

# TSCA

WHY SHOULD I CARE?

Presented by:

AnnMarie Sanford

Member | Troy, MI

November 9, 2022



# AGENDA

- I've Ignored TSCA This Long, Why Should I Care Now?
- TSCA 101
- Recent TSCA Actions and Why You Should Pay Attention

# TSCA 101



# HISTORY OF THE TOXIC SUBSTANCES CONTROL ACT (“TSCA”)

- Enacted in 1976 to address concerns about chemical safety
  - In practice, it was not effective at regulating chemicals
- 2005 GAO Study on TSCA identified significant shortcomings
- Increased public concern regarding chemical safety
- In 2016, Congress passed the Frank R. Lautenberg Chemical Safety for the 21<sup>st</sup> Century Act, or “New TSCA”

# TSCA 101: KEY DEFINITIONS

- “Chemical Substances”
  - Exclusions:
    - Any mixture
    - Pesticides
    - Tobacco
    - Regulated nuclear material
    - Firearms
    - Regulated food, drugs or devices
- “Mixtures”
  - Subject to §4, §6 and §8, not subject to §5

# TSCA 101: KEY DEFINITIONS

- “Manufacturer” includes importers
- “Processor” includes companies that use a substance to produce an article which contains either that substance itself or another substance derived from it during production of an article.
- “Conditions of Use” (added in new TSCA)
- “Potentially Exposed or Susceptible Subpopulation (“PESS”) (added in new TSCA)



# TSCA 101: KEY SECTIONS

- Section 4: Testing of Chemical Substances and Mixtures
  - EPA can require the development of test information regarding health and environmental effects
  - As part of new TSCA, EPA is not required to make any legal finding to require this testing.

# TSCA 101: KEY SECTIONS

- Section 5: Manufacturing and Processing Notices (PMNs)
  - Generally requires companies to notify EPA prior to manufacturing or processing new chemicals that are not on the TSCA inventory, or significant new uses of existing chemicals
  - Exemptions from PMN requirements





# TSCA 101: KEY SECTIONS

- Section 6: Prioritization, Risk Evaluations, and Regulation of Chemical Substances and Mixtures
  - Allows EPA to restrict or ban chemicals upon a showing they present an unreasonable risk of injury to health or the environment
  - Must consider PESS if EPA requires
  - EPA is required to conduct risk evaluation on all high-priority chemicals

# TSCA 101: KEY SECTIONS

- Section 8: Reporting and Retention of Information
  - Provides EPA with broad authority to require companies to report information
  - New TSCA required an “Inventory Reset” to determine which chemicals are active and which are inactive.



# TSCA 101: KEY SECTIONS

- Section 14: Confidential Business Information (“CBI”)
  - New TSCA limited what can be claimed as CBI
  - Requires CBI claims to be substantiated upon submission

# RECENT EPA ACTION

*WHY YOU SHOULD PAY ATTENTION*



# RECENT EPA ACTION

- Section 8 Data Call-In
  - July 2021 EPA issued first data call-in under Section 8 since 2008
- Section 4 Test Orders
  - Since 2021, EPA has issued 11 test orders, including to processors

## SECTION 8 PFAS DATA CALL-IN

- June 28, 2021, EPA proposed a rule to require manufacturers (including importers) of PFAS to report for each year since January 1, 2011
  - Rule must be finalized by January 1, 2023
- At least 1,364 different PFAS constituents are subject to this rule
- No exemptions for *de minimis* amounts of PFAS
- Byproducts and impurities are included
- **Articles are included – THIS IS WHY YOU NEED TO PAY ATTENTION**
- EPA will create a new reporting tool
- Reporting deadline is January 2024

## SECTION 8 PFAS DATA CALL-IN

- EPA suggests that most respondents will be from the following NAICS codes (with the exception of articles manufacturers):
  - 324—Petroleum and Coal Product Manufacturing
  - 325—Chemical Manufacturing
  - 326113—Unlaminated Plastics Film and Sheet (except Packaging) Manufacturing
  - 327910—Abrasive Product Manufacturing
  - 333999—All Other Miscellaneous General Purpose Machinery Manufacturing
  - 334511—Search, Detection, Navigation, Guidance, Aeronautical, and Nautical System and Instrument Manufacturing
  - 336111—Automobile Manufacturing
  - 423510—Metal Service Centers and Other Metal Merchant Wholesalers
  - 424690—Other Chemical and Allied Products Merchant Wholesalers
  - 447190—Other Gasoline Stations
  - 551112—Offices of Other Holding Companies
  - 562—Waste Management and Remediation Services



## SECTION 8 PFAS DATA CALL-IN

- No exemption for small manufacturers and processors
- Article manufacturers (including importers) are required to report
  - Anyone that has made a product with PFAS or that has imported a product that contains PFAS is required to report under this rule
  - This will affect companies that have never reported under TSCA, including auto suppliers that import parts, and even retailers that import products.



## SECTION 8 PFAS DATA CALL-IN

### • THE REQUESTED INFORMATION INCLUDES:

- Chemical name (multiple if mixture), or the generic name(s) if the chemical name(s) is CBI
- Chemical ID(s) (CASRN, TSCA Accession Number, or LVE case number)
- Trade name or common name
- Representative molecular structure
- Physical form of chemical or mixture
- Industrial processing and use:
  - Type of process or use;
  - Sector(s);
  - Functional use category(ies);
  - Percent of production volume for each use
- Consumer and commercial use:
  - Indicator for whether this is a consumer and/or commercial product
  - Product category; functional use category(ies)
  - Percent production volume for each use; maximum concentration in any product
  - Indicator for use in products intended for children



## SECTION 8 PFAS DATA CALL-IN

- THE REQUESTED INFORMATION INCLUDES:
  - Production volumes:
    - Domestically manufactured;
    - Imported;
    - Directly exported;
    - Maximum first 12 months production volume;
    - Maximum yearly production volume in any 3 years
  - Indicator for imported but never physically at site
  - Indicator for site-limited
  - Maximum quantity stored on-site at any time
  - Total volume recycled (on-site)
- For byproducts produced during the manufacture, processing, use, or disposal of each PFAS:
  - Chemical name(s) or description (if identity is unknown), or the generic name(s) if the byproduct name(s) is CBI;
  - Chemical ID(s) (CASRN, TSCA Accession Number, or LVE case number);
  - Indicator for whether the byproduct(s) production resulted from manufacture, process, use, or disposal; and
  - Indicator for whether the byproduct(s) is released to the environment; if so, volume of byproduct(s) released and to which environmental media



## SECTION 8 PFAS DATA CALL-IN

- THE REQUESTED INFORMATION INCLUDES:
  - Worker exposure: Description of worker activity(ies) at manufacturing site
  - Worker exposure at the manufacturing site:
    - Number of workers reasonably likely to be exposed at the manufacturing site, for each worker activity;
    - Maximum duration of exposure for any worker, for each worker activity (both hours per day and days per year)
  - Worker exposure for each industrial process and use:
    - Number of workers reasonably likely to be exposed for each industrial process and use;
    - Maximum duration of exposure for any worker for each industrial process and use (both hours per day and days per year)
  - Worker exposure for each commercial use:
    - Number of workers reasonably likely to be exposed for each commercial use;
    - Maximum duration of exposure for any worker for each commercial use (both hours per day and days per year)



## SECTION 8 PFAS DATA CALL-IN

- THE REQUESTED INFORMATION INCLUDES:
  - Description of disposal process(es), and description of any changes to the disposal process or methods since 2011
  - Total volume released:
    - a. Land disposal;
    - b. Water releases;
    - c. Air releases
  - Total volume incinerated (on-site) and incineration temperature
  - All existing information related to health and environmental effects, using the Organization of Economic Cooperation and Development (OECD) harmonized template relevant to the existing study, as well as full study reports and any other supporting information
  - Other data relevant to health and environmental effects (e.g., range-finding studies, preliminary studies, OSHA medical screening or surveillance standards reports, adverse effects)



## SECTION 8 PFAS DATA CALL-IN

What is the Reporting Standard?

- “Known to or reasonably ascertainable by” includes “all information in a person’s possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know.”
- This standard requires due diligence
- The information-gathering activities and the amount of due diligence may vary from case-to-case



## SECTION 8 PFAS DATA CALL-IN

- How Should Article Manufacturers/Importers Prepare?
  - Establish a process for gathering data and substantiating steps taken to comply
  - Determine which products manufactured by the company contain PFAS
  - Review purchasing and supply chain information to identify articles that have been imported since January 1, 2011
  - Assess which of those potentially could have contained PFAS
    - Research historical PFAS usage in the subject products
    - Coordination with suppliers will be crucial since PFAS may not be specifically identified
  - For identified products, begin gathering the requested information
  - Evaluate any CBI claims
  - Document the process used to identify products and gather information to defend any claims the submission was insufficient.

# QUESTIONS

AnnMarie Sanford

[ASanford@dickinsonwright.com](mailto:ASanford@dickinsonwright.com)