How I survived a Compreshenisve EPA TSCA Audit

ZEON

SCHC Meeting, September 25, 2024

A blue sky summer day, 2023……..

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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ELECTRONIC MAIL
CONFIRMATION OF EMAIL RECEIPT REQUESTED

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Re: Notice of Inspection
Toxic Substances Control Act

What is included in a comprehensive EPA TSCA audit?

The inspection will be conducted pursuant to Section 11 of the Toxic Substances Control Act (TSCA) to determine compliance with TSCA Sections 4, 5, 8, 12 and 13. As applicable, among the specific issues to be addressed are the chemical substances or mixtures manufactured, imported, exported, processed, stored, used, or disposed of in relation to or associated with your establishments, facilities or other premises. The inspector will (1) review files, data and correspondence that are either required to be maintained by TSCA or applicable to the chemical substances or mixtures within your facilities and (2) interview personnel if necessary. Among the specific issues to be addressed are:

What is included in a comprehensive EPA TSCA audit?

- Premanufacture Notices (PMNs) submitted by the facility, or requests for exemption from the PMN review process, including Low Volume Exemptions (LVEs), Test Marketing Exemptions (TMEs), Low Release and Low Exposure Exemptions (LoREX), and Polymer Exemptions (PEs).

- Notice of Commencements (NOCs), Bonafide Intent to Manufacture Letters, and Significant New Use Notices (SNUNs) submitted by the facility and any associated TSCA Section 5(e) or (f) Consent Orders issued by the EPA.

- Research and development activities and procedures in effect at the facility, specifically as related to compliance with the requirements of a TSCA Research and Development (R&D) Exemption.

- Records maintained by the facility pursuant to TSCA Sections 8(a), (c), (d) and (e), including the 2020 Chemical Data Reporting (CDR) Rule report.

- Facility and/or Corporate Headquarters' operations and practices developed to ensure compliance with TSCA Sections 4, 5, 8, 12 and 13.

- Manufacturing and process flow diagrams for some chemical substances that are manufactured at the facility.

What information were we required to provide to EPA?

- Process flow diagrams for certain products including – raw materials and CASRN for each step in the manufacturing process including intermediates, byproducts, and catalysts.

- For chemical substances manufactured for 2018 and 2019, we were required to provide CASRN, product names, manufacture date, volume per batch, batch number, and percentage of each substance in a production of a mixture.

What information were we required to provide to EPA?

- For substances imported 2018 – 2019, we were required to provide CASRN, product names, import date, quantity per import, percentage of each substance imported as part of a mixture, and Safety Data Sheet.

- For chemical substances purchased from domestic suppliers in 2021 and 2022, we were required to provide CASRN, the manufacturer or supplier name and address, and Safety Data Sheet

What information were we required to provide to EPA?

- For substances exported in 2021 and 2022, we were required to provide CASRN, chemical name, manufacture date, a copy of the export paperwork, and the destination country.

What information were we required to provide to EPA?

- Records demonstrating compliance with Section 5(e)/(f) consent orders, Significant New Use Rules,
- Records demonstrating compliance with LVE's, TME's and PE's as well as EPA responses in the last 5 years.
- List of PMN's and SNUN's submitted by or transferred to your company.
- List of NOC's submitted by your company.
- Provide company information such as history of the business, corporate struction, list of facitlities, number of employees, shifts, and gross annual sales

What information were we required to provide to EPA?

- List of facility and/or corporate policies developed to ensure compliance with TSCA Sections 4, 5, 8, 12, and 13.
- A list of R&D chemicals manufactured or imported at the facility, including name and address of anyone who received the R&D chemicals, the amount distributed per shipment, and the SDS or any notice provided to customers of the R&D chemicals.
- For Section 4 of TSCA, provide any letters of intent to conduct testing, requests for exemptions from testing, for any chemical manufactured or used subject to a test order.

What information were we required to provide to EPA?

- For Section 5(h), research and development activities and procedures, especially records related to recordkeeping requirements, documentation of prudent laboratory practice, and operating manuals or procedures that are used by laboratory personnel to manage chemicals with unknown hazards.
- For Section 8(b), for the CDR, provide a copy the report filied on behalf of the facility and one sample calculation of the volumes reported for the 2020 CDR.

What information were we required to provide to EPA?

- For Sections 8(c), 8(d), and 8(e), provide documentation of allegations subject to 8(c) reporting, a copy of **OSHA Injury and Illness Forms 300, 300A, and 301**, a list of 8(d) health and safety studies submitted to EPA and copies of any known health and safety information that were not submitted to EPA, provide Section 8(e) substantial risk information not know to th EPA or previously submitted to

Some things I learned

- First, we have a pretty stellar program because there have been no findings of non-compliance.
- WRITTEN programs are important.
- Immediately call a good TSCA lawyer when you get the notice of inspection.
- Check all CASRN’s before sending the information to EPA.
- CBI must be certified, substantiated. AND santitized versions of information submitted to EPA must accompany CBI versions of information.

Some things I learned

- Conduct internal audits. You can’t build a program at the moment you get a notice of inspection.
- Talk to a TSCA lawyer before beginning internal audits. Be sure findings are covered under attorney/client privilege.

References for my program

Bergeson, L.L. & Auer, C.M. *New TSCA: A Guide to the Lautenberg Chemical Safety Act and Its Implementation*. ABA Book Publishing. 2017.