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Everchanging TSCA Landscape

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Agenda

The Everchanging TSCA Landscape and How It Affects Hazard Communication – Thursday, September 26, 10:45-11:15A

01 **What is GHS, OSHA, TSCA?**

02 **What are Articles?**

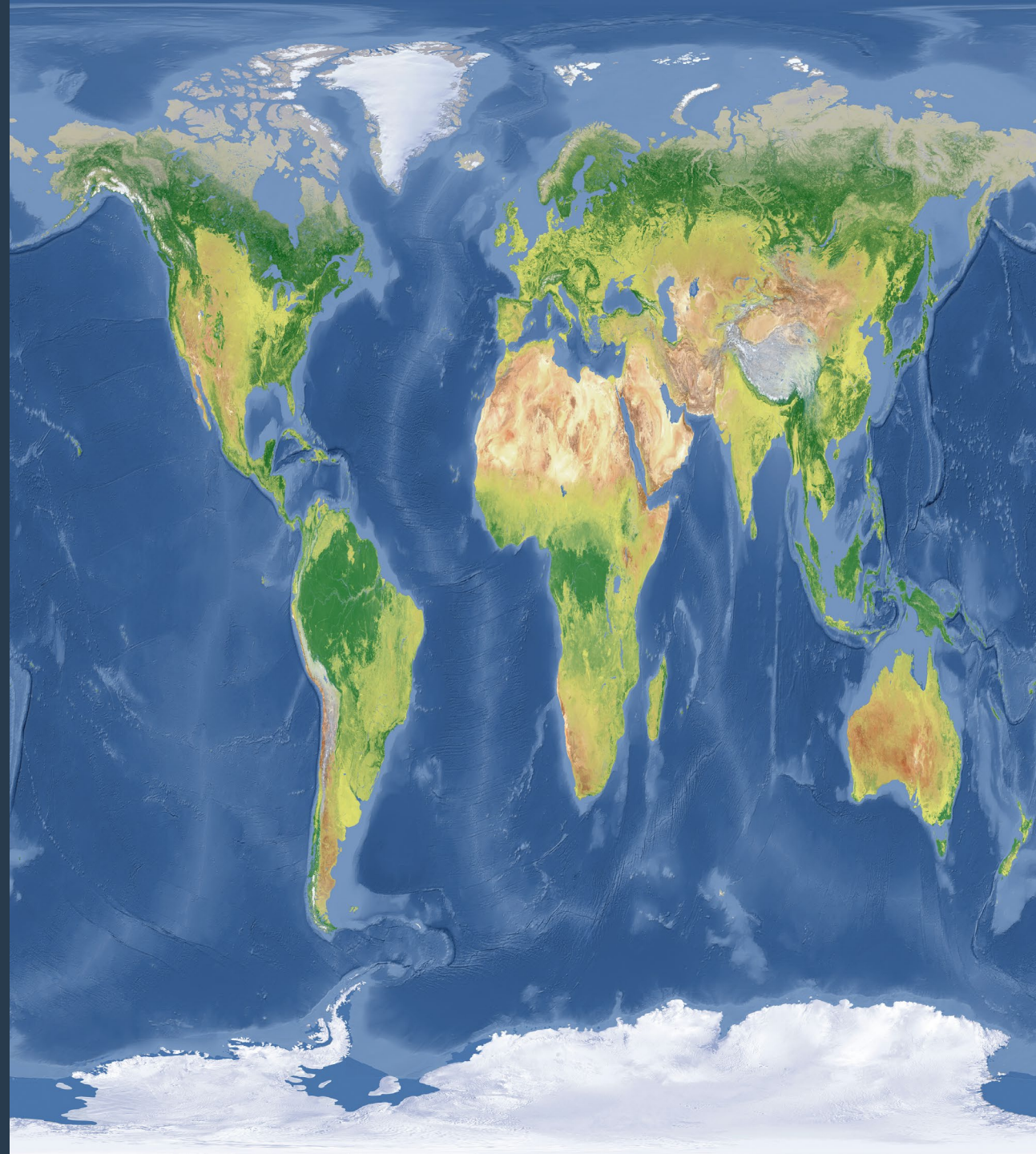
03 **When is an Article not an Article?**

04 **PFAS**

05 **How Companies can prepare**

01

What are GHS, OSHA, TSCA?



GHS, OSHA, TSCA

The **Globally Harmonized System (GHS)** is an internationally agreed-upon standard for classifying and labeling chemicals based on their potential health, physical, and environmental hazards.

The GHS has been updated and revised every two years since its adoption, with the most recent revision being the tenth revised edition (GHS Rev.10) published in 2023. A new revised edition is expected to be published in 2025.

The **Occupational Safety and Health Act** of 1970 is a US labor law governing the federal law of occupational health and safety in the private sector and federal government in the United States.

The Act created the Occupational Safety and Health Administration (OSHA) and the National Institute for Occupational Safety and Health (NIOSH). OSHA was established by Congress on April 28, 1971, as part of the OSH Act. The agency was created in response to political pressures stemming from rising injury rates during the 1960s. It is an agency in the Department of Labor

The **Toxic Substances Control Act** (TSCA) of 1976, a US law, gives the Environmental Protection Agency (EPA) the authority to regulate chemicals produced or imported into the United States. The TSCA's purpose is to protect human health and the environment from unreasonable risks posed by chemicals.
EPA is under the US Department of the Interior.

02

What are Articles?

GHS

GHS

Scope of the system:

- GHS applies to pure substances and their dilute solutions and to mixtures. Articles as defined by the Hazard Communication Standard (29 CFR 1910.1200) of the OSHA (Administration) are outside the scope of the system.
- There is discussion of explosive or projectile articles and articles for transport

OSHA

29 CFR 1910.1200 Occupational Safety and Health Standards

(c) Article means a manufactured item other than a fluid or particle:

(i) Which is formed to a specific shape or design during manufacture;

(ii) Which has end use function(s) dependent in whole or in part upon its shape or design during end use; and

(iii) Which under normal conditions of use does not release more than very small quantities, e.g., minute or trace amounts of a hazardous chemical (as determined under paragraph (d) of this section), and does not pose a physical hazard or health risk to employees.

TSCA

The Toxic Substances Control Act (TSCA) defines an article as a manufactured item that meets the following criteria

40 CFR 704.3:

“Article” means a manufactured item

(1) which is formed to a specific shape or design during manufacture,

(2) which has end use function(s) dependent in whole or in part upon its shape or design during end use, and

(3) which has either no change of chemical composition during its end use or only those changes of composition which have no commercial purpose separate from that of the article, and that result from a chemical reaction that occurs upon end use of other chemical substances, mixtures, or articles; except that fluids and particles are not considered articles regardless of shape or design.

Chemical substances that are part of articles and that are not intended to be removed and have no separate commercial purpose are generally exempt from certain TSCA regulations (e.g., TSCA premanufacture notification (PMN)). Chemical substances contained in articles that are designed to be used separately from the article or released (i.e., ink in pens) are not considered to be part of an article for the purposes of an article exemption where applicable.

03

When is an Article not an Article

TSCA

The EPA's Michal Freedhoff, stated that the chemicals in articles are subject to TSCA. This indicates that the EPA is moving towards regulating finished products more under TSCA.

- PBT
- PFAS
- CDR

- Chemical Data Reporting (CDR) 40 CFR 711.10(b)

711.10 Activities for which reporting is not required.

- A person described in § 711.8 is not subject to the requirements of this part with respect to any chemical substance described in § 711.5, when:

  (b) The person imported the chemical substance as part of an article.

PBT AND ARTICLES

Substance Identity	Rule Summary	Use
2,4,6-tris(tert-butyl)phenol (2,4,6-TTBP) (CASRN 732–26–3)	Prohibits the distribution in commerce of and products containing at concentrations above 0.3%,	a reactant in processing that is also used as an additive in fuels and lubricants;
Hexachlorobutadiene (HCBD) (CASRN 87–68–3)	Prohibits all manufacturing (including import), processing, and distribution in commerce and containing products or articles, recognizing that there is unintentional production of HCBD as a byproduct	used as a solvent and as a hydraulic, heat transfer or transformer fluid, and can be produced as a byproduct during the manufacture of chlorinated hydrocarbons.
Pentachlorothiophenol (PCTP) (CASRN 133–49–3)	Prohibits the manufacture (including import), processing, and distribution in commerce and products and articles containing, unless PCTP concentrations are below 1% by weight.	used to make rubber more pliable

TSCA

In March 2021, EPA announced a 60-day public comment period to collect additional input on these final rules.

Additionally, EPA issued a temporary 180-day “No Action Assurance” indicating that the agency will exercise its enforcement discretion regarding the prohibitions on processing and distribution of PIP (3:1) for use in articles to ensure that the supply chain of these important articles is not interrupted while EPA continues to collect the information needed to best inform subsequent regulatory efforts and allow for the issuance of a final agency action.

EPA will exercise its enforcement discretion to not pursue enforcement actions for violations of the prohibitions on processing and distribution of PIP (3:1)

Once PIP (3:1) is identified, a suitable alternative or replacement component may need to be tested for industry safety or performance standards.

PIP was not regulated in other jurisdictions.

Substance Identity	Rule Summary eol=end of life	Use/Exposure
Decabromodiphenyl Ether (DecaBDE) CASRN 1163–19–5 Jan 2021 final	Prohibits all manufacture (including import), processing, and distribution in commerce of, or containing products or articles: phased in 2021 plastic pallets: 2022 hospital curtains: 2023 cables: 2024 new aerospace; 2036 motor vehicles: can still recycle the articles, but no new decaDBE: keep business records for 3 years and present to the EPA upon request	a flame retardant used in televisions, computers, textiles and other applications; dust inhalation, dairy use
rule coming October 2024	Require PPE for dust and dermal; labeling; notice to workers; no release to water; extend phase out date; not regulating disposal; no proposed testing	Cont; document PPE use and training; date for removal in wires extended asking for info, records for 5 (not 3) years

PBT AND ARTICLES

Substance Identity	Rule Summary	Use/exposure
Phenol, Isopropylated Phosphate (3:1) (PIP 3:1) final Jan 2021 – no action assurance	Prohibits the processing and distribution containing products, with specified exclusions, and prohibits the release to water during manufacturing, processing, and distribution. Allowed in aviation, military if no alternative. Phased in: 2025 adhesives: can still recycle the articles, but no new PIP: records for 3 years: For new 60 day or as soon as practicable: believes viable substitutes	used as a flame retardant in consumer products, as a plasticizer and as a lubricant and hydraulic fluid in aircraft and industry; PIP (3:1) is used as a plasticizer, a flame retardant, an anti-wear additive, or an anti-compressibility additive in hydraulic fluid, lubricating oils, lubricants and greases, various Industrial coatings, adhesives, sealants, and plastic articles./PBT
rule coming October 2024	Phase-in prohibitions: not regulating disposal: no technically feasible alternatives: broadening allowed industries:	15-year phase in motor vehicles: 30-year replacement parts: wire/circuit boards-impracticable to prohibit: marine antifouling limited to Dept. Defense

PBT AND ARTICLES

Substance Identity	Rule Summary	
rule coming October 2024	Cont. semi-conductor Additional 20 years from Oct. 31, 2024: considering a 30-year for aerospace; low exposure so no specific PPE for PIP, workers should use normal PPE; will require engineering controls:	Cont. extend record keeping from 3 to 5 years

4.1

Regulatory Management of PFAS

PFAS –Management

- According to the US government, over 1000, 4000 (13,000) chemicals in commerce are considered PFAS
- Many PFAS are subject to the Toxic Substances Control Act (TSCA), Significant New Use Rules (SNUR) or Consent Orders that provide specific conditions with which a company must comply for the manufacture, processing, distribution or disposal of the substance. In some instances, the EPA is rescinding SNUR.
- EPA will not accept Low Volume Exemptions (LVE) for PFAS
- EPA is expanding the scientific understanding of PFAS
- Actions include contaminated site cleanup tables, new toxicity assessments
- Engaged with the public- EPA's PFAS work was informed by public webinars, stakeholder meetings, Congressional testimony, and engagement with EPA's federal advisory committees.

PFAS –Management

Safe Drinking Water

In December 2021, EPA finalized the fifth Unregulated Contaminant Monitoring Rule, which expanded PFAS testing nationwide by requiring monitoring for 29 PFAS in drinking water.

In April 2022, EPA released draft recommended water quality criteria for Perfluorooctanoic acid (PFOA) and Perfluorooctanesulfonic acid (PFOS) that are intended to provide the best-available scientific recommendations from EPA on how States and Tribes can protect against harmful effects to aquatic life.

04.2

Reporting Rule- TSCA Final Rule for reporting and recordkeeping of PFAS

PFAS – Reporting Rule

September 28, 2023

Requires each company who has manufactured during January 1, 2011, to December 2022 to submit a report.

EPA plans to use this information to support actions to address PFAS exposure and contamination, including PFAS activities and programs under other environmental statutes (e.g., Resource Conservation and Recovery Act (RCRA),Clean Water Act (CWA), Safe Drinking Water Act (SDWA), and Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA).

PFAS – Reporting Rule

- Anyone who has manufactured or imported PFAS in any year since January 1, 2011.
- This includes:
    - Manufacturers of PFAS
    - Importers of PFAS
    - Importers of mixtures containing PFAS
    - Importers of articles containing PFAS
- The scope of the rule includes many types of consumer, industrial, and commercial products and goods.
- Processors of PFAS (purchase PFAS domestically and process into other mixtures or articles) are not required to report.

PFAS – Reporting Rule

PFAS that are excluded are uses not under the TSCA jurisdiction (e.g., pesticides, food, food additives, drugs, cosmetics, medical devices, etc.).

Non-commercial R&D activities (e.g., scientific experimentation conducted by academic, government or nonprofit research organizations).

Waste management activities involving importation of municipal solid waste streams for purpose of disposal or destruction.

But none of the typical TSCA reporting exemptions are included. The rule includes:

- Coincidental manufacture of PFAS as byproducts or impurities
- R&D PFAS that were manufactured for a commercial purpose
- Trace amounts of PFAS
- Intentionally added PFAS and unintentionally present PFAS
- Small businesses

PFAS – Reporting Rule

PFAS are defined as including at least one of these three structures:

- R-(CF2)-CF(R’)R’’, where both the CF2 and CF moieties are saturated carbons;
- R-CF2OCF2-R’, where R and R’ can either be F, O, or saturated carbons; and
- CF3C(CF3)R’R’’, where R’ and R’’ can either be F or saturated carbons.

EPA will provide a non-exhaustive list 1,462 (13,000) substances that meet this definition.

Fluoropolymers meeting the rule’s definition of PFAS must be reported.

PFAS – Reporting Rule

- EPA is requiring any person that manufactures (including import) or has manufactured (including imported) PFAS or PFAS-containing articles in any year since January 1, 2011, to electronically report information regarding PFAS uses, production volumes, disposal, exposures, and hazards.
- The requirements of this rule also apply to PFAS manufactured as a byproduct or impurity or in articles or mixtures.
- For any reporter who is reporting under this part exclusively pursuant to §705.18(a) (article importers), and is also considered a small manufacturer under the definition at 40 CFR 704.3, the submission period shall begin on July 11, 2025, to January 2026, and last for 12 months for small entities: July 11, 2025, through July 11, 2026
- Examples of articles that may contain PFAS include but are not limited to: textiles, electrical equipment and components, automotive components, pipes, wires and cables, cookware, and transportation equipment.

PFAS – Reporting Rule - Information that must be reported

- Company and site information
- Chemical-specific information
- Categories of use
- Total amounts manufactured/imported of each PFAS (including the amounts manufactured in each calendar year for each category of use)
- Number of individuals exposed
- Byproducts and disposal information
- Health and environmental effects
- Streamlined reporting option for article importers and low volume commercial R&D (under 10 kg/year)

PFAS – Reporting Rule – Standard of Diligence

"Known to or reasonably ascertainable by" the manufacturer or importer - CASE BY CASE ANALYSIS

- "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."
    - Company files, files maintained by employees and agents
    - Commercial databases in which the company has purchased access
    - Marketing studies, sales reports, customer surveys
    - Information from Chemical Abstract Services (CAS) or Dun & Bradstreet
    - SDSs, supplier notifications

- No duty to test or conduct exhaustive surveys.

- But standard may require inquiries outside of company to "fill gaps in knowledge."

PFAS – Reporting Rule – Timing

The rule went into effect on November 13, 2023.

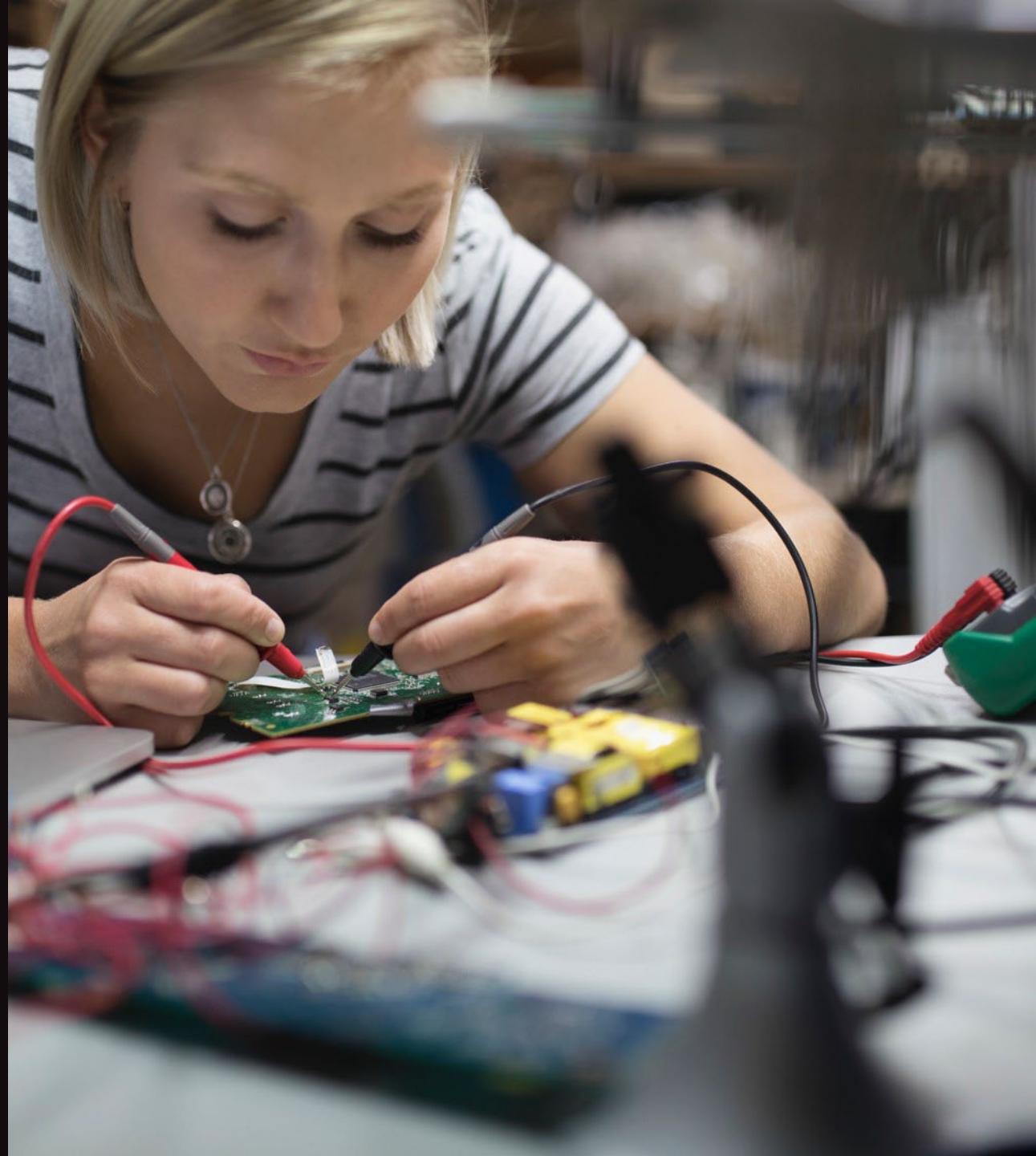
The US Environmental Protection Agency (EPA) issued a direct final rule on September 5 that will delay the beginning of the reporting period until July 11, 2025. The reporting period was previously set to begin on November 12, 2024. Most companies reporting PFAS data under the TSCA rule will now have until January 22, 2026 to meet their reporting obligations.

Small manufacturer: a manufacturer (including importer) that meets either of the following standards:

1. The total annual sales, when combined with those of its parent company (if any), are less than $120 million, and the annual production/importation volume of the substance at any individual site owned or controlled by the manufacturer/importer is <45,400 kg (100,000 lbs).
2. The 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 (including importer).

04.3

Framework for TSCA New Chemicals Review of PFAS Premanufacture Notices (PMNs) and Significant New Use Notices (SNUNs)



PFAS – PMN SNUN

The New Chemicals Program developed this framework (“PFAS Framework”) to help ensure that the Program effectively and efficiently reviews and makes appropriate decisions on new PFAS or significant new uses of existing PFAS reviewed through premanufacture notices (PMNs) and significant new use notices (SNUNs).

The framework outlines EPA’s planned approach when reviewing new PFAS and new uses of PFAS to ensure that these chemicals & uses do not present unreasonable risk to human health and the environment.

- Provides consistency in the review approach and predictability and transparency of process

PFAS – PMN SNUN

After EPA has concluded that the substance is a PFAS and determined the key components of interest (e.g., the substance itself, or potential metabolites or degradants), EPA will begin reviewing all available data on the PFAS and its metabolites and degradants.

While there are thousands of different PFAS, only a small fraction have been well studied.

The PMN or SNUN must include all information in the possession or control of the submitter that can inform the evaluation of the human health or environmental effects of the chemical substance (insofar as known or reasonably ascertainable to the submitter).

Often, however, EPA receives submissions for chemical substances that lack critical data on physical-chemical properties, fate, and toxicity.

PFAS – PMN SNUN

Early in the review process, EPA will consider whether the PFAS is a persistent, bioaccumulative and toxic (PBT) chemical.

In the 1999 PBT policy statement (64 FR 60194) and the 2018 Points to Consider policy document, EPA established criteria for identifying PBTs for the New Chemicals Program, which involves considering physical-chemical properties, as well as structural activity alerts, analogue data, and test data on the new chemical substance to quantify on a scale of 1 to 3 the potential for persistence (P), bioaccumulation (B), and toxicity (T) for a given new chemical substance.

EPA identifies and assesses the PBT properties of new chemical substances on a case-by-case basis using the reasonably available data.

05

How Companies Can Prepare

Take Aways:

- Articles are no longer “easily” exempt from TSCA.
- Industries said they had been unaware, but were now discovering, that the substance is used in thousands of products, ranging from computers and clothes dryers to manufacturing equipment and military supplies.
- What you need to do for OSHA does not translate to what you need to do for TSCA

Practical Points to consider Now! PFAS and any other Reporting Rule: DO YOU MANUFACTURE, IMPORT, PROCESS OR DISTRIBUTE?

- Is there an alternative?
- Assurances from supplier?
- It might be good to start with a few of the restricted substance requirements holistically.
- This will allow you to implement practical and sustainable solutions.
- Ask yourself what is your highest commercial risk.
- Need Expertise:
  - Regulatory;
  - Supplier Engagement Team;
  - Testing resources; and
  - Software

PFAS – How Companies Can Stay Prepared

Companies can be proactive in their quest to maintain compliance by:

- Staying informed on current and upcoming regulations;
- Performing an internal audit of activities, services, and products they are involved with;
- Conducting a material risk assessment to analyze potential hazards and opportunities associated with the raw materials used in a business;
- Testing; and
- Educating and obtaining assurance from supply chains.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