

Toxic Substance Control Act (TSCA) NOTES & DEFINITIONS

This page provides a short overview of key TSCA concepts and definitions. For specific information pertaining to compliance with the R&D exemption; please refer to the [TSCA Implementation and Compliance Guide](#).

NOTES

1) Chemicals or Activities Regulated by other Agencies or Regulations

- Foods, food additives, drugs, cosmetics or devices regulated by **FDA**, including those chemicals used solely for the manufacture of such items, as well as synthesis intermediates are excluded from TSCA regulation.
- Radioactive materials regulated by the **NRC** are excluded from TSCA regulation.
- Tobacco, tobacco products and ammunition regulated by **ATF** are excluded from TSCA regulation.
- Pesticides regulated by **FIFRA** include only those pesticides officially recognized as pesticides through an experimental use permit or otherwise. FIFRA regulated pesticides are excluded from TSCA regulation. Individual components of a pesticide are regulated by TSCA.

2) Overview of Research and Development (R&D) Exemption Requirements

- **Shipments:** Chemicals shipped to other institutions or entities must be shipped for R&D purposes only. Containers of these chemicals and shipping documentation must be labeled. The environmental and health risks of these chemicals must also be evaluated and communicated to the receivers.
- **Imports:** Any chemicals imported from outside the US Customs Territory must be certified as TSCA compliant or not regulated by TSCA at the time of import.
- **Exports:** Any chemicals exported outside the US Customs Territory must be screened against certain EPA chemical lists. Some particular chemicals may require additional actions required by EPA prior to or within several days of export.
- **Recordkeeping:** Laboratories must create and maintain records of significant adverse effects to human health or the environment alleged to have been caused by an R&D chemical.
- **Reporting:** Laboratories must report to EPA any information about an R&D substance that indicates that it may present a “substantial risk” to human health or the environment.

3) Commercial Activities

Activities whose results are directly intended to produce commercial gain for those involved in the oversight or performance of the activity. Academic educational activities and research activities performed in accordance with the Office of Sponsored Research’s Principles and Policies that Govern Your Research and Other Professional Activities or the Faculty of Medicine’s Statement on Research Sponsored by Industry are not considered commercial activities.

DEFINITIONS

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 (*individual components are chemical substances*).
- (2) Any pesticide when manufactured, processed, or distributed in commerce for use as a pesticide.
- (3) Tobacco or any tobacco product.
- (4) Any source material, special nuclear material, or byproduct material.
- (5) Any pistol, firearm, revolver, shells, or cartridges.
- (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.

Laboratory is a contained research facility where relatively small quantities of chemical substances are used on a non-production basis, and where activities involve the use of containers for reactions, transfers, and other handling of substances designed to be easily manipulated by a single individual.

Prudent and safe handling practices means the implementation of safe chemical handling practices as delineated in the Chemical Hygiene Plan.

Small quantities solely for research and development (or "small quantities solely for purposes of scientific experimentation or analysis or chemical research on, or analysis of, such substance or another substance, including such research or analysis for the development of a product") means quantities of a chemical substance manufactured, imported, or processed or proposed to be manufactured, imported, or processed solely for research and development that are not greater than reasonably necessary for such purposes.

Technically qualified individual means a person or persons (1) who, because of education, training, or experience, or a combination of these factors, is capable of understanding the health and environmental risks associated with the chemical substance which is used under his or her supervision, (2) who is responsible for enforcing appropriate methods of conducting scientific experimentation, analysis, or chemical research to minimize such risks, and (3) who is responsible for the safety assessments and clearances related to the procurement, storage, use, and disposal of the chemical substance as may be appropriate or required within the scope of conducting a research and development activity.