Impact of TSCA Consent Orders and Significant New Use Rules on HazCom Compliance and Recordkeeping

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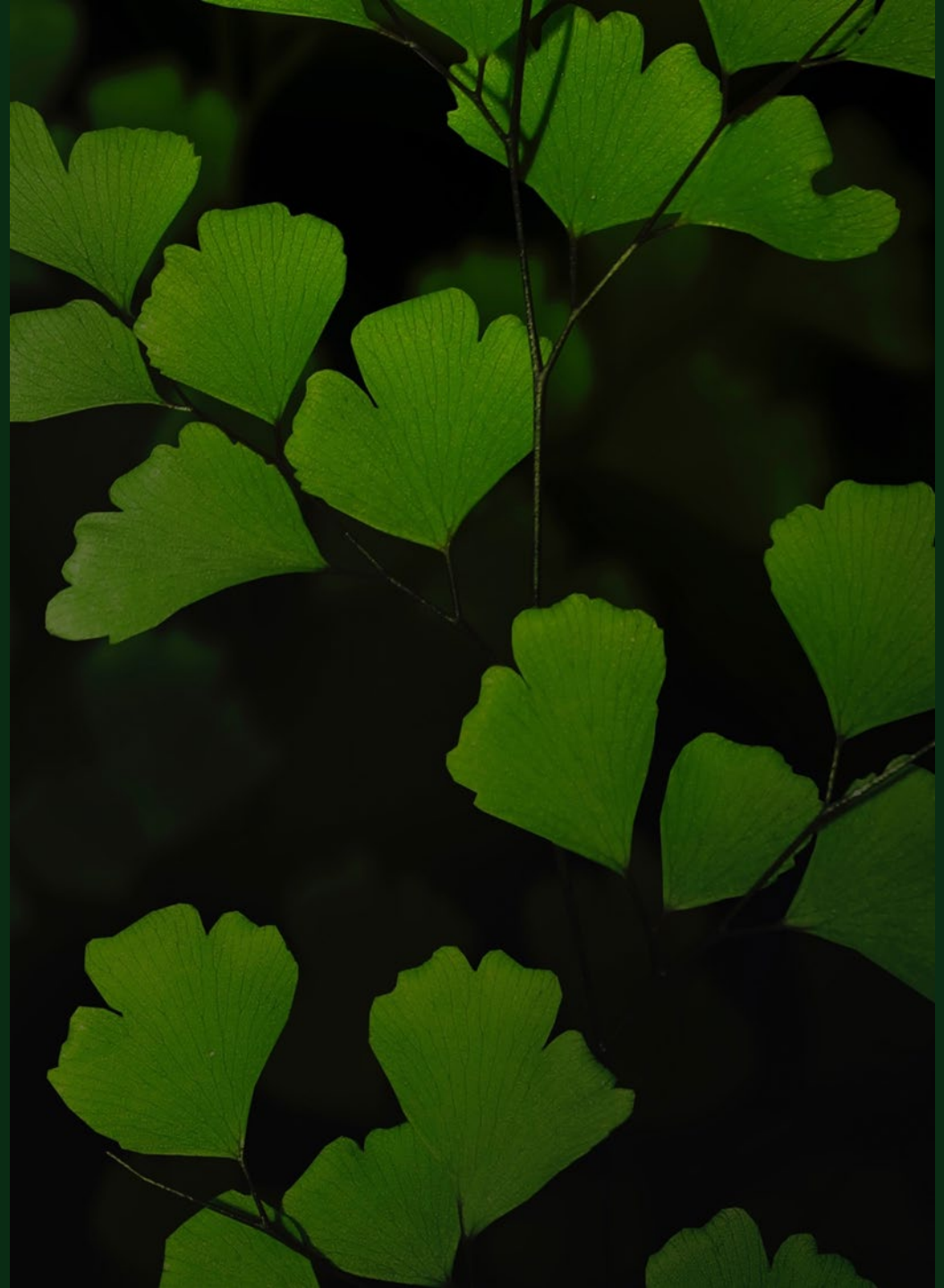


Session Goals

- Determine which chemicals are subject to consent orders (CO) and Significant New Use Rule (SNUR) under the Toxic Substances Control Act (TSCA).
- Review the differences in these regulatory tools and their legal applicability to companies.
- Identify resources for locating these documents.
- Understand common provisions of the regulations.
- Recognize the impacts on site compliance, employee training, hazard communication and recordkeeping.

The Challenge

Increased Regulatory Actions in the United States under TSCA

Regulatory actions on industrial chemicals have increased significantly since the 2016 Lautenburg amendments

Many product stewards are now tasked with ensuring effective hazard communication, ***as well as*** confirming compliance with all TSCA requirements

Requirements can affect information included in safety data sheets and labels and impact site compliance

The Approach

TSCA Inventory Checks and Identification of Regulatory Actions

It is generally the obligation of the manufacturer or processor supplying a chemical to notify the customer of the regulatory status of a chemical and potential restrictions, but that doesn't always happen!

It is best practice to confirm if a chemical is "listed" and "active" on the TSCA Inventory (or otherwise properly excluded or exempt), before accepting shipments or sending chemicals to your customers.

The inventory includes "flags" for chemical substances that are regulated under TSCA.

TSCA Inventory – Public Version

(https://www.epa.gov/tsca-inventory)

ID	CASRN	casregno	ChemName	FLAG	ACTIVITY
10	50-30-6	50306	Benzoic acid, 2,6-dichloro-	PMN; S; 5E	ACTIVE
9197	1690-76-2	1690762	2-Piperidinone, 1,3-dimethyl-	PMN; S; 5E	INACTIVE
4739	499-90-1	499901	Benzoic acid, 4-fluoro-, sodium salt (1:1)	PMN; S; 5E	ACTIVE
4734	499-57-0	499570	Benzoic acid, 3-fluoro-, sodium salt (1:1)	PMN; S; 5E	ACTIVE
10575	2589-57-3	2589573	Propanoic acid, 2,2'-(1,2-diazenediyl)bis[2-m	PMN; S; 5E	ACTIVE

PMN - indicates it was approved for use and added to the TSCA inventory via a commenced PMN

5E - indicates a substance that is the subject of a section 5e consent order (CO)

S - indicates a substance that is subject to a final Significant New Use Rule (SNUR)

- *(SP will indicate a proposed Significant New Use Rule, but assume terms will become final)*

TSCA Inventory – Confidential Version

(https://www.epa.gov/tsca-inventory)

ID	PMNNO	ACCNO	GenericName	FLAG	ACTIVITY
3052	P110533	263093	Polyfluorinated alkyl thio polyacrylamide	PMN; S; 5E	ACTIVE
3057	P110543	263435	Polyfluorinated alkyl quaternary ammoni	PMN; S; 5E	ACTIVE
8805	P901642	123785	Dialkyl phosphorodithioate phosphate co	PMN; S; 5E	INACTIVE
10202	P940047	150595	Polyurethane	PMN; S; 5E	INACTIVE
5407	P840107	62625	Disubstituted tetrafluoroalkane	PMN; S; 5E	ACTIVE

When chemical identity is masked, it is best practice to provide accession number (ACCNO) **SDS Section 15** for easier compliance checks down the supply chain.

NOTE: TSCA "exemptions" may also apply to allow commercial use. Some exemptions are self certifying with no EPA review and regulation (e.g., polymer exemption, R&D) while other exemptions require EPA approval (e.g., LVE, LOREX) and will often have unpublished restrictions. If an exemption was used, that should be communicated on the SDS along with any restrictions.

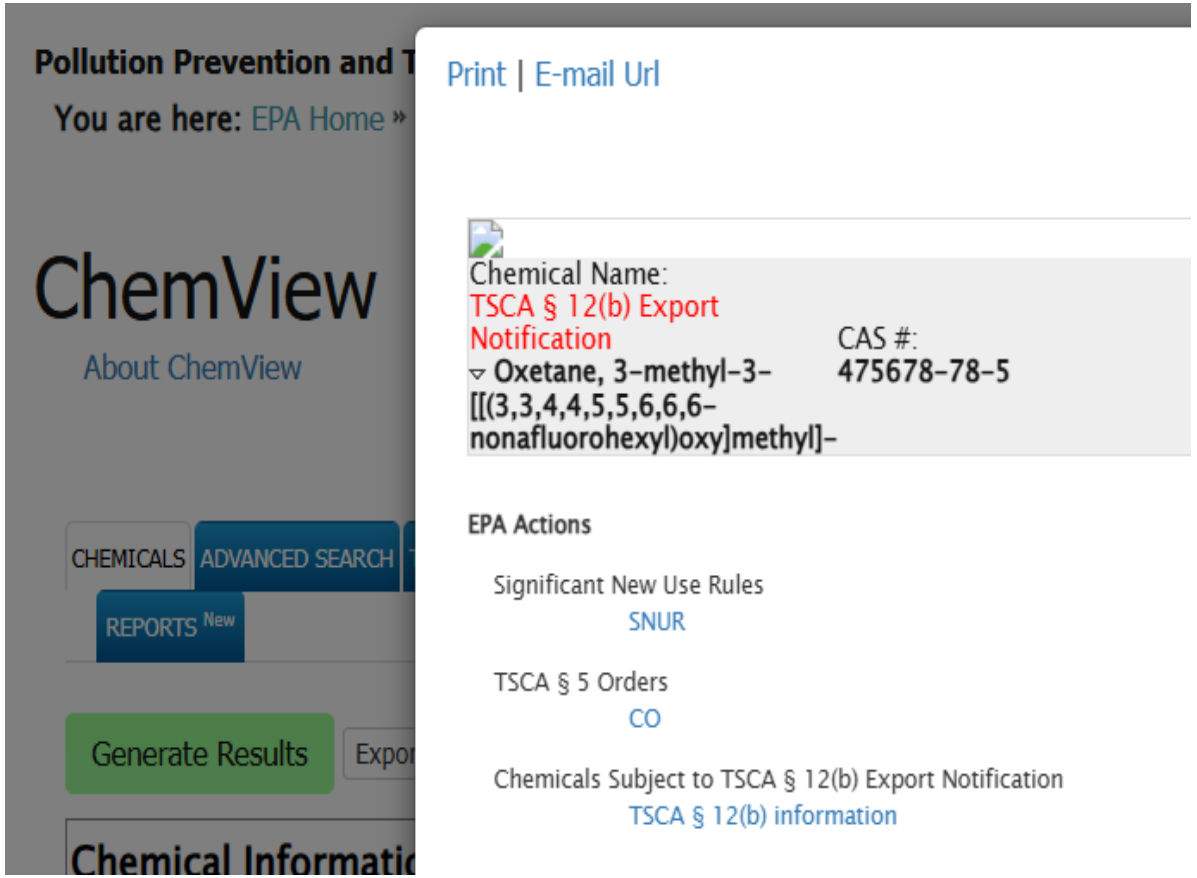
What do I need to know?

- Am I potentially affected by a CO and/or SNUR?
- What do the regulations say and how does this impact site compliance and reporting?
- How does this influence HazCom and training?
- What are my recordkeeping obligations?

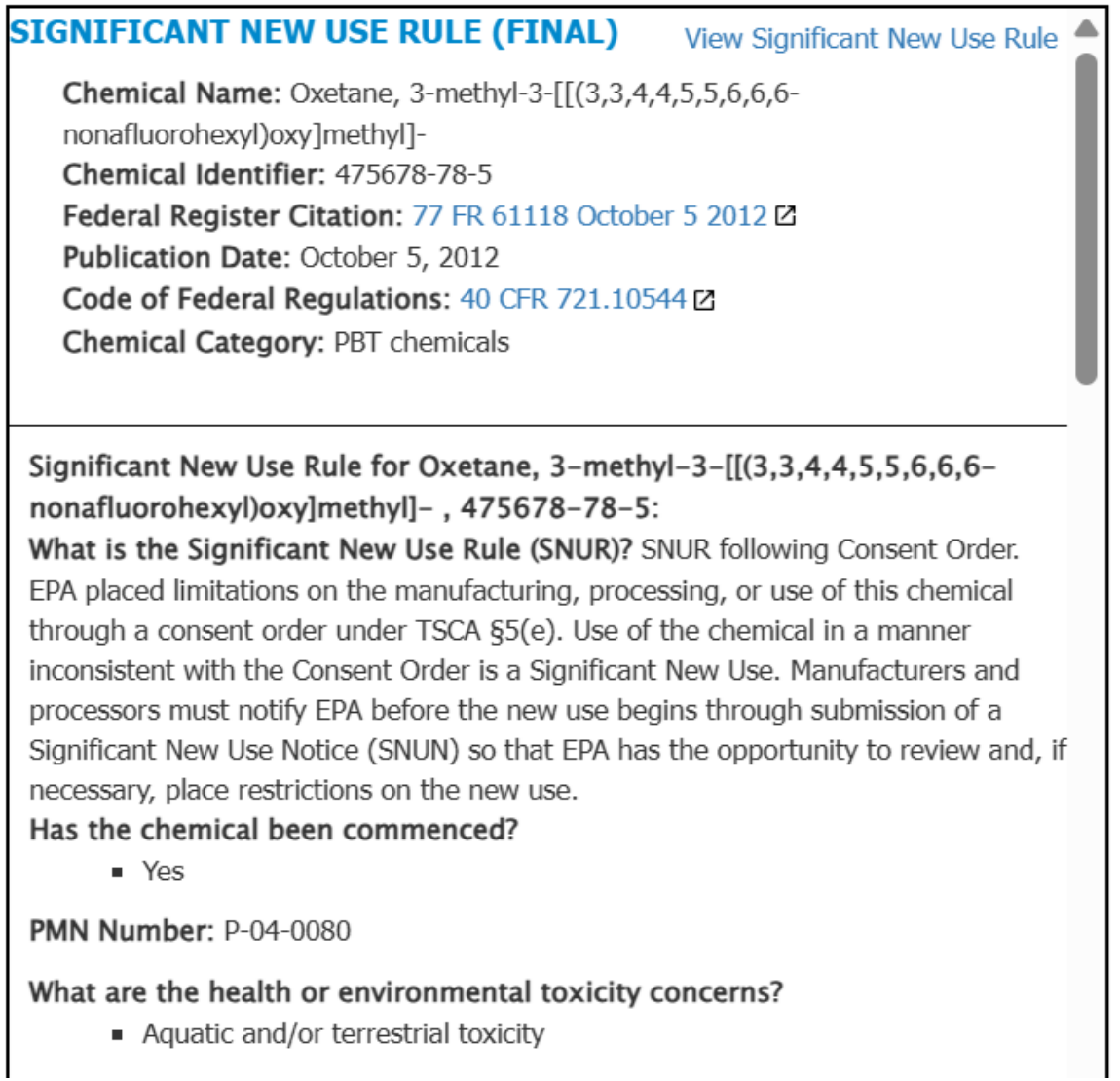
Let's look at some tools to locate the corresponding documents.

EPA ChemVIEW

https://chemview.epa.gov/chemview/)



https://chemview.epa.gov/chemview/



Federal Register (FR)

https://www.federalregister.gov/

*CFR citation:*40 CFR 721.10543.

PMN NUMBER P-04-80

Chemical name: Oxetane, 3-methyl-3-[[(3,3,4,4,5,5,6,6,6-nonafluorohexyl)oxy]methyl]-.

CAS number: 475678-78-5.

Effective date of TSCA section 5(e) consent order: December 28, 2004.

Basis for TSCA section 5(e) consent order: The PMN states that the substance will be used as a monomer in the production of reactive polymers for surface coating materials and other polymer intermediates. EPA has identified health and environmental concerns because the substance may be a persistent, bio-accumulative, and toxic (PBT) chemical, based on physical/chemical properties of the PMN substance, as described in the New Chemical Program's PBT category (64 FR 60194; November 4, 1999) (FRL-6097-7). Also, based on SAR analysis of test data on analogous oxetanes, EPA identified

Code of Federal Regulations (CFR)

https://www.ecfr.gov/

EDITORIAL NOTE ON PART 721

Editorial Note: Nomenclature changes to part 721 appear at 87 FR 39764, July 5, 2022.

§ 721.10544 Oxetane, 3-methyl-3-[[(3,3,4,4,5,5,6,6,6-nonafluorohexyl)oxy]methyl]-.

(a) *Chemical substance and significant new uses subject to reporting.*

(1) The chemical substance identified as oxetane, 3-methyl-3-[[(3,3,4,4,5,5,6,6,6-nonafluorohexyl)oxy]methyl]- (PMN P-04-80; CAS No. 475678-78-5) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this rule do not apply to quantities of the PMN after it has been completely reacted (cured).

(2) The significant new uses are:

(i) ***Protection in the workplace.*** Requirements as specified in § 721.63 (a)(1), (a)(2)(i), (a)(2)(iii), (a)(3), (b)(concentration set at 0.1 percent), and (c).

The Regulatory Tools

	Consent Order	SNUR
Legal Authority*	Section 5(e)	Section 5(a)(2)
Applicability	Only the original submitter(s) *(Or the successor in interest)*	Applies to everyone else *(May specify actions for manufacturers, processors, or users individually)*
Enforceability	Binding Agreement	Regulation
Document Publicly Available?	Not always	Federal Register (FR) Code of Federal Regulations (CFR)
Timing	Issued during review	Published post-review

** Although the authority may vary, orders and rules share many similar regulatory requirements.*

Compliance Implementation

Now that we understand how to identify regulated chemicals, who they apply to and where to find the related documents, let's go over recent EPA updates, common restrictions in order and rules, and key HazCom and site compliance issues!

Recent Change Impacting HazCom and Worker Safety

https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/boilerplate-language-orders-under

The US EPA recently updated its boilerplate language for Section 5 Consent Orders. The revisions were intended to:

Strengthen worker protections by addressing hazcom, labeling, safety data sheets, and training	**Improve clarity** through revised formatting, added definitions, and removal of outdated text	**Ensure access to information** for workers and their representatives

Updated Requirements in Consent Orders

EPA restored prior requirements for hazard communication programs, labeling, safety data sheets, and employee information and training, including:

- ✓ Keeping a copy of the written hazard communication program in a clearly visible, readily accessible location and provide it to workers and their representatives upon request.
- ✓ Keeping records documenting compliance with the employee training requirements.
- ✓ Including contractors in the employee training.

Updated Requirements in Consent Orders

The latest update to the boilerplate language strengthens worker protections by including new requirements to:

- ✓ Keep a copy of the TSCA consent order in a clearly visible, accessible location in each work area where the chemical is handled.

- ✓ Provide a copy of the order to workers and their representatives upon request.

The Argument

- New requirement is not needed given the well-established OSHA HazCom standards, training and SDS requirements ***designed*** to inform workers of chemical hazards.

- COs are highly technical documents containing complex hazard, exposure, and risk summaries not always relevant under normal operating conditions.

- Workers who don't have specialized training in toxicology, risk assessment, or TSCA regulations could misunderstand the information.

- It is unclear how this provision will be included in the follow-on Significant New Use Rule (SNUR), making it only applicable to the CO holder and not all users.

The Confusion - Whole Supply Chain can be Impacted!

- Chemical processors and users often assume regulations only impact ***manufactures*** of the chemicals.

- Restrictions may apply to downstream ***formulators and users***, and this is catching companies off guard as the requirements increase in volume and cascade down through the supply chain.

- Let's explore common provisions found in ***both orders and rules***, and how they might affect site compliance, the creation of safety data sheets and labels, and worker protection programs.

Operation Restrictions and Engineering Controls

Provisions are intended to minimize exposures and mitigate risks throughout the supply chain. **May impact SDS Section 1, 8, 15**

For example, orders and rules may state a chemical can only be manufactured, processed or used:

- **In an enclosed system** *(to prevent all exposures and releases)*
- **Only in the form of a liquid** *(to prevent dusting, worker inhalation exposure and particulate release)*
- **At a concentration less than X% in consumer products** *(to prevent potential consumer hazards)*

Use Restrictions

For example, orders and rules may state:

- **For a specific use only**
  - **Impact SDS Section 1**

The EPA must look at ***all possible uses*** of a chemical, but it can decide how to approach risk management, either by:

✓ Focusing on the intended use (use-based restriction)

✓ Considering all possible uses in the risk management action, often eliminating the need for a use restriction (whole chemical approach).

This topic has been hotly debated in the existing chemicals program, but the new chemicals program has applied both approaches depending on the uncertainty in the assessment, magnitude of identified risks, and input from the submitter.

Disposal Methods

Provisions are intended to limit disposal methods to address secondary impacts to the environment and downstream general population. **May impact SDS Section 13, 15**

For example, orders and rules may state:

- **Water release may not exceed 5 ppb** *(to minimize general population impacts from drinking water uptake or fish ingestion for chemicals know to be hazardous and bioaccumulative)*
- **Disposal only to incineration** *(to prevent any water release)*

This restriction adds another compliance layer to a facility's wastewater and air permitting activities and plants will need to document compliance.

Workplace Protection Requirements

Provisions are intended to protect the worker populations who are directly handling the material. **May impact SDS Section 8, 15**

For example, orders and rules may state

- **Use of Personal Protective Equipment (PPE)** such as respirators and gloves.
- **Monitoring of workplace exposures**, can be required or voluntary depending on whether the companies seeks to lift PPE restrictions.

Respirators are required by the EPA when a significant potential inhalation concern is detected. This kind of personal protective equipment (PPE) is highly protective, but creates its own set of challenges to implement in the workplace.

New Chemical Exposure Limit (NCEL)

As an alternative to the specified respirator requirement, companies may have the option to comply with the requirements of a New Chemical Exposure Limit that sets air concentration limits.

Before deviating from the respirator requirements, generally you must:

1. Submit sampling and analytical methods to EPA that are appropriate for the chemical of interest;
2. Obtain exposure monitoring results;
3. Submit the exposure monitoring results and selection criteria to EPA.

Should OSHA/NIOSH requirements be less stringent, the requirements of the order or rule apply. Similar to TSCA risk-based existing chemical exposure limits (ECELs).

Hazard Statement

Provisions are intended to describe requirements for labels, Safety Data Sheets (SDS) and other warning material, based on results from an EPA review. **May impact SDS Section 2, 11, 12, 15**

Common requirement that often causes confusion/concern.

Not to be confused with GHS classification requirements!

VIII. Required Human Health and Environmental Hazard Statements

The following human health and environmental hazard statements must appear on each label and SDS:

A. Human Health Hazard

EXAMPLES: Skin irritation, Eye irritation, Specific Target Organ Toxicity

B. Environmental Hazard

EXAMPLE: Toxic to Aquatic Life

Hazard Communication Statements

Required hazard statements generally provided in section 2 (other hazards – precautionary statements) or Section 15 (Regulatory Information), and do not necessarily impact the classification approach for the chemical.

Pictogram:

Signal word: Danger

Hazard statements:
Highly flammable liquid and vapour (H225)
Causes skin irritation (H315)
Suspected of damaging fertility or the unborn child (H361)
May cause damage to organs (nervous system) through prolonged or repeated exposure (H373)
Harmful to aquatic life (H402)

Precautionary statements:

EPA identified concerns for acute toxicity, skin irritation, skin corrosion, eye irritation, serious eye damage, reproductive toxicity, specific target organ toxicity based on analog data during review under section 5 of TSCA.

Section 15: REGULATORY INFORMATION

Toxic Substances Control Act (United States)

Listed and Active on the TSCA Inventory. Regulated with a Section 5e order and Significant New Use Rule (*FR reference*). The US EPA identified concerns for acute toxicity, skin irritation, reproductive toxicity, and specific target organ toxicity based on analog data during review under section 5 of TSCA.

Regulations on the Safety Management of Hazardous Chemicals (Decree No. 591 of the State Council of China, 2011)

List of Dangerous Chemicals (2015), Dangerous Chemicals Catalogue for Supervision and Management, List of Explosive Precursors: Not Listed

Recordkeeping, Reporting and Additional Obligations

The requirement for tracking volumes, location details, sales, and transfers are straightforward, but there may be specific records needed to show compliance with restrictions, such as:

- Detailed records of manufacturing, processing, and use operations;
- Disposal methods and/or contracts with third party waste vendors;

The presence of orders and rules also trigger other regulatory requirements such as export notification under Section 12(b) and can lower the reporting volume thresholds under the Chemical Data Reporting (CDR) rule.

Want to Change Any Provisions?

- **Consent Order Modification**
  - No fee/cost, but no specified review timeline either
  - Pursued by the CO signer, and if modified will trigger updates to the corresponding SNUR.
- **Significant New Use Notice (SNUN)**
  - Currently $37,000 fee and usual TSCA timeline
  - Pursued by the general regulated community and does not trigger changes to the original CO (but could be the basis of a CO modification request later)

Successful requests include new information or data that address the EPA's initial risk concerns.

Thank you

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Any Questions?