part 716), which was developed to gather health and safety data on specifically listed chemical substances and mixtures for which EPA requires information (e.g., to support the testing program and risk assessment). Information from these studies is intended to be used in making regulatory decisions under TSCA sections 4, 5 and 6. EPA will require reporting of unpublished health and safety studies when the agency is considering action to control exposure or is conducting a risk assessment on a chemical. Chemicals may also be added to the rule by request from other federal agencies represented on the section 4(e) Interagency Testing Committee (ITC) for their agency's purposes as well. However, only chemicals specifically added individually or as part of a category are subject to reporting requirements and only for the reporting period provided under the rule, typically a 60-day reporting period.

> ***Tip:*** *As of writing this manual, all existing 8(d) rules have been sunset, so inspectors need only check for newly promulgated rules that are potentially applicable to the facility in question.*

Persons who must report during the reporting period include:

- Manufacturers and importers who fall within the NAICS Subsector 325 (chemical manufacturing and allied products) or Industry Group 32411 (petroleum refiners) who either have proposed to manufacture, or import, or have actually manufactured or imported the substance or mixture, in the 10 years preceding the effective date, as of the effective date, or after the effective date on which a substance or mixture is added to 40 C.F.R. 716.120.
- Manufacturers, importers, or processors specifically required to report by rule.

A list of studies subject to, and exempt from, the section 8(d) rule is found in 40 C.F.R. 716.

Section 8(e): Notification of Substantial Risks

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

of such information. Such information need not establish conclusively that such a risk exists. In general, the chemical industry derives its section 8(e) reports from two sources: (1) results of human, animal, and environmental studies; and (2) incidents involving chemicals, mixtures, effluents, or processes.

To facilitate understanding and compliance with TSCA section 8(e) reporting requirements, EPA issued a TSCA Section 8(e) Reporting Guide in June 1991, a Policy Statement in the Federal Register on June 3, 2003 (68 Fed. Reg. 33129), which was revised on January 12, 2005 (70 Fed. Reg. 2162).

All chemicals and mixtures subject to TSCA itself are subject to TSCA section 8(e), including chemicals that are byproducts, intermediates (isolated and non-isolated), wastes, catalysts, R&D chemicals, etc.

All companies regardless of size, market share, or assets, that produce, import, process, or distribute a TSCA chemical substance are subject to TSCA section 8(e) reporting should they receive reportable substantial risk information about the chemical.

Persons who obtain information that appears to constitute substantial risk information, but who do not manufacture, process, or distribute the subject chemical are not required to report under section 8(e).

Section 8(e) requires substantial risk information to be reported to EPA immediately. EPA considers information immediately reported if they receive information within 30 calendar days. Supplemental information received after the submission of a section 8(e) notification should also be immediately reported.

Recordkeeping Requirements

No mandatory recordkeeping requirements exist for section 8(e) submissions.

Tip: *As of the publication of this manual, the TSCA Inventory now contains approximately 86,557 chemicals of which 41,864 are active in United States commerce. Collectively these chemicals are considered existing chemicals. Of this universe of active chemicals, there are approximately: 164 chemicals subject to Section 4 (rulemaking including proposals, or orders); 2038 chemicals subject to Section 5 (rulemaking including proposals, or orders); and 16 chemicals subject to Section 6 (rulemaking including proposals). By contrast, there are over 9000 chemicals reported through Chemical Data Reporting (CDR).*

Section 11: Inspections and Subpoenas

Inspections

Under TSCA section 11, designated representatives of EPA have the authority to inspect any establishment, facility, or other premises in which chemical substances or mixtures are manufactured, imported, processed, stored, or held before or after their distribution in commerce. This authority also extends to any conveyance (i.e., vehicle) being used to transport chemical substances or mixtures. Such inspections may be conducted only upon the presentation of appropriate credentials and a written notice to the owner, operator, or agent in charge of the premises or conveyance. A separate notice is required for each inspection, but not for each entry made during the period covered by the inspection. Inspections must be reasonable in their timing, manner, and limits.

An inspection conducted pursuant to section 11(a) extends to everything within the premises or conveyance bearing on TSCA compliance. No inspection under section 11(a) may extend to financial data, sales data (other than shipment data), pricing data, personnel data, or research data (other than data required by other sections of TSCA or a rule promulgated thereunder), unless the nature and extent of such data are described with reasonable specificity in the required written notice.

Subpoenas

Under section 11(c), EPA may issue administrative subpoenas to 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. A TSCA subpoena will be enforced by a federal court where the information sought is relevant and material to a TSCA investigation, unless the party receiving the subpoena can demonstrate that the inquiry is unreasonably overbroad or unduly burdensome. While EPA has broad authority to request information under its subpoena authority, failure to answer a subpoena is not a violation until a Court orders a party to respond to the subpoena.

Section 12: Exports

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

- testing data are required under TSCA sections 4 or 5(b);
- an order has been issued under TSCA section 5;

- a rule has been proposed or promulgated under TSCA sections 5 or 6; or
- an action is pending, or relief has been granted under TSCA sections 5 or 7.

As per 40 C.F.R. § 707.65, the notice must only be for the first export or intended export by an exporter to a particular country when the chemical substance or mixture is the subject of:

- an order issued, an action that is pending, or relief that has been granted under section 5(e);
- a rule that has been proposed or promulgated under section 5(a)(2) (i.e., a SNUR); or
- when data are required under sections 4 or 5(b).

The notice must be for the first export or intended export by an exporter to a particular country ***in a calendar year*** when the chemical substance or mixture is the subject of:

- an order issued, an action that is pending, or relief that has been granted under section 5(f);
- a rule has been proposed or promulgated under section 6; or
- an action that is pending or relief that has been granted under section 7.

The notice must be postmarked within 7 days of forming the intent to export (acceptance of a definite contractual obligation to export or an equivalent intracompany agreement to export) or on the date of export, whichever is earlier. More information on notices can be found at 40 C.F.R. §§ 707.65 and 707.67.

After EPA has received the notification from the exporter, EPA then notifies the importing country's government as described in 40 C.F.R. § 707.70.

A list of the chemicals subject to TSCA section 12(b) can be accessed on EPA's website.

Export Only Exemption

Pursuant to TSCA section 12(a)(1)(B), if a company is manufacturing a substance which is not on the TSCA inventory (i.e. a new chemical substance) and selling it overseas, they must comply with the manufacture for export only exemption and "bear a stamp or label stating that such substance, mixture, or article is intended for export" when said substance, mixture, or article is distributed in commerce. Exceptions to this rule are laid out in TSCA section 12(a)(2) and 12(b). Associated regulations can be found at 40 C.F.R. § 720.3(s) (defining manufacture solely for export) and 40 C.F.R. § 720.30(e) (chemicals not subject to notification requirements).

Prohibition on Export of Elemental Mercury and Mercury Compounds (Mercury Export Ban Act (MEBA) 2008)

TSCA section 12(c) prohibits the export of elemental mercury and compounds identified in TSCA section 12(c)(7) from the United States, with few exceptions. EPA may grant an "essential use exemption" pursuant to the elements laid out in TSCA section 12(c)(4). Requests for an essential use exemption would only be granted through notice-and-comment rulemaking. At the time of publishing this manual, no exemptions have been applied for and none have been granted. EPA's Office of Pollution Prevention and Toxics (OPPT) provides guidance on substances which are not subject to TSCA section 12(c). Inspectors should familiarize themselves with OPPT's website on the Mercury Export Ban Act and have knowledge of which materials are not subject to TSCA section 12(c).

Section 13: Entry Into Customs Territory[5] of the US

In addition to complying with all the same TSCA regulations as domestic manufacturers, importers have to certify to U.S. Customs at the time of entry that all chemicals in their shipment either comply with TSCA or are excluded from TSCA.

Under U.S. Customs and Border Protection (CBP) regulations implementing TSCA section 13, importers are required to certify that imported chemicals either comply with TSCA (positive certification) or, if they are not clearly identified as excluded from TSCA, are not subject to TSCA (negative certification). Certain chemicals require no certification.

TSCA section 13 requires CBP to refuse entry into the CBP territory of the United States of any chemical substance or mixture offered for entry if it fails to comply with any rule in effect under TSCA, or if it is offered for entry in violation of TSCA sections 5, 6 or 7. Since TSCA defines importers as manufacturers, importers may be subject to testing requirements under TSCA section 4, and PMN requirements under TSCA section 5. Note that according to an EPA Policy statement, at 40 C.F.R. 707.20(c)(1)(iii), the TSCA certification applies only to TSCA sections 5, 6, and 7. Therefore, importers may be in violation of certain parts of TSCA (e.g., failure to file as required by the Chemical Data Rule under section 8 and still be able to import without violating section 13.

Certification of compliance with TSCA is required for the importation of chemical substances or mixtures. The rule does not require certification for chemical substances imported as part of

[5] As defined in the US Code of the Toxic Substances Control Act (https://uscode.house.gov/view.xhtml?path=/prelim@title15/chapter53&edition=prelim) and the Harmonized Tariff Schedule of the United States (https://www.usitc.gov/publications/docs/tata/hts/bychapter/1400gn.pdf#page=3)

articles, unless EPA requires reporting under a specific TSCA rule such as for Formaldehyde Emission Standards for Composite Wood Products, found at 40 C.F.R § 770.30, and which must comply with the import certification regulations for "Chemical Substances in Bulk and As Part of Mixtures and Articles," as found at 19 CFR 12.118 through 12.127.

The Chemical Substances Import Rule (CBP Rule), 19 C.F.R. §§ 12.118-127 and 127.28, sets forth general certification requirements and detention procedures. EPA issued a policy, codified at 40 C.F.R. 707.20, to explain how EPA interprets and executes its responsibilities outlined in the CBP Rule. An importer must certify in writing or electronically that the chemical shipment complies with all applicable rules and orders under TSCA by filing one of the following certification statements with CBP:

Positive certification for shipments subject to TSCA:

> "I certify that all chemical substances in this shipment comply with all applicable rules or orders under TSCA and that I am not offering a chemical substance for entry in violation of TSCA or any applicable rule or order thereunder."

Negative certification for other shipments:

> "I certify that all chemical substances in this shipment are not subject to TSCA."

After March 22, 2019, 40 C.F.R. 770.30(d) requires import certifications for ***articles*** that are regulated composite wood products. Reporting must comply with the import certification regulations for "Chemical Substances in Bulk and As Part of Mixtures and Articles," as found at 19 C.F.R. §§ 12.118 through 12.127. More information is available on EPA's website.

TSCA-Excluded Chemicals

Under the CBP Rule, chemicals that are clearly identified as excluded from TSCA, including food additives, pesticides, drugs, cosmetics, tobacco products, and firearms, do not require a certification statement. Note that these products may be considered clearly identified when they are associated with another relevant agency's entry documentation or electronic entry filing requirements (e.g., Notice of Arrival for pesticides or applicable entry documentation for FDA regulated products). TSCA-excluded chemicals that do not meet these identification requirements, must certify in writing or electronically, that the chemical shipment is not subject to TSCA. More information is available on EPA's website.

Section 14: Confidential Information

Section 14 of TSCA provides for protection from disclosure of confidential business information (CBI) obtained under the Act, including data obtained during an inspection (except that section 14 does not prohibit the disclosure of health and safety studies and related data if that data were submitted to EPA under TSCA, and the chemical has been offered for commercial distribution, testing is required under section 4, or notification is required under section 5). The manufacturer, importer, processor, or distributor may designate information as CBI, and EPA will not disclose that information except as provided in section 14(c) of TSCA and 40 C.F.R. Part 2.

Section 15: Prohibited Acts

Under TSCA section 15, it is unlawful for any person to:

(1) fail or refuse to comply with any rule promulgated or order issued under section 4 or any requirement prescribed, rule promulgated, or order issued under section 5 or 6;
(2) use for commercial purposes a chemical substance or mixture that the person knew or had reason to know was manufactured, processed, or distributed in commerce in violation of TSCA sections 5 or 6, a rule or order under sections 5 or 6, or an order issued in action brought under section 5 or 7;
(3) fail or refuse to establish or maintain records; submit reports, notices, or other information; or permit access to or allow the copying of records as required by TSCA or a rule thereunder; and
(4) fail or refuse to permit entry or inspection as required by section 11.

Section 16: Penalties

TSCA section 16 authorizes civil and criminal penalties for violations of section 15. A civil penalty for a violation of section 15 may not exceed $37,500 per violation, the statutory maximum, with each day of continuing violation constituting a separate offense. *See* section 16(a). The current maximum, taking into account the inflation adjustment is $40,576, at the time of publication. Increases in maximum civil penalties are mandated by the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended in 2015 by the Federal Civil Penalties Inflation Adjustment Act Improvements Act (the 2015 Act). The 2015 Act prescribes a formula for annually adjusting the statutory maximum amount of civil penalties to reflect inflation.

Section 17: Specific Enforcement and Seizure

Section 17 of TSCA describes the process for obtaining specific enforcement of TSCA requirements or seizure of a violating chemical substance, mixture, or product. 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. Section 17 is an effective tool for obtaining compliance, however, judicial actions for injunctive relief are generally also more resource intensive than civil penalty actions. EPA may decide to seek injunctive relief under TSCA section 17 if a civil penalty action is not sufficient to obtain timely compliance to protect human health or the environment. For example, judicial action for injunctive relief could be used to prevent the importation of a chemical substance that violates TSCA section 5 or to compel a company to follow the requirements of a TSCA section 5(e) order. EPA is rarely interested in seizing a substance and then bearing the cost of disposal for that item. Nonetheless, EPA has the authority to ask for seizure or condemnation of a chemical substance which has been manufactured, imported, processed, or distributed in commerce in violation of the Act or rule or order under the Act.

Title VI: Formaldehyde Standards for Composite Wood Products

The Formaldehyde Standards for Composite Wood Products Act of 2010 established emission standards for formaldehyde from composite wood products and directed EPA to finalize a rule on implementing and enforcing a number of provisions covering composite wood products for the manufacture, including import, distribution, and sale of composite wood products. The 2016 regulation also includes recordkeeping, reporting, and labeling provisions. The final rule is under 40 C.F.R. Part 770.

TSCA Title VI requires that composite wood products be tested and certified, ensuring only compliant products enter the product supply chain. Composite wood products must be certified to meet emissions standards by an EPA-recognized third-party certifier (i.e., EPA TSCA Title VI TPC). The three composite wood products regulated under TSCA Title VI are:

- Hardwood Plywood
- Medium-Density Fiberboard (MDF), including thin MDF
- Particleboard

The regulation also applies to household goods, component parts, and finished goods fabricated containing composite wood products. These composite wood products must be labeled as TSCA Title VI compliant.

The final rule also established a third-party certification program for laboratory testing and oversight of formaldehyde emissions from manufactured and/or imported composite wood products.

By including provisions for laminated products, product-testing requirements, labeling, recordkeeping, and import certification, the final rule ensures that hardwood plywood, medium-density fiberboard, and particleboard products sold, supplied, offered for sale, imported to, or manufactured in the United States are in compliance with the emission standards.

A summary of the key dates in the final rule is captured below.

- As of June 1, 2018, regulated composite wood products manufactured in or imported into the U.S., must be certified as compliant with emission standards by a third-party certifier (TPC) approved by California Air Resources Board (CARB) and recognized by EPA.
- After March 22, 2019, regulated products certified as compliant with the CARB ATCM Phase II emission standards must be labeled as compliant with the TSCA Title VI. Regulated products manufactured in or imported into the United States after March 22, 2019 may not rely on the CARB reciprocity of 40 C.F.R. 770.15(e) and must be certified and labeled as TSCA Title VI compliant by an EPA TSCA Title VI TPC with all of the required accreditations. See 40 C.F.R. 770 Subpart C—Composite Wood Products
- After March 22, 2019, CARB-approved TPCs must comply with additional accreditation requirements in order to remain recognized as an EPA TSCA Title VI TPC and to continue certifying products as TSCA Title VI compliant.
- After March 22, 2019, TSCA section 13 import certification is required upon import into the customs territory of the U.S. Importers of articles that are regulated composite wood products, or articles that contain regulated composite wood products, must comply with the import certification regulations for "Chemical Substances in Bulk and As Part of Mixtures and Articles, as found at 19 C.F.R. 12.118 through 12.127.
- Beginning March 22, 2024, non-exempt laminated products are regulated as hardwood plywood and must comply with panel producer requirements.

Import Certification Requirements for Formaldehyde Composite Wood Products

TSCA section 13 import certification became effective March 22, 2019. Certification occurs during the import filing process within CBP's Automated Commercial Environment (ACE). Similar to the importation of other TSCA chemical substances, importers must certify

compliance with TSCA of formaldehyde composite wood products using the standard the following TSCA section positive import certification statement:

> "*I certify that all chemical substances in this shipment comply with all applicable rules or orders under TSCA and that I am not offering a chemical substance for entry in violation of TSCA or any applicable rule or order thereunder"*.

The TSCA Title VI import certification does not apply to chemicals otherwise regulated under TSCA which may be present in those imported composite wood product articles.

TSCA Title VI does not have a negative certification statement. If a shipment has been flagged as potentially subject to TSCA Title VI and is not regulated composite wood product then importers are to use a disclaim code "A" in ACE.

Chapter 3 Pre-Inspection Planning

Contents

Background

The purpose of the Core TSCA enforcement program is to monitor compliance and bring violators into compliance with goals of establishing an enforcement presence and providing a deterrent effect on the regulated community. It is important that the Core TSCA enforcement program focus its limited resources on significant, enforceable, and nationally important cases that maximize the potential to mitigate hazards to health or the environment.

Targeting Approach

When identifying facilities for inspections, i.e., targeting facilities, the Core TSCA enforcement program generally maintains a neutral scheme compliance monitoring approach, based on clearly stated, previously established priorities. Priorities are established in the TSCA Compliance Monitoring Strategy, OECA National Program Guidance, and National Compliance Initiatives. OECA works closely with the Office of Chemical Safety and Pollution Prevention (OCSPP), and subsequently, OECA may refer to the priorities identified in the OCSPP National Program Guidance for targeting additional areas of concern. Additional areas of focus may also be set by the Administrator. Recent National Focus Areas for Core TSCA compliance monitoring, include:

- TSCA section 5
    - PMN and NOC requirements
    - SNUR and SNUN requirements
    - Section 5(e) Orders
    - Section 5 Exemptions
- Chemicals of concern: Per- and Polyfluoroalkyl Substances (PFAS) and High Priority Chemicals
- TSCA section 12 Exports, particularly 12(b) export notifications and 12(c) Mercury Export Ban Act (MEBA)
- TSCA section 6
    - New TSCA section 6 Rules
- Section 4 and 8 reporting requirements, particularly section 4 test rule reporting, section 8(a) CDR and 8(e) substantial risk notification
- Section 13 imports

All targeting methods must meet the standard prescribed in Marshall v. 'Barlow's Inc., 436 U.S. 307 (1978) that requires EPA to use a Neutral Administrative Inspection Scheme (NAIS) when selecting facilities for inspection. A NAIS provides a rationale for selection of specific facilities. A neutral inspection approach allows for a non-arbitrary method of identifying inspection targets and the neutral selection of establishments for inspection.

Frequently, EPA Regions and offices will have strategies for selecting Core TSCA inspection targets, which dictate how facilities are selected for potential inspection. These strategies may be based on priorities, available resources, and compliance monitoring activities (e.g., inspection, subpoena/information request, partnering with state or local agencies to conduct multi-program inspection). Inspectors should check with their office to determine if there is a particular strategy that should be followed when targeting facilities for Core TSCA inspections.

EPA may use the following as criteria for prioritizing targeting, in no particular order:

- Tips and complaints,
- Referrals from OCSPP/OPPT,
- Multi-media targets,
- High-risk chemicals,
- Environmental Justice and,
- Geographic targets.

Pre-Inspection Planning

Planning for an inspection ensures the inspection is focused and conducted efficiently. When planning for an inspection, inspectors should:

- Review available information;
- Develop any required written plans;
- Notify the facility, if applicable; and,
- Gather inspection supplies.

Each of these is discussed further below.

Review Available Information

Inspectors should review documentation and other information prior to the inspection to gain background knowledge on the facility being inspected. This background is necessary to focus the inspection and allows inspectors to target questions on specific issues, such as historical violations that may be an indicator for ongoing noncompliance.

There is a wide variety of information that can be reviewed, including new TSCA rules, general facility information, compliance information, and information reported by the facility under various EPA regulations, as detailed in Figure 3-1. Inspectors must decide what information to review prior to the inspection, depending on availability and utility of the information for the site being inspected.

Figure 3-1. Types of Information to Review

New TSCA Rules

- Federal Register
  - Look for announcements of new or proposed TSCA rules that may have come into effect in the past 5 years
  - New 8(a) PAIR rules and 8(d) Health & Safety Studies - sunset dates for all rules have passed; the facility would only be subject to new rules
  - Amendments to existing rules (e.g., CDR reporting requirements)
  - New section 6 rules (these are likely to increase under the amended TSCA)
  - Additional section 8(c) requirements to report allegations of adverse reactions for specific chemicals

General Facility and Chemical Information

- Company website
  - Look for general information such as types of products manufactured at the site, industries serviced, safety data sheets (SDSs), research and development (R&D) capabilities, import/export operations, size of the company, contact information
- Dun and Bradstreet
  - Acquire the facility's DUNS number and review company profile to ensure the facility is active, and to identify contacts
- Substance Registry Service (SRS)
  - Database searchable by chemical name, CASRN, or EPA ID providing program and regulatory information (statutes the chemical is regulated under) with relevant links for more information.
- ChemView
  - Database searchable by chemical that provides regulatory information, health and safety data, and manufacturing, processing and use data maintained by EPA.

Compliance Status

- ECHO
  - Look for past or ongoing compliance issues under TSCA and other EPA statutes
  - Identify NPDES permit or air release permits (this may be useful when considering release restrictions under section 5 Orders, SNURs, or other TSCA rules)
- Previous inspection reports and resulting enforcement actions
  - Review previous TSCA and other statute inspection reports for descriptions of compliance issues
  - Inquire about enforcement actions with the respective EPA office
- General Online Search
  - Perform online search for any relevant news stories or ongoing litigation the company is involved in

Facility Reporting

- Reporting databases (i.e., CDR, TRI, ACE, national emissions inventory [NEI], DMR loading tool)
  - Check if reported information is consistent with the facility information found on the company website and ECHO
  - Identify chemicals that may be of specific interest (e.g., chemicals subject to section 5 Orders or SNURs or section 6 rules)
  - Check the Automated Commercial Environment (ACE) and/or Import Genius for import certifications.
- EPA CBI network
  - Review the facility's TSCA submissions available on EPA's CBI network via Chemical Information System (CIS) for additional information and correspondence with EPA staff with releveant knowledge

Develop Written Plans

Depending on the EPA Region or Office, inspectors may need to develop a written inspection plan, health and safety plan, and/or quality assurance project plan. Inspection plans are the most common type of written plan Core TSCA inspectors will need to develop. Health and safety plans are often also required. Quality assurance project plans, however, are rare for Core TSCA inspections because they are only required in the event of sampling or field measurements.

When developing written plans, inspectors should be sure to check with their offices for existing templates and example plans to use as reference.

Inspection Plan

Inspection plans include the objectives and scope of the inspection, tasks, and procedures for fulfilling the objectives, and logistical information such as inspection schedule and personnel attending the inspection. If an inspection plan is not required, it is still recommended inspectors develop some form of a plan. Inspectors should think through the following types of questions when developing an inspection plan:

- What is the focus of the inspection?
- Will the inspection address certain sections of TSCA or certain TSCA rules?
- What tasks need to be accomplished? What information needs to be collected and what records need to be reviewed during the inspection?
- What procedures will need to be followed during the inspection?
- What resources are needed for the inspection, such as what personnel need to be part of the inspection and what equipment should be brought to the inspection (e.g., cameras)?
- What is the schedule of the inspection? When will it occur and what is the order of the inspection tasks?

Health and Safety Plan

A health and safety plan (HASP) addresses health and safety hazards associated with the inspection and what can be done to lessen those hazards. HASPs identify factors such as the site conditions, specifically relating to factors pertaining to chemicals manufactured on site, weather conditions, the job functions to be performed on-site and the associated required personal protective equipment (PPE), any personnel medical conditions, and proximity to local hospitals, police stations, and emergency responders.

Quality Assurance Project Plan

A quality assurance project plan (QAPP) is required for inspections that involve sampling or other field measurement activities. A QAPP defines the goals and scope of the project, the need and plan for sample or field measurement collection, a description of the data quality objectives, and the quality assurance/quality control activities necessary to ensure data validity and usability.

Notifying the Facility

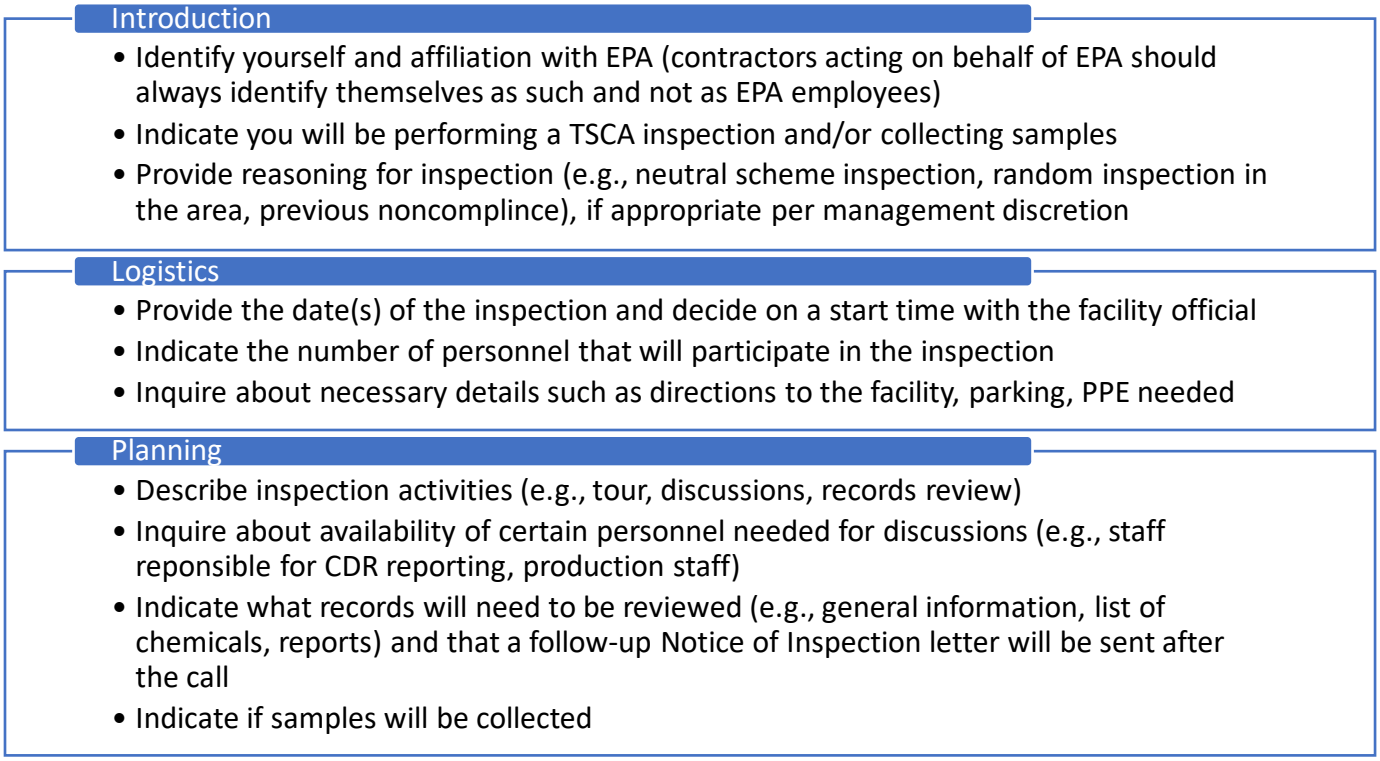
EPA frequently conducts unannounced inspections. However, there are advantages to providing a facility with advanced notice of a Core TSCA inspection. Advanced notice allows the facility time to prepare documents the inspector may need to review during the inspection and to ensure that proper facility personnel are available at the time of the inspection.

> ***Tip:*** *Inspectors should check with their management to determine if notifying the facility of the inspection is appropriate.*

If advanced notice is to be given, inspectors must identify the appropriate facility contact to notify. This may be the plant manager, regulatory manager, environmental manager, or some other official. Inspectors should check the information resources previously described for contact information. If no contact is determined, inspectors may need to call a general number and ask for the appropriate official. Also, inspection notification may be made to the state/local authorities.

Typically, notification occurs between one week and one month prior to the inspection, depending on EPA management instructions and the inspector's availability. The inspector should provide the initial notification by telephone. Figure 3-2 provides some typical inspection notification topics to cover during the call. Following the notification call, the inspector should follow-up with the notified official as soon as possible to provide a Pre-Inspection Information Request Letter (PIIRL). EPA will send the official PIIRL to the facility via certified mail; however, inspectors may send an unofficial electronic version of the PIIRL via email so that the facility receives it sooner than the mailed version. The PIIRL is important because it is an official notification for the facility's records. Additionally, the PIIRL details the records that will be needed for review, thus providing the facility with time to gather the records. Inspectors should check with their offices for existing templates and example PIIRLs to use when developing a PIIRL.

Figure 3-2. Typical Inspection Notification Topics



Gather Inspection Supplies

The inspector should gather all necessary supplies for the inspection. Supplies may include:

- Inspection notebook and pens;
- Inspector credentials and business cards;
- Required forms (discussed in Chapter 4 Opening Conference);
- Inspection plan and/or checklist;
- Copies of any important documents (e.g., regulations, diagrams, 5(e) orders);
- Laptop with the most recent copy of the TSCA Inventory downloaded;
- Personal protective equipment;
- Sunscreen, bug repellant, weather-appropriate clothing, as needed; and
- Sampling or field measurement equipment, if necessary.

Chapter 4 Conducting the Inspection

Contents

Introduction

The following subsections describe each portion of the Core TSCA inspection in sequential order from gaining entry to conducting the inspection through the closing conference. This is meant to be a general guide and suggested format for the inspection. However, the order of inspection activities (except for the opening and closing conferences) may be modified based on facility- and/or inspection-specific needs such as staff availability, joint inspections with other statutes (e.g., Clean Air Act, Clean Water Act, etc.), joint inspections with states, or inspector preferences.

Core TSCA Inspection Checklist contains an example Inspection Checklist that the inspection team can use to guide the inspection and ensure all relevant sections of the Core TSCA inspection are covered.

Statutory Inspection Authorities

TSCA section 11 authorizes designated representatives of EPA to inspect any establishment, facility, or other premises in which chemical substances or mixtures are manufactured, imported, processed, stored, or held before or after their distribution in commerce. This authority also extends to any conveyance (i.e., vehicle) being used to transport chemical substances or mixtures. Such inspections may be conducted only upon the presentation of appropriate credentials and a written notice to the owner, operator, or agent in charge of the premises or conveyance. A separate notice is required for each inspection, but not for each entry made during the period covered by the inspection. Inspections must be reasonable in their timing, manner, and limits.

An inspection conducted pursuant to section 11(a) extends to everything within the premises or conveyance bearing on TSCA compliance. No inspection under section 11(a) may extend to financial data, sales data (other than shipment data), pricing data, personnel data, or research data (other than data required by other sections of TSCA or a rule promulgated thereunder), unless the nature and extent of such data are described with reasonable specificity in the required written notice.

Under section 11(c) EPA may issue subpoenas to require the attendance and testimony of witnesses and the production of reports, papers, documents, answers to questions, and other information that the Administrator considers necessary under TSCA.

Gaining Entry

To conduct an inspection, the inspector must gain entry to private property. The U.S. Constitution guarantees a reasonable expectation of privacy as to private property. Therefore, to gain entry to private property to conduct an inspection, EPA needs to obtain a warrant **UNLESS** the inspector receives *informed, voluntary consent* from the owner of the property or from a person in control of the property in the absence of the owner. If consent is denied and a warrant is necessary, a warrant can be based on “probable cause” or a “neutral administrative inspection scheme.” Probable cause is a reasonable suspicion that a violation has occurred or is occurring. EPA conducts inspections pursuant to a neutral inspection approach when it is not doing for-cause inspections.

Consent for Entry

An inspector can enter private property to conduct inspections by obtaining valid consent. Consent to enter must be freely and voluntarily given and not given because of duress, misrepresentation, or coercion (either expressed or implied). While the law does not require that a subject be advised of his/her right to refuse to give consent, if the inspector believes such knowledge may be helpful in validating the consent and in overcoming any taint of implied coercion, he/she may inform the consenting party of his/her right to refuse voluntary entry. In addition, the person granting the consent must be authorized to do so. The inspector must be reasonably certain that the consenting party is the property owner or has the premises under his/her control and has at least the apparent authority to give consent.

If an inspector plans to make multiple visits to the same location for inspection or sampling purposes, the inspector must gain consent for each entry unless the inspector obtained prior consent to cover all necessary entries. Accordingly, at the onset of an inspection, the inspector must seek to gain consent sufficient to authorize all entry and sampling activities he/she contemplates will be necessary to complete the inspection.

Once the inspector has consent to enter, the inspector may enter the private property and conduct the inspection.

Steps for Obtaining Informed Consent for Entry

Upon arrival, the inspector must:

1. Find the Right Person — Identify and introduce himself/herself to the owner, operator, or agent in charge (responsible official of the facility); known as the person authorized to give consent.
2. Inform the Person Authorized to Give Consent for Entry —
    a. Present EPA credentials. Do not relinquish possession of the credential and do not allow anyone to make copies of the credential.
    b. Discuss the purpose of the inspection with the person authorized to give consent for entry.
    c. Present the person authorized to give consent for entry a completed Notice of Inspection (required by TSCA).
3. Document the Informed Consent — Issue the owner, operator, or agent in charge a completed Notice of Inspection (NOI) (EPA Form 7740-3), which contains the statutory authority for the inspection and provides notification to the facility if the inspection will extend to information generally prohibited by Section 11(b) of TSCA (i.e., financial data, sales data, pricing data, personnel data and research data). The signature of the person

authorized to give consent is important since it documents that informed consent was given for entry to the property to inspect. Although written consent is preferred, oral consent can be granted so long as the circumstances surrounding the consent is documented in a contemporaneous way. A copy of the completed Notice of Inspection form must be provided to the facility.

These entry procedures are critical to ensure that an inspection is conducted legally, with the informed consent of the responsible official of the establishment and that any evidence gathered during the inspection can be used in an enforcement proceeding.

As stated above, the absence of a Facility Official's signature will not invalidate the Notice of Inspection, nor establish that consent to the inspection was not provided or that proper procedures were not followed.

Oftentimes, communication with the facility has occurred prior to the inspection and a date and time for the inspection has been agreed upon.

What to Do if Consent for Entry to Inspect is Denied

Where consent for entry is denied, the inspector should promptly and courteously leave the property and, thereafter, document the basis for the refusal. If there is a threat of bodily harm at any time during these discussions, then the inspector should exit the site as quickly as possible. Inspectors should exercise good judgment and avoid conflict. Consent to enter private property is considered denied where:

- There is no one on the premises authorized to give consent at the time of inspection, and no such person has granted consent in advance.
- The person authorized to give consent explicitly refuses to allow entry.
- The person authorized to give consent refuses to sign the NOI *and* refuses to provide oral consent for entry.
- The person authorized to give consent initially allows entry but later withdraws consent.
- The person authorized to give consent places conditions upon entry that impede an inspector's ability to conduct a thorough inspection. Examples include photographic restrictions, some requirements for health and safety gear or training, or denial of access to certain areas of the facility.
- The person authorized to give consent places conditions upon entry that attempts to limit liability.

How to Monitor Compliance Where Consent for Entry is Denied

Where access to the property is denied or available information indicates that access will be denied, and the Region has determined that an on-site inspection (rather than other form of compliance monitoring) is necessary, the inspector should consult with the Office of Regional Counsel (ORC) to determine if seeking a warrant from a federal district court is appropriate, and to comply with any policies and procedures that the Region may have established for seeking warrants. Generally, to obtain a search warrant, the U.S. Attorney's Office for the district in which the property is located prepares the necessary documents with the assistance of the EPA inspector and attorney. If a warrant is issued by the court, then the inspector must execute the warrant without delay by entering the premises and conducting the inspection strictly in accordance with the warrant. Where there is probability that EPA will be refused entry even with a warrant, or there exists a likelihood of threats of violence, then the inspector must be accompanied by the appropriate law enforcement official such as a U. S. Marshal, county sheriff, or state or local police officer. If the inspector is refused entry even when holding a warrant but not accompanied by a law enforcement officer, then the inspector must leave the property promptly and so inform the U. S. Attorney's Office and the designated EPA attorney who will take appropriate action.

Additionally, the inspector should consult with ORC to consider issuing a subpoena to obtain records. If the region determines that a subpoena is necessary, the region is expected to consult with its Office of Regional Counsel prior to issuing the subpoena. Also, because EPA may subsequently need assistance from the U.S. Department of Justice (DOJ) to obtain court enforcement of the subpoena, the region may consult with OECA and DOJ prior to the region issuing the subpoena.

Alternatives to Entry Based on Consent

EPA has several options for monitoring compliance if an inspector is unable to obtain access to private property for a site inspection. The inspector should consult his/her Office of Regional Counsel for guidance on a case-by-case basis on the several theories that may be utilized as alternatives to entry based on consent a, if necessary.

Open Fields

"Open fields" are areas where a property owner normally does not have a reasonable expectation of privacy (for example, open land). While the preferred procedure is to obtain valid consent prior to entry, the courts have established that inspectors may enter open, private lands in the official performance of their duties.

Plain View

There is no reasonable expectation of privacy concerning things in "plain view." The plain view doctrine is an acknowledgment by the courts that an inspector lawfully engaged in the course of his/her duties is not required to wear blinders or close his/her eyes to whatever is occurring around him/her. The following elements are required for a plain view observation:

Lawfully present—The inspector must be justified in being where he/she is at the time the plain view observation is made. Lawful presence may be gained through such avenues as statutory authority, a valid search warrant, consent or "open fields."

Inadvertent discovery—The inspector must discover the evidentiary items accidentally. The plain view doctrine will not apply if the inspector has probable cause to believe that an item is on certain premises and goes on those premises with the intention of searching for that item; such a discovery is not inadvertent.

Apparently incriminating nature—The inspector must have reasonable grounds to believe immediately, without further investigation, that the item in plain view constitutes evidence of a violation of the law.

Opening Conference

IMPORTANT: *Inspectors should never relinquish physical possession of their credentials or allow them to be duplicated (copied, scanned, etc.)*

The opening conference serves as the introduction of EPA's inspection team (including contractors acting on behalf of EPA) and key facility representatives who will be participating in the inspection and outline all participant roles. After introductions, the inspection team should present their credentials to facility representatives and explain that they have been authorized by EPA to conduct the inspection and handle TSCA CBI. The inspector can cite TSCA section 11(a) as the statutory authority for the inspection if asked by facility representatives.

Presentation of Notice of Inspection and Credential

To conduct an inspection using TSCA authority, inspectors must present EPA credentials, use EPA forms and EPA procedures. Showing appropriate credentials and providing an adequate NOI serve an important function in gaining entry, under these circumstances, and informs the property owner as to the purpose and authority for the inspection. The main function of a NOI is to satisfy the requirement in TSCA section 11(a) to present a written statement as to the reason for the inspection. Securing consent to enter private property is a Constitutional requirement and is different from the TSCA section 11(a) presentation requirement. Consent to enter may be given to the inspector verbally (and noted by the inspector in field notes) or by signing the NOI. The absence of a Facility Official's signature on the NOI does not invalidate the NOI or establish that consent to the inspection was not provided or that the proper procedures were not followed.

IMPORTANT: *In some instances, the facility may choose to have an attorney present to provide guidance on completing forms and answering questions. While it is acceptable for attorneys to be present throughout the inspection, the inspection team should not engage with the attorney unless an EPA attorney is also present (not typical for most inspections). All questions and requests should be directed to the facility representatives. If the attorney questions the validity of any request or directs facility representatives to deny a request for information, the inspection team may try to explain to the facility representatives the necessity of such information for compliance determination (and cite specific regulatory text, if appropriate). Alternatively, or if the facility representatives still refuse to provide the requested information, the inspection team should simply make note that the request was denied in their inspection notebook and include that information in the inspection report such that EPA attorneys can take the appropriate response after the inspection.*

The inspection team should then present the four inspection forms:

- Notice of Inspection (EPA Form 7740-3) – This form indicates that the facility has willfully agreed to the inspection and should be signed by the lead inspector and a facility representative prior to the start of the document review.
- TSCA Inspection Confidentiality Notice (EPA Form 7740-4) – This form outlines the facility's ability to claim information discussed and provided during the inspection process as confidential and should also be signed by a facility representative prior to the start of the document review.
- Receipt for Samples and Documents (EPA Form 7740-1) – This form provides a list of all documents being collected on the day of the inspection.

- Declaration of Confidential Business Information (EPA Form 7740-2) – This form documents which documents being collected contain TSCA CBI. This form may not be completed if the company does not make a claim of confidentiality under TSCA.

The Receipt of Samples and Documents and Declaration of Confidential Business Information will be filled out and signed by the inspector and a facility representative at the closing conference (see Chapter 4: Closing Conference) but an overview of the two forms should be given during the opening conference so the facility can ensure an appropriate representative is available to sign the forms during the closing conference. The inspector must provide a copy of all completed inspection forms to the facility.

Before beginning the document review, the inspection team should provide a general overview and procedures for the inspection, including:

- Reason for the inspection (e.g., neutral, targeted, follow-up on past noncompliance, etc.);
- Scope of the inspection (i.e., TSCA sections 4, 5, 6, 8, 12, and 13);
- Expected duration of the inspection (typically one day for most neutral scheme TSCA inspections, but can span multiple days);
- Inspection activities (e.g., document review, intent to do tours of the plant and/or research and development (R&D) laboratories, facility interviews, closing conference);
- Collection of samples; and
- Procedures for claiming and handling TSCA CBI.

Throughout the inspection, the inspection team may request information/documents the facility is unable to provide within the timeframe of the inspection. During the opening conference, the inspection team should explain that if any such situations arise, the inspection team will make note of the requested information/documents and ask that they be provided as part of the follow-up requests (discussed further in Chapter 5 Post Inspection Activities).

IMPORTANT: *The TSCA Inspection Confidentiality Notice should be signed by a representative authorized to make CBI claims. If no such person is present the notice and all other inspection information will be sent to the company's CEO.*

General Information Review

Following the opening conference, the inspection team should begin the document review portion of the inspection, beginning with the general information review. This portion of the inspection should provide the inspection team information to guide the remainder of the inspection and determine which sections of Core TSCA apply to the facility.

> ***Tip:*** *The inspection team should leave this portion of the inspection with a strong understanding of the facility's operations as this will help them ask the proper questions throughout each subsequent section of the inspection.*

The inspection team should begin by requesting an overview of the facility. This may be provided as a presentation slide deck, summary document, or other form the facility and inspection team agree upon. The overview should include:

- A brief history of the company and facility;
- Corporate structure;
- Gross annual sales;
- Number of employees at the corporate and facility level;
- The North American Industry Classification System (NAICS) and Standard Industrial Classification (SIC) codes that apply to the facility;
- Dun and Bradstreet D-U-N-S® (D&B) number;
- Importer of Record ID (if applicable);
- General industries the facility services;
- Major product types (e.g., paints, adhesives, petroleum products); and
- Trade association affiliations.

The inspection team should also ask for an overview of the scope of operations at the facility (i.e., the manufacture, import, export, processing, and/or use of TSCA chemicals; research and development activities; and the manufacture, import, export, processing, and/or use of biotechnology or nanotechnology).

After the facility overview, the inspection team should ask to review a list of chemical IDs (CAS Registry Number (CAS or CASRN) and/or Accession numbers) for chemicals manufactured, imported, exported, processed, or used at the facility. The inspection team should compare the list of chemical IDs to the latest public TSCA Inventory to identify chemicals subject to various TSCA actions (e.g., section 4 test rules, section 5 orders or SNURs, section 6 rules, etc.). If the list of chemical IDs cannot be compared to the TSCA Inventory while the inspector is on-site, the inspector should complete this activity as part of the post-inspection activities and follow-up (see Chapter 5).

Tip: *For facilities that have a large list of chemicals, the inspection team can request a spreadsheet or CSV file with a non-CBI version of the chemical ID list be provided on a flash drive so the inspection team can upload the list to their computer and easily compare the list of chemicals using the Microsoft Access version of the public TSCA Inventory. If this is not possible within a reasonable timeframe, the inspection team should perform a "spot check" of the chemicals using manual searches of the Inventory to determine if there are any regulatory flags.*

***It is important that the list be non-CBI to prevent CBI information being saved on inspectors' computers.*

After the inspection team reviews the list of chemicals and identifies regulatory flags, they should request facility representatives provide a detailed process description for each TSCA-regulated operation. This should include process flow diagrams (PFDs) for each operation including the chemical name and/or CASRN for each raw material, intermediate, byproduct, and reaction product of the process, where possible. An example of some questions the inspectors should consider asking facility representatives during this review are provided in Table 4-1 below.

The inspection team should then review Certificates of Analysis (CoAs) to evaluate that the Quality Assurance (QA) testing results match the list of manufactured chemicals provided during the inspection. Depending on the number of chemicals produced by the facility, it may not be reasonable to review all CoAs during the inspection. Instead, the inspection team can review a subset of the CoAs during the inspection and if no issues are identified, leave the remaining to be reviewed during post-inspection work.

Tip: *Throughout the review of the list of chemical IDs, PFDs, and CoAs, the inspection team should be looking for any potential discrepancies between the chemicals listed in each item to identify indications of noncompliance or omissions by the facility.*

At the end of the general information review, the inspection team should have an understanding of the information to be covered in the remainder of the inspection, and should develop a list of personnel (e.g., R&D lab supervisors and/or technicians, process engineers, production staff) that the team may need to interview during the inspection. It is best to provide the facility with the list of personnel so facility representatives can make them available during the inspection.

Tip: *The inspection team should develop the list of personnel to interview as early in the inspection process as possible so facility representatives can work to make the appropriate staff available with as little disruption of daily operations as possible.*

Table 4-1. Example Questions to Ask During PFD Reviews

Question	Important Items to Note and Potential Follow up Questions	Importance of Question
Are there any non-isolated intermediates (NIIs) within the process?	• Potential for some or all of the NII to become isolated from the reaction equipment. • Identifiers of equipment that may isolate the NII (these should be inspected during the plant tour). • Processes with NIIs (these should be inspected during the plant tour to identify equipment not included in PFDs that may result in isolation of the NIIs). • Does the isolation of the NII have a technical relationship (e.g., heating, cooling, maintenance, analytical sampling) to the overall manufacturing process (if so, the chemical may not be considered "isolated")? • What is the purpose of [equipment XYZ] that is auxiliary or supplemental to the reaction vessel (equipment that serves the manufacturing process such as filtration, distillation, drying, size reduction, heating, or cooling are not considered isolating)	NIIs are exempt from PMN (section 5) and CDR (section 8(a)) reporting; however, any portion of the volume that becomes isolated may trigger reporting requirements. If a facility misinterprets what is considered isolation of the chemical, they may have a violation for failure to submit either (or both) reports. Information gathered here can help the inspection team identify such issues.

Question	Important Items to Note and Potential Follow up Questions	Importance of Question
Are there any byproduct chemicals produced by the facility?	• Was the byproduct manufactured in non-integral equipment (e.g., pollution control equipment or boiler equipment)? *[Note: byproducts manufactured in such equipment are exempt beginning in the 2020 CDR reporting cycle, they were reportable in previous reporting cycles.]* • Is it site-limited and recycled or used in a physically enclosed process at the facility? *[Note: byproducts used in such manners are exempt beginning in the 2020 CDR reporting cycle, they were reportable in previous reporting cycles.]* • What is the use of the byproduct?	Certain byproducts may be exempt from PMN and CDR reporting. Information gathered here will help the inspection team evaluate whether the company is properly claiming an exemption from submitting either report during the relevant section 5 and 8 reviews.
What chemicals are released to the environmental or generated and managed as waste for disposal at the facility?	• Potential (purposeful or accidental) for chemical to enter wastewater streams. • Potential (purposeful or accidental) for chemical to be released to air (stack or fugitive). • What, if any, pollution control devices are used to limit releases of chemicals? • How is waste collected and stored for disposal? i.e. drums, etc.?	Certain chemicals may have restrictions on the concentrations or volumes that can be released directly to the environment under section 5 SNURs or section 5(e)/(f) orders. Information reviewed here can help the inspection team familiarize themselves with how the facility handles various wastes.

Facility Process Inspection

The facility process inspection is meant to help the inspection team improve their understanding of facility operations provided during the PFD review and make process-specific observations on TSCA-related requirements, as warranted. In some situations, the inspection team may determine a facility process inspection is unnecessary. Some example scenarios where facility process inspections may not be required are provided in Table 4-2.

Table 4-2. Example Facilities Where Facility Process Inspection May Not Be Required

Description of Facility	Rationale for not Touring
Corporate facility without any on-site chemical processes or chemical storage	There are no facility operations to inspect or chemicals on site.
Facility that only imports and only has warehouses for storage or repackaging	A full understanding of operations can likely be obtained from the general information review. A tour of the warehouse is unlikely to uncover additional observations or compliance issues.
Processing facility where the facility only operates blend tanks for blending raw materials together to create final products (no chemical manufacturing or importing at the facility)	The facility only has simple operations with a limited number of process equipment. A full understanding of operations can likely be obtained from the general information review. A tour of the blending tank area is unlikely to uncover additional observations or compliance issues.

To help focus the facility process inspection, the inspection team should ask facility representatives for an overview of chemicals subject to any TSCA section 5(e) Orders or SNURs. If possible, the inspection team should familiarize themselves with the requirements of section 5 orders and SNURS applicable to the facility prior to the inspection. In the absence of prior knowledge of this information, specifically, the inspection team should familiarize themselves with any PPE and release restrictions in the section 5 Orders/SNURs ahead of the tour. The inspection team does not need to do a complete review of records related to the section 5 Orders and SNURs prior to the tour (this occurs during the section 5 review). This only needs to provide the inspection team with enough information such that they can make the appropriate observations during the tour. Alternatively, the inspection team may decide to perform the facility process inspection after the Core TSCA section document reviews, so they have a full understanding of the facility's TSCA requirements. The example questions in Table 4-3 may be used to help identify potential compliance issues during the facility process inspection.

IMPORTANT: *The inspection team may decide to perform a walkthrough of the facilities in Table 4-2 (or any other facility) if they determine it will help them better understand the process operations or if the facility has one or more chemicals on-site subject to release or PPE restrictions under TSCA section 5 such that a plant tour is required to appropriately identify potential compliance issues.*

During the facility walkthrough, the inspection team may wish to interview production staff – provided the facility representatives approve, the appropriate staff are available, and it results in minimal disturbance of the plant's operations. If this is not possible, or if the inspection team or facility representatives prefer, the interviews can take place during the document review portion of the inspection.

Table 4-3. Example Questions to Ask During Facility Process Inspection

Question	Important Items to Note and Potential Follow up Questions	Importance of Question
Does this process use any chemicals with PPE requirements under TSCA?	• Worker PPE usage during tour (is PPE being used and what types). • Note the types of respirator cartridges and glove materials in use and provided to plant employees.	This allows the inspection team to compare observations in the field with information provided during the document review to identify any discrepancies or deficiencies.
Where in this process are NIIs (if any) manufactured and consumed?	• Equipment not shown in PFDs. • Potential areas resulting in isolation of the NII.	See Table 4-1 for importance of NIIs. This allows the inspection team to identify discrepancies between PFDs and actual plant practice, such as additional equipment that may isolate the NII not observed in the PFD.
Where in this process are byproducts (if any) manufactured and where do they end up?	• Equipment not shown in PFDs. • Potential uses or process streams that deviate from information provided in the PFD review.	See Table 4-1 for importance of byproducts. This allows the inspection team to identify discrepancies between PFDs and actual plant practice and to identify potential practices that do not meet the use of byproduct exemptions.

Question	Important Items to Note and Potential Follow up Questions	Importance of Question
For any chemicals with water release restrictions: does water enter the process and come into contact with the chemical? Does the facility monitor (sampling and analysis) its wastewater streams for the chemicals?	• What happens to water that comes in contact with the chemical? • Are there any scrubbers within the process that use water? • Note any process water or steam lines that are seen within the process and try to follow them to a discharge point or pollution control equipment. • Are there any treatment operations prior to discharge of wastewater? ○ If yes, a tour of wastewater operations may be appropriate. • Collect any wastewater and process water sampling and analysis data.	This allows the inspection team to make field observations regarding handling of water releases and ensure information provided during the document review corroborates actual plant practice.
For any chemicals with air release restrictions: Where do process equipment connect and vent to the stack?	• Note any vent lines that are observed in the process and try to follow them to stack or pollution control equipment. • Is there any pollution control equipment used to mitigate emissions? • Are there any vent lines that are not sent to pollution control equipment? • How are fugitive emissions handled?	This allows the inspection team to make field observations regarding handling of air releases and ensure information provided during the document review corroborates actual plant practice.

Research and Development Laboratory Tour

If the facilty has any R&D activities, the inspection team should request to perform a tour of the R&D lab. The purpose of this tour is to compare actual lab practices with regards to R&D exempt chemicals against the R&D exemption requirements and ensure consistency with the information provided during the document review. Examples of questions to ask during the R&D lab tour are provided in Table 4-4. Further discussion of the R&D portion of the inspection is provided in Chapter 4: R&D Exemption Review. During the R&D lab tour, the inspection team may choose to interview lab personnel to aid in the evaluation of the facility's compliance with R&D exemption requirements.

Tip: *The inspection team should clarify the definition of "R&D" under TSCA. Facility representatives often misinterpret questions about R&D to extend to new product formulations. If all chemicals in the new product are TSCA listed and are not subject to a TSCA action, the R&D recordkeeping requirements do not apply (and by extension a tour of the lab may not be necessary).*

Table 4-4. Example Questions to Ask During R&D Lab Tour

Question	Important Items to Note and Potential Follow up Questions	Importance of Question
Please provide an example of a container containing an R&D exempt chemical, including any labeling.	• Is this a typical container size for the chemical? • How many containers do you receive per week/month/year? • Note the contents of the label.	This will help the inspection team evaluate if proper hazard communication is provided on the label and determine the quantities of the chemical that the facility receives.
What happens to R&D chemicals after use in the lab?	• Observation of disposal methods in practice.	This allows the inspection team to compare actual practice for handling R&D chemicals after use against the information provided during the document review.
What are the practices in place to handle R&D chemicals?	• Note the use of lab hoods or other controls to limit exposure. • Note PPE used by laboratory technicians.	This allows inspection team to check if prudent laboratory practices are in place to protect workers from chemicals with unknown hazards and

		to corroborate information provided during the document review.

Recognizing Potential Criminal Violations

If during an inspection, Core TSCA inspectors become aware of any potential criminal violations that occurred at the facility, such as knowing or willing behavior, or fraudulent reporting, they should clearly document any evidence in their inspection notebooks and refer the matter to the Criminal Investigative Division (CID) of the Office of Criminal, Enforcement, Forensics and Training (OCEFT). For more information regarding criminal violations, refer to Chapter 6 Criminal Enforcement.

Section 4 Review

The purpose of the TSCA section 4 review is to ensure the facility has submitted all reports required by a section 4 rule, order, or enforceable consent agreement (ECA). The inspection team should have a list of chemicals subject to section 4 testing from the general Inventory search described in Chapter 4 General Information Review. A list of chemicals subject to test rules, orders, or ECAs and their regulatory citations is available on EPA's website. For each chemical on the list, the inspection team should check to see if:

Tip: *Each test rule specifies who is required to conduct testing and may include manufacturers/importers, processors, or both. In some instances, processors may be considered Tier II reporters, only required to report if certain conditions of the rule are met.*

1. The facility conducted and submitted results for the appropriate testing;
2. The facility is not subject to the test rule, order, or ECA; or
3. The facility is subject to the test rule, order, or ECA but did not conduct or submit results for the appropriate test.

The following subsections describe how the inspection team should proceed depending on whether the facility falls under category 1, 2, or 3 above for each chemical (note: a facility could fall under different categories for each chemical subject to a section 4 action).

Facilities that Conducted Tests and Submitted Results

For facilities that have conducted the required testing and submitted results to EPA, the inspection team should confirm that both the notice of intent to conduct testing and the testing results were submitted within the timeframe specified in the rule, and the required information is complete and accurate. The inspection team may have already completed this review during

the pre-inspection planning (see Chapter 3 Pre-Inspection Planning of this manual). The inspection team should verify the following information in the intent to conduct testing:

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

The inspection team should also confirm that results from each test required under the rule, order, or ECA were submitted, as rules may require multiple tests. The inspection team is not required to evaluate whether the specifics of the testing method used by the facility match the methodology specified in the rule. This is likely beyond the expertise of the inspection team and should have been evaluated by the appropriate EPA staff when the testing data was submitted.

Facilities Not Subject to the Rule, Order, or ECA

For facilities claiming they are not subject to the section 4 testing, the inspection team should review who is required to report under the rule (e.g., manufacturers/importers and/or processors), and then make a determination on whether the facility has appropriately determined that they do not fall into the category of sites required to report under the rule. It may be appropriate to re-examine the relevant PFDs to corroborate claims about the use of the chemical made by facility representatives.

Facilities Subject to the Rule, Order, or ECA but did Not Conduct Tests or Submit Test Results

Facilities that meet the requirements for section 4 testing but did not conduct tests or submit test results may either be claiming an exemption or be in violation of TSCA section 4. If the facility claims an exemption from section 4 testing, the inspection team should review the exemption application and confirm that it was submitted within the timeframe specified in the rule, the information submitted is accurate, and

IMPORTANT: *A facility is only exempt from testing if EPA granted the exemption. Simply applying for the exemption does not automatically mean the facility did not have to conduct testing.*

EPA granted the exemption. The inspection team should verify that the exemption application includes:

- Identification of the test rule;
- The chemical identity and the CAS Registry Number (CAS or CASRN) of the test substance that the application is in reference to; the specific testing requirement(s) from which an exemption is sought and the basis for the exemption request (i.e., another company is planning to conduct the tests, and the identity of that company);
- Name, address, and telephone number of the applicant;
- Name, address, and telephone number of the appropriate individual to contact for further information;
- A sworn statement of financial responsibility to reimburse their fair share of the test costs to the company that conducted the testing if applying for an exemption based on testing data submitted by a different company within the past 5 years, or if the sunset date for section 4 testing requirements of the chemical in question has not passed; and
- If required in the test rule to establish equivalence, the chemical identity of the test substance on which the application is based and the equivalence data.

Section 5 Review

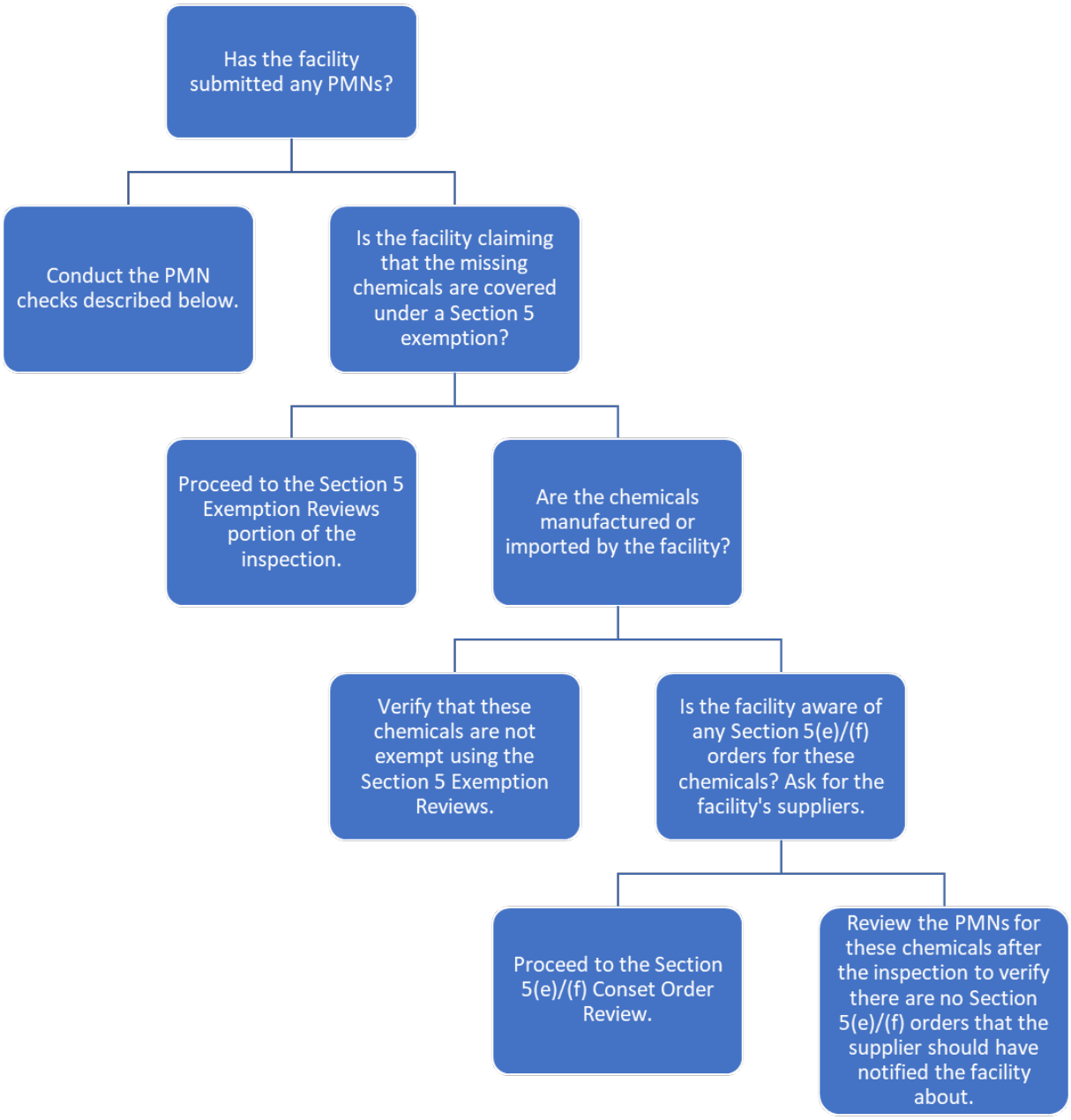
The purpose of the TSCA section 5 review is to ensure compliance with PMN requirements and SNUR requirements, section 5(e)/(f) orders, and exemptions to these rules.

Section 5(a) PMN Review

Section 5(a) of TSCA requires facilities to submit PMNs for new chemicals that they manufacture or import. New chemicals are defined as chemicals that are not listed in the TSCA Inventory. The inspection team should first compare a list of chemicals manufactured, imported, exported, processed, or used at the facility against the latest public TSCA Inventory, as described in Chapter 4 General Information Review. If all the facility's chemicals are on the Inventory, then the PMN review is complete and the inspection team should proceed to the SNUR review in Chapter 4 Section 5(a)(2) SNUR Review.

If the inspection team identifies chemicals that are not on the TSCA Inventory, a PMN may have been required. The inspection team should follow the logic diagram in Figure 4-1 to determine the next steps in the inspection process.

Figure 4-1. Logic Diagram for PMN Review



If facility representatives indicated PMNs have been submitted, the inspection team should conduct the following checks:

1. Review records for PMNs submitted by the facility to ensure PMN technical content accuracy. The inspection team should use information obtained from discussions with facility personnel, production records, and observations from the plant tour to ensure

accuracy of the content of the PMN. For more information on how to check PMN information accuracy, refer to Chapter 4 Section 5(e)/(f) Order Review, which discusses how to check compliance with section 5(e)/(f) orders. For efficiency, the inspection team can simultaneously check PMN content and compliance with section 5(e)/(f) orders.

2. Check that a Notice of Commencement (NOC) was submitted for all PMN chemicals the facility began manufacturing/importing. While checking NOC documentation, the inspection team should:
    a. Verify the dates listed in the NOC for the first commercial manufacture or import of the PMN chemical match production or import records.
    b. Verify with production or import records that the facility submitted all NOCs within 30 days of the first instance of commercial manufacture or import of the PMN chemical.
3. Check that the facility did not commence the manufacture or import of a PMN chemical prior to EPA making an affirmative finding on the safety of the PMN chemical (e.g., approval of the PMN, issuance of a 5(e)/(f) order). This is a new requirement under the amended TSCA. Formerly, TSCA allowed the commencement of chemicals after the 90-day PMN review period. The inspection team should review production or import records for the first instance of commercial manufacture or import of the PMN chemical and compare this to the date EPA approved the PMN or issued a 5(e)/(f) order.

> ***Tip:*** *NOCs submitted prior to the effective date of the amended TSCA may not reflect the new requirement for an affirmative finding on safety prior to commencement.*

4. Ask the facility for any section 5(e)/(f) orders EPA issued for PMNs submitted by the facility. The inspection team should then check the facility's compliance with section 5(e)/(f) orders, as described in Chapter 4 Section 5(e)/(f) Order Review.

Section 5(a)(2) SNUR Review

Section 5(a)(1) requires facilities to submit Significant New Use Notices (SNUNs) for chemicals subject to a Significant New Use Rule (SNUR). Chemicals subject to SNURs are flagged as such in the TSCA Inventory. A SNUN is required from manufacturers, importers, and processors who manufacture, import, and/or process a chemical substance for a significant new use. The SNUR review portion of the inspection is similar to the PMN review and the inspection team should do the following:

1. Compare a list of chemicals manufactured, imported, exported, processed, or used at the facility against the latest public TSCA Inventory. If a chemical is flagged as having a

SNUR, determine what restrictions are contained in the SNUR. EPA's **ChemView** website is a useful resource for finding the regulatory citations for SNURs. A SNUR can restrict not only the "use," but also environmental releases, worker exposure, and manufacturing/processing details.

2. For any chemicals subject to a SNUR, the inspection team should ask the facility representatives how these chemicals are used and to provide documentation of such use and any records required to be kept by the SNUR. This information will help determine if the facility manufacturing, processing, or use of the chemicals is deemed a significant new use(s) as listed in the SNUR.
    a. If the facility does not manufacture, import, process, or use the chemical subject to a SNUR outside the scope of the SNUR, no further information is needed at this time.
    b. If the facility does not manufacture, import, or process the chemical subject to the SNUR, but is the end user and does use the chemical outside the scope of the SNUR, determine who is supplying the chemical to the facility. The supplier, once aware that a customer is not abiding by the SNUR, must cease distribution of the chemical to that customer.
    c. If the facility does manufacture, import, or process the chemical in a manner classified as a significant new use, the inspection team should ask the facility if they have submitted any SNUNs and proceed with the same checks listed in Chapter 4 Section 5(a) PMN Review for PMNs/new chemicals, except in the context of SNUNs and the significant new use.

Section 5(e)/(f) Order Review

EPA can restrict a new chemical or significant new use of an existing chemical with a section 5(e) or section 5(f) order. Section 5(e) orders are issued when insufficient information is available to fully evaluate the potential hazards of the new chemical or significant new use or in the absence of such information, the manufacture, processing, distribution in commerce, use or disposal of the chemical substance may present an unreasonable risk of injury to human health or the environment. Section 5(e) orders may also be issued if the chemical substance is or will be produced in substantial quantities and 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 chemical substance section 5(f) orders are issued when sufficient data exists to confirm an unreasonable risk associated with the new chemical or significant new use. Both 5(e) and 5(f) orders provide restrictions to minimize exposures and releases, such as with requirements related to PPE, engineering controls, waste treatment and disposal, labeling, or customer notification, among other types of requirements. Under section 5(f), EPA has the

authority to issue a proposed rule under section 6(a). Such a proposed rule shall be effective upon its publication in the Federal Register.

During a section 5 inspection, the inspection team should evaluate facility compliance with section 5(e) or (f) orders:

- Issued to the facility as a result of a PMN or SNUN submitted by the facility.
- Issued for raw materials used at the facility, for which the facility was not the PMN or SNUN submitter.
    - The facility's suppliers should provide notification to the facility if the raw material is subject to a section 5(e) or (f) order.
    - These chemicals may also be flagged in the TSCA Inventory as being subject to a section 5(e) or (f) order.

To evaluate compliance with a section 5(e) or (f) order, the inspection team may need to speak with facility personnel, conduct a plant tour, and/or review documents. Speaking with facility personnel is useful for inspectors to hear the steps the facility takes to ensure compliance. However, the inspection team should verify the measures explained by the facility personnel are being implemented by conducting a plant tour (described in Plant Tour) and/or reviewing documentation.

IMPORTANT: *Do not forget to document findings during the plant tour and document review in inspection notes, photographs, and by obtaining copies of records.*

The requirements of each section 5(e) or (f) order can vary, so the documentation needed may not be the same for each inspection. Some documents that may be useful to review during this portion of the inspection are included in Figure 4-2.

Figure 4-2. Examples of Documentation to Check Compliance with Section 5(e)/(f) Orders

Batch Records	• Check the facility is adhering to production volume restrictions
Process flow diagrams	• Verify that the facility's processes are consistent with those described in the PMN, SNUN, or 5(e)/(f) order
Standard Operating Procedures (SOPs)	• Ensure the facility has the required PPE, engineering controls, cleanout practices, and waste disposal mechanisms
PPE matrices	• Ensure the facility has the required PPE and is using it in areas where the regulated chemical is present
Stack or wastewater testing	• Check release concentrations, release quantities, and/or treatment removal efficiencies
Technical data sheets, brochures, or other product literature	• Ensure product is marketed/sold/used as described; check restrictions in composition
Distribution/sales records	• Ensure product is marketed/sold/used as described
Product labels, SDSs	• Check that labels and SDSs contain the required information (e.g., hazards, PPE requirement)
Disposal records (e.g., waste manifests, invoices/receipts/bills of lading for waste shipments)	• Ensure wastes associated with the regulated chemical are disposed of as required
Employee training materials and attendance logs	• Verify the scope of the training includes the order requirements and that operational employees are receiving training
Correspondence with customers	• Check for notifications to customers stating that the chemical is subject to an order and that the customer must adhere to applicable requirements of the order

Section 5 Exemption Reviews

Under section 5(a) there are exemptions to PMN requirements, which are listed in Table 4-5 below. For some of these exemptions, the manufacturer or importer does not need to notify or apply for exemption with EPA and does not have additional regulatory requirements. For other exemptions, the manufacturer or importer is required to apply for exemption with EPA and follow certain regulations. Failure to meet the exemption may result in non-compliance with the underlying section 5 requirements and in addition, in some cases the exemptions have additional independent regulatory requirements: the R&D Exemption, Test Marketing Exemption (TME), Low Volume Exemption (LVE), Low Releases and Low Exposures (LoREX) Exemption, Instant Film Chemical Exemption (IFCE), and Polymer Exemption (PE).

Regardless of the type of exemption, the inspection team should:

1. Review the facility's exemption claims against the applicable regulations to ensure that the facility's claims meet the regulatory exemption criteria.
    a. The exemption review is completed for exemptions in Table 4-5 that do not have additional regulatory requirements.
2. For exemptions with additional regulatory requirements (e.g., R&D, TME, LVE, LoREX, IFCE, and PE), the inspection team should document compliance with those requirements. The requirements and the activities inspection teams should follow for each of these exemptions are summarized in Chapter 4 R&D Exemption Review and Chapter 4 LVE, LoREX, TME, PE, and IFCE Exemption Review.

> ***Tip:*** *Chemicals for which exemptions are granted by EPA under Section 5 are not included on the TSCA Inventory, except for Polymer Exemptions, which are listed and flagged as such on the TSCA Inventory.*

Table 4-5. TSCA Section 5 Exemptions

Regulation (40 C.F.R.)	Summary of Exemption Criteria	Additional Regulatory Requirements
720.22(b)(1)	A new chemical imported as a part of an article	None
720.30(b)	A mixture as defined in 40 C.F.R. 720.3(u)	None
720.30(c)	A new chemical that will be manufactured or imported in small quantities solely for research and development	40 C.F.R. 720.36 (R&D Exemption)

Regulation (40 C.F.R.)	Summary of Exemption Criteria	Additional Regulatory Requirements
720.30(d)	A new chemical that will be manufactured or imported solely for test-marketing purposes	40 C.F.R. 720.38 (TME)
720.30(e)	A new chemical manufactured solely for export	40 C.F.R. 720.30(e)(1) and (2) for conditions
720.30(f)	A new chemical that is manufactured or imported under section 5(h)(4) exemptions	40 C.F.R. 723.50 (LVE and LoREX), 723.175 (IFCE), and 723.250 (PE)
720.30(g)	A byproduct if its only commercial purpose is to burn as a fuel, dispose of as waste, or extract component substances	None
720.30(h)	A new chemical with no commercial purposes separate from the substance, mixture, or article. Specifically, impurities, byproducts, non-isolated intermediates, and others included in 40 C.F.R. 720.30(h).	None
720.30(i)	A new chemical manufactured solely for non-commercial R&D, unless the activity is for eventual commercial purposes	None

R&D Exemption Review

To meet the exemption for research and development, the following conditions must be met:

- The new chemical substance is manufactured or imported only in small quantities solely for research and development.
- The manufacturer or importer notifies all users of the new chemical substance of any potential risk to human health.
    - The manufacturer or importer need not evaluate this risk and provide notification so long as prudent lab practices are used to control exposure to chemicals with unknown toxicity.

    - Notification includes labeling containers and safety data sheets with any known human health hazards. In addition, if the chemical substance is distributed to persons not under its employ, the manufacturer or importer must additionally provide written notice that the chemical substance is for R&D use only (this may be included on the container label or SDS).
- The new chemical substance is used under the direct supervision of a technically qualified individual.

In addition to the exemption conditions, users of exempt R&D substances must dispose of the used substances in accordance with federal, state, and local regulations unless the substance is used for one of the following allowed commercial uses:

- Sale or commercial use of substances containing the R&D substance only as an impurity, if the substances were generated in the course of legitimate R&D.
- Sale or commercial use of articles incorporating R&D substances, if the articles were produced in the course of legitimate R&D.
- Burning residual R&D substance as a fuel.
- Reacting residual R&D substance to form other chemical substances for commercial use.

No application is required for this exemption. However, manufactures and importers claiming this exemption need to maintain records per 40 C.F.R. 720.78(b) which demonstrate compliance with the R&D exemption requirements. Records include: copies of information used to determine the need to make any notification of risk to human health; documentation of labels and any other written notices used to notify users of risk to human health and that the chemical substance is for R&D use only; documentation of prudent laboratory practices, names and addresses to whom the substance is distributed; and identity of the chemical substance and production volume (if greater than 100 kg/year). These records must be retained for five years.

When documenting compliance with the R&D exemption requirements, the inspection team should request and review all the documentation required per 40 C.F.R. 720.78(b) to ensure the exemption conditions are being met. In addition, the inspection team should conduct a tour of any R&D laboratories at the facility as described in Chapter 4 Research and Development Laboratory Tour. The lab tour should focus on ensuring the exemption conditions listed above are being met by observing lab practices and interviewing lab personnel. For efficiency, the R&D exemption records review may be completed in conjunction with the lab tour.

LVE, LoREX, TME, PE, and IFCE Exemption Review

The inspection activities for the remaining exemptions with additional requirements (e.g., LVE, LoREX, TME, PE, and IFCE) are all similar. A summary of the requirements for each exemption and the associated inspection activities is included in Table 4-6 below.

Table 4-6. Section 5 Exemptions with Additional Requirements

Exemption	Applicability	Reporting Requirements	Conditions	Inspection Checks
LVE	New chemicals that are manufactured or imported at a production volume of 10,000 kg/year or less.	• Facilities seeking this exemption must apply for exemption with an LVE notice at least 30 days prior to commencement. • Submitter must submit an LVE modification for changes to the granted LVE (as indicated at 40 C.F.R. 723.50(j)).	• Submitter is held to the production volume, conditions of use, sites of manufacture, physical form, and the exposure and release controls (including physical form) specified in the LVE notice. • Submitter must provide notification to customers that the customer must comply with the specified uses and exposure and release controls in the LVE notice. • Submitter must follow recordkeeping requirements at 40 C.F.R. 723.50(n).	1. Request all reports, notices, and records required per 40 C.F.R. 723.50(n). 2. Follow the PMN review instructions in Section 5(a) PMN Review to check the accuracy of the LVE notice and Chapter 4 Section 5(e)/(f) Order Review to ensure the submitter is adhering to the LVE conditions.

Exemption	Applicability	Reporting Requirements	Conditions	Inspection Checks
LoREX	New chemicals with low environmental releases and human exposures – eligibility criteria at 40 C.F.R. 723.50 (c)(2) – regardless of production volume.	• Facilities seeking this exemption must apply for an exemption with a LoREX notice at least 30 days prior to commencement. • Submitter must submit an LoREX modification for changes to the granted LoREX (as indicated at 40 C.F.R. 723.50(j)).	• Submitter is held to the conditions of use, sites of manufacture, physical form, and the exposure and release controls (including physical form) specified in the LoREX notice. • Submitter must provide notification to customers that the customer must comply with the specified uses and exposure and release controls in the LoREX notice. • The submitter's customers must not further distribute the chemical. • Submitter must follow recordkeeping requirements at 40 C.F.R. 723.50(n).	1. Request all reports, notices, and records required per 40 C.F.R. 723.50(n). 2. Follow the PMN review instructions in Chapter 4 Section 5(a) PMN Review to check the accuracy of the LoREX notice and Chapter 4 Section 5(e)/(f) Order Review to ensure the submitter is adhering to the LoREX conditions.

Exemption	Applicability	Reporting Requirements	Conditions	Inspection Checks
TME	New chemical substances that are manufactured or imported for test marketing purposes (the distribution in commerce to explore market capability).	• Facilities seeking this exemption must apply for exemption with a TME notice prior to commencement.	• Submitter is held to the production volume, number of persons to whom the new chemical may be distributed, number of persons who may be exposed to the new chemical, description of test marketing activities, and time period of test marketing listed in the TME notice. • EPA may impose additional restrictions. • Submitters must follow recordkeeping requirements at 40 C.F.R. 720.78(c).	1. Request all reports, notices, and records required per 40 C.F.R. 720.78(c). 2. Follow the PMN review instructions in Chapter 4 Section 5(a) PMN Review to check the accuracy of the TME notice and Chapter 4 Section 5(e)/(f) Order Review to ensure the submitter is adhering to the TME conditions.

Exemption	Applicability	Reporting Requirements	Conditions	Inspection Checks
PE	New chemicals meeting the definition of polymer at 40 C.F.R. 723.250(b) and the exemption criteria at 40 C.F.R. 723.250(e) and not excluded per 40 C.F.R. 723.250(d).	• No application prior to commencement is required for this exemption. • Companies must submit an annual report listing the number of polymers that were manufactured or imported under this exemption the year prior.	• Submitters must identify and maintain records of polymer identities and structure per 40 C.F.R. 723.250(g). • Submitters granted exemptions prior to May 26, 1995 are subject to NOC requirements per 40 C.F.R. 723.250(i). • Submitters must follow recordkeeping requirements at 40 C.F.R. 723.250(j).	1. Request all reports, notices, and records required per 40 C.F.R. 723.250(j). 2. Follow the PMN review instructions in Chapter 4 Section 5(a) PMN Review to check the accuracy of reports and Chapter 4 Section 5(e)/(f) Order Review to ensure the submitter is adhering to the PE conditions. 3. For exemptions granted prior to May 26, 1995, follow instructions in Chapter 4 Section 5(a) PMN Review to check NOC requirements.
IFCE	New substances used in or for the manufacture or processing of instant photographic and peel-apart film articles.	• Facilities seeking this exemption must submit an IFCE notice when the manufacture of the new chemical begins.	• Submitters must limit worker exposure to the new chemical with PPE, monitoring, engineering controls, employee training, labeling, and other conditions set forth in 40 C.F.R. 723.175(e)-(h). • Submitters must follow recordkeeping requirements at 40 C.F.R. 723.175(j)	1. Request all reports, notices, and records required per 40 C.F.R. 720.78(c).

Exemption	Applicability	Reporting Requirements	Conditions	Inspection Checks
				2. Follow the PMN review instructions in Chapter 4 Section 5(a) PMN Review to check the accuracy of the IFCE notice and Chapter 4 Section 5(e)/(f) Order Review to ensure the submitter is adhering to the IFCE conditions.

Section 6 Review

The purpose of the TSCA section 6 review is to ensure compliance with section 6 rules and specific requirements.

Each promulgated section 6(a) rule may have different requirements due to the nature of the risks and approaches to risk management based on the chemical or uses of that chemical. As such, it is important that the inspection team take the time to review the specific requirements for any rule applicable to chemicals at the facility. The documentation needed, therefore, may not be the same for each inspection. Some documents that may be useful to review during this portion of the inspection are included in the section 5 Review in Chapter 4 General Information Review and included in Figure 4-2.

To evaluate compliance with a section 6 rule, the inspection team may need to speak with facility personnel, conduct a plant tour, and/or review documents. Speaking with facility personnel is useful for inspectors to hear the steps the facility takes to ensure compliance. However, the inspection team should verify the measures explained by the facility personnel are being implemented by conducting a plant tour (described in Chapter 4 Plant Tour) and/or reviewing documentation.

Tip: *Refer to the final risk statements in the Risk Evaluation to determine the terms of conditions of use to ensure compliance with the rule.*

The inspection team should identify chemicals manufactured, imported, processed, or used by the facility with restrictions under a section 6(a) rule during the general inventory review described in Chapter 4 General Information Review. For each chemical subject to a section 6(a) rule, the inspection team also should check to determine if:

- The facility has commented on the rule during the rulemaking process.
- Existing Chemical Exposure Limits (ECELs) are met. The facility may also be held to other exposure limits for other statutes, but the scope should be limited to EPA ECELs.
- The facility is complying with all restrictions and/or requirements established by the rule. Bills of lading, manufacturing data, sales data, etc. may be useful in helping to determine compliance with the conditions of use.

IMPORTANT: A company may have multiple facilities using a section 6(a) chemical for different uses with varying risk management requirements.

Similar to section 5(e) and (f) orders, section 6(a) rules can implement restrictions to minimize exposures and releases, such as with requirements related to PPE, engineering controls, waste treatment and disposal, labeling, or customer notification, among other types of requirements. Where unreasonable risks cannot be mitigated by other means, section 6(a) can also ban one or more conditions of use of a chemical. Unlike TSCA section 5, where chemicals new to commerce often are regulated by TSCA to date, chemicals subject to a TSCA section 6 rule may also be subject to other laws and regulations, such as Occupational Health and Safety Administration (OSHA) Permissible Exposure Limits (PELs).

IMPORTANT: *Do not forget to document findings during the plant tour and document review in inspection notes, photographs, and by obtaining copies of records.*

The section 6 rules for polychlorinated biphenyls (PCBs) and asbestos are not performed during Core TSCA inspections, therefore, these rules are not discussed here.

Section 7 Review

TSCA section 7 authority is important for inspectors to understand and be aware of for two reasons:

1. First, when an inspector is on site they may need to report back to EPA if they see an "imminently hazardous situation"; one which "is likely to result in such injury to health or the environment before a final rule under section 6 can protect against such risk.[6]"
2. Second, an inspector may inspect a site where a TSCA section 7 is appropriate based on RCRA 7003, SDWA 1431, CAA 303 or other similar civil action which granted temporary or permanent relief[7] had occurred in the past or a site which purchased such products if a recall, replacement or repurchase is necessary[8]. The inspector may need to ensure that such activity has ceased, or the chemical substance or article has been properly recalled or replaced.

Section 8 Review

TSCA inspections require review of records pertaining to TSCA section 8, which is comprised of subsections 8(a) through 8(e). Chapter 4 Section 8 Review provides guidance to inspectors for conducting a review of records pertaining to the various requirements covered under TSCA section 8.

6 Id.
7 TSCA § 7(b)(1)
8 TSCA § 7(b)(2)

Section 8(a) CDR/PAIR Rule Review

Among other things, TSCA section 8(a) outlines Chemical Data Reporting ("CDR") requirements under TSCA, as well as requirements for manufacturers and importers of substances regulated under existing Preliminary Assessment Information Rules ("PAIR rules"). During records review pertaining to TSCA section 8(a), the inspection team should focus on facility efforts to remain compliant with CDR and applicable PAIR Rule requirements.

PAIR Rule Review

The general reporting requirements for facilities importing/manufacturing/using chemicals subject to PAIR rules include:

- Location of plant site;
- Quantity imported or manufactured;
- Quantity lost to the environment/in wastes;
- Information on the number of workers involved in manufacturing and handling/their exposure; and
- Data concerning end-uses of the chemical.

There is considerable overlap between PAIR rule reporting requirements and CDR reporting requirements. Inspectors can refer to the CDR records review in CDR Review for guidance on reviewing the types of information listed in the PAIR rule reporting requirements above.

Inspectors should check for new PAIR rules potentially applicable to the facility prior to the inspection. If a new PAIR rule has indeed been promulgated, the inspection team should confirm if the facility is subject to PAIR reporting as part of records review. If the facility is subject to PAIR reporting, the inspection team should confirm that the report was submitted, and the information included in the report was accurate.

Additionally, the inspection team should review all claims of PAIR reporting exemptions by the facility. Examples include:

- R&D exemptions;
- article exemptions;
- small quantity exemptions;
- small manufacturer exemptions; and
- certain byproducts.

> ***Tip:*** *All existing PAIR rules have been sunset, so inspectors need only check for newly promulgated rules that are potentially applicable to the facility in question.*

Considerable overlap exists between PAIR rule and CDR records review regarding the types of exemption criteria inspectors

should review for facilities claiming one of the above exemptions. Thus, the reviews described in the CDR Review section contain information also potentially applicable for PAIR rule exemption records review. Failures to report where exemptions do not apply or were applied incorrectly by the facility should also be identified.

CDR Review

Review of the facility's CDR reporting records will focus on calculated/measured import and production volumes. To start, the inspection team should request a description of how the facility determines CDR reporting volume thresholds for each chemical. The typical reporting threshold is 25,000 pounds manufactured/imported during the calendar year in question, except for substances that are:

- Subject to a rule proposed or promulgated under TSCA section 5(a)(2), 5(b)(4), or 6;
- Subject to an order in effect under TSCA section 4, 5(e) or 5(f); or
- Subject to relief that has been granted under a civil action under TSCA sections 5 or 7.

Tip: *The inspection team should have already identified chemicals produced/imported at the facility that are subject to lower CDR reporting thresholds, as part of the inventory review conducted during the Opening Conference/General Information Review and pre-inspection planning.*

Chemicals that fall under one of the above categories are subject to a 2,500 pounds annual threshold for CDR reporting. Additionally, the threshold may be 100,000 lbs. for companies that qualify for the small manufacturer definition. Annual manufacturing and import volumes for all chemicals should then be reviewed to determine which chemicals at the facility are subject to CDR reporting.

Tip: *Small manufacturers are defined as manufacturers and imports that meet either of the following standards:*

1. *total annual sales, when combined with those of its parent company (if any), are less than $120 million. However, if the annual production or importation volume of a particular substance at any individual site owned or controlled by the manufacturer or importer is greater than 45,400 kilograms (100,000 lbs.), the manufacturer or importer will not qualify as small for purposes of reporting on the production or importation of that substance at that site, unless the manufacturer or importer qualifies as small under #2 below;*
2. *total annual sales, when combined with those of its parent company (if any), are less than $12 million, regardless of the quantity of substances produced or imported by that manufacturer or importer.*

CDR Reporting Exemptions

The inspection team should review all claims of full CDR reporting exemptions by the facility, summarized below in Table 4-7.

Table 4-7. Summary of Full CDR Exemptions

Regulation (40 C.F.R.)	Summary of Exemption Criteria	Additional Regulatory Requirements
711.6(a)(1)	Polymers, enzymes, lignin, polysaccharides, proteins, rubber, siloxane, silicone, or silsesquioxane	Not applicable to polymeric substances that have been depolymerized, hydrolyzed, or otherwise chemically modified
711.6(a)(2)	Living microorganisms that meet the definition of "microorganism" as defined at 40 C.F.R. § 725.3	Chemical substances produced from a living microorganism are still reportable unless otherwise excluded
711.6(a)(3)	Naturally occurring chemical substances as described in 40 C.F.R. § 710.4(b)	Chemical substances produced from such a naturally occurring chemical substance are still reportable unless otherwise excluded
711.6(a)(4)	Water and certain forms of natural gas	CASRN List: • 7732-18-5 (water); • 8006-14-2 (natural gas); • 8006-61-9 (gasoline, natural); • 64741-48-6 (natural gas (petroleum), raw liq. mix); • 68410-63-9 (natural gas, dried); • 68425-31-0 (gasoline (natural gas, natural); • 68919-39-1 (natural gas condensates)
711.10(a)	Substances manufactured/imported in small quantities solely for research and development	None

Regulation (40 C.F.R.)	Summary of Exemption Criteria	Additional Regulatory Requirements
711.10(b)	Substances imported as part of an article	None
711.10(c)	Substances manufactured in a manner described in 40 C.F.R. § 720.30(g) or (h)	None
711.10(d)(1)(i)	Byproduct substances that are recycled or otherwise used within a site-limited, enclosed system that is part of same overall process in which the byproduct was generated, and when the site is reporting the byproduct or a different chemical substance that was manufactured from the recycled byproduct or generated in the same overall process	Specific to certain chemicals manufactured as byproducts in Portland Cement Manufacturing and Kraft Pulping Process; the specific chemicals are listed in the rule
711.10(d)(2)	Byproducts generated solely in (i) pollution control equipment or (ii) boilers used to generate heat/electricity for the facility when it is not integral to the chemical manufacturing process(es) of the site.	None

Partial exemption claims, for example, facilities with petroleum product manufacturing streams, may manufacture chemicals with partial exemption claims that trigger CDR reporting requirements, should also be reviewed. Failures to report where exemptions do not apply or were applied incorrectly by the facility should be identified.

Tip: *During pre-inspection planning, the inspection team should have already identified chemicals produced/imported at the facility that are ineligible for certain full or partial exemptions, as part of the inventory review conducted during the Opening Conference/General Information Review.*

Additionally, substances for which the facility claims an exemption under 40 C.F.R. 711.10(a) (R&D) should be reviewed with increased scrutiny by the inspection team. Because of considerable overlap between CDR and TSCA section 5 R&D exemption criteria, see R&D Exemption Review for examples of what the inspection team should check for (i.e., SDS, labels, etc.) to confirm that a substance is indeed only used for R&D purposes.

Toll Manufacturing

For CDR purposes, toll manufacturing refers to a kind of co-manufacturing situation involving two parties: one company contracts with a second company to domestically produce a chemical substance exclusively for the first company. The first company, or contracting company, determines the specific chemical identity of the substance, and controls the total amount produced and the basic technology for the manufacturing process. The second company, or toll manufacturer, generally provides the site, staff, and equipment necessary to manufacture the chemical substance.

Tip: *EPA expects that in most instances, a person that contracts with a toll manufacturer will generally know more about the particular chemical substances, and will usually be in a better position to report about industrial processing and use of a chemical substance, and about commercial and consumer uses of products containing the chemical substance. Similarly, EPA expects that the toll manufacturer will generally be in a better position to report the number of workers and other information associated with the manufacturing site.*

For CDR reporting purposes, 40 C.F.R. 711.22(c) states that while the companies can work out among themselves who should report, EPA holds both of the parties (i.e., contracting company and toll manufacturer) responsible for the submission of a report by either one of the parties. The toll and contracting manufacturers can share information and agree between themselves that one or the other will undertake all or a portion of the work associated with meeting the CDR regulations for a given co-manufactured chemical substance.

When encountering a toll manufacturing situation, the inspection team should conduct CDR records review as normal, regardless of whether the facility in question undertook CDR reporting responsibilities. If the facility in question did not undertake CDR reporting responsibilities, they should still be able to present CDR-related records maintained/generated by their co-manufacturing partner.

Importer of Record

CDR reporting requirements are applicable regardless of whether the substance was manufactured or imported. For imported substances, CDR records review may require

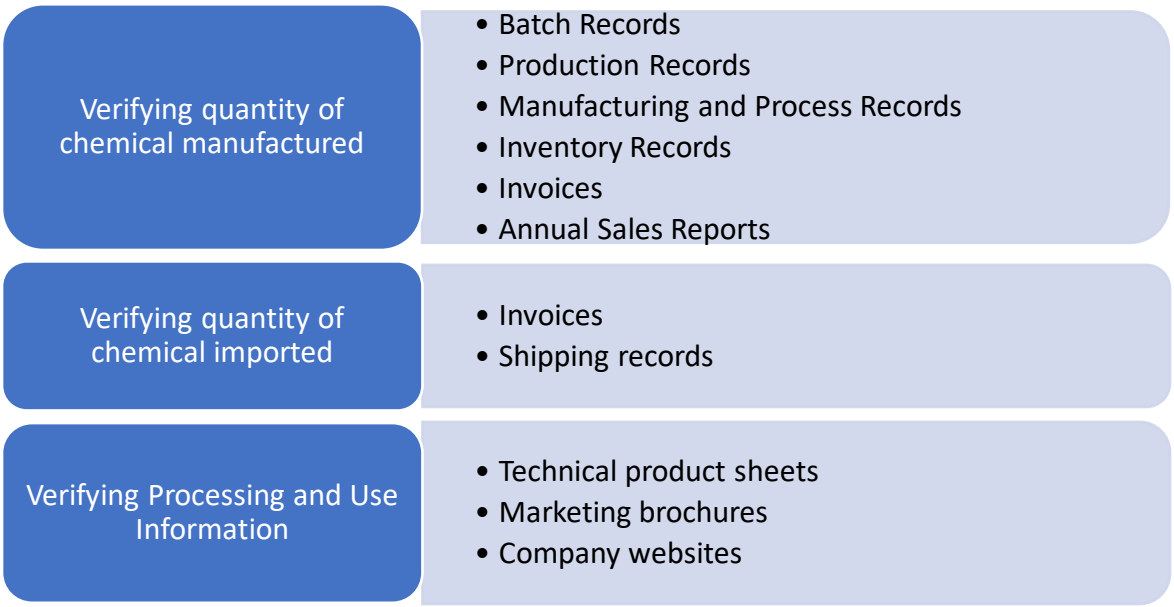
additional attention given to importer of record information and discussion. Often, the facility's corporate headquarters will be the importer of record, frequently referred to as "consignee" in import records, even when the substance is never shipped to the headquarters site, but instead directly sent to their various processing/use sites. When this is the case, the inspection team should check that the reported exposure information is accurate specifically for the import site (i.e., code W1 (fewer than 10 workers exposed) should be reported as the substance is never physically on-site). The reported production volume should be the aggregate of the total volume imported, regardless of whether the substance was ever physically shipped to the importer of record site. Also, the reported industrial processing and use and consumer and commercial use information should be for all plants, whether owned by the company in question or not.

In many cases, another company (i.e. import brokers) may act as the importer of record. When reviewing CDR reporting information submitted by a broker, the site address may potentially be for the broker if they have a domestic operating "site" as defined at 40 C.F.R. 711.3. Further, 40 C.F.R. 711.3 states that if no such operating site exists, the domestic address of an agent acting on behalf of the importer may be used. See Chapter 4 Section 13 Review for more information regarding importer of record/import certifications/shipping documents review.

Confirming Completeness/Accuracy of Reported CDR Information

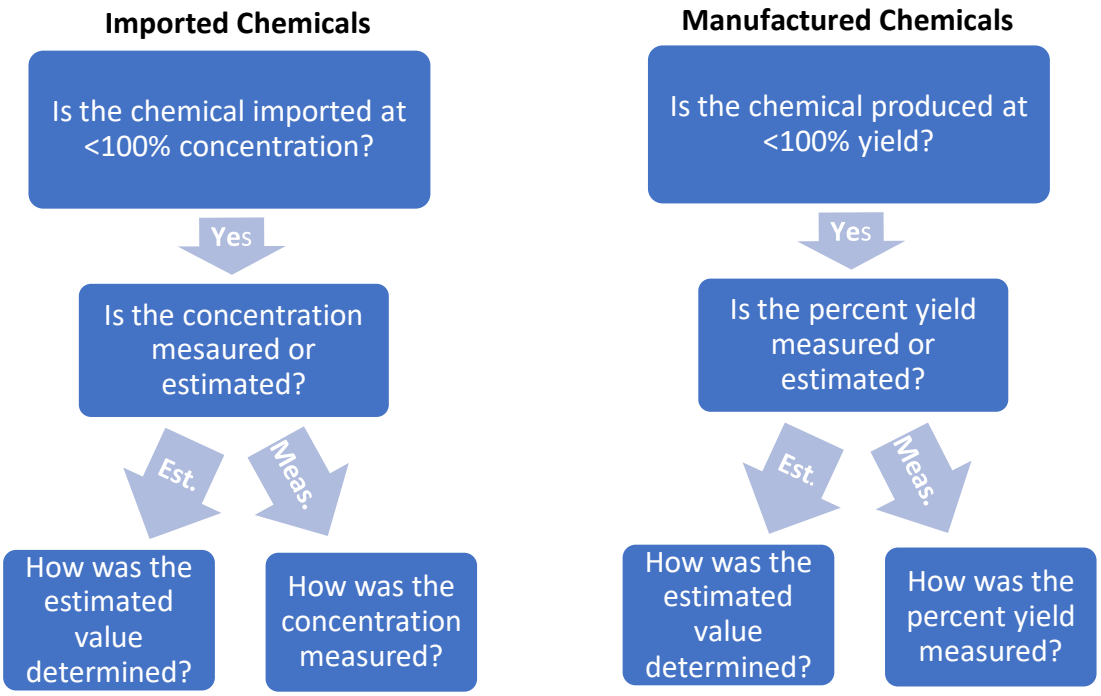
Production records (e.g. batch records or invoices) should be reviewed to confirm that the reported volumes are accurate. Figure 4-3 below provides a list of documents/discussion points to review as part of confirming reported volumes. Additionally, the inspection team should request a description of how the facility determines Part III on the CDR reporting form, Form U information (i.e. industrial processing and use and commercial/consumer use information). Technical product sheets, SDSs, or other information should be subsequently reviewed to confirm that the marketed uses match the CDR reported uses.

Figure 4-3. Confirming CDR Reporting Volumes Summary



For chemicals subject to CDR reporting, the inspection team should request a description of how reporting volumes are calculated, which will typically be in the form of a sample calculation. When reviewing sample calculations for reporting volumes, the inspection team should confirm that the facility calculations are not only accurate but thorough, meaning they consider chemical concentrations <100%, yields for manufactured chemicals <100%, etc. Inspectors should also ascertain how sample calculation parameters such as concentrations and yields are determined by the facility. Figure 4-4 below presents two example lines of questioning (one for imported chemicals, one for manufactured) that an inspector may ask during review of sample calculations for CDR reporting volumes.

Figure 4-4. Example Lines of Questioning for CDR Records Review



Section 8(b) Inventory Review

Section 8(b) of TSCA pertains to the compilation, upkeep, and publishing of the TSCA Chemical Substance Inventory ("TSCA Inventory"). Records review pertaining to TSCA section 8(b)

IMPORTANT: *Inspectors should conduct this review of the TSCA Inventory for chemicals manufactured/imported at the facility prior to the inspection, if possible, or before the detailed records review (as part of the Opening Conference/General Information Review) to identify any substances at the facility flagged for various action (see Chapter 4* General Information Review *for additional information.) During the general review of the TSCA Inventory, inspectors should also confirm that all chemicals currently being manufactured, imported, processed, or used at the facility are listed as active. Additionally, substances manufactured/imported at the facility that are not on the TSCA Inventory should be identified during review of records pertaining to TSCA section 5 (specifically section 5(a) PMN review; see Chapter 4* Section 5(a) PMN Review *for further information). Therefore, this portion of the records review may not need to be repeated as part of TSCA section 8(b) records review.*

requires inspectors to perform a general check of the TSCA Inventory for substances manufactured/imported at the facility.

TSCA section 8(b) also requires manufacturers/importers and processors keep EPA up to date on the activity status (i.e. active vs. inactive) of the TSCA-regulated substances used at their facilities. The TSCA Inventory indicates the activity status of each TSCA-regulated substance, which is facilitated via Notices of Activity ("NOAs") submitted to EPA by the domestic manufacturers/importers of the substance.

Under the Lautenberg Amendments, EPA promulgated the TSCA Inventory Notification (Active-Inactive) Rule, found at 40 C.F.R. Part 710, to require manufacturers and importers to file a NOA using Form A during the initial reporting period from August 11, 2017 until February 7, 2018 and processors to file a NOA using Form A from August 11, 2017 until October 5, 2018. Starting August 5, 2019, manufacturers, importers, and processors are required to notify EPA before reintroducing inactive substances into U.S. commerce (e.g. facilities seeking to manufacture/import an inactive substance) using NOA Form B. Both forms require the following information which should be assessed for accuracy/completeness during records review:

- Company name/address;
- Authorized official name/address;
- Technical contact name and telephone number;
- Chemical specific information (CASRN/CA Index name for non-CBI substances, TSCA Accession Number and generic name for CBI substances); and
- Certification statements.

In addition to the above information, Form B NOAs also require the facility to provide the anticipated date for the change in activity status (i.e. date by which inactive substance will be domestically manufactured/imported). If a Form B NOA is filed for a substance prior to the effective date of the chemical's inactive designation, then the most recent date of manufacturing/importing/processing may be provided in lieu of an anticipated date. This information should be assessed for accuracy/completeness.

Inspectors should assure the accuracy of the active status of all chemicals manufactured, imported, and processed at the facility. Inspectors should review Form B NOA forms submitted by the facility and compare to production records for manufactured, imported and processed chemicals to verify that Form B NOA forms for substances designated as "inactive" were submitted accurately and timely to change the inventory status to "active." Additionally, inspectors should identify any chemicals listed as inactive on the TSCA inventory that are still

produced/in use at the facility, and determine if the facility failed to notify EPA or is claiming an exemption such as:

- R&D exemptions;
- Article exemptions;
- Small quantity exemptions;
- Small manufacturer exemptions; and
- Certain byproducts.

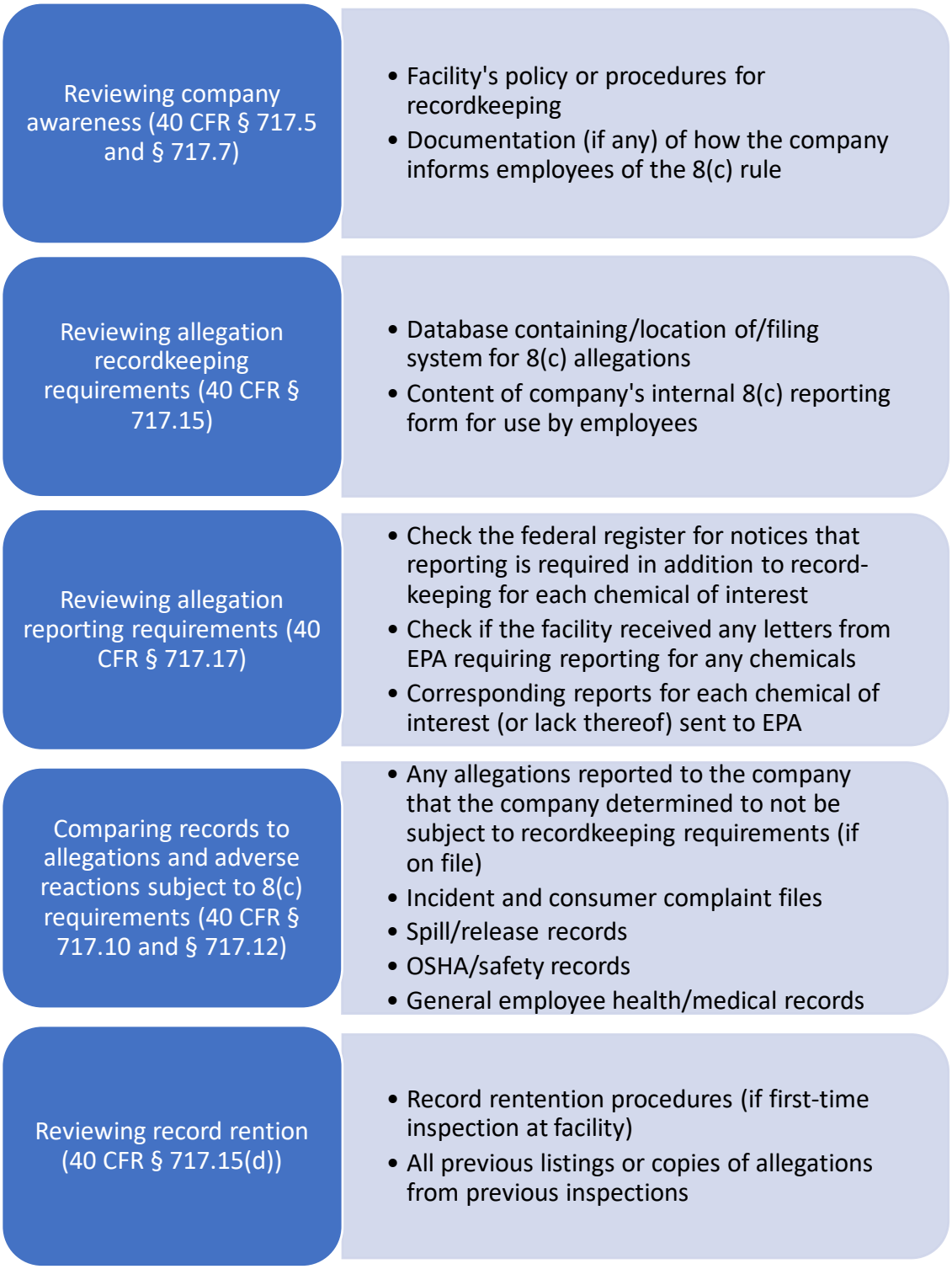
If an exemption is claimed for an inactive substance, a records review pertaining to the exemption should be conducted. There is considerable overlap between section 8(b) and CDR records review regarding the types of exemption criteria inspectors should review for facilities claiming one of the above exemptions. Thus, the CDR Review in Chapter 4 CDR Review contains information also potentially applicable for section 8(b) exemption records review. Failures to report where exemptions do not apply, or were applied incorrectly by the facility, should also be identified.

Section 8(c) Allegations of Significant Adverse Reactions Review

TSCA section 8(c) requires manufacturers/importers maintain records of allegations of significant adverse reactions to health or the environment alleged to be caused by the substance in question. This encompasses adverse reactions alleged to be caused by the manufacture, processing, use, and/or distribution of said substance.

As part of TSCA section 8 records review, the inspection team should request and ascertain a description of how the facility tracks, records, and reports (if applicable) any section 8(c) allegations. Figure 4-5 below provides a list of documents and discussion points to review to assess compliance with section 8(c) reporting requirements. A review of these records should be conducted, to confirm that section 8(c) allegations are being tracked/recorded/reported accurately.

Figure 4-5. TSCA Section 8(c) Records Review Summary



Perhaps the most difficult aspect of assessing section 8(c) compliance is identifying missing allegations and/or verifying compliance for facilities with no recorded allegations. Inspectors

should request the documents and information listed in the corresponding section of Figure 4-5 above when performing section 8(c) records review at facilities claiming no allegations. If these records suggest that an allegation was not recorded, the inspection team should record the name of the alleger, date(s) of the incident(s), symptoms and effects, the chemical and/or mixture and process involved, expert opinions, and the company's response.

Section 8(d) Health and Safety Data Reporting Review

TSCA section 8(d) outlines Health & Safety Data Reporting requirements for TSCA regulated substances. As part of TSCA section 8 records review, the inspection team should request and ascertain a description of how the facility tracks section 8(d) reporting rules and procedures, and review any reported Health & Safety Data studies submitted under the rule applicable to substances used and/or produced at the facility. Figure 4-6 below provides a list of documents and discussion points to review to assess compliance with section 8(d) reporting requirements. Additionally, the inspectors should identify any failures to meet TSCA section 8(d) reporting requirements by the facility.

Figure 4-6. TSCA Section 8(d) Records Review Summary

Reviewing company awareness (40 CFR § 716.5)	•Identify the contact person (or lack thereof) responsible for section 8(d) compliance •Identify database or central filing/office location (or lack thereof) where a copy of the section 8(d) rule and amendments are maintained •Identify internal procedures for monitoring/tracking studies subject to 8(d) reporting requirements •Determine whether there is an on-site testing facility or the name(s)/address(es) of company's testing facility(ies) not located on-site (if applicable)
Reviewing information in health and safety studies (40 CFR § 716.10, § 717.20, § 717.21, and § 716.50)	• Review copies of 8(d) submission(s) before insepction (if possible) • Obtain list of studies submitted to EPA • Request all testing, monitoring, and risk assessment files for chemical(s) of interest (including files for ongoing testing)
Reviewing reporting requirements (40 CFR §717.30, §717.35, §717.40, §717.60, and §717.65)	• Check 40 C.F.R. § 716.120 for each chemical of interest to determine if reporting is required in addition to recordkeeping • Check 40 C.F.R. § 716.20 for reporting exemptions • Corresponding reports for each chemical of interest (or lack thereof) sent to EPA

Section 8(e) Substantial Risk Review

TSCA section 8(e) requires EPA be immediately notified when substances or mixtures present a substantial risk of injury to human health or the environment. Table 4-8 below summarizes the types of information that would constitute substantial risk.

Tip: *While the regulation uses the term "immediately," EPA guidance indicates substantial risk notifications should be submitted within 30 calendar days of obtaining substantial risk information.*

Table 4-8. Summary of Substantial Risk Information

Citation	Type of Reaction	Type of Substantial Risk Information
43 FR 11112	Human Health	• Any instance of cancer, birth defects, mutagenicity, death, or serious or prolonged incapacitation, including the loss or inability to use a normal bodily function with a consequently relatively serious impairment of normal activities, if one (or a few) chemical(s) is strongly implicated • Any pattern of effects or evidence that reasonably supports the conclusion that the chemical substance or mixture can produce cancer, mutation, birth defects, or toxic effects resulting in death, or serious or prolonged incapacitation
43 FR 11112	Environmental	• Widespread and previously unsuspected distribution in environmental media* • Pronounced bioaccumulation. Measurements and indicators of pronounced bioaccumulation previously unknown to the Administrator should be reported when coupled with potential for widespread exposure and any nontrivial adverse effect • Any nontrivial effect, previously unknown to the Administrator, associated with a chemical known to have bioaccumulated to a pronounced degree or to be widespread in environmental media • Ecologically significant changed in species' interrelationships (changes in population behavior, growth, survival, etc., that in turn affect other specie's behavior, growth, or survival) • Facile transformation or degradation to a chemical having an unacceptable risk
43 FR 11112	Emergency*	Any environmental contamination by a chemical substance or mixture to which any of the above adverse effects have been ascribed and which because of the pattern, extent, and amount of contamination:

		• Seriously threatens humans with cancer, birth defects, mutation, death, or serious prolonged incapacitation, or • Seriously threatens nonhuman organisms with large-scale or ecologically significant population destruction

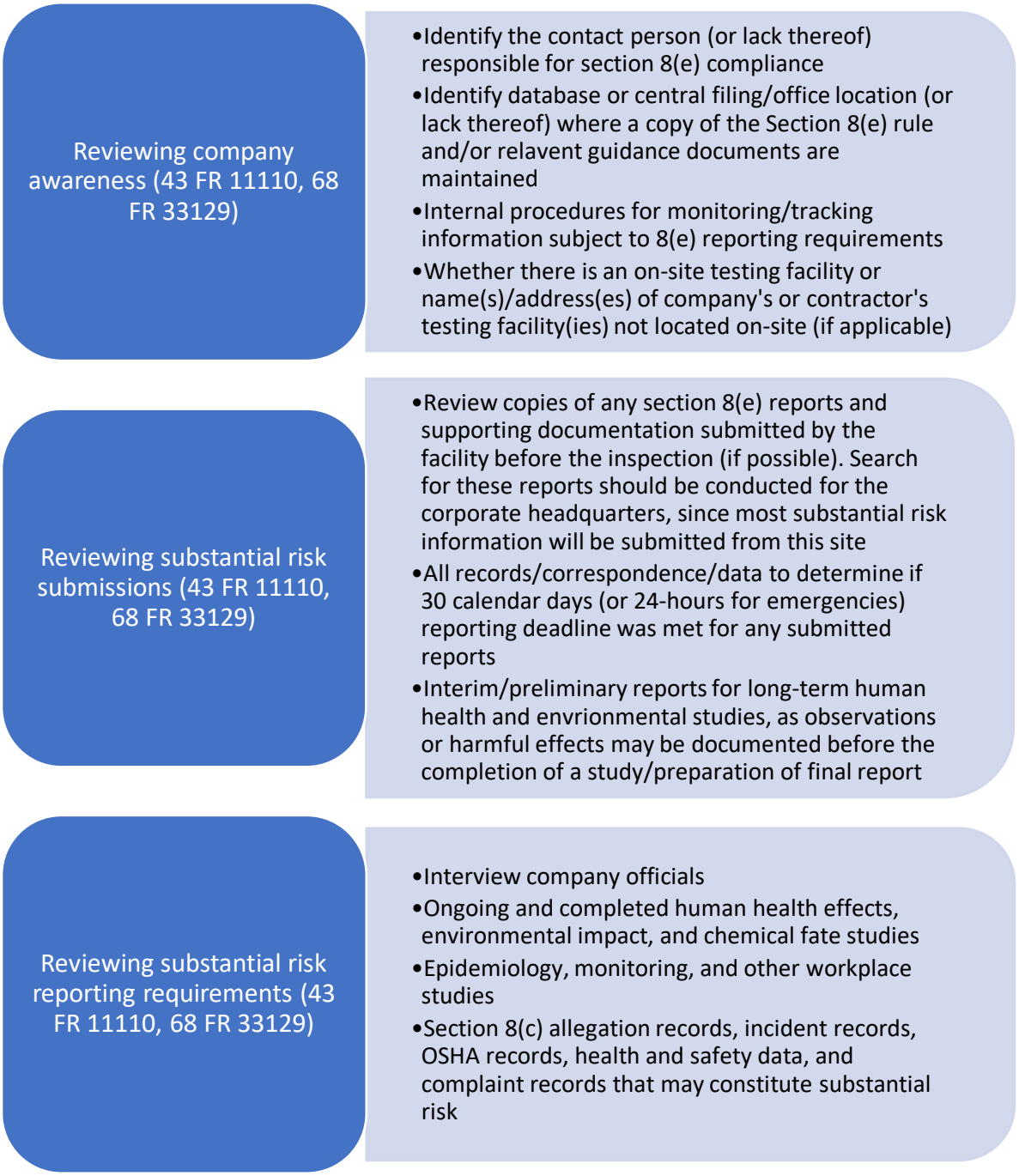
* In 56 FR 28459, EPA suspended the applicability of Part V(b)(1) (i.e., widespread and previously unsuspected distribution in environmental media) and Part V(c) (i.e. emergency incidents of environmental contamination) of the TSCA 8(e) Policy Statement in determining the type of information to be submitted under section 8(e).

As part of TSCA section 8 records review, the inspection team should request and ascertain a description of how the facility evaluates whether any section 8(e) reporting is required. If the facility has submitted any section 8(e) substantial risk reports, the inspection team should review the documentation to ensure it is accurate and was submitted correctly. Figure 4-7 below provides a list of documents and discussion points to review to assess compliance with section 8(e) reporting requirements.

Tip: *The inspection team should request a copy of the TSCA section 8(e) corporate policy and copies of corporate TSCA 8(e) procedures and any relevant SOPs or procedures, including a description of the corporate structure for conducting health and safety studies and a description of how, where, and by whom records of health and safety studies are normally kept.*

Additionally, the inspectors should identify any failures to meet TSCA section 8(e) reporting requirements by the facility. This includes any harmful effects suspected to have been observed earlier than reported, studies aborted due to deaths or poor health of study animals, or ongoing studies for which harmful effects are evident, but no report has yet been submitted.

Figure 4-7. TSCA Section 8(e) Records Review Summary



Inspectors should request the documents and information listed in the corresponding section of Figure 4-7 when performing section 8(e) records review at facilities that appear not to have reported substantial risk information. If these records suggest substantial risk information was not reported, the inspection team should document and obtain copies of the supporting information and data.

Section 12 Review

During the general inventory review described in Chapter 4 General Information Review, the inspection team should have identified chemicals the facility exports that are subject to export notification requirements under TSCA section 12(b). The inspection team should request a record of each notification submitted by the facility and should compare the date of notification to the date of the intent to export and the date of export.

The inspection team should verify that the notification was prior to the first shipment of the chemical or mixture to a particular country for each chemical subject to the following:

- An order, pending action, or relief that has been granted under TSCA section 5(e);
- A proposed or promulgated rule under TSCA section 5(a)(2); or
- Submission of data under TSCA section 4 or 5(b).

The inspection team should verify the notification was prior to the first shipment of the chemical *within the calendar year* to a particular country for each chemical subject to the following:

- An order, pending action, or relief that has been granted under TSCA section 5(f);
- A proposed or promulgated rule under TSCA section 6; or
- An action that is pending or relief that has been granted under TSCA section 7.

IMPORTANT: *Export notifications sent to EPA must be postmarked within 7 days of forming the first intent to export or the first date of export (whichever is earlier).*

Tip: *The inspection team should review the date the relevant TSCA action was proposed when comparing export dates to the date the export notification was submitted. Exports that occurred prior to EPA proposing the action were not subject to the 12(b) notifications requirements.*

When reviewing export documentation, the inspection team should request the actual export shipping documentation or have facility representatives show actual exports tracked through their Enterprise Resource Planning (ERP) system (or other data management system) as proof of the export dates. The inspection team should not accept spreadsheets compiled for the inspection as sufficient evidence that the export notifications were submitted on time. If exports occurred prior to notification, the inspection team should make note of the number of shipments that occurred prior to the notification and the date of each such shipment. The inspection team should request facility representatives also provide the shipping documents for each shipment that occurred prior to the notification as part of the inspection documentation.

Section 13 Review

A TSCA section 13 review allows the inspection team to confirm the facility has appropriately submitted TSCA certifications (negative or positive) for all imports for which they are the importer of record. The inspection team should ask to review shipping documents for each import shipment of a chemical. If the facility receives many import shipments, the inspection team may choose to review only a subset of the import documents (including TSCA certifications) during the inspection and collect the remainder as follow-up documentation. Blanket certifications are no longer accepted.

> ***Tip:*** *Importers are required to provide an electronic certification as a written declaration on the commercial invoice in the Automated Commercial Environment (ACE) for each entry (each individual shipment) indicating a positive or negative declaration.*

> ***IMPORTANT:*** *Some facilities may choose to use a broker to handle imports for them. In these cases, the inspection team needs to determine the appropriate importer of record and party responsible for completing the import certifications. The facility is often still the importer of record and liable for the import certifications, even if the broker ultimately completes the certifications. However, in some instances the broker (or other party) is the importer of record. The recipient on the bill of lading for a shipment is a general indication of the responsible party.*

When reviewing positive TSCA import certifications and shipping documents, the inspection team should check for the following:

- Date on the certification matches the date on the shipping labels (provided the facility submits per shipment);
- The chemical(s) on the import certification match the chemical(s) in the shipment; and
- The chemical(s) are listed on the TSCA Inventory (may have been identified during the general Inventory review described in Chapter 4 General Information Review and/or during the section 5 review).

TSCA import certifications submitted through ACE by the importer of record or a broker may not be available to review during an inspection and follow-up may be necessary. A search of ACE filings as part of pre-inspection activities may provide this information prior to the inspection.

If the facility completed a negative TSCA import certification, the inspection team should confirm that the imported chemical meets one of the following conditions:

- It was imported solely for the use as a pesticide as defined by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA);
- It was source material, special nuclear material or byproduct material as defined by the Atomic Energy Act;
- It was imported only for use as a firearm, shell, or cartridge (taxable under § 4181 of the Internal Revenue Code of 1954); or
- It was imported solely for use as a food, food additive, drug, cosmetic, or device as defined by the Federal Food Drug and Cosmetic Act.

> ***Tip:*** *EPA has prepared a TSCA section 13 Import Compliance Checklist for industry members which may be useful for the inspection team in identifying potential compliance issues. The document can be found here.*

Similar to export document reviews, when reviewing import documentation, the inspection team should request actual import shipping documentation or have facility representatives show actual imports tracked through their ERP (or other data management system) as proof of import dates and the chemicals imported. Spreadsheets compiled for the inspection should not be accepted as sufficient documentation of all imports for which the facility is responsible or evidence that the import certifications were submitted with the proper shipments. If the inspection team identifies any potential compliance issues with the certifications, they should request all shipping documents for each import in question.

Formaldehyde Standards for Composite Wood Products

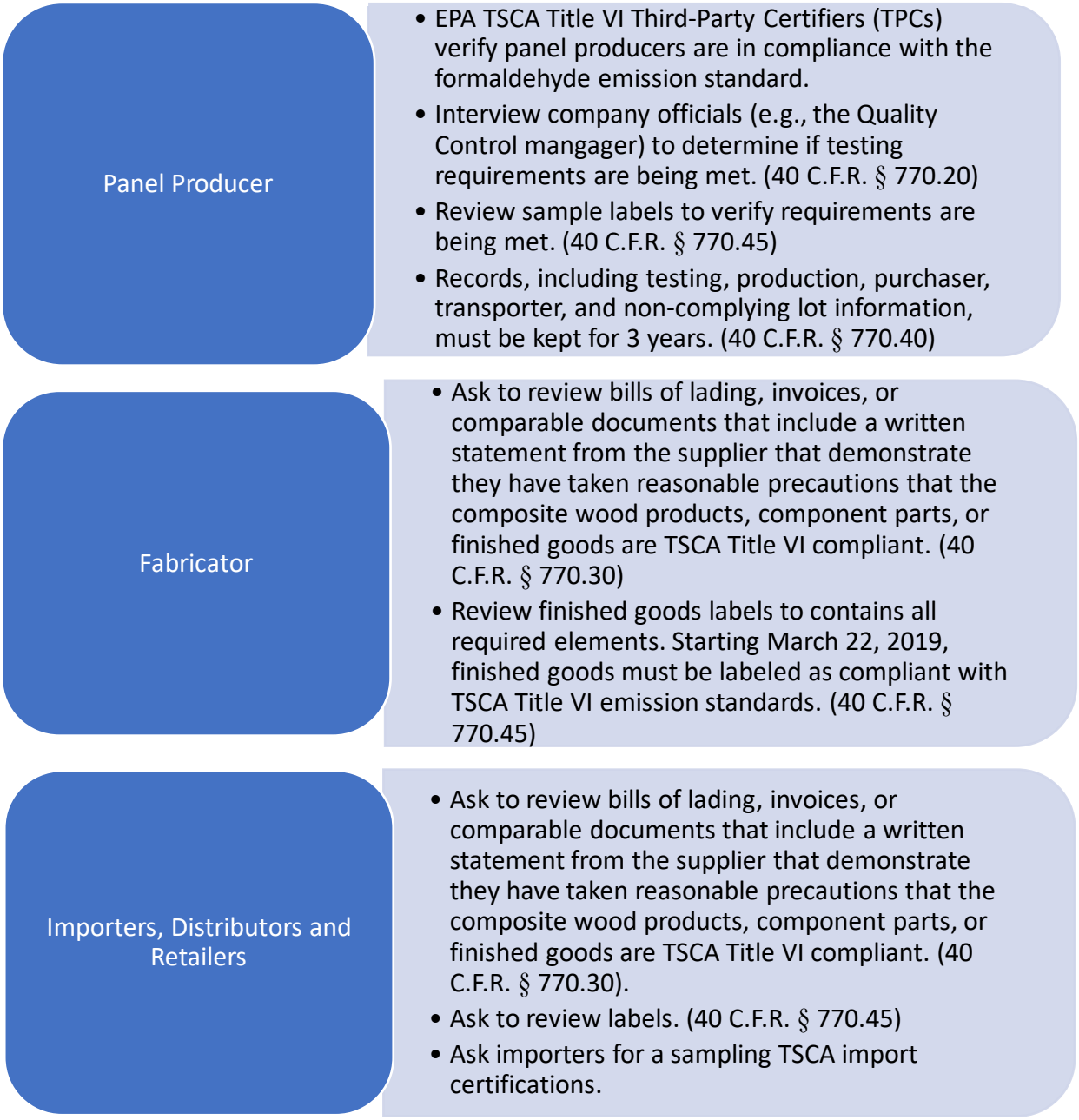
The TSCA Title VI - Formaldehyde Rule review allows the inspection team to confirm if the panel producer manufacturer, including importer, distributor, and/or retailer of composite wood products has taken reasonable precautions to ensure that any composite wood products it sells, supplies, offers for sale, or holds for sale (whether in the form of panels, component parts, or finished goods) comply with TSCA Title VI. This inspection manual does not cover regulatory requirements for Third-Party Certifiers (TPCs).

As part of TSCA Title VI records review, the inspection team should request and ascertain a description of how the facility tracks, records, and reports (if applicable) compliance with the Formaldehyde Rule. Figure 4-8 below provides a list of documents and discussion points to review to assess compliance with Title VI requirements for each regulated universe. A review of these records should be conducted, to confirm compliance.

NOTE: *Until March 22, 2019, regulated products certified as compliant with the CARB ATCM Phase II emission standards must be labeled as compliant with TSCA Title VI or CARB ATCM Phase II emission standards (which are set at identical levels).*

After March 22, 2019, regulated products manufactured in or imported into the U.S. may not rely on CARB reciprocity (40 C.F.R.770.15(e)) and must be certified and labeled as TSCA Title VI compliant.

Figure 4-8 TSCA Title VI Records Review Summary



For panel producers, the inspection team should interview the facility official responsible for ensuring compliance with TSCA formaldehyde rule requirements about its process to maintain certification. The panel producer making the certified product must get inspected by its EPA TSCA Title VI TPC quarterly as well as meet the testing requirements under § 770.20. The inspector should also review sample labels to verify it includes the panel producer's name, the

lot number, the number of the EPA TSCA Title VI TPC, and a statement that the products are TSCA Title VI certified.

For fabricators, distributors, and retailers, the inspection team should verify that the entity has taken reasonable precautions to ensure that the composite wood products they sell, supply, offer for sale, or hold for sale, whether in the form of panels, component parts, or finished goods, comply with the emission standards and other requirements of this subpart by reviewing bills of lading, invoices, or comparable documents that include a written statement from the supplier that the composite wood products, component parts, or finished goods are TSCA Title VI compliant.

For importers, the inspection should review bills of lading, invoices, or comparable documents that include a written statement from the supplier that the composite wood products, component parts, or finished goods are TSCA Title VI compliant and import documents to verify that proper TSCA import certification have been made.

Import Certification Requirements for Formaldehyde Composite Wood Products

TSCA section 13 import certification became effective March 22, 2019. Certification occurs during the import filing process within CBP's Automated Commercial Environment (ACE). Similar to the importation of other TSCA chemical substances, importers must certify compliance with TSCA of formaldehyde composite wood products using the standard the following TSCA section positive import certification statement:

"*I certify that all chemical substances in this shipment comply with all applicable rules or orders under TSCA and that I am not offering a chemical substance for entry in violation of TSCA or any applicable rule or order thereunder"*.

The TSCA Title VI import certification does not apply to chemicals otherwise regulated under TSCA which may be present in those imported composite wood product articles.

TSCA Title VI does not have a negative certification statement. If a shipment has been flagged as potentially subject to TSCA Title VI and is not regulated composite wood product then importers are to use a disclaim code "A" in ACE.

Closing Conference

The closing conference allows the inspection team to summarize the inspection and provide the facility with next steps. This includes completion of the Receipt of Samples and Documents form and Declaration of Confidential Business Information form (EPA Form 7740-1 and EPA Form 7740-2, respectively). The Receipt of Samples and Documents form will provide a list of all documents being collected on the day of the inspection and the Declaration of Confidential Business Information form will document which documents being collected contain TSCA CBI.

IMPORTANT: *During the closing conference, the inspection team should present to the facility representatives any findings identified during the inspection. This may include discussions of the absence or presence of certain documents; however, it should* ***never*** *include discussions of potential violations including linking of findings to specific sections of TSCA.*

The inspection team also should not let facility representatives see or make copies of their notes. This information can only be provided to the facility if they submit a Freedom of Information Act (FOIA) request. Facility representatives are permitted to take their own notes during the inspection.

The best practice for the inspection team is to request facility representatives provide a flash drive or CD containing electronic files for the documents requested in the Notice of Inspection Letter, as well as any additional documents reviewed during the inspection. If the facility is providing both CBI and non-CBI documents, the inspection team should request two flash drives or CDs: one for CBI information and one for non-CBI information. Occasionally, the inspection team may request documents for which electronic copies cannot easily be created. In these instances, the inspection team should ask facility representatives to make a copy of the files and collect the hard copy documents in addition to the flash drive(s) or CD(s). Depending on the inspectors' preferences, they can take the documents with them at the end of the inspection or request that facility representatives deliver the documents directly to their DCO via courier with delivery tracking.

IMPORTANT: *Any CBI documents collected on the day of the inspection need to be marked as such and handled following appropriate TSCA CBI handling procedures. See TSCA CBI Security Manual.*

The Receipt of Samples and Documents form is also used to communicate a list of follow-up documents that were not available during the inspection for which the inspection team is requesting be provided for review after the inspection. The inspection team should review the

list of follow-up documents with facility representatives and agree on a due date for the documents to be delivered. The specific documents and due date(s) should be indicated on the Receipt of Samples and Documents form.

IMPORTANT: *The maximum amount of time the inspection team should give for completing follow-up requests is three weeks. After the inspection, if facility representatives communicate with the inspection team that they need additional time, the inspectors can negotiate a new due date.*

After the inspection team fills out the appropriate information in each form, the lead inspector, and a facility representative (the same representative that signed the NOI and TSCA Inspection Confidentiality Notice form) should sign each form. The inspection team should then request two copies of each of the four forms completed during the inspection. Both the facility and the inspector should have a copy of each form as well as a set of file copies for EPA records. Each form indicates which party should receive the original copy of the form in the lower right-hand corner of the form; the other parties should receive a copy.

Chapter 5 Post Inspection Activities

Contents

Post Inspection Activities

The effectiveness of a Core TSCA compliance inspection depends on many factors, including the thoroughness of the inspection, observations noted by the inspector, the evidence collected by the inspector, and the cooperation of the facility being inspected. After accounting for all documentation requested prior to and during the inspection and any follow-up activities and requests at the conclusion of the inspection, there are four steps that follow the inspection that are critical to the success of the inspection process:

1. Obtaining outstanding requests made during the conclusion of the inspection;
2. Conducting additional necessary follow-up activities;
3. Data/document review; and
4. Preparing the inspection report.

This section discusses follow-up activities and report preparation and provides guidance on what to do with the inspection report once it is completed. Follow-up activities are necessary to ensure that any outstanding data pertaining to the facility and the inspection are obtained as soon as possible following the inspection for inclusion in the inspection report and case file for case development. The primary function of the inspection report is to serve as the main document upon which EPA Case Development Officers (CDOs) will base enforcement decisions concerning the facility. The inspection report should identify those documents requested but not yet received or reviewed at the time the inspection report is completed.

Follow Up Activities

Requests for Follow-Up Information

Follow-up activities include obtaining answers to questions that were not addressed during the inspection or obtaining outstanding relevant documents. It may be necessary for the inspector to collect information that clarifies data already obtained. To obtain such supplementary information, it is recommended that follow-up activities be documented by, for example, sending a letter or email requesting that the outstanding information be submitted. It is advisable to set a specific time frame for the regulated entity's response so that inspection activities can be concluded in a timely manner. Ten business days is appropriate in most cases. A follow-up visit may be required in some circumstances.

> ***Tip:*** *The inspection team should discuss each requested follow-up document prior to ending the closing conference. This will ensure that facility representatives have a clear understanding of all the requested documents and give them the opportunity to inform the inspections team of potential difficulties or issues that could arise and cause a delay in delivering the documents to EPA.*

The purpose of conducting follow-up activities is to ensure that facility representatives follow-up on EPA's requests for the facility to supply missing data concerning the inspection. Before preparing the inspection report, the inspector should compile and account for all of the documentation requested from the inspection. Note that the Interim Policy on Inspection Report Timeliness and Standardization requires that inspectors should compile and account for all of the documentation requested from the inspection in the inspection report and provide the inspected facility with the finalized inspection report within 60 days of the inspection. Moreover, additional questions may arise

after reviewing the documentation provided that may indicate that the company has not in fact provided the information requested. This request and related requests should be included in the inspection report. The inspection report should also document what information has been received that has not been reviewed and indicate if there are outstanding requests that have not yet been received and reviewed.

An inspection report does not need to include new information requested by the inspector after leaving a facility through a formal or informal information request based on analysis of inspection documents as these are considered part of the process for case development.

Requests for Information from Other Sources

Before preparing the inspection report, all documentation from the inspection should be compiled. Documentation includes records/reports maintained by the facility, the investigation summary, observations made by the inspector, affidavits (if taken), samples (if taken), laboratory analysis reports, and photographs. Some of these documents will be made part of the inspection report. In some situations, additional documents or information may still be needed by the inspector to complete the inspection report. These may include:

- Additional documents or information requested after the inspection, when further review of collected information or records by the inspector indicates that such information is needed;
- Copies of additional pertinent records, data, or correspondence that are located by the facility representatives after the inspection;
- Copies of any relevant documents or correspondences between EPA and the facility concerning certain submissions (e.g., CDR reportability, PMN or exemption submissions, etc.);
- Copies of data, records, or other documents available from another facility of the company; and
- Voluntary written statements by personnel of the inspected facility regarding findings and recommendations given by the inspection team during the closing conference.

While conducting follow-up activities, the inspector should attempt to obtain answers to questions that were not addressed during the inspection and to obtain outstanding relevant documents. The inspector should focus on obtaining information necessary to fill in such gaps in material already obtained from EPA records and/or the facility pertaining to facility operations and compliance with TSCA. The inspector should also collect information that clarifies the data already in the inspector's possession.

Other follow-up can be through EPA Headquarters (late reports), other contacts suggested onsite, or other program offices, if warranted. For example, the inspector may need to search the confidential TSCA Inventory; this search would be performed by OPPT.

Referrals to Other Enforcement Programs

There may be instances in which an inspector may identify potential violations of other statutes and may need to make a referral to another part of EPA or another agency. Based on the nature of the potential violation, the inspector should follow-up with the applicable EPA or State program office or other Federal or State agency, following regional office procedures.

Inspection Report

An inspection report is a document written by the inspector that includes accurate and objective observations and environmental conditions during a field inspection, along with other associated information from an inspection, that may be used to determine a facility's compliance with environmental regulations.

The purpose of the inspection report is to present a complete and factual record of the inspection process from opening conference, through the inspection/collection of data and samples, to closing conference. The inspector should keep in mind that the report should contain enough information about the facility and the inspection (as well as observations made during the inspection) to enable CDOs to make enforcement decisions pertaining to the subject facility and to develop a case, as necessary.

The report shall not contain any opinions of the inspector and shall not make any conclusions of law. However, the inspection report must contain information and documentation about the inspection that will enable a CDO to determine:

- The facility's compliance with TSCA, and
- That the inspector followed statutory and regulatory requirements including:
    - Presenting credentials,
    - Issuing a Notice of Inspection, containing a reason for the inspection,
    - Consent to enter private property, if applicable,
    - Collecting evidence and issuing a Receipt for Samples,

- Managing Confidential Business Information.

IMPORTANT: *The inspection report should only include details of what occurred during the inspection and any reviews of follow-up documents received immediately following the inspection. It should list findings/observations made during the inspection and review of follow-up documents; however, it should* ***never*** *make conclusions on violations.*

The inspector should prepare the inspection report as soon as possible following the inspection. EPA guidance on Interim Policy on Inspection Report Timeliness and Standardization states that the report be finalized within 60 days of the inspection.

Writing the Report

Step 1—Plan

By planning how facts must be presented in the inspection report prior to the inspection, the inspector can improve the quality of the inspection report as well as the inspection itself. It should be noted that some elements that will need to be included in or with the report (i.e., samples analysis) may not be available at the time of report preparation. Do not delay preparing the report while waiting for sample analysis. Sample analysis can be added as an exhibit to the report when it becomes available.

Tip: *EPA typically uses a standard report template for TSCA inspections that will help the inspection team plan the report and organize the information in an appropriate manner.*

Step 2—Organize the Material

All information gathered during the inspection must be reviewed for relevance and completeness. This includes inspection report forms, field notebooks and checklists. The field notebook and/or inspection checklists are useful tools for developing the narrative report but cannot replace a narrative report. Any identified gaps in the information must be resolved by follow-up information requests or follow-up inspections and identified in the inspection report as an outstanding item. The material must then be organized in the order that it will be presented in the report.

Step 3—Write

While writing the inspection report, keep the following in mind:

- The inspection report should be a complete record of what occurred at the inspection, including conversations that took place, documentation that was collected and physical samples that were collected. Photographic evidence should be included when appropriate.

- Just report the facts as to what was observed. Do not include opinions or conclusions of law. Keep the reader in mind. When preparing an inspection report, assume that the reader knows nothing about the case except what is in the report. The report must construct a complete and accurate picture of the entire inspection, step-by-step.
- The report should be peer-reviewed before it is finalized.

Step 4—Evaluate

After writing the report, review the report from the viewpoint of the reader and answer the following questions:

- Does it answer the questions—who, what, when, where, why, and how?
- Is each asserted fact supported, with a citation provided, by a document, picture, sample, recorded observation, or statement from an individual?
- Is it fair, concise, complete, accurate and logical? Is any part ambiguous?
- Does it communicate clearly?
- Is there any other information needed to fulfill the purpose of the investigation?
- Can supervisors and reviewers make appropriate decisions based on this report?
- Are any further inquiries necessary?

Proofread the report to check for inconsistencies, unnecessary repetition, tone, omissions, and typographical errors.

Step 5—Rewrite

Correct those portions of the narrative that were identified as needing improvement.

Essentials of A Good Report

- **Fairness**—The report must be objective, impartial, unbiased, and unemotional. Convey facts so they speak for themselves. To test for fairness, read the material aloud to ensure the report is conveying the proper tone for the reader and the purpose of the report.
- **Accuracy**—The information must be stated precisely and accurately in plain language. The inspection report must under no circumstances include the inspector's conclusions regarding compliance or noncompliance. The goal is to present the facts clearly.
- **Completeness**—Include all information observed. Something that may seem irrelevant at the time of the inspection may prove relevant later on. All known facts should be reported either in the text or as an attachment, so that no further explanation is needed. The report must answer the questions "who, what, when, where, why and

how." Each asserted fact should be supported, with a citation provided, by a document, picture, sample, recorded observation, or a statement from an individual.

- **Sources of evidence**—Always report the source of information (including their job title) and document where samples were obtained.
- **Attachments**—The report will consist of a narrative portion with appropriate attachments that are labeled and consistently referenced in the report so that they are easy to follow and find. The attachments will support and document that the inspector followed statutory requirements and will be used as the basis to make a decision as to a facility's compliance status. Always reference attachments parenthetically in the narrative portion of the report and consecutively number in the order mentioned.
- **Facts indicating weaknesses in the case**—Explanations from the individuals being interviewed or important facts that point to weaknesses in the case should not be omitted. Subsequent disclosure of facts indicating weaknesses that were known by the report writer but not disclosed may compromise any potential enforcement action. Disclosure of any potential weaknesses in the report will give reviewers an opportunity to determine the appropriate a course of action.
- **Conciseness**—Concise writing includes facts, details, and necessary explanation, but is free of all that is elaborate or non-essential. Conciseness is not what is said, but how it is said. Use short sentences with active verbs and paragraphs whenever possible.
- **Clarity and logical presentation**—The report must be written clearly in order to avoid misinterpretations. Writing takes time and effort. Order thoughts and arrange them logically and select the words that will best convey the thoughts to the reader.

Elements of the Inspection Report

While inspection reports may vary in general content and format, certain elements should be contained in each inspection report to ensure that necessary information is not inadvertently overlooked, see Interim Policy on Inspection Report Timeliness and Standardization and The EPA Quality Assurance Field Activity Procedures (QAFAP) for common elements that should be included in the inspection report. The report should always contain enough information so the reader can determine:

- The date of the Notice of Inspection letter and request for information;
- The specific reason for the inspection (neutral or for cause);
- Participants in the inspection;
- Date/time of inspection;
- Compliance with all required notices, receipts, and other legal requirements, including:
    - Consent to enter received by authorized official,
    - Notice of Inspection,

    - TSCA Inspection Confidentiality Notice,
    - Receipt for Samples and Documents,
    - Declaration of Confidential Business Information
- Inspection events (in chronological order);
- Statements, records, physical samples, and other evidence obtained;
- Specific facility information, including
    - Company name, address, and telephone number,
    - Names, titles, and telephone numbers of facility officials and/or representatives,
    - Primary SIC/NAICS code,
    - Type of facility,
    - Number of employees,
    - Approximate sales (year),
    - Organizational structure,
    - Special facility entry requirements, and
    - Corporate structure (e.g., headquarters, subsidiaries);
- Observations made; and
- Results of sample analyses (when appropriate).

The report should also include relevant historical information and any knowledge of prior violations obtained during the pre-inspection process. The inspector should keep in mind that the report should contain enough information about the regulated entity, inspection location facility and the inspection to enable adequate enforcement decision-making. The inspection report should provide notice to the inspected facility about potential non-compliance simply by stating the facts and observations made during the inspection.

Oftentimes, an addendum to the finalized inspection report may be necessary to sufficiently provide a more complete review of the inspection files and any subsequent post inspection documents received after the inspection.

The inspection report should not, under any circumstances, include the inspector's conclusions regarding compliance or noncompliance, as providing conclusions as to the statutory or regulatory compliance is outside the scope of the inspector’s duties. The reason for this is that in an enforcement case, the entire inspection report is subject to discovery by the opposing side. If conclusions or opinions are in the report, it may weaken the inspector's credibility by suggesting bias. In addition, the inspector may misidentify one or more violations that EPA does not pursue. This could be revealed through discovery and would again weaken the inspector's credibility.

In writing the report, the procedures used in, and the findings resulting from, the evidence-gathering process should be recorded in a factual manner. The report should refer to routine procedures and practices used and describe in detail the facts relating to potential violations and discrepancies but should not suggest or conclude that there may be or are potential violations.

Releasability of Written Reports and Records

Per the Interim Policy on Inspection Report Timeliness and Standardization, June 29, 2018 memo issued by OECA, inspection reports are required to be released to the facility and the public upon finalization. Furthermore, the regulated community may make requests for copies of written reports and records associated with inspections. The Freedom of Information Act (FOIA) governs the disclosure of information to industry and the public and is discussed in Chapter 1. Do not release any notes, documents, reports, etc. obtained or prepared in connection with a TSCA inspection until authorized.

CBI Considerations

All documents and other materials that have been claimed CBI are stored with the DCO 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 CBI.

In preparing the inspection report it is recommended that CBI be referenced in a non-confidential manner (i.e., by Document Control Number and a general description of the information contained in the document). Per the Interim Policy on Inspection Report Timeliness and Standardization, inspection reports are to be free from CBI and PII. A sanitized (non-TSCA CBI) version of the inspection report, therefore, must be prepared for all TSCA CBI inspection reports.

Supporting Documentation

The inspector may find that the field notebook, pictures, videos and/or an inspection checklist are useful for developing the narrative portion of the inspection report. These tools can help the inspector recall and include in the narrative important details concerning the inspection.

Field Notebooks

The field notebook is an important record in inspection documentation. The field notebook (preferably bound) is part of the Agency's files and is not the inspector's personal record. Notebooks must be held indefinitely as supporting documentation to the inspection file. The

field notebook is intended to provide accurate and inclusive documentation of all inspection activities and to provide a basis for written inspection reports. Inspectors shall record only facts and pertinent observations using objective language, free of personal feelings.

It is essential for the inspector to keep detailed records of inspections, investigations, samples collected, etc. to serve as an aid in writing reports and giving testimony. The following types of information shall be included in the field notebook:

IMPORTANT: *Field notebooks are part of the inspection files and can be used as evidence in legal proceedings against a facility. The inspection team should always be cognizant of that as they take notes throughout the inspection.*

- **Observations**. Record all conditions, practices and other observations that will be useful in preparing the inspection report or will contribute to establishing valid evidence.
- **Unusual conditions and problems**. Note and describe in detail any unusual conditions and problems encountered during the course of the inspection visit.
- **General information**. List names and titles of personnel encountered and the activities they perform, along with any statements they may have made and other general information.

Inspectors should have separate field notebooks for each inspection, and they should be included in the case file.

Photographs

Photographs are valuable as evidence as they provide an objective record of the conditions at the time of inspection. EPA encourages inspectors to use high-resolution digital photography to document the products and devices observed during inspection. When taking photographs during an inspection, follow these steps:

- Follow the guidelines in the EPA Digital Image Guidance for EPA Civil Inspections and Investigations.
- All photos should be recorded on the EPA Photo Log.
- Chain-of-custody procedures apply to photos. Keep all digital and/or original hard copy photos in a secure location and do not alter photos in any way. If an alteration is necessary (cropped, enlarged, etc.), save a copy of the original for reference.
- 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, such as a person, car, coin, or ruler will help indicate the size of the subject. This is known as using a reference by which to judge size, distance, or location.

- Do not take photographs of written records or reports that are or may be considered CBI.
- Videography is also appropriate in enforcement documentation. The same recommendations apply to videography as apply to photography.

Chapter 6 Case Development and Enforcement

Contents

Role of the Inspector in Case Development

The inspector plays an important role in case development and enforcement support. In some instances, the inspector and the case development officer (CDO) are one and the same. It is critical that the inspector prepare the case file as if the case were to go to hearing. The role of

the inspector in case development and enforcement includes assisting the CDO and/or enforcement personnel with some or all of the following:

- Determining if evidence has been obtained lawfully;
- Evaluating evidence to ascertain that the Agency's burden of proof has been met and lawfully gather further evidence necessary to support the Agency's burden of proof;
- Selecting, preparing, and initiating an enforcement action in accordance with Federal law and EPA policy;
- Providing compliance and technical support to litigation team;
- Monitoring compliance with enforcement agreements;
- Evaluating the evidence for potential criminal activity.

Case Development Overview

In general, case development consists of reviewing and verifying the documentation submitted as part of the inspection and any follow up activities post inspection for compliance with the appropriate statutes and regulations. In many instances, case development officers should cross reference documents provided by the facility with public and confidential databases, such as the public inventory, export notification list, sunset dates of chemicals list, system of registries or use the Virtual Desktop Interface (VDI) to access the CBI LAN to review submitted PMNs, NOCs, or CDRs and other notifications submitted to EPA. In certain circumstances, CDOs should obtain certified statements from OPPT concerning when certain submissions (e.g., CDR, PMN) were received, and certified statements concerning the Inventory status of specific chemicals.

> ***Tip:*** *The CDO should work closely with the inspection team to ensure they have the same understanding of findings and observations from the inspection and follow-up activities. The inspection team can also brief the CDO on any outstanding items needed from the facility.*

As a general rule, CDOs should first determine the applicability of TSCA by identifying all chemical substances and/or mixtures manufactured, imported, processed, and exported by the facility. Chemical substances and/or mixtures, such as pesticides or cosmetics, that qualify for exclusions from TSCA and fall within the purview of FIFRA or the FDA, for example, should be excluded from the case investigation. Several other exclusions are provided in section 3(2)(B), including (i) mixtures, (ii) pesticides, (iii) tobacco and tobacco products, (iv) nuclear materials and byproducts, (v) pistols, firearms, revolvers, shells, cartridges, certain ammunition (bullets and shot), (vi) food, food additives, drugs, cosmetics, and devices. In addition to a review of all chemical substances and/or mixtures manufactured, imported, and processed by the facility for

inclusion on the public and confidential TSCA Inventories, further investigation may be necessary to determine TSCA applicability. It may be prudent for CDOs to identify all chemical substances identified in a manufacturing process from the Process Flow Diagrams (PFDs) starting with raw materials, intermediates and ending with the final products.

Enforcement Overview

Inspectors perform a vital role throughout the regulatory enforcement process. Most enforcement actions begin with the inspector collecting and documenting on-site evidence. Inspectors contribute to the strong cases that EPA files by conducting quality inspections, ensuring any necessary follow-up actions are taken, and clearly documenting the inspection results. Inspectors' collection and documentation of evidence during and after an inspection is the basis for a strong enforcement case. Any inspection may result in an enforcement action. Therefore, inspectors should approach each inspection as if it will go to trial. Case Development Officers rely on the inspection report and other documents prepared by inspectors to identify violations and build enforcement cases. Inspectors may also be called upon throughout the case development and enforcement processes for clarification and supporting documents/evidence. In rare cases, an inspector may be called upon to provide testimony in an active case.

> ***Tip:*** *Legal proceedings resulting from inspections can occur years after the inspection. However, note that there is typically a 5-year Statute of Limitations (SOL) regarding when an enforcement action may be issued. In addition to the inspection report, the inspection notebook is an invaluable tool to help the inspector remember the activities and reviews that occurred during the inspection. Therefore, it is vital that the inspection team take notes that are clear and detailed throughout the inspection process and not trust that they will remember events that happened several years prior.*

Role of the inspector in enforcement:

1. Follow all jurisdictional requirements of the statute to insure lawful entry.
2. Lawfully gather all evidence necessary to support the Agency's burden of proof.
3. Arrange all evidence collected so it may be evaluated to determine the appropriate enforcement action.
4. Provide declarations and testimony if needed to support Agency's action.

Civil Enforcement

Many TSCA violations are resolved through administrative civil penalty actions. TSCA does not explicitly authorize federal courts to entertain an action or suit in which a civil penalty is sought.

Section 16(a)(2)(A) of TSCA, 15 U.S.C. § 2615(a)(2)(A) states that "[a] civil penalty for a violation of Section 2614 or 2689 [of TSCA] shall be assessed by the Administrator [of the EPA] by an order made on the record . . . ." Section 17 of TSCA, 15 U.S.C. § 2616 explicitly provides district courts with jurisdiction to restrain violations of TSCA or its implementing regulations, to compel actions required by TSCA, or to seize and condemn any chemical substance, mixture, or product manufactured, processed, or distributed in violation of the provisions of TSCA. This type of relief is known as injunctive relief. EPA does not have authority to seek injunctive relief from an administrative tribunal.

EPA typically initiates civil proceedings for penalties by filing an administrative complaint with the Office of Administrative Law Judges (OALJ), or initially, a Regional Judicial Officer (RJO) for regional cases pursuant to the procedural rules set forth in 40 C.F.R. Part 22. The Part 22 "Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits" govern all administrative proceedings for the assessment of an administrative civil penalty under TSCA.

Prior to initiating an administrative enforcement action, a case must be thoroughly developed from a technical and legal standpoint; this includes gathering supporting evidence and applying the appropriate Enforcement Response Policy to calculate the penalty, among other things. Case attorneys may decide based on the facts of the case to pursue prefiling negotiations or to issue a complaint. An administrative enforcement action is initiated by filing a complaint, followed by an answer to the complaint and settlement or hearing.

Prefiling Negotiations

Prior to filing an administrative complaint, the case team my opt to engage in "prefiling negotiations." EPA may contact the Respondent to notify them of the alleged violations and give them an opportunity to respond and consider settlement.

Prefiling negotiations also offer the case team a chance to assess the respondent's interest in settlement as well as the defenses and arguments they are likely to raise should EPA litigate the case. As the case team obtains new information about the respondent's arguments, the inspector and/or CDO may need to clarify or provide additional details regarding the inspection.

Often, cases will settle during this prefiling negotiation stage. If this occurs, a complaint is not filed and the parties instead rely on a Consent Agreement and Final Order (CAFO) to identify the alleged violations, specify the penalty to be paid and resolve the case. Information from a TSCA inspection is critical, not only to the identification of violations, but also to the penalty calculation.

Settlements

Pursuant to 40 C.F.R. § 22.13 (b) of the Consolidated Rules of Practice where the parties agree to settlement of one or more causes of action before the filing of a complaint, a proceeding may be simultaneously commenced and concluded by the issuance of a consent agreement and final order pursuant to 40 C.F.R. § 22.18(b)(2) and (3). EPA encourages settlement of cases at any time. To prepare for settlement discussions, the case team will rely heavily on documents prepared by the inspector and may rely on the inspector to interpret and clarify such documents. Respondents are encouraged to come into compliance with TSCA regulations as soon as possible during settlement negotiations with EPA. Of the cases that do not settle, a substantial majority of the legal actions take place in the EPA administrative law system rather than in federal courts. Major differences distinguish administrative from federal courts, such as rapid processing and the absence of a jury. Despite the differences between these two legal proceedings, the inspector's role in the enforcement process and as a witness will remain predominantly the same. For purposes of this manual, the Administrative process will be the focus.

Consent Agreements

Consent Agreements and Final Orders (CAFO) are used to conclude an administrative case. A CAFO only becomes enforceable upon signature of the Final Order by either the Environmental Appeals Board (EAB) at headquarters or the Regional Judicial Officer (RJO) for regions. A CAFO can be executed before or after a complaint has been filed. If a complaint has not been filed prior to a CAFO, then the consent agreement must also set out the allegations for each violation. Consent agreements signed by all parties or their representatives are used to record any and all terms and conditions of the settlement. It is important that the consent agreement accurately describe the alleged violations and the facts relevant to those violations. The case team relies on statements in inspection documents when drafting CAFOs, and it is therefore critical that all inspection documents be thorough, precise, and accurate. Civil administrative settlements only resolve those actions described in the settlement and cannot give any release concerning potential criminal violations.

Complaint

An administrative case is commenced by filing a complaint. The complaint must include the factual basis of each alleged TSCA violation, as set forth in 40 C.F.R. § 22.14. The inspection report is the primary source of information regarding the factual basis of the alleged violations identified in the complaint. The case team will rely on information obtained from the inspector to develop a complaint identifying the alleged violations. A complaint may be issued after communication with the regulated entity, based on the facts and findings from an inspection,

following case development by a CDO and review by an EPA attorney. For cases brought in the regions, a Regional Judicial Officer (RJO) initially handles the case. Whereas for cases brought at EPA HQ, an Administrative Law Judge (ALJ) handles the case.

The rules at 40 C.F. R Part 22 set forth the hearing process and identify the timing for: when an answer must be filed by the Respondent; when an Administrative Law Judge (ALJ) gets assigned to the matter; when alternative dispute resolution is available; and the pre-trial, hearing and post-trial processes.

Quick Resolution

A respondent may resolve the proceeding at any time pursuant to 40 C.F.R. § 22.18 by paying the specific penalty proposed in the complaint or in the complainant's prehearing exchange in full as specified by the complainant and by filing with the Regional Hearing Clerk for regional cases and the OALJ hearing clerk for HQ cases, a copy of the check or other instrument of payment. When parties agree to resolve a matter without litigation, they most often do so through a settlement memorialized in a consent agreement. A consent agreement is a resolution to an enforcement case that has been agreed upon by the parties. EPA encourages settlement of cases at any time.

Hearings

If the parties cannot resolve a case through quick resolutions or settlement discussions, the parties will present their respective arguments to a judge at a hearing. As part of the enforcement team, the inspector's knowledge is critical in determining the violations and preparing documents for hearings. Most importantly, the inspector may be called upon to serve as a fact and/or expert witness and may be required to provide testimony and documents in support of EPA's enforcement action.

Preparation for a Hearing

Any inspection may result in an enforcement action. Therefore, inspectors should approach each inspection as if it will go to trial. Preparation is the key to giving accurate and effective testimony. If the inspector is called upon to present testimony to a court, the assigned attorney will meet with the inspector to discuss the scope of the expected testimony. The attorney should explain to the witness what they intend to prove by the inspector's testimony, and how the attorney intends to use any documents or items of potential evidence collected during the inspection. Other items should also be discussed, including the field notebook, photographs, and the inspector's qualifications. The inspector should inform the EPA attorney of any problems, questions, or concerns regarding the case as early as possible. An example of one such concern is the confidential business information (CBI) procedures inspectors must adhere

to. CBI procedures that bind inspectors during inspections also have implications for the legal proceeding.

During one-on-one preparation, the attorney and the inspector should discuss:

- Times and dates that require the inspector's attendance
- Legal etiquette and procedure
- General legal framework of the case
- Significance of the inspector's testimony in this framework
- Probable areas of questioning, including direct and cross-examination
- What documents, if any, will be used by the inspector during testimony

Tip: *Appearing in court can be nerve-racking, especially if it is the inspector's first time. Therefore, it is important the inspector do a proper review of the inspection documents to ensure they are confident in their knowledge of the case.*

Serving as a Witness in a Hearing

The inspector's role in a hearing is to help the judge understand the facts that support why it is appropriate to penalize the Respondent for violations. The inspector will serve as a fact witness by describing what was observed. Expert witnesses may also be called upon to provide expert opinions on relevant matters. The attorney then explains how the facts demonstrate a violation of the law. The attorney may also discuss the harm associated with the violation.

IMPORTANT: *Inspectors are a representative of EPA and should always act professionally, treat both EPA and opposing attorneys with respect, and answer questions honestly.*

As with cases that settle, the case team will rely on the information compiled by inspector and, in addition, may call on the inspector as a fact witness. A fact witness describes personal knowledge obtained through one of the five senses. Everything an inspector hears, sees, samples, or records during an inspection may become evidence about which he or she may be questioned. The inspection report and field notebook thus must be sufficiently detailed and legible to allow the inspector to reconstruct the inspection for the case team and, if necessary, "on the record" in court. If an inspector is called upon as a witness, the EPA attorney will work with the inspector to prepare them for the hearing.

Pre-hearing Exchange

Before any hearing, the ALJ will order the parties to provide "pre-hearing exchange" of information. This exchange includes the name of witnesses along with a short summary of what they will testify to. More importantly the pre-hearing exchange includes any documents that

will be used at hearing. Among those documents is a penalty calculation that applies the facts of the case to the statutory factors using the appropriate policies. The Respondent must file the same pre-hearing documents and explain why a penalty is not appropriate or should be lower than that requested by EPA. If an inspector is to be a fact witness in a case, they would be identified as such in this pre-hearing exchange. This is like "discovery" in a judicial forum where each party may request relevant information from the other side in an attempt to discover pertinent facts.

Direct Examination

Any direct examination of an inspector would be conducted by the EPA attorney. Direct examination provides an opportunity for the inspector to state the facts uncovered and observations made during the inspection. Direct examinations often have open ended questioning such as "what happened?" followed up with "and then what happened?" Before the hearing, the EPA attorney will prepare the inspector by reviewing every question that will be asked during direct examination and every answer the inspector will give. The EPA attorney might also ask, "Is there anything else?" to signal to the inspector that something has been left out.

The EPA attorney will ask the inspector to identify themselves and describe their connection to the case. This will "lay the foundation" for the inspector's testimony. The inspector will then be asked about their first-hand knowledge of pertinent facts in the case. This will establish the inspector as a fact witness and will identify the intended subject of the testimony.

Most inspectors will serve as a fact witness and will testify to what they did, saw and heard. If the inspector will also serve as an expert witness, a foundation will be laid to establish the specialized knowledge or skills that qualify him/her as an expert. Typically, questions that will establish the requisite expertise will focus on education, training, or experience.

Cross Examination

Cross examination is conducted by opposing counsel and is an opportunity for the defense to point out any irregularities with how the case is being handled, or weaknesses in the facts, accuracy of testing, and/or other samples that conflict with the samples the inspection team has used.

The purpose of cross examination is to cast doubt on the direct testimony. This can be done by parsing the regulatory requirements and putting the burden on EPA that the inspector complied with requirements. This often includes casting doubt about observations, showing inconsistencies between testimony and inspection notes, and providing additional data that disputes the facts in your testimony. The inspector should project a calm, professional

demeanor and avoid being defensive. Under cross examination, the inspector will be subject to more vigorous questioning than under direct examination.

Tips for cross examination are provided below:

- Always pause before answering a question to give the EPA attorney an opportunity to object, where appropriate.
- Opposing counsel may try to confuse you or get you angry. This is intentional. Remain calm, do not react, and answer the question to the best of your ability.
- Opposing counsel may ask compound questions (more than one question at a time) or rapid questions. You may ask for clarifications or for questions to be repeated or restated.
- Opposing counsel will deliberately ask questions to elicit a "yes" or "no" answer. However, if you need to elaborate, do so.
- If you make an error while testifying, correct it at the first opportunity during testimony. If you discover the error after you have completed your testimony and have been dismissed as a witness, discuss the matter with the EPA attorney as soon as possible, so that the attorney can include an explanation in post hearing briefs.

IMPORTANT: *If the inspector has been called as a "fact witness" they should ensure all answers they provide during direct and cross examinations pertain only to the facts of the inspections. Providing opinion or professional judgement may inadvertently bring the inspector's credibility into question or contradict the opinion of expert witnesses and weaken EPA's case.*

Criminal Enforcement

EPA may initiate a criminal action in federal court to address *knowing or willful* TSCA violations.

The Criminal Investigative Division (CID) of the Office of Criminal, Enforcement, Forensics and Training (OCEFT) in Washington, D.C., has Special Agents operating out of field offices in all EPA regions.

Any TSCA inspector who detects what he/she believes to be any type of possible criminal environmental violations must bring this fact promptly to the attention of their EPA supervisor and, in turn, notify the EPA criminal enforcement counsel and/or Special Agents.

It is possible that a civil inspector who uncovers a crime will be asked to be a witness in a criminal action. Be sure to consult carefully with your EPA attorney about the way to proceed in such a situation. The criminal rules are very stringent about assuring the accused receives certain information in the government's possession. Similarly, the criminal process is very

protective of certain information such as grand jury proceedings to assure nothing influences the proper administration of justice.

For the inspector, accurate and complete notes, records, and reports are essential for ensuring a successful enforcement action whether administrative, civil, or criminal. Further, notes and records must be factual and contain no opinions, speculation, or biases of the inspector. All materials associated with a criminal investigation must be stored in accordance with security procedures.

Criminal Provisions of TSCA

TSCA section 16(b)(1) makes the knowing or willful violation of any provision of TSCA section 15 punishable as a crime subject to criminal penalties, including a fine and/or a term of imprisonment.

A TSCA inspector should be alert to the fact that the knowing or willful violation of section 15 may represent a criminal case.

In addition, "[a]ny person who knowingly and willfully violates section 15 or 409, and who knows at the time of the violation that the violation places an individual in imminent danger of death or serious bodily injury" is subject to criminal penalties, including a fine and/or a term of imprisonment, under section 16(b)(2). These crimes are applicable to individuals and companies.

TSCA's Relationship to Other Federal Criminal Laws

Environmental crimes cases often involve more than violations of the environmental statutes alone. Frequently, they also include behavior that constitutes criminal culpability under one or more provisions of Title 18 of the U.S. Code for offenses such as false statements, conspiracy, obstruction of justice, mail fraud and wire fraud.

Criminal Enforcement at EPA

OCEFT works closely with DOJ and other federal law enforcement partners; state environmental agencies; state, tribal and local law enforcement agencies; and other EPA programs.

The National Enforcement Investigations Center (NEIC) has specialized laboratories that employ scientists, engineers, analysts, technicians, and environmental and computer specialists to perform the essential science for environmental investigations. The NEIC provides forensic analytical support. Additionally, NEIC provides multi-disciplinary teams that conduct

investigations in support of civil case development. The investigations include multi-media and single-media inspections led by NEIC regulatory and technical experts who work closely with regional and state enforcement partners to identify potential compliance deficiencies.

CID's National Computer Forensics Laboratory (NCFL) has Special Agents trained to seize and analyze digital evidence, such as that found on computers, tablets, and cell phones.

Regional Criminal Enforcement Counsels (RCECs) located in each Regional office work with OCEFT's Special Agents and DOJ in the investigation and prosecution of criminal cases. However, the criminal enforcement program generally cannot discuss grand jury materials or privileged information with its civil enforcement counterparts.

Recognizing Potential Criminal Violations

Core TSCA inspectors should not attempt an in-depth investigatory analysis of whether criminal conduct has occurred or is occurring at regulated sources. Special Agents are specifically trained to collect evidence necessary to support any criminal charges. Core TSCA inspectors should refer to the CID any conduct or action that may potentially constitute criminal violations, such as:

- **Knowing or willful behavior**—defined as criminal under all federal statutes, or
- **Fraudulent reporting**—defined under all statutes and the United States code as criminal behavior.

IMPORTANT: *If the inspector becomes aware that there is a potential criminal violation that occurred at the facility, they should clearly document any evidence to such a finding in their inspection notebooks. They can then review this with EPA enforcement staff (CDO and attorneys) to determine if the observation was indeed a criminal violation. As always, the inspector should never discuss this or any other potential violation with facility representatives.*

It is important to use the phone, rather than email, when analyzing the requirements of law or characterizing the facts of any matter, particularly one that seems likely to involve criminal misconduct. Civil inspectors should be proactive in speaking to criminal agents and prosecutors about possible criminal issues in a case.

The primary factor distinguishing a criminal case from a civil case is the **INTENT of the VIOLATOR**. Environmental crimes are committed either knowingly or willfully. Courts have generally held that "knowing" environmental offenses require knowledge of the facts which constitute the offense, but not knowledge of the law. In other words, the government is required to prove that the violator intended to act as s/he did (i.e., not by accident or mistake),

but does not have to prove that the violator knew such conduct was unlawful. A willful violation, however, means that the violator intended to commit an unlawful act, or engage in the prohibited conduct and knew that the act was prohibited by law or regulation.

TSCA inspectors are in a unique position to identify possible criminal activities such as falsified information in records and reports. Facility staff employees may also volunteer information to inspectors about possible criminal activities. If any of these or other problems raise the inspector's suspicions, he/she should attempt to obtain further information through interviews, observations and records reviews and promptly inform criminal findings to CID. Talk to your supervisor and to EPA counsel to see if it's appropriate to involve CID. Circumstantial evidence can be used to show guilt in a criminal proceeding.

For more information about Criminal Enforcement at EPA, refer to the FIFRA Inspection Manual.

Multiple Remedies

In rare instances, a particular situation will present facts that suggest that more than one final action should be taken.

Parallel Civil and Criminal Proceedings

TSCA includes both civil and criminal enforcement authorities and EPA may use both authorities to identify and resolve TSCA violations. TSCA inspectors should note that the Agency may pursue criminal and civil enforcement actions on separate but "parallel" tracks. Even if the parallel criminal and civil enforcement actions relate to the same violation, EPA maintains a clear distinction between the two proceedings. TSCA inspectors must follow these guidelines when involved in ongoing parallel proceedings:

- TSCA inspectors may continue to collect information/data from potential defendants for a civil enforcement action.
- EPA reserves the right to take criminal or civil enforcement action based on information obtained by TSCA inspectors. Therefore, TSCA inspectors shall never tell a person or entity that EPA will not use the information obtained during an inspection as evidence in a criminal or civil case.
- Direct any questions concerning parallel proceedings to the criminal or civil enforcement counsel at EPA.

Appendix

Appendix A Summary of Key TSCA Regulations

The key Core TSCA Regulations are summarized below.

Part 700—General

40 C.F.R. Part 700 establishes requirements for the collection of fees by EPA from manufacturers, importers, and processors who submit notices and applications to EPA under section 5 of TSCA.

Part 702 - General Practices and Procedures

TSCA section 20 permits any person to file suit against the Administrator to compel EPA performance of any non-discretionary acts or duties, or against any person who is alleged to be in violation of TSCA or regulations promulgated under section 4, 5, or 6 or of any order issued under section 5 to restrain such violation. 40 C.F.R. Part 702 includes the procedures for citizens to provide EPA or the person alleged to have committed the violation with the prerequisite notice of intent to sue.

Part 704 - Reporting and Recordkeeping Requirements

40 C.F.R. Part 704 contains reporting and recordkeeping requirements for certain section 8(a) rules. Subpart A specifies definitions and general reporting and recordkeeping procedures imposed under section 8(a) of TSCA for manufacturers, importers, and processors of chemical substances and mixtures listed in Subpart B (other rules, such as the CDR rule, in Part 711, also use the Part 704 definitions). The Subpart A requirements are applicable to all reporting under Part 704.

40 C.F.R. § 704.5 defines key terms and exempts the following substances from reporting requirements unless the exemption is superseded by any section 8(a) rule:

- Substances identified in this part that are imported or processed or proposed to be imported or processed solely as part of an article.
- Substances identified in this part that are manufactured or imported or proposed to be manufactured or imported solely as part of a byproduct.

- Substances identified in this part that are manufactured, imported, or processed or proposed to be manufactured, imported, or processed solely as an impurity.
- Substances identified in this part that are manufactured or proposed to be manufactured solely as a non-isolated intermediate.
- Substances identified in this part that are manufactured, imported, or processed or proposed to be manufactured, imported, or processed in small quantities solely for research and development.
- Substances manufactured or imported by small manufacturers or importers as defined in the subpart.

40 C.F.R. § 704.7 authorizes any person submitting a notice under this rule to assert CBI claims for all or any part of the notice. 40 C.F.R. § 704.11 requires that the following records be maintained for three (3) years from the date they are compiled by persons subject to the chemical-specific reporting requirements:

- A copy of each report submitted.
- Materials and documentation sufficient to verify or reconstruct the values submitted in the report.
- A copy of each notice sent to customers to inform them of their reporting obligations.
- Return receipts signed by customers who received the notice.

Subpart B establishes chemical-specific reporting and recordkeeping requirements for individual chemicals, under "stand alone" 8(a) rules. These provisions identify the substances for which reporting is required and specify who must report, what information must be reported, a schedule for reporting, and what records must be maintained.

Part 707 - Chemical Imports and Exports

40 C.F.R. Part 707, Subpart B adopts as EPA policy the regulations of the U.S. Customs Service (19 C.F.R. §§ 12.118 - 12.127 and 127.28) that implement TSCA section 13 (Entry Into Customs Territory of the U.S.). See discussion of section 13 above.

40 C.F.R. Part 707, Subpart D implements the section 12 requirement that persons who export or intend to export a chemical substance or mixture notify EPA of the export, in writing, if any of the following actions have been taken under the Act with respect to that chemical or mixture:

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

Depending on which type of action triggered the notification, the notification must be made either one time for each country, or once per year for each country (40 C.F.R. § 707.65). 40 C.F.R. §§ 707.65-67 specify the timing and contents of the notice. Upon receiving a notice of pending export, EPA must notify the importing country of the chemical, regulatory action taken, data available under TSCA section 4 or 5(b), and name of the EPA contact, and provide a copy of the pertinent *Federal Register* notice.

Part 710—Compilation of the TSCA Chemical Substance Inventory

40 C.F.R. Part 710 includes reporting requirements for the establishment of the original TSCA Inventory of chemical substances, as required under section 8(b). This inventory was first published in 1979, revised in July 1980 and provides the basis for distinguishing between existing chemicals and new chemicals for purposes of PMN requirements imposed under section 5. New substances are added to the Inventory following Section 5 premanufacture review, and after a Notice of Commencement is received by EPA (see 40 C.F.R. § 720.102). In the past, Part 710 also included the Section 8(a) Inventory Update Rule (IUR), but the IUR was moved to Part 711, revised, and renamed the Chemical Data Reporting (CDR) rule in 2011.

Part 711 – Chemical Data Reporting Rule

40 C.F.R. Part 711 is the Chemical Data Reporting (CDR) rule, which is an information collection rule authorized by section 8(a). Every four years, EPA collects data from chemical manufacturers concerning where, when, what, and how much of each chemical they produce or import. Information on physical form, uses, and human exposure is also collected. The CDR has several reporting thresholds based on production volume and whether a chemical is subject to certain regulations and includes exemptions for small businesses and certain types of chemicals. Starting in 2012, all CDR data must be reported electronically, using an EPA-provided reporting system.

Beginning in the 2016 reporting period, manufacturers and importers of certain chemicals listed on the TSCA Inventory are required to report information about those chemicals manufactured and/or imported in volumes of 25,000 pounds (11,340 kilograms) or more at their site during any calendar year since the last principal reporting year. The current reporting frequency is every four years.

Also beginning in the 2016 reporting period, the reporting threshold is 2,500 pounds (1,134 kilograms) for chemicals that are:

- Subject of a rule proposed or promulgated under TSCA sections 5(a)(2), 5(b)(4) or 6;
- Subject of an order issued under TSCA sections 5(e) or 5(f);

- Subject of relief that has been granted under a civil action under TSCA sections 5 or 7.

Part 712 - Chemical Information Rules

Part 712 establishes the requirements that implement the Preliminary Assessment Information Rule (PAIR), the Agency's initial model reporting rule under section 8(a). The PAIR consists of a two-page reporting form intended to collect production, use, and exposure-related information on specified chemicals listed in the rule (40 C.F.R. § 712.30). Under the PAIR, manufacturers and importers must report for each site on each listed chemical substance manufactured or imported during the reporting period specified in the rule. Processors are not subject to the PAIR. The following persons or entities are exempt from reporting under the PAIR:

- Persons who manufacture or import a listed substance solely for R&D.
- Persons who during the reporting period manufactured or imported fewer than 500 kilograms of a chemical at a single plant site.
- Small manufacturers or importers (defined as companies with total annual sales from all sites owned by the parent company below $30 million and that produced less than 45,400 kg [100,000 pounds] of the listed substance at the plant or site).
- Persons who manufactured the chemical as a non-isolated intermediate, an impurity, or, under certain conditions, a byproduct.

The elements of the PAIR report include:

- Quantity of chemical manufactured or imported for sale or use.
- Quantity lost to the environment and in wastes.
- Manufacturing processes and worker exposure.
- Manufacturer products.
- Customer uses and products.
- Trade names.
- Customer's process categories.

Part 716 - Health and Safety Data Reporting

40 C.F.R. Part 716 specifies requirements for the submission of lists and copies of health and safety studies under section 8(d). EPA typically requires the submission of this existing data for chemical substances and mixtures that are under consideration for testing rules under section 4(a) and to help fulfill other responsibilities under TSCA.

Manufacturers or importers who fall under the North American Industry Classification System (NAICS) Subsector 325 (chemical manufacturing and allied products) or Industry Group 32411 (petroleum refineries) and who manufacture or import, or propose to manufacture or import a

substance or mixture listed in 40 C.F.R § 716.120 on, or subsequent to, the date the substance is listed must submit existing health and safety studies, as specified in the rule. Persons manufacturing or importing, or proposing to manufacture or import the substances and mixtures in 40 C.F.R. § 716.120 must also submit lists of studies that are ongoing, initiated, and known but not in possession, as well as unpublished studies sent to a federal agency without claim of confidentiality. General exclusions for certain kinds of studies and chemical-specific reporting requirements are listed in 40 C.FR. §§ 716.20 and 716.21.

Part 717 - Records and Reports of Allegations that Chemical Substances Cause Significant Adverse Reactions to Health or the Environment

40 C.F.R. Part 717 implements section 8(c), which requires that manufacturers, importers, and processors of chemical substances and mixtures maintain records of significant adverse reactions to health or the environment alleged to have been caused by a chemical substance or mixture. The manufacturers, importers, and processors must allow EPA to inspect these records and/or must submit them to EPA when the Agency requests that they be submitted by letter or notice in the *Federal Register*.

Manufacturers are subject to this part, as are processors who produce mixtures (i.e., formulators) or who repackage chemical substances or mixtures (i.e., repackagers). The following persons are exempt from maintaining allegation files (40 C.F.R. § 717.7):

- Persons whose manufacturing activities consist of mining or other solely extractive functions.
- Persons who are solely distributors. If a distributor also repackages chemicals or mixtures, then the distributor is a processor and not exempt from the rule.
- Persons who are retailers of a chemical substance unless such persons are also manufacturers or processors who are subject to the rule.

An allegation subject to this part may be written or oral and consists of a statement made, without formal proof or evidence, that a chemical substance or mixture has caused a significant adverse reaction to health or the environment. Significant adverse reactions include reactions that may indicate a substantial impairment of normal activities, or long-lasting or irreversible damage to health or the environment. Known human health effects are exempt from these recordkeeping and reporting requirements, as are environmental impacts that are directly attributable to a spill, discharge, permit violation or other incident that must by law be reported to the federal government. All allegations received by persons subject to this part made after November 21, 1983 are covered.

Records of significant adverse reactions should be kept at the firm's headquarters or at any other appropriate location central to the firm's chemical operations. The records must contain the original allegation and an abstract, the name and address of the plant, the date the allegation was received, the implicated substance, process information, description of the alleging party and the alleged health effects, description of environmental effects, results of company investigations, and required records and reports. Employee allegations must be kept on file for 30 years; allegations by others must be kept for 5 years.

Part 720 - Premanufacture Notification

40 C.F.R. Part 720 establishes requirements and procedures for reporting information on new chemical substances by manufacturers and importers, as required under TSCA section 5.

Any chemical substance not listed on the TSCA Inventory is a new chemical. Manufacturers of chemicals that are not excluded or exempt from TSCA requirements or from the PMN requirements must submit a PMN 90 days prior to commencing commercial manufacturing or importing activities. EPA has 90 days (which may be extended by EPA up to 180 days for good cause) to review the PMN. The Lautenberg Amendments now require EPA to make a determination before the submitter may submit a notice of commencement.

The manufacturer or importer must submit a NOC of manufacture or import within 30 days after commencing manufacture or import. (The NOC is due 30 days after commencement of manufacture, regardless of whether the manufacture starts on day 91, or sometime later.) Upon receiving the NOC, EPA will add the PMN substance to the TSCA Inventory.

PMN exemptions are listed in 40 C.F.R. § 720.30. 40 C.F.R. § 720.22(b)(1) also provides that chemical substances imported as part of an article are not subject to PMN requirements.

Information that must be provided in the PMN form includes the submitter's identity; the specific chemical identity; production, import, and use information; worker, user, and consumer exposure information; environmental fate information; and health and safety studies. This information must be provided to the extent it is known or reasonably ascertainable.

Part 721 - Significant New Uses of Chemical Substances

40 C.F.R. Part 721 identifies uses of chemical substances that EPA has determined constitute significant new uses. It also specifies procedures for manufacturers, importers, and processors to report on these new uses.

Although EPA may have already placed a chemical substance on the TSCA Inventory, the original manufacturer or another manufacturer may use the chemical in a different way that could substantially increase human or environmental exposure to the chemical. The SNUR essentially converts an "existing" chemical conditionally into a "new" chemical with regard to the designated significant new use.

If the Agency determines that a particular use of a chemical constitutes a significant new use, and that use is not presently ongoing, EPA may issue a SNUR. Once a SNUR is promulgated in final form, anyone wishing to manufacture, import, or process a chemical substance for a use that EPA has determined is a significant new use must submit a SNUN 90 days prior to such activity. A SNUN is the functional equivalent of a PMN (i.e., it is submitted on the same form and contains the same information). The requirement to submit a SNUN applies to all manufacturers, importers, and processors. Documentation of the information contained in a SNUN must be maintained for five years.

40 C.F.R. Part 721 Subpart B lists several categories of “generic” SNUR terms that EPA uses for most SNURs. These categories include:

- Protection in the workplace.
- Hazard communication program.
- Industrial, commercial, and consumer activities.
- Disposal.
- Release to water.

For example, citation of the appropriate Protection in the Workplace terms in a particular SNUR would make failure to use impervious gloves where the worker is reasonably likely to be exposed a significant new use of that particular chemical.

40 C.F.R. Part 721 Subpart C establishes recordkeeping requirements that EPA may impose upon manufacturers, importers, or processors of SNUR substances. The recordkeeping requirements include:

- Date and volume of manufacture and import of a substance.
- Volume and date of substances purchased in the United States by processors and the name and address of suppliers.
- Offsite persons to whom the manufacturer, importer, or processor sells or transfers the substance, including dates and quantities.
- Documentation of programs addressing personal protective equipment and hazard communication.
- Documentation of determinations regarding chemical protective clothing.

- Copies of labels and material safety data sheets.
- Documentation of compliance with applicable industrial, commercial, and consumer use limitations.
- Documentation of compliance with applicable disposal requirements.
- Implementation of procedures that ensure compliance with any applicable water discharge limitation.

40 C.F.R. Part 721 Subpart D establishes expedited rulemaking procedures that EPA can use to establish SNURs for chemical substances that have completed PMN review, limits the circumstances under which EPA can use these procedures to promulgate SNURs on chemicals that were not the subject of TSCA section 5(e) orders, and creates a procedure by which persons affected by an expedited SNUR can petition EPA to modify or revoke it. These procedures include direct final rulemaking, interim final rulemaking, and notice and comment rulemaking.

EPA may use Subpart D's expedited procedures to promulgate a SNUR for chemicals that are subject to section 5(e) orders, and for chemicals that are not subject to section 5(e) orders. A SNUR for a chemical that is the subject of a section 5(e) order is promulgated to extend the restrictions in the order to other manufacturers (or processors) of the chemical substance. EPA can also use the expedited SNUR procedures to regulate any chemical that completed the PMN process but was not subject to a TSCA section 5(e) order, provided the chemical meets the "concern criteria" listed in Subpart D. These criteria apply to chemicals of suspect toxicity and to chemicals structurally similar to toxic chemicals.

40 C.F.R. Part 721 Subpart E lists the chemicals that are subject to SNURs and the new uses that EPA has designated as significant. The following persons do not need to submit a SNUN for a chemical substance listed in Part 721 Subpart E, unless otherwise specified in a section in Subpart E (See TSCA § 721.45 for more details):

- Persons granted a TME for the new use.
- Persons who manufacture, import, or process the chemical for the new use only in small quantities for R&D.
- Persons who manufacture, import, or process the chemical for the new use only as an impurity.
- Persons who manufacture, import, or process the chemical for the new use only as a byproduct, which either has no commercial purpose or is burned as a fuel, disposed of as a waste, or used to provide components (which are extracted from it) for commercial purposes.
- Persons who import or process the chemical substance as part of an article.

- Persons who manufacture the chemical substance solely for export and comply with the applicable labeling requirements.
- Persons who submit a SNUN and have received written notification of compliance from EPA.
- Persons operating under a section 5(e) order that is inconsistent with the SNUR.

Part 723 - Premanufacture Notification Exemptions

Certain additional exemptions from the PMN requirements are found in 40 C.F.R. Part 723. Under 40 C.F.R. § 723.50 manufacturers and importers that manufacture or import chemical substances in quantities of 10,000 kilograms or less per year (LVE) or that manufacture or import chemical substances with low environmental releases and human exposures (LoREX) may be eligible for exemption from the PMN requirements. To manufacture or import chemicals under the LVE or LoREX exemptions, manufacturers and importers must submit a notice to EPA 30 days prior to commencing manufacture or importation and EPA must grant the exemption for those chemicals. Generally, chemical substances manufactured or imported under the LVE or LoREX exemptions must be manufactured at the site or sites described, for the uses described, and under the human exposure and environmental release controls described in the exemption notice. Records of production volume and documentation of information in the notice must be maintained for five years. Access to these records must be provided and such records must be submitted upon EPA's written request. LVE and LoREX substances are not added to the Inventory.

40 C.F.R. § 723.250 provides an exemption for the manufacture and importation of certain chemical substances that meet the definition of "polymer" in 40 C.F.R. § 723.250(b). Persons that manufacture and import polymers under this exemption must submit a report of manufacture or import by January 31st of the year subsequent to the initial commercial manufacture or import. The report only states the number of exempt polymers, not their specific chemical identity. These exempted polymers are not added to the Inventory. The manufacturer or importer must comply with specified recordkeeping requirements.

Part 725 – Microorganism Review Process

EPA regulations for implementing its review program for new intergeneric microorganisms under section 5 of the Toxic Substances Control Act (TSCA) are found in the in 40 C.F.R. Part 725. These rules are designed to ensure that EPA can adequately identify and regulate risk associated with microbial products of biotechnology.

Microorganisms subject to this rule are "new" microorganisms used commercially for "TSCA purposes," such as production of industrial enzymes and other chemicals; agricultural practices

(e.g., biofertilizers); biosensors; production of biofuels, and break-down of chemical pollutants in the environment. (See 40 C.F.R. § 725.8(c)(1)). According to EPA's rule, new microorganisms are those "intergeneric" microorganisms (including bacteria, fungi, algae, viruses, protozoa, etc.) formed by combining genetic material from organisms in different genera. (See 40 C.F.R. §§ 725.1(a) and 725.3.) A genus (pl. genera) is a level in a taxonomic classification system based on the relatedness of organisms. EPA believes that intergeneric microorganisms have a sufficiently high likelihood of expressing new traits or new combinations of traits to be termed "new" and warrant review. Microorganisms that are not intergeneric are not considered "new", and thus are not subject to reporting under section 5 of TSCA. When defining "intergeneric microorganism," in the case of chemically synthesized genes, EPA has followed a similar principle. The genetic sequence of the synthesized gene may be identical to a sequence known to occur in an organism in the same genus as the recipient microorganism. If so, the resulting microorganism is considered intrageneric and thus not new. Conversely, the sequence of the synthesized gene may be different or not known to be identical to a sequence in the genus of the recipient microorganism, in which case, the resulting product is considered intergeneric.

The TSCA section 5 notification specifically required for microorganisms is the Microbial Commercial Activity Notice (MCAN) (40 C.F.R. Part 725 Subpart D). Persons intending to manufacture or import intergeneric microorganisms for commercial purposes in the United States must submit an MCAN to EPA at least 90 days before such manufacture or import. EPA has 90 days to review the submission in order to determine whether the intergeneric microorganism may present an unreasonable risk to human health or the environment. If EPA makes that determination, EPA may impose appropriate regulatory restrictions on the microorganism.

The regulations also cover intergeneric microorganisms used in research and development (R&D) for commercial purposes. The TSCA section 5 notification required for R&D testing of new microorganisms that are released in the environment is the TSCA Experimental Release Application (TERA) (40 C.F.R. Part 725 Subpart E, §§ 725.250-725.288). A TERA must be submitted to EPA at least 60 days prior to initiating such field trials. The TERA is designed, in recognition of the needs of researchers, to provide a high measure of flexibility and a shorter review period (60 days). R&D for commercial purposes are those activities that are funded directly, in whole or in part, by a commercial entity, regardless of who is actually conducting the research, or which will obtain for the researcher an immediate or eventual commercial advantage.

EPA's biotechnology rule contains several exemptions from the requirement to submit a MCAN, if the manufacturer meets criteria defining eligible microorganisms and specified use conditions. Exemptions for R&D are contained in Subpart E. A test market exemption is

provided in Subpart F. Subpart G provides two exemptions limited to specified recipient microorganisms and introduced genetic material that is limited in size, well-characterized, poorly mobilizable, and free of certain sequences. The "Tier I" exemption requires certain certifications and recordkeeping while the "Tier II" exemption requires certain certifications and a notification to EPA, and EPA review of specific physical containment and control technologies.

The new chemicals regulated under TSCA include certain biofuels and certain microorganisms used in the production of biofuels. Some biofuels and synthetic fuels may be new chemicals, and thus, would be subject to Premanufacture Notice (PMN) reporting requirements, and as described above, there are analogous rules requiring MCAN submission for "new" microorganisms (including bacteria, fungi, algae, viruses, protozoa, etc.) that are "intergeneric" genetically-engineered microorganisms.

Part 750 – Procedures for Rulemaking Under Section 6 of TSCA

EPA published final and amended procedural regulations at 40 C.F.R Part 750 to implement the TSCA section 6 procedural requirements. These procedural regulations are quite detailed with respect to the contents of Notices of Proposed Rulemaking, hearing procedures, the handling of public comments, and docketing of comments and other supporting materials. The Lautenberg Amendments directs EPA to take action against unreasonable risks presented by chemical substances or mixtures and requires EPA meet specific deadlines and procedures for prioritizing chemicals for risk evaluations, conducting the risk evaluations and promulgating regulations to address unreasonable risks that are identified. Notably, once unreasonable risks have been identified through a risk evaluation, TSCA section 6(c)(1) now requires EPA to issue a proposed rule to address the risks no later than one year after the final risk evaluation is published, and the final rule must be issued no later than two years after the final risk evaluation is published, subject to the limited extension authorized by TSCA section 6(c)(1)(C).

40 C.F.R. Part 750 Subpart B establishes procedural rules for manufacturing exemptions.

40 C.F.R. Part 750 Subpart C establishes procedural rules for processing and distribution in commerce exemptions.

Part 751 – Regulation of Certain Chemical Substances and Mixtures under Section 6 of TSCA

40 C.F.R. Part 751 regulations set forth requirements under section 6(a) of TSCA regulating the manufacture, import, processing, distribution, use, or disposal of certain chemical substances and mixtures in order to address unreasonable risks to the extent necessary, so that the chemical substance or mixture no longer presents such risk. 40 C.F.R. Part 751 Subpart A establishes general provisions for certain chemical substances subject to section 6 by outlining

basic requirements for exports and imports, enforcement, and inspections. 40 C.F.R. Part 751 Subpart B lays the groundwork for the regulation of Methylene Chloride. 40 C.F.R. Part 751 Subpart B sets certain restrictions on the manufacture, import, processing, and distribution of methylene chloride for consumer paint and coating removal to prevent unreasonable risks of injury to health due to acute human lethality. 40 C.F.R. § 751.105 enumerates the specific restrictions and prohibited acts. Downstream notifications and recordkeeping requirements are set forth in 40 C.F.R. §§ 751.107 and 751.109, respectively. More information on the methylene chloride rule can be found below.

40 C.F.R. Part 751 Subpart E establishes prohibitions and restrictions on the manufacturing, processing, and distribution of persistent, bioaccumulative, and toxic chemicals (PBT chemicals) in accordance with TSCA section 6(h).

The PBT Chemicals with final rules, and the corresponding regulations, include:

1) Decabromodiphenyl ether (DecaBDE), 40 C.F.R. § 751.405
2) Phenol, isopropylated phosphate (3:1) (PIP (3:1)), 40 C.F.R. § 751.407
3) 2,4,6-Tris(tert-butyl)phenol (2,4,6-TTBP), 40 C.F.R. § 751.409
4) Pentachlorothiophenol (PCTP), 40 C.F.R. § 751.411
5) Hexachlorobutadiene (HCBD), 40 C.F.R. § 751.413

More information on the final rules can be found below.

Part 770 – Formaldehyde Standards for Composite Wood Products

40 C.F.R. Part 770 contains formaldehyde emission standards, testing and certification provisions, and other requirements for the manufacture, import distribution, and sale of composite wood products, component parts that contain composite wood products, and finished goods that contain composite wood products.

40 C.F.R. Part 770 Subpart B outlines the requirements for Third-Party Certification including applications, notifications, and reports.

40 C.F.R. Part 770 Subpart C lays out regulations pertaining to Composite Wood Products. Relevant regulations include, but are not limited to formaldehyde emission standards (§ 770.10), certification (§ 770.15), testing requirements (§ 770.20), importers, fabricators, distributors and retailers (§ 770.30), reporting and recordkeeping (§ 770.40) and labeling (§ 770.45).

Parts 790 through Part 799 - Procedures Governing Testing Consent Agreements, Test Rules, and Testing Guidelines

In general, the 40 C.F.R. Parts 790-799 regulations govern the conduct of tests, results, procedures, documentation, and laboratory standards. The rules establish procedures for gathering information, developing and implementing test rules or consent agreements regarding chemicals regulated under TSCA section 4, and establishing reimbursement for testing costs incurred under TSCA; codify good laboratory practices for conducting studies and guidelines for health effects, environmental effects, and chemical fate testing; and identify the chemical substances and mixtures for which data must be developed. The Lautenberg Amendments expanded authority to obtain testing information for prioritizing or conducting risk evaluations on a chemical and expedites the process with new order and consent agreement authorities.

Section 6 Rules

Prioritization and Risk Evaluation of Chemical Substances and Mixtures

Pursuant to TSCA section 6(b), a risk-based screening prioritization process is warranted for categorizing chemical substances or mixtures as either high or low priority for risk evaluations. Factors to consider when designating the priority of chemical substances or mixtures include, but are not limited to, the following:

(i) persistence within the environment,
(ii) potential for bioaccumulation,
(iii) toxicity,
(iv) storage proximity near sources of drinking water, and
(v) the possibility of exposure to susceptible subpopulations.

High priority chemical substances or mixtures may pose significant harm via greater potential for exposure to the chemicals and/or greater susceptibility to the effects of these probable chemical exposures. High priority chemicals that may present an unreasonable risk warrant a full risk evaluation. In contrast, low priority chemical substances or mixtures are those that do not meet high priority standards and are set aside for review at a later date.

Risk prioritization and risk evaluations are done in accordance with 40 C.F.R. Part 702.

The list of chemicals currently undergoing risk evaluation is available at EPA's website.

EPA will be constantly conducting new risk prioritizations and evaluations. It is important to check if a chemical substance or mixture has undergone such review and if there is a resulting TSCA section 6 rule that might need to be addressed during an inspection.

TSCA also allows manufacturers of a chemical to request an EPA-conducted risk evaluation on the chemical. A manufacturer may request a risk evaluation for conditions of use of interest to the manufacturer. EPA requirements for submissions of manufacturer requests for risk evaluations are found at 40 C.F.R. § 702.37.

Chemicals that are Persistent, Bioaccumulative, and Toxic (PBT Chemicals)

As a result of the Lautenberg Amendments, EPA shall propose rules under section 6(a) with respect to chemicals that EPA has reasonable basis to conclude are toxic, persistent or bioaccumulative, and exposure to which under the conditions of use is likely to the general population or to a potentially exposed or susceptible subpopulation or the environment on the basis of an exposure and use assessment. For chemicals deemed toxic, persistent, or bioaccumulative, no risk evaluation is required. The rule shall address the risks of injury to health or the environment that are presented by the chemical substance and reduce exposure to the substance to the extent practicable.

Existing Risk Management Practices and Regulations

Final TSCA Section 6 Rules under Amended TSCA

Amended Procedural Rule

On December 21, 2016, EPA issued a direct final rule removing portions of outdated procedural regulations promulgated under the old version of TSCA. The old procedures are not consistent with the timelines and requirements of TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act. As amended, TSCA no longer mandates an informal hearing and instead mandates certain timeframes for taking regulatory action on identified unreasonable risk after a chemical has undergone risk evaluation. Read the direct final rule here.

Methylene Chloride "dichloromethane" (DCM)

On March 15, 2019, EPA issued a final rule under Section 6 of TSCA to address the unreasonable risks presented by methylene Chloride in paint and coating removal for consumer use. Read the final rule here.

Following an unreasonable risk determination, EPA issued a final rule under section 6(a) of TSCA prohibiting the manufacture, processing, and distribution of methylene chloride in paint

removers for consumer use. Methylene chloride is a volatile chemical generally used as a heat transfer liquid and remains prominent in the following industries: paint and coating removal, plastic processing, metal cleaning and degreasing, and adhesive manufacture.

Unreasonable risks associated with acute exposures to methylene chloride (especially in enclosed spaces) include rapidly induced dizziness, loss of consciousness, heart failure and death. The chemical ultimately acts as a lethal neurotoxicant, affecting the brain's neurological responses.

Pursuant to section 6(a) of TSCA, the final rule:

(i) Prohibits the manufacturing, processing, and distribution in commerce for paint and coating removal for all consumer purposes;
(ii) Prohibits the distribution in commerce of methylene chloride in paint and coating removal products to and by retailers (any person or business entity that distributes or makes available paint and coating removal products to consumers);
(iii) Requires manufacturers, processors, and distributors of methylene chloride for any use, excluding retailers, to provide downstream notification of the prohibitions in this final rule through Safety Data Sheets (SDS) by adding to Sections 1(c) and 15 of the SDS the following language: "This chemical/product is not and cannot be distributed in commerce (as defined in TSCA section 3(5)) or processed (as defined in TSCA section 3(13)) for consumer paint or coating removal;" and;
(iv) Requires recordkeeping relevant to these prohibitions.

Methylene Chloride regulations can be found at 40 C.F.R. Part 751.

Persistent, Bioaccumulative and Toxic (PBT) Chemical Substances

TSCA section 6(h) specifically requires EPA to classify chemical substances or mixtures that are persistent, bioaccumulative, and toxic (PBT) and take expedited action to reduce exposure. Although risk evaluations are not required, management regulations of PBT chemical substances and mixtures must be issued to reduce exposure to the extent practicable. Currently, five PBT chemicals under TSCA section 6(h) are under risk management and include the following:

1) Decabromodiphenyl ether (DecaBDE)
2) Phenol, isopropylated phosphate (3:1) (PIP (3:1))
3) 2,4,6-Tris(tert-butyl)phenol (2,4,6-TTBP)
4) Pentachlorothiophenol (PCTP)
5) Hexachlorobutadiene (HCBD)

The final rules and risk management actions for the five PBT chemical substances can be found on EPA's website.

Regulations for the PBT Chemicals can be found at 40 C.F.R. Part 751.

DecaDBE

EPA issued a final rule under section 6(a) of TSCA prohibiting all manufacture, import, processing, and distribution of DecaDBE, or DecaDBE containing products or articles, with some exclusions. The rule requires recordkeeping related to compliance with the prohibitions, restrictions, and other provisions of the rule.

PIP (3:1)

EPA issued a final rule under section 6(a) of TSCA prohibiting all processing and distribution of PIP (3:1), or PIP (3:1)-containing products or articles, after March 8, 2021. Additionally, the rule prohibits releases to water during manufacture, processing and distribution and all persons are required to follow all applicable regulations and best management practices for preventing the release of PIP (3:1) to water during commercial use. The rule requires recordkeeping related to compliance with the prohibitions, restrictions, and other provisions of the rule. The final rule establishes downstream notifications.

2,4,6-TTBP

§ 751.409 prohibits all distribution in commerce of 2,4,6-TTBP at any concentration above 0.3 percent by weight, in containers with a volume less than 35 gallons after January 6, 2026. After January 6, 2026, all persons are prohibited from all processing and distribution in commerce of 2,4,6-TTBP oil and lubricant additives at any concentration above 0.3 percent by weight. The rule requires recordkeeping related to compliance with the prohibitions, restrictions, and other provisions of this section. These records must be maintained for a period of three years from the date the record is generated.

PCTP

§ 751.411 prohibits all manufacturing and processing of PCTP or PCTP-containing products or articles, unless PCTP concentrations are at or below 1% by weight after March 8, 2021. After January 6, 2022, all persons are prohibited from all distribution in commerce of PCTP or PCTP-containing products or articles, unless PCTP concentrations are at or below 1% by weight. The rule requires recordkeeping related to compliance with the prohibitions, restrictions, and other

provisions of this section. These records must be maintained for a period of three years from the date the record is generated.

HCBD

§751.413 prohibits all manufacturing, processing, and distribution in commerce of HCBD and HCBD-containing products or articles after March 8, 2021, except for the following:

- Unintentional production of HCBD as a byproduct in the production of chlorinated solvents; and
- Processing and distribution in commerce of HCBD for burning as a waste fuel.

After March 8, 2021, the rule requires recordkeeping related to compliance with the prohibitions, restrictions, and other provisions of this section. These records must be maintained for a period of three years from the date the record is generated.

Asbestos

EPA issued a final rule under TSCA section 6 to ensure the discontinuance of asbestos products and the inability to reintroduce these products back into commerce without proper risk evaluation. This evaluation process also pertains to risks associated with ongoing uses of asbestos. Upon discovery of an unreasonable risk to human health or the environment, EPA will take prompt action to address the risk(s) by establishing necessary restrictions or prohibiting asbestos uses in products altogether. Asbestos regulations can be found at 40 C.F.R. Part 763.

Pursuant to section 6 of TSCA, the final rule:

(i) Prohibits the manufacturing, processing, and distribution in commerce for uses of asbestos no longer on the market and that are not covered under other laws or regulations.
(ii) Prohibits new uses of asbestos, to which individuals subject to this stipulation are required to notify EPA at least 90 days before commencing any manufacturing, importing, or processing of asbestos or asbestos-containing products covered under the rule. These uses are prohibited until EPA conducts a thorough review of the notice.
(iii) Retains pre-determined banned uses of asbestos under the Partial 1989 Ban; no prohibited products may return to the market.
    a. In accordance with the Partial 1989 Ban, the manufacture, importation, processing, and distribution of five asbestos-containing products are banned under TSCA. These products include corrugated paper, roll board, commercial paper, specialty paper, flooring felt, and any new commercial uses that begin following August 25, 1989.

Polychlorinated biphenyls (PCBs)

EPA formalized the statutory ban contained in section 6(e) of TSCA in final regulations issued on May 31, 1979, 44 FR 31542. Subsequently, EPA has taken numerous actions to regulate PCB uses and disposal.

Pursuant to section 6 of TSCA, the final rule:

(i) Prohibits the manufacture, processing, distribution in commerce, or any use of any PCB in any manner other than in a totally enclosed manner;
(ii) Requires prescribed methods for the disposal of PCBs;
(iii) Requires PCBs to be marked with clear and adequate warnings and instructions for processing, distribution in commerce, use, or disposal.

PCB regulations are found at 40 C.F.R. Part 761.

Proposed Risk Management Practices and Regulations

More information pertaining to the following proposed rules can be found on EPA's website.

Methylene Chloride in Commercial Paint and Coating Removal

EPA issued a proposed rule under section 6(a) of TSCA requiring training and certification of commercial users of Methylene Chloride in paint removers for commercial use.

The proposed rule would require training, certification, and limited access requirements that could address any unreasonable risks that EPA could potentially find to be presented by methylene chloride when used for commercial paint and coating removal. Such a program could allow access to paint and coating removal products containing methylene chloride only to commercial users who are certified as properly trained to engage in use practices that do not present unreasonable risks.

Trichloroethylene (TCE) Use in Vapor Degreasing

EPA issued a proposed rule under section 6(a) of TSCA prohibiting the manufacture of TCE for use in vapor degreasing.

The proposed rule would:

(i) Prohibit the manufacture (including import), processing, and distribution in commerce of TCE for use in vapor degreasing;
(ii) Prohibit commercial use of TCE in vapor degreasing;

(iii) Require manufacturers, processors, and distributors, except for retailers of TCE for any use, to provide downstream notification of these prohibitions throughout the supply chain; and
(iv) Require limited recordkeeping.

N-Methylpyrrolidone (NMP) in Paint and Coating Removal

EPA issued a proposed rule under section 6(a) of TSCA of NMP for all consumer and commercial paint and coating removal. NMP is a solvent used in paint and coating removal.

The proposed rule would:

(i) prohibit the manufacture (including import), processing, and distribution in commerce of NMP for all consumer and commercial paint and coating removal;
(ii) prohibit the use of NMP for all commercial paint and coating removal;
(iii) require, consistent with methylene chloride restrictions, downstream notification of these prohibitions throughout the supply chain;
(iv) require recordkeeping.

An alternative proposed rule would:

(i) require commercial users of NMP for paint and coating removal to establish a worker protection program for dermal and respiratory protection;
(ii) prohibit use of paint and coating removal products that contain greater than 35 percent NMP by weight (except for product formulations destined to be used by DoD or its contractors performing work only for DOD projects);
(iii) require processors of products containing NMP for paint and coating removal to reformulate products such that these products do not exceed a maximum of 35 percent NMP by weight; and
(iv) identify gloves that provide effective protection for the formulation and provide warning and instruction labels on the products.

Trichloroethylene (TCE) Use in Aerosol Degreasing and for Spot Cleaning at Dry Cleaning Facilities

EPA issued a proposed rule under section 6(a) of TSCA prohibiting the manufacture of TCE for use in aerosol degreasing and for spot cleaning in dry cleaning facilities.

The proposed rule would:

(i) prohibit the manufacture, processing, and distribution in commerce of TCE for use in aerosol degreasing and for use in spot cleaning in dry cleaning facilities;

(ii) prohibit commercial use of TCE for aerosol degreasing and for spot cleaning in dry cleaning facilities;
(iii) require manufacturers, processors, and distributors, except for retailers of TCE for any use, to provide downstream notification of these prohibitions throughout the supply chain; and
(iv) require limited recordkeeping.

Appendix B Core TSCA Pre-Inspection Telephone Contact Form

Date:

Company Name:

Telephone Number:

EPA Caller Name:

1. Request to speak with Environmental Manager or use specific title, if known

2. State your name, agency & office, type of inspection

    a. Hello, my name is [*name*]. I'm with the United States Environmental Protection Agency in Region [*region #*], in [*office location*]. I plan to conduct an inspection under the Toxics Substance Control Act which will cover TSCA sections 4, 5, 6, 8, 12 and 13.

3. Verify the contact information for the person who will be giving consent for the inspection.

    a. Contact Person:

    b. Contact Info:

    c. Title:

    d. Site Address (location):

    e. Type/Scope of Business:

4. Additional Info (if they are the appropriate contact person and are aware of this info):

    a. Has your company submitted any pre-manufacture notices (PMNs) in the last 4 years? (yes/no)

    If Yes….

        i. Do you have any notice of commencement (NOC) associated with PMNs? (yes/no)

    b. Have you submitted any of these in the past 4 years?

        i. Low volume exemption (LVE): (yes/no)

ii. Test market exemption (TME): (yes/no)

c. Have you submitted any of these in the past 4 years?

i. Bonafide intents: (yes/no)

ii. Significant new use rule notices (SNUNs): (yes/no)

iii. TSCA section 5(e)/(f) orders: (yes/no)

d. Is the facility engaged in R&D activities? (yes/no)

e. Did your facility submit a 2016/2020 CDR? (yes/no)

5. Mention: This is primarily a records inspection. I will send a letter that outlines the scope of the inspection to help you prepare and gather the appropriate documents.

6. Ask: Are you available on [*date*]? If the date isn't good, you can ask the facility, 'Could you have someone else be available'?

a. Proposed date of inspection is:

b. Proposed start time of inspection is:

Appendix C Pre-Inspection Information Request Letter (PIIRL)

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Appendix D Core TSCA Inspection Sign-In Sheet

Name	Job Title	Phone	Email

Appendix E Core TSCA Inspection Checklist

Core TSCA Inspection Checklist

Company Name: _____

Address: _____

_____

Telephone: _____ Email: _____

Date: _____ Time: _____

OPENING CONFERENCE

General Facility Background

Review of Process Operations

TSCA SECTIONS TO REVIEW

_____ SECTION 4 TEST RULE OR ORDERS

_____ SECTION 5a PRE-MANUFACTURE NOTICE

_____ SECTION 5a SNURS OR 5E/5F ORDERS

_____ SECTION 5h R&D Exemptions

_____ SECTION 6a RULES

_____ SECTION 8a PRELIMINARY ASSESSMENT INFORMATION RULE

_____ SECTION 8b CHEMICAL DATA REPORTING

_____ SECTION 8c ALLEGATIONS OF ADVERSE REACTIONS

_____SECTION 8d/e HEALTH & SAFETY STUDIES, SUBSTANTIAL RISK INFORMATION

_____SECTION 12b EXPORT NOTIFICATION LETTERS

_____SECTION 13 IMPORT CERTIFICATIONS

FACILITY TOUR

DOCUMENTATION PREPARATION

CLOSING CONFERENCE

Appendix F Inspection Report Template

TOXIC SUBSTANCES CONTROL ACT – NEW AND EXISTING CHEMICALS PROGRAM

COMPLIANCE MONITORING INSPECTION REPORT

Company X

ADDRESS

CITY, STATE, ZIP

Report Date: **[Date]**

Report Prepared By: **Inspector X**

U.S. Environmental Protection Agency, Region X

Branch/Section

Address

City, State, Zip

Inspectors: **Inspector X (Lead) EPA Region X, TSCA-NEC Inspector**

Inspector Y EPA Region X, TSCA-NEC Inspector

Inspector Z EPA Region X, TSCA-NEC Inspector

Inspection Date: **[Date]**

1.0 Introduction

1.1 Inspection Objectives

1.2 Representatives Present

Company Representatives:

U.S. Environmental Protection Agency:

1.3 Company Information

- Company/Site Name:
- Facility Name:
- Year Established:
- Number of Employees:
- Type of Ownership:
- Year of Last TSCA NEC Inspection
- Gross annual sale in 2015:
- Nature of Business:
- Site Latitude and Longitude:

1.4 Opening Conference

1.5 Facility Process Inspection

2.0 Inspection Observations/Findings

2.1 Section 4-Test Rules and Orders

2.2 Section 5

2.2.1 Section 5(a)(1)-Pre-Manufacture Notices

2.2.1.1 Exemptions

2.2.2 5(a)(2)-Significant New Use Rules

2.2.3 Section 5(e)-Orders

2.2.4 Section 5(h)-R&D Activities

2.3 Section 6

2.4 Section 8

2.4.1 Section 8(a)-Chemical Data Reporting (CDR)

_____

Signature

[NAME]

TSCA Inspector

6.2 Report-Reviewer

_____

Signature

[NAME]

TSCA Inspector

6.3 Report-Approver

_____

Signature

[NAME]

Branch Chief, Branch