

SCHC Annual Meeting 2025  
**Being prepared for a TSCA  
inspection**

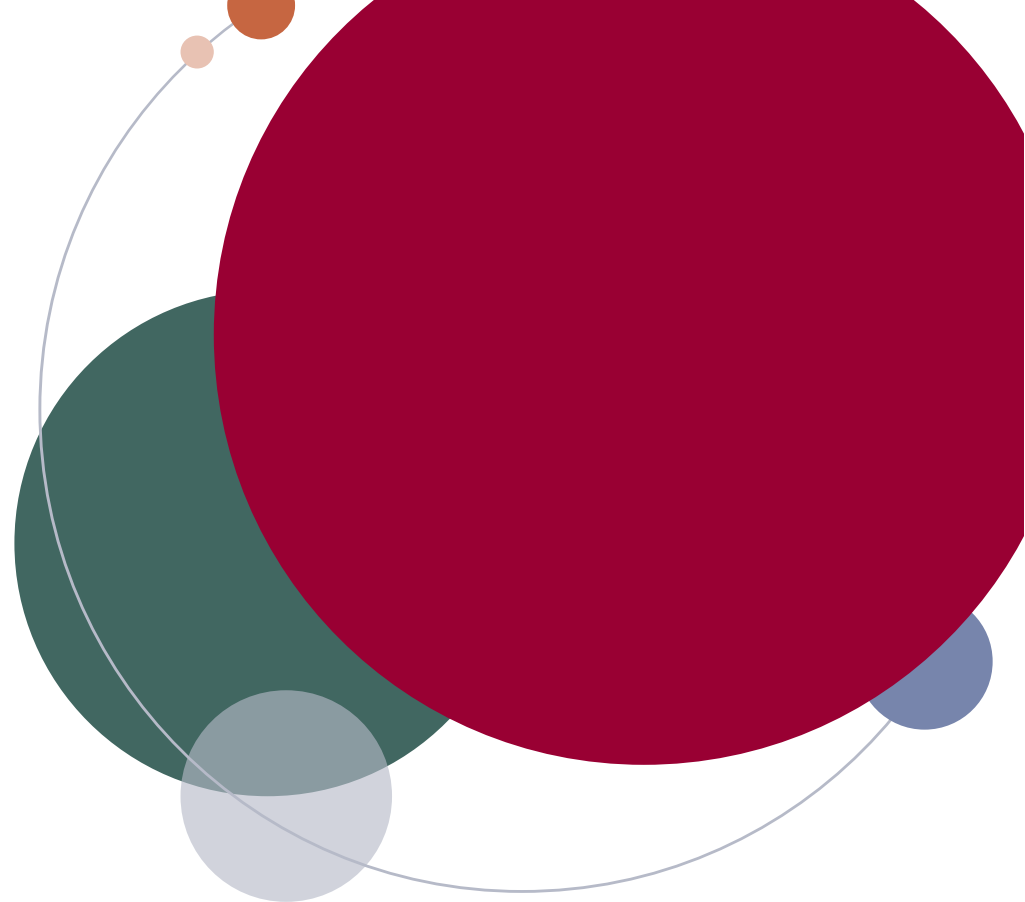
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Society for Chemical Hazard Communication




# TSCA inspections – background

- “Core TSCA” (titles I and VI of TSCA) is a federal-only program.
  - The U.S. Environmental Protection Agency (USEPA or the Agency) implements and enforces the program with no state involvement.
- In theory, USEPA Headquarters and any of the ten USEPA Regional Offices can initiate and conduct a Core TSCA inspection.
  - In practice, only USEPA Headquarters (HQ) and some of the Agency’s Regional Offices have the capacity to conduct Core TSCA inspections.
  - Ongoing reorganization of the enforcement office at USEPA HQ further complicates the situation.
- USEPA conducts two kinds of Core TSCA inspection.
  - In an inspection “for cause”, the Agency inspects based on evidence of a potential violation, e.g., an anonymous tip, a complaint, or a whistleblower.
  - In a “neutral administrative inspection scheme” inspection, USEPA has selected your facility or company based on previously established and clearly stated enforcement priorities.
- The Agency can conduct inspections in person or remotely, e.g., by correspondence.

## USEPA's inspection authority – TSCA § 11(a)

- USEPA may inspect any establishment, facility, or other premises in which TSCA chemical substances or mixtures are manufactured, imported, processed, stored, or held before or after their distribution in commerce.
  - Authority extends to any conveyance (vehicle) being used to transport chemical substances or mixtures in connection with their distribution in commerce.
- The inspector must present appropriate credentials and a written notice to the owner, operator, or agent in charge of the premises or conveyance to be inspected (see slides 5-6).
- The inspector must start and end the inspection with reasonable promptness.
- The inspector must conduct the inspection
  - at reasonable times,
  - within reasonable limits, and
  - in a reasonable manner.

## USEPA's inspection authority – TSCA § 11(b)

- The inspector may examine all things within the premises or conveyance being inspected, including records, files, papers, processes, controls, and facilities, bearing on whether Core TSCA requirements applying to the chemical substances and mixtures within the premises or conveyance have been complied with.
- The inspector may not examine the following information, unless the inspection notice describes the nature and extent of the information with reasonable specificity:
  - Financial information
  - Sales information other than shipment information
  - Pricing information 
  - Personnel information
  - Research information other than information required by Core TSCA or under a rule promulgated, order issued, or consent agreement entered into under Core TSCA

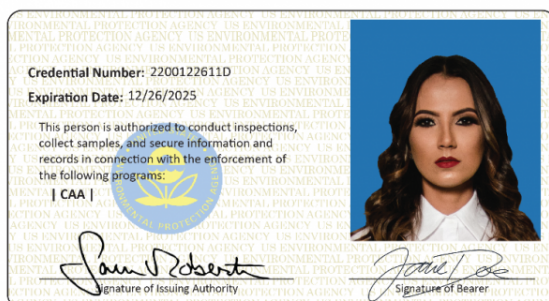
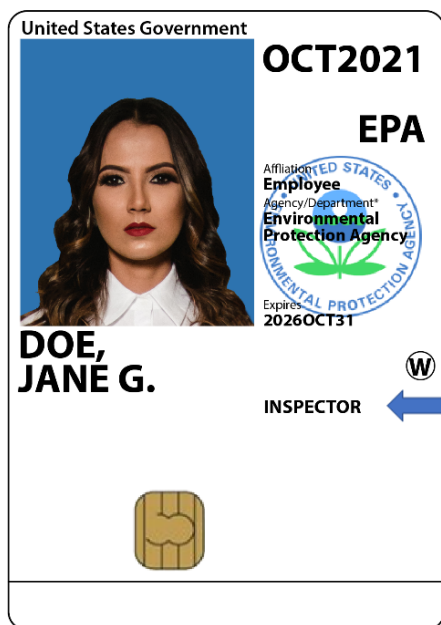


# Notice of inspection

- The inspector must provide written notice of the time and place of the inspection to the owner, operator, or agent in charge of the premises or conveyance to be inspected.
- The inspector can show up unannounced.
- Usually, there will be 7-30 days' prior notice by telephone, followed by a Pre-Inspection Information Request Letter (PIIRL) delivered by certified mail.
- In addition, the inspector usually sends an unofficial copy of the PIIRL by electronic mail.
- A separate notice is required for each inspection but not to reenter the premises or conveyance being inspected during the time covered by a given inspection notice.

# Presentation of credentials

- The inspector must present his or her federal inspection credentials (often does in opening conference).
- There are two types of USEPA inspector credentials, for federal employees (L) and non-federal employees (R).



- Non-federal employees (often contractors) cannot collect your confidential business information.
- The inspector will not relinquish the credentials or let you make copies.
- The inspector will typically have and leave you his or her business card.

# What information will the inspector request?

- General company information
  - Brief company history, including ownership and nature of business
  - Corporate structure, including domestic and foreign parent companies
  - Facilities owned by the company located in the U.S., including subsidiaries (name and location)
  - Numbers of employees at the facility and corporate levels
  - The gross [year] annual sales ranges for the facility and corporate levels
  - Identifying information for the facility and U.S. parent company, including Data Universal Numbering System Numbers
  - U.S. Customs and Border Protection Importer of Record Identification Number for all sites that import into the U.S. and are owned by the U.S. parent company
  - Scope of business, main North American Industry Classification System Codes under which the facility operates, and main industries that the U.S. parent company and facility supply


# What information will the inspector request? (cont'd)

- Process flow diagrams
  - Manufacturing and process flow diagrams listing each raw material input and the resulting products (by Chemical Abstracts Service Registry Number (CASRN)) for each step between the particular raw material and the commercial product, including intermediates, byproducts, and catalysts that are part of the commercial production but are not intended for sale or distribution [in commerce per se]. Indicate all steps, including on-site use, marketing, transfer, recycling, and waste disposal. Provide the certificate of analysis from a representative lot for each manufactured product that is used in commerce.
- TSCA section 4 records (last three years)
  - For chemical substances that were manufactured or imported and subject to a TSCA section 4 test rule, make available the letters of intent to conduct testing or requests for exemption from testing.
  - For chemical substances that were manufactured, imported, or processed and subject to a TSCA section 4 test order, make available the company's response to the test order.
  - If applicable, provide proof of data submission.

# What information will the inspector request? (cont'd)

- TSCA section 5(a)(1) and (2) records (last three years)
  - Bona fide intent to manufacture notices submitted.
  - Premanufacture notices, low volume exemptions, test marketing exemptions, and polymer exemptions, with any USEPA responses.
  - Significant new use notices, with any USEPA responses.
  - Notices of commencement and associated production records.
- TSCA section 5(e) and (f) records (last three years)
  - TSCA section 5(e)/(f) orders to which the facility is subject, with the applicable records.
- TSCA section 5(h) documentation
  - Research and development (R&D) activities and procedures in effect at the facility, specifically as related to compliance with the requirements of a TSCA R&D exemption. Provide documentation of prudent laboratory practices and of the notification and evaluation of risks, where appropriate. Also include operating manuals or written procedures that are used by laboratory personnel to manage chemicals with unknown hazards.

# What information will the inspector request? (cont'd)

- TSCA section 8(a) and 8(b) records (last three years)
  - Preliminary Assessment Information Rule information.
  - The [year] Chemical Data Reporting Rule report, with the applicable production records.
- TSCA section 8(c), (d), and (e) records (last five years)
  - Documentation of allegations of significant adverse reactions to health or the environment alleged to have been caused by the chemical substances/mixtures that were manufactured, processed, or distributed by the facility.
  - A list of any and all TSCA section 8(d) health and safety studies submitted to USEPA and copies of any and all health and safety information known by the facility that was not submitted to the Agency.
  - Documentation pertaining to the submission of substantial risk information associated with the chemical substances that were manufactured, processed, or distributed by the facility.
- Corporate policies and procedures 
  - Facility and/or corporate policies developed to ensure compliance with TSCA sections 4, 5, [6,] 8, 12, and 13.

# What lists will the inspector request?

- Chemical substances that were manufactured by the facility in [*years*], including
  - Accepted chemical name; CASRN or EPA Accession Number; production date; quantity produced per batch/per day; and identification number used to track each batch.
- Chemical substances that were imported by the facility in [*years*], including
  - Accepted chemical name; CASRN or EPA Accession Number; percentage of each chemical substance in any mixture; import date; quantity imported per shipment; identification number used to track each shipment; and safety data sheet for each chemical substance/mixture imported.
- For chemical substances and mixtures purchased from domestic suppliers (U.S. distributors) and used at the facility in manufacturing or processing activities between [*dates*], including the following information for each chemical substance/mixture:
  - Brand name or product name; accepted chemical name(s) of each component; CASRN or EPA Accession Number; if any CASRN is proprietary, provide a safety data sheet from the supplier; indicate the physical form and any product specification changes that have occurred; and supplier name and location (address).

## What lists will the inspector request? (cont'd)

- Chemical substances and mixtures exported from the U.S. by the facility during the period covering [dates], including
  - Accepted chemical name (for mixtures, indicate the accepted chemical name for each chemical substance and the estimated percentage of that chemical substance present in the mixture); CASRN or EPA Accession Number; if applicable, indicate the physical form and any product specification changes that have occurred; indicate that the chemical substance is a byproduct or impurity; export date; final destination (country); and a copy of any export notices required under TSCA section 12(b).



## What lists will the inspector request? (cont'd)

- Prepare a list of all R&D chemicals manufactured or imported at the facility and an indication of whether each R&D chemical is transferred off site or outside the control of the facility for the purposes of manufacture, processing, use, transport, storage, or disposal related to the R&D activities. For those chemical substances transferred off site, also provide
  - names and addresses of those who received the R&D chemical;
  - the amount distributed to each addressee; and
  - safety data sheet or other documentation constituting the written notification to the recipient (i) that the R&D chemical is for R&D use only and (ii) of the potential risks of the R&D chemical identified by the facility.

For all chemical substances for which the facility has concluded that the R&D exemption applies and the amount manufactured is greater than 100 kilograms per calendar year, also provide the amount manufactured and the disposition of each chemical.

- Prepare a list of all health and safety studies relating to any chemical substance that the facility manufactured under the R&D exemption (not just substances that have commercial potential).

# What is a sufficient supplier certification?

- If a supplier will not identify its product for TSCA purposes, and you cannot find an alternative supplier who cooperates with information requests intended to assist your company's compliance with TSCA, obtain a sufficient TSCA compliance certification statement from the supplier on U.S. business letterhead and signed by a named person at the U.S. business address:

## *Model statement:*

All chemical substances contained in [*Product*] are listed in the Toxic Substances Control Act (TSCA) Chemical Substance Inventory with an active commercial status designation, and no substance in [*Product*] is subject to (1) a rule, order, or action under section 4, 5, 6, 7, or 12 of TSCA or (2) the Preliminary Assessment Information Rule, the Health and Safety Data Reporting Rule, the PFAS Reporting and Recordkeeping Rule, or any chemical-specific reporting rule in 40 C.F.R. pt. 704, subpt. B.

In the event of any question from the U.S. Environmental Protection Agency (USEPA) about the status or compliance of [*Product*] under TSCA, [*Supplier*] understands and acknowledges that [*Your Company*] will provide this TSCA compliance certification statement to USEPA and will invite them to contact [*Supplier*] directly with any questions.

# Before the inspection

- If the inspector telephones you, pause to take notes.
- Inform your legal counsel and the most senior responsible executive in your organization as soon as you know about any inspection.
- When you receive a written inspection notice (e.g., PIIRL), read it carefully and ensure that you understand it.
- Carefully prepare and review in advance as much of the requested information as possible.
  - In preparing lists for USEPA, remember the exclusions from TSCA, and obtain legal help, if needed.
- Be aware of what information to be produced to USEPA is TSCA confidential business information (CBI) and follow all applicable procedures to assert and substantiate all CBI claims.
- Choose the team who will attend the inspection for your organization.
- Choose a location for the meeting with the inspector – a quiet visitor space outside of your facility's secured areas is a good idea.
- The meeting room should contain only the information that you bring for the inspection.

# Entry

- The inspector must obtain consent sufficient to authorize all entry and sampling activities that he or she contemplates will be necessary to complete the inspection.
- Once the inspector has consent to enter, the inspector may do so and conduct the inspection.
- If you deny entry to the inspector, he or she will obtain and return with an administrative warrant based on probable cause or a neutral administrative inspection scheme.
- If the inspector thinks that he or she will be denied entry with a warrant or will be subject to violence, he or she will bring a U.S. Marshal or other law enforcement official.
- It is unlawful to deny entry to the inspector when he or she presents a lawful warrant.


# Three parts of an inspection

- Part 1 – opening conference
  - Introduction of all participants and discussion of their roles
  - Presentation of the inspection team's credentials and explanation of their authority
  - Presentation of four USEPA forms:
    - Notice of Inspection (EPA Form 7740-3) – lead inspector will sign and ask facility representative to do so.
    - TSCA Inspection Confidentiality Notice (EPA Form 7740-4) – outlines the facility's ability to claim information discussed or produced during the inspection as TSCA CBI; lead inspector will ask facility representative to sign.
    - **Receipt for Samples and Documents (EPA Form 7740-1)** – a list of all documents collected during the inspection; lead inspector will sign at the closing conference and ask facility representative to do so.
    - **Declaration of Confidential Business Information (EPA Form 7740-2)** – a list of all documents collected during the inspection that contain TSCA CBI; lead inspector will sign at the closing conference and ask facility representative to do so.
  - A general overview and procedures for the inspection

## Three parts of an inspection (cont'd)

- Part 2 – document review
  - Will usually track the information requested in the PIIRL or other written inspection notice.
  - The inspection team will ask the facility to submit information electronically, e.g., on a flash drive, and may start to review your lists on the spot.
  - If the facility cannot produce any information during the inspection, the inspector will ordinarily allow the facility to produce the information afterwards.
  - To better understand process flow diagrams, the inspection team may conduct a facility process inspection.
  - If the facility conducts any R&D, the inspection team is likely to inspect any R&D laboratory.
- Part 3 – closing conference
  - The inspection team will summarize the inspection and provide the facility with next steps.
  - The Receipt of Samples and Documents and Declaration of Confidential Business Information (EPA Forms 7740-1 and 7740-2, respectively) will be completed and signed.
  - The Receipt of Samples and Documents will identify any information to be produced after the inspection.

# During the inspection

- The inspector is not your friend and is not there to help. 
- Know the limits of USEPA's inspection authority under TSCA § 11 (slides 3-4).
- Be calm and professional – neither friendly nor aggressive.
- Do not offer information other than what is (lawfully) requested.
- Document every piece of information that you produce to the inspector, regardless of the format or medium.
  - The inspector will create and leave copies of USEPA forms discussed above that will be receipts for the information collected, but verify the forms' accuracy and completeness using your own notes.
- Do not produce any information to the inspector that is CBI unless you have previously ensured that you have correctly asserted and substantiated your CBI claims, as necessary.

## After the inspection

- The inspector will collect from you any information not available during the inspection.
- The inspector will prepare a report: request a copy.
  - The report is not supposed to contain the inspector's opinions or any legal conclusions.
- The inspector's report will go to a Case Development Officer (CDO) who will evaluate the case for potential prosecution.
  - Sometimes the inspector and the CDO are the same person.
- You may not hear from USEPA for a long time after an inspection, if you hear anything at all.
- There is a five-year statute of limitations (SOL) for violations of Core TSCA.
  - Will eliminate all one-day violations in due course.
  - Will not eliminate continuing violations but can limit the total liability for them.
  - SOL may be tolled in other circumstances (e.g., fraudulent concealment of violations).



**Questions?**

**Thank you!**



**Step toe**



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