

TSCA 2025

A&WMA ACE 2025:
Regulatory Updates

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Raleigh, NC



VERDANT
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What is TSCA?

Toxic Substances Control Act

Federal Chemical Regulation

Chemicals regulated by TSCA

Any organic or inorganic substance of a particular molecular identity.

(15 U.S.C. §2602)



Exceptions

- Pesticides (as defined in the Federal Insecticide, Fungicide, and Rodenticide Act)
- Tobacco and tobacco products
- Nuclear materials
- Shells and cartridges
- Food, food additive, drug, cosmetic, or device (as defined in the Federal Food, Drug, and Cosmetic Act)

Implications for manufacturing



It shall be unlawful for any person to use for commercial purposes a chemical substance or mixture which such person knew or had reason to know was manufactured, processed, or distributed in commerce in violation of rules and orders issued under §§2604, 2605, and 2606
(§2614. Prohibited acts)

Regulatory Developments

Developments in...

1. Regulation of new chemicals/new uses

PMNs, COs, SNURs and SNUNs

2. Regulation of existing chemicals

Prioritization, risk evaluation, risk management

3. Other regulatory efforts

PFAS reporting rule, health and safety study reporting

Manufacturing new chemicals


Except as provided in subparagraph (B) of this paragraph no person may manufacture a new chemical substance on or after the 30th day after the date on which the Administrator first publishes the list required by section 2607(b) of this title.
(§2604. Manufacturing and processing notices)

Manufacturing new chemicals, cont.

→ *PMNs*

PART 720—PREMANUFACTURE NOTIFICATION

This part establishes procedures for the reporting of new chemical substances by manufacturers under section 5 of the Toxic Substances Control Act, [15 U.S.C. 2604](#). This part defines the persons and chemical substances subject to the reporting requirements, prescribes the contents of section 5 notices, and establishes procedures for submitting notices. (**§ 720.1 Scope.**)

Form App		
U.S. ENVIRONMENTAL PROTECTION AGENCY		
	PREMANUFACTURE NOTICE	
FOR NEW CHEMICAL SUBSTANCES		
When completed, send this form to:	If sending by Courier: Office of Pollution Prevention and Toxics Document Control Office (7407M) US EPA, 1201 Constitution Ave NW WASHINGTON, D.C. 20460 Contact Numbers: 202-564-8930/8940	If sending by US Mail: Office of Pollution Prevention and Toxics Document Control Office (7407M) US EPA, 1200 Pennsylvania Ave NW WASHINGTON, D.C. 20460
Total Number of Pages		TS Number
18		
GENERAL INSTRUCTIONS		

Part 720 Premanufacture Notification

§ 720.1 Scope.

§ 720.3 Definitions.

§ 720.22 Persons who must report.

§ 720.30 Chemicals not subject to notification requirements.

§ 720.36 Exemption for research and development.

§ 720.45 Information that must be included in the notice form.

§ 720.50 Submission of test and other data concerning health and environmental effects.

§ 720.65 Incomplete submissions; and false and misleading statements.

§ 720.70 Notice in the Federal Register.

§ 720.75 Determination.

§ 720.78 Recordkeeping.

(<https://www.ecfr.gov/current/title-40/chapter-I/subchapter-R/part-720>)

(d) *Determinations.*

EPA will make one of the following five determinations:

- (i) The chemical substance presents an unreasonable risk of injury to health or the environment.
- (ii) Information available to EPA is insufficient to permit a reasoned evaluation of the health and the environmental effects of the relevant chemical substance.
- (iii) In the absence of sufficient information to permit EPA to make such an evaluation, the chemical substance may present an unreasonable risk of injury to health or the environment.
- (iv) The chemical substance is or will be produced in substantial quantities, and such substance either 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 substance.
- (v) The chemical substance is not likely to present an unreasonable risk of injury to health or the environment.

89 Federal Register 102773

December 18, 2024

Summary: The Environmental Protection Agency is amending the new chemicals procedural regulations under the Toxic Substances Control Act. These amendments align the regulatory text with the amendments to TSCA's new chemicals review provisions contained in the Frank R. Lautenberg Chemical Safety for the 21st Century Act, will improve the efficiency of EPA's review processes, and update the regulations based on existing policies and experience implementing the New Chemicals Program. This final rule includes amendments that will increase the quality of information initially submitted in new chemicals notices and improve the Agency's processes for timely, effective completion of individual risk assessments and the new chemicals review process overall.

Guidance on Updates to New Chemicals Regulations

Level of detail required in new chemicals notices whenever data are known to or reasonably ascertainable by the submitter:

- Category of Use
- Site Identity
- Worker Exposure
- Environmental Release Reporting
- Physical/Chemical Properties
- Environmental Fate Characteristics

(<https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/updates-new-chemicals-regulations>)

Restrictions on new chemicals

→ COs



If EPA's review of a PMN determines that:

- the information in the notice is insufficient to allow the Agency to make a reasoned evaluation of the health and environmental effects of the new chemical substance, or
- in the absence of sufficient information, the manufacture, processing, distribution in commerce, use or disposal of the chemical may present an unreasonable risk to health or the environment, or
- the chemical substance is or will be produced in substantial quantities and will either enter the environment in substantial quantities or there may be significant or substantial human exposure to the substance.

EPA must issue an order under TSCA section 5(e).

Consent Orders

Conditions:

- Testing for toxicity or environmental fate
- Use of worker personal protective equipment
- New Chemical Exposure Limits for worker protection
- Hazard communication language
- Distribution and use restrictions
- Restrictions on releases to water, air and/or land

Distribution and use restrictions

Prior to distributing the New Chemical Substance to any person, the Company must obtain from that person a written agreement that the person will:

1. Comply with the terms and restrictions :
 - a. Protection in the Workplace and Hazard Communication Program
 - b. Terms of Processing
 - c. Terms of Disposal
 - d. Release to Water
2. Not further distribute the New Chemical Substance to any other person except for the purposes of disposal unless there will be no release or exposure.

Restrictions on new chemicals, cont.

→ *SNURs and SNUNs*

No person may manufacture or process any chemical substance for a use which the Administrator has determined is a significant new use unless such person submits to the Administrator a notice intention to manufacture or process such substance and complies with any applicable requirement.

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 721

[EPA-HQ-OPPT-2024-0332; FRL-12563-01-OCSP]

RIN 2070-AB27

Significant New Use Rules on Certain Chemical Substances (24-4.5e)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing significant new use rules (SNURs) under the Toxic Substances Control Act (TSCA) for

§ 721.3155 3,8-Dioxa-4,7-disiladecane, 4,4,7,7-tetraethoxy-.

The significant new uses are:

Industrial, commercial, and consumer activities.

Requirements as specified in [§ 721.80\(y\)\(1\)](#).

§ 721.80 Industrial, commercial, and consumer activities.

a significant new use of the substance is:

(y) Use involving an application method that generates:

(1) A vapor, mist, or aerosol.

Question to EPA

Q. The substance would be fed into a vapor chamber -- a fully enclosed system with no exposures/releases. Is this a Significant New Use?

A. Yes

Now what?

- SNUN
- 721.30 EPA approval of alternative control measures.
- 721.185 Limitation or revocation of notification requirements.

Existing chemicals framework



§2605. Prioritization, risk evaluation, and regulation of chemical substances

Prioritization

The Administrator shall designate as a high-priority substance a chemical substance that the Administrator concludes, without consideration of costs or other nonrisk factors, may present an unreasonable risk of injury to health or the environment because of a potential hazard and a potential route of exposure under the conditions of use, including an unreasonable risk to a potentially exposed or susceptible.

****Upon designating a chemical substance as a high-priority substance, the Administrator shall initiate a risk evaluation.***

Risk Evaluation



Initial risk evaluations. Not later than 180 days after June 22, 2016, the Administrator shall ensure that risk evaluations are being conducted on 10 chemical substances.

Additional risk evaluations. Not later than three and one half years after June 22, 2016, the Administrator shall ensure that risk evaluations are being conducted on at least 20 high-priority substances.

Continuing designations and risk evaluations. The Administrator shall designate at least one high-priority substance upon the completion of each risk evaluation.

Preference. The Administrator shall give preference to chemical substances listed in the 2014 TSCA Work Plan.

Risk Evaluation (cont.)

Requirements

- (i) integrate and assess available information on hazards and exposures
- (ii) describe aggregate or sentinel exposures considered
- (iii) not consider costs or other nonrisk factors
- (iv) consider the likely duration, intensity, frequency, and number of exposures under the conditions of use of the chemical substance
- (v) describe the weight of the scientific evidence for hazards and exposures

EPA Releases Draft TSCA Risk Evaluations for Phthalates DBP and DEHP for Public Comment and Peer Review

- Public comments due August 4, 2025.
- Public meeting of the SACC August 4–8, 2025.
- Comments for consideration by the SACC must be submitted by July 21, 2025.

Risk Management

If the Administrator determines that a chemical substance presents an unreasonable risk of injury to health or the environment, the Administrator shall propose in the Federal Register a rule restricting the manufacture or use of the substance to the extent necessary so that the chemical substance or mixture no longer presents such risk.



Regulatory Developments

- Risk Evaluation Process
- Risk Management Rules

EPA Announces Path Forward on Chemical Reviews to Protect Public Health, Increase Efficiency and Follow the Law

Consistent with [President Trump's Executive Order 14219](#) requiring the review of regulations to ensure consistency with Administration policy and agencies' statutory authority, EPA has completed a review of ... After completing this review and considering public comments and concerns ... the agency intends to initiate further rulemaking ...

United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union, AFLCIO, v. EPA

Declaration in Support of Motion for Voluntary Remand

After the new Administration took office on January 20, 2025, the President issued several Executive Orders calling for careful review of agency actions for compliance with applicable law. Of note is Executive Order 14219, which requires reviewing all regulations subject to an agency's jurisdiction for "consistency with law and Administration policy" and identifying "regulations that are based on anything other than the best reading of the underlying statutory authority or prohibition." "Ensuring Lawful Governance and Implementing the President's 'Department of Government Efficiency' Deregulatory Initiative," § 2(a), (a)(iii), 90 Fed. Reg. 10,583, 10,583 (Feb. 25, 2025). Accordingly, EPA is conducting a review of its rules, including rules promulgated by OCSPP to implement TSCA. 5. OCSPP has determined that the 2024 Rule at issue in this petition for review should be reconsidered through further rulemaking. Accordingly, EPA, by and through OCSPP, believes that remand of this action for further reconsideration is appropriate and necessary to effective implementation of its TSCA program.

Trichloroethylene (TCE) Regulation Under TSCA 89 FR 102568; December 17, 2024

In ongoing litigation over the rule EPA stated

- The Agency has “determined that the TCE Rule . . . should be reconsidered through further rulemaking.”
- EPA plans to solicit early stakeholder input, issue a proposed rule seeking public comment on potential changes to the TCE Rule, and finalize a new rule based on public input.

EPA Proposes Temporary Relief to Ensure Lab Compliance with Methylene Chloride Regulations under TSCA

PRE-PUBLICATION NOTICE

On May 20, 2025, Lee Zeldin, the EPA Administrator, signed the following document:

Action: **Proposed Rule**
Title: **Methylene Chloride; Regulation under the Toxic Substances Control Act (TSCA); Compliance Date Extensions**
FRL #: **8155.1-01-OCSP**
Docket ID #: **EPA-HQ-OPPT-2020-0465**

Resources

<https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/prioritization-actions-under-tsca>

<https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/ongoing-and-completed-chemical-risk-evaluations-under>

<https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-management-existing-chemicals-under-tsca>

Other regulatory efforts

- PFAS reporting rule
- Health and safety study reporting

EPA Extends Reporting Period for PFAS Manufacturers

May 12, 2025 EPA announced an interim final rule to extend the dates of the reporting period for data submitted on the manufacture of perfluoroalkyl or polyfluoroalkyl substances (PFAS).

- Start of the submission period delayed nine months, from July 11, 2025, to April 13, 2026.
- Submissions now due by October 13, 2026, for most manufacturers (by April 13, 2027, for small manufacturers reporting exclusively as article importers.)

*****EPA also considering a separate action to reopen other aspects of this rule for public comment.***

EPA Finalizes Health and Safety Data Reporting Rule for 16 Chemicals Being Considered for Risk Evaluation under TSCA

- On December 13, 2024, EPA published a final rule requiring manufacturers (including importers) of 16 chemicals to report data from unpublished health and safety studies. And unpublished studies on environmental effects and occupational, general population, and consumer exposure.
- In March, EPA issued a rule to extend the reporting deadline to June 11, 2025, for vinyl chloride and to September 9, 2025, for the other substances.
- Last week, the Agency announced that it will extend the reporting deadlines to May 22, 2026.

Questions?



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