

1. Overview

Learning Objectives:

At the end of section one you should be able to:

- ☐ Provide a brief overview of the scope of the TSCA act.
- ☐ State if this regulation impacts your work or not.
- ☐ State what motivated the U.S. to enact the Toxic Substance Control Act (TSCA).



When you see the above icon it indicates that one of the learning objectives is being covered.



Provide a brief overview of the scope of the act.

T S C A

oxic
ubstance
ontrol
ct of 1976



An Act to regulate commerce and protect human health and the environment by requiring testing and necessary use restrictions on certain chemical substances, and for other purposes.



Does TSCA apply to your work?



- ☐ Are you involved in bringing new products to market in the United States?
- ☐ If you, or a toll manufacturer you hire, are involved in making a Neo product for sale in the United States – you have specific duties.
- ☐ If you sell Neo products into the United States – you have specific duties.



State if this regulation impacts your work or not.

How it all got started...

SEC. 2. FINDINGS, POLICY, AND INTENT.

(a) FINDINGS.—The Congress finds that—

(1) human beings and the environment are being exposed each year to a large number of chemical substances and mixtures.

(2) among the many chemical substances and mixtures which are constantly being developed and produced, there are some whose manufacture, processing, distribution in commerce, use, or disposal may present an unreasonable risk of injury to health or the environment; and

(3) the effective regulation of interstate commerce in such chemical substances and mixtures also necessitates the regulation of intrastate commerce in such chemical substances and mixtures.

(b) POLICY.—It is the policy of the United States that—

(1) adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment and that the development of such data should be the responsibility of those who manufacture and those who process such chemical substances and mixtures;

(2) adequate authority should exist to regulate chemical substances and mixtures which present an unreasonable risk of injury to health or the environment, and to take action with respect to chemical substances and mixtures which are imminent hazards; and

(3) authority over chemical substances and mixtures should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation while fulfilling the primary purpose of this Act to assure that such innovation and commerce in such chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment.

- Why did the U.S. Congress decide to write this legislation?



State what motivated the U.S. to enact the Toxic Substance Control Act (TSCA).

Statement on signing TSCA

I HAVE signed S. 3149, the Toxic Substances Control Act. I believe this legislation may be one of the most important pieces of environmental legislation that has been enacted by the Congress.

This toxic substances control legislation provides broad authority to regulate any of the tens of thousands of chemicals in commerce. Only a few of these chemicals have been tested for their long-term effects on human health or the environment. Through the testing and reporting requirements of the law, our understanding of these chemicals should be greatly enhanced. If a chemical is found to present a danger to health or the environment, appropriate regulatory action can be taken before it is too late to undo the damage.

The legislation provides that the Federal Government, through the Environmental Protection Agency, may require the testing of selected new chemicals prior to their production to determine if they will pose a risk to health or the environment. Manufacturers of all selected new chemicals will be required to notify the Agency at least 90 days before commencing commercial production. The Agency may promulgate regulations or go into court to restrict the production or use of a chemical or to even ban it if such drastic action is necessary.



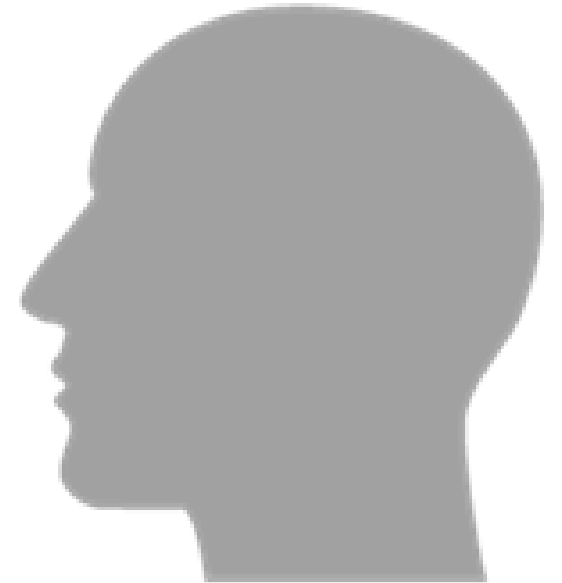
www.presidency.ucsb.edu



2. TSCA Inventory Learning Objectives:

At the end of section two you should be able to:

- ☐ Determine when our products must be on the TSCA inventory.
- ☐ Find a copy of the TSCA inventory.
- ☐ Know what to do if you cant find the substance on the published TSCA Inventory.
- ☐ Understand the function of “flags” and how it might impact our ability to market the product.



PMN Exemption 10,000kgs or less

§ 723.50 Chemical substances manufactured in quantities of 10,000 kilograms or less per year, and chemical substances with low environmental releases and human exposures.

Link to an amendment published at [80 FR 42746](#), July 20, 2015.

(a) *Purpose and scope.*

(1) This section grants an exemption from the premanufacture notice requirements of section 5(a)(1)(A) of the Toxic Substances Control Act ([15 U.S.C. 2604\(a\)\(1\)\(A\)](#)) for the manufacture of:

(i) Chemical substances manufactured in quantities of 10,000 kilograms or less per year.

(ii) Chemical substances with low environmental releases and human exposures.

(2) To manufacture a new chemical substance under the terms of this exemption a manufacturer must:

(i) Submit a notice of intent to manufacture 30 days before manufacture begins, as required under [paragraph \(e\)](#) of this section.

(ii) Comply with all other provisions of this section.

(3) This section does not apply to microorganisms subject to part 725 of this chapter.

Researchers and potential importers – please highlight the requirements for this exemption.

Small Quantities Solely for R&D

§ 720.36 Exemption for research and development.

(a) This part does not apply to a [chemical substance](#) if the following conditions are met:

(1) The [chemical substance](#) is [manufactured](#) or imported only in small quantities solely for research and development.

(2) The [manufacturer](#) or [importer](#) notifies all [persons](#) in its employ or to whom it directly distributes the [chemical substance](#), who are engaged in experimentation, research, or analysis on the [chemical substance](#), including the [manufacture](#), processing, use, transport, [storage](#), and [disposal](#) of the substance associated with [research and development activities](#), of any risk to health, identified under [paragraph \(b\)](#) of this section, which may be associated with the substance. The notification must be made in accordance with [paragraph \(c\)](#) of this section.

(3) The [chemical substance](#) is used by, or directly under the supervision of, a [technically qualified individual](#).

(b)

(1) To determine whether notification under [paragraph \(a\)\(2\)](#) of this section is required, the [manufacturer](#) or [importer](#) must review and evaluate the following information to determine whether there is reason to believe there is any potential risk to health which may be associated with the chemical substance: **For more, please see 40 CFR 720.36**

Researchers and potential importers – please highlight the requirements for this exemption.

TSCA Inventory - Flags

ID	RN	IN	casregno	DF	UV	FL
51904	8160 1313-97-9	Neodymium oxide (Nd ₂ O ₃)	1313979			

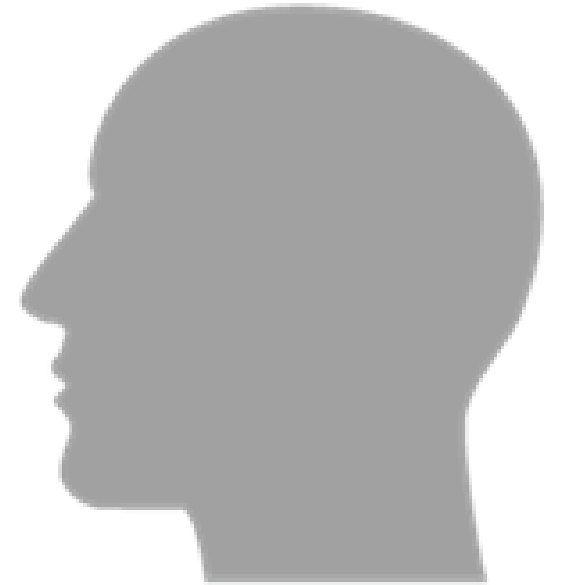
- E - indicates a substance that is the subject of a Section 5(e) Consent Order under TSCA.
- F - indicates a substance that is the subject of a Section 5(f) Rule under TSCA.
- N - indicates a polymeric substance containing no free-radical initiator in its Inventory name but is considered to cover the designated polymer made with any free-radical initiator regardless of the amount used.
- P - indicates a commenced Premanufacture Notice (PMN) substance.
- R - indicates a substance that is the subject of a Section 6 risk management rule under TSCA.
- S - indicates a substance that is identified in a final Significant New Uses Rule.
- SP - indicates a substance that is identified in a proposed Significant New Uses Rule.
- T - indicates a substance that is the subject of a final Section 4 test rule under TSCA.
- TP - indicates a substance that is the subject of a proposed Section 4 test rule under TSCA.
- XU - indicates a substance exempt from reporting under Chemical Data Reporting Rule (formerly the Inventory Update Reporting Rule), i.e., Partial Updating of the TSCA Inventory Data Base Production and Site Reports (40 CFR 711).
- Y1 - indicates an exempt polymer that has a number-average molecular weight of 1,000 or greater.
- Y2 - indicates an exempt polymer that is a polyester and is made only from reactants included in a specified list of low-concern reactants that comprises one of the eligibility criteria for the exemption rule.

Please highlight any TSCA flag, that if it was on your product it would concern you.

3. Chemical Substance Learning Objectives:

At the end of section three you should be able to:

- ☐ Apply the term “chemical substance”.
- ☐ Recognize the “hydrates” exemption from the list.





Apply the term
“chemical substance”.

§ 710.3 Definitions.

For purposes of this part:

(a) The following terms will have the meaning contained in the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321 *et seq.*, and the regulations issued under such Act: *Cosmetic, device, drug, food, and food additive*. In addition, the term *food* includes poultry and poultry products, as defined in the Poultry Products Inspection Act, 21 U.S.C. 453 *et seq.*; meats and meat food products, as defined in the Federal Meat Inspection Act, 21 U.S.C. 60 *et seq.*; and eggs and egg products, as defined in the Egg Products Inspection Act, 21 U.S.C. 1033 *et seq.*

(b) The term *pesticide* will have the meaning contained in the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. 136 *et seq.*, and the regulations issued thereunder.

(c) The following terms will have the meaning contained in the Atomic Energy Act of 1954, 42 U.S.C. 2014 *et seq.*, and the regulations issued thereunder: *Byproduct material, source material, and special nuclear material*.

stance produced without separate commercial intent during the manufacture or processing of another chemical substance(s) or mixture(s).

Chemical substance means any organic or inorganic substance of a particular molecular identity, including any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and any chemical element or uncombined radical; except that “chemical substance” does *not* include:

- (1) Any mixture,
- (2) Any pesticide when manufactured, processed, or distributed in commerce for use as a pesticide,
- (3) Tobacco or any tobacco product, but not including any derivative products,
- (4) Any source material, special nuclear material, or byproduct material,
- (5) Any pistol, firearm, revolver, shells, and cartridges, and
- (6) Any food, food additive, drug, cosmetic, or device, when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device.

What a chemical substance is.

What a chemical substance is not

Mixture Definition

Mixture means any combination of two or more chemical substances if the combination does not occur in nature and is not, in whole or in part, the result of a chemical reaction; except that “mixture” does include:

(1) Any combination which occurs, in whole or in part, as a result of a chemical reaction if the combination could have been manufactured for commercial purposes without a chemical reaction at the time the chemical substances comprising the combination were combined and if, after the effective date or premanufacture notification requirements, none of the chemical substances comprising the combination is a new chemical substance, and

(2) Hydrates of a chemical substance or hydrated ions formed by association of a chemical substance with water.

Please read the definition, highlight key parts and make notes.



4. Chemical Data Reporting

Learning Objectives:

At the end of section four you should be able to:

- ☐ State who must participate in Chemical Data Reporting.
- ☐ State how frequently you must supply chemical inventory information to the EPA.
- ☐ Determine if a substance is greater than the reporting threshold or not.



5. Allegation of Adverse Effects

Learning Objectives:

At the end of section five you should be able to:

- ☐ Determine when allegation reporting is applicable.
- ☐ Given an allegation about a chemical, determine if it meets the definition of a TSCA allegation.
- ☐ State how to report a TSCA allegation,
- ☐ State your responsibility for reporting a TSCA allegation.
- ☐ Recognize the company's obligation to report substantial risks to the EPA when they are identified.





Determine when allegation reporting is applicable.

We must keep records of allegations about:

- products we produce in the U.S. at a Neo factory or at one of our toll manufacturer's facilities,
- products we import into the U.S.,
- raw materials and other products we buy for use in our U.S. based manufacturing facilities.

It also applies to our customers. If they notice health or environmental issues, they must keep records of allegations of adverse effects.

Please read when allegations of adverse reaction must be reported and highlight any scenario where you might hear an allegation.

Allegations about our products or other company's products at our facilities.



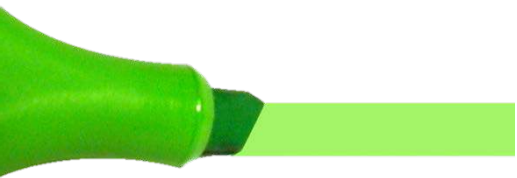
Allegations about our products at customer sites





Important Terms

- **Allegation** - an oral or written statement made without proof or regard to evidence, stating that a chemical substance or mixture has caused a **significant adverse reaction** to health or the environment.
- **Significant Adverse Reaction** - a reaction that may indicate a substantial impairment of normal activities, or long lasting or irreversible damage to health or the environment.



Please highlight the key elements of these definitions.

This does not include allegations of well known effects unless it is determined that the effect is much stronger than previously known.

1. Important Terms Exercise

- **Allegation** - an oral or written statement made without proof or regard to evidence, stating that a chemical substance or mixture has caused a significant adverse reaction to health or the environment.
- **Significant Adverse Reaction** - a reaction that may indicate a substantial impairment of normal activities, or long lasting or irreversible damage to health or the environment.

This does not include allegations of well known effects unless it is determined that the effect is much stronger than previously known.

An employee at our Quapaw plant, in the U.S., alleges that sulfuric acid causes skin burns. Is this an example of a TSCA allegation? _____

Sulfuric Acid SDS

2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

GHS Classification in accordance with 29 CFR 1910 (OSHA HCS)

Corrosive to metals (Category 1), H290

Skin corrosion (Category 1A), H314

Serious eye damage (Category 1), H318

For the full text of the H-Statements mentioned in this Section, see Section 16.

2.2 GHS Label elements, including precautionary statements

Pictogram



Signal word

Danger

Hazard statement(s)

H290

H314

Precautionary statement(s)

P234

P264

P280

P301 + P330 + P331

P303 + P361 + P353

May be corrosive to metals.

Causes severe skin burns and eye damage.

We already know this →

Keep only in original container.

Wash skin thoroughly after handling.

Wear protective gloves/ protective clothing/ eye protection/ face protection.

IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.

IF ON SKIN (or hair): Take off immediately all contaminated clothing.

Rinse skin with water/shower.

2. Important Terms Exercise

- **Allegation** - an oral or written statement made without proof or regard to evidence, stating that a chemical substance or mixture has caused a significant adverse reaction to health or the environment.
- **Significant Adverse Reaction** - a reaction that may indicate a substantial impairment of normal activities, or long lasting or irreversible damage to health or the environment.

This does not include allegations of well known effects unless it is determined that the effect is much stronger than previously known.

A customer in New York tells one of our sales representatives that a small amount of neodymium oxide was spilled on the ground near his factory and cleaned up, but he suspects that a small amount of it made it's way into a nearby stream. He walks by the stream everyday and it is his opinion that there are more dead fish than normal. He thinks a small amount of Nd Oxide caused an increase in fish deaths. The sales representative checks our Safety Data Sheet and toxicology information and can find nothing to indicate that Nd Oxide would cause a fish kill.

Is this an example of a TSCA allegation?

Significant Adverse Reaction Reporting

Distribution Policy:

- ☐ Executive Vice President
- ☐ Your Supervisor
- ☐ V.P. HESS

Significant Adverse Reaction Report - TSCA 8(c)

Date of Allegation:

Person or Organization Making Allegation:

Address of Location:

Chemical Substance(s):

Alleged Health or Environmental Effect:

Results of any Self-implemented Investigation:

Name of Employee that Received the Allegation:

Your report can be
in electronic form,
but this
information must
be on the report.

TSCA 8(e) – Substantial Risk Notification

“Any person who manufactures, processes or distributes in commerce a chemical substance or mixture and who obtains information which reasonably supports the conclusion that such substances or mixtures present a substantial risk of injury to health or the environment shall immediately inform the Administrator of such information unless such person has actual knowledge that the Administrator has been adequately informed of such information.”

TSCA 8(c) requires us to keep records of significant allegations. Highlight what is different about 8(e) requirements.



What is substantial risk?


- **Environmental Effects (Non-Emergency)**
 - Pronounced bioaccumulation
 - Ecologically significant changes in a species
 - Population
 - Behavior
 - Growth
 - Survival
 - Facile transformation or degradation to a chemical having unacceptable risk
- **Environmental Incidents (Emergency)**

Any contamination that:

 - Causes human health effects
 - Seriously threatens non-human organisms with large-scale or ecologically significant population destruction

- **Human Effects**

- Cancer
- Birth defects
- Mutagenicity
- Death
- Serious or prolonged incapacitation



In some way, the term “substantial risk” is self explanatory. Please highlight anything that you would not have assumed to be within the scope of “substantial risk.”

Rules on Substantial Risk Notification

EPA POLICY: TSCA SECTION 8(e)—SUBSTANTIAL RISK NOTIFICATION

Federal Register / Vol. 68, No. 106 / Tuesday, June 3, 2003 / Notices

33129

The rules for when and how to report 8(e) Substantial Risk Notifications were published on June 3, 2003 in the Federal Register.

In the event that we need to make an 8(e) notification, we intend to consult the regulations and enlist the help of an Occupational Physician from Intrinsik. We may also enlist the help of a firm of TSCA experts named Bergeson and Campbell.

ENVIRONMENTAL PROTECTION AGENCY

[OPPT-2002-0067; FRL-7287-4]

TSCA Section 8(e); Notification of Substantial Risk; Policy Clarification and Reporting Guidance

AGENCY: Environmental Protection
Agency (EPA).

ACTION: Notice.

SUMMARY: EPA is hereby finalizing revisions to certain parts of EPA's "Statement of Interpretation and Enforcement Policy; Notification of Substantial Risk" (policy statement) issued March 16, 1978, concerning the reporting of "substantial risk" information pursuant to section 8(e) of the Toxic Substances Control Act (TSCA). EPA is making these revisions

At the end of section six you should be able to:

- ☐ Provide a summary of the key changes required by TSCA reform.

