



Toxic Substances Control Act (TSCA) Fact Sheet

The Toxic Substance Control Act (TSCA), part of the Environmental Protection Agency's (EPA) [New Chemical Program](#), authorizes the Environmental Protection Agency (EPA) to regulate and screen all chemicals produced or imported into the United States, with the intent of ensuring that the risks posed to human health and the environment by imported chemical substances are identified and adequately addressed prior to production or transport of those substances into the United States. A new chemical is a chemical substance that is produced or imported and not yet listed on the TSCA Chemical Substance Inventory.

This fact sheet is designed to provide university laboratories with an overview of the requirements and impacts of Toxic Substances Control Act (TSCA).

As the importer of a chemical or material, responsibility for TSCA compliance rests almost entirely with you and your research group. Your laboratory or research group are responsible for determining if TSCA applies to your laboratory activities.

Activities Regulated under TSCA:

- Research conducted for commercial purposes
- Importation and exportation of chemicals
- Shipment of chemicals to locations within U.S.
- Adverse significant reactions to chemicals
- Significant risks of chemicals discovered during research

Chemical substances regulated by TSCA include:

"Any organic or inorganic substances of a particular molecular identity including any combination of such substances occurring, in whole or in part, as a result of chemical reaction or occurring in nature and any element or uncombined radical."

Chemical substances not regulated or excluded by TSCA include:

- Pesticides regulated by FIFRA
- Tobacco and tobacco products regulated by ATF
- Radioactive materials regulated by NRC
- Foods, food additives, drugs, cosmetics or devices regulated by FDA

Research and Development (R&D) Exemption

Laboratories at Harvard are generally not subject to most requirements of TSCA if they meet the Research and Development (R&D) exemption. **However**, all appropriate forms must be filled out and sent with the shipments regardless of the exemption. The forms are required so that the EPA can monitor the amount of chemicals shipped between borders. Any chemical substance is exempted from many of the requirements of TSCA when it is:

- Imported, manufactured or used in small quantities, **and**
- Solely for purposes of non-commercial scientific experimentation, analysis or research (this includes ensuring that grant and other funding documentation indicates that funding for the imported material is intended for research activities and not commercial purposes), **and**
- Under the supervision of a technically qualified individual.

To maintain this exemption status, laboratories engaged in research and development must comply with the following TSCA requirements:

- **Import of Chemical** – certify TSCA status of imported material of R&D substances, in writing.
- **Export of Chemicals** – Notify receiving countries of exports of certain R&D substances, in writing.
- **Shipment of chemical to a location within the US** - Label containers, shipping containers and shipping papers of any substance shipped for R&D purposes with language to that effect.
- **Evaluate and communicate risks** for any shipped R&D substance by preparing and shipping an MSDS and/or shipment form with the substance.
- **Allegations of Adverse Reactions** – Create and maintain records of any allegations of effects to human health or the environment potentially caused by R&D substances.
- **Discovery of Substantial Risk** – Document and report any significant risks to human health or the environment potentially associated with R&D substances.

Note that the chemical manufacturer will not automatically include this documentation – **you** must request and ensure that they include these documents, labels, and language with the shipment.

Chemical substances that do not meet this definition, or laboratories that do not meet the requirements of the R&D exemption are subject to additional TSCA requirements.

Compliance Guidance

Preparing for your R&D exempt import:

1. The TSCA Import Certification Form should be completed by the research group and sent along with the purchase order so the form can be available to the customs officer upon arrival in the United States and sent along with your shipment. You should select “negative certification” and specify the R&D exemption.
2. Ensure that shipping documentation contains language that indicates that the shipped materials are for research purposes only, and contains a Safety Data Sheet or other documentation communicating risk information.
3. Upon receiving the certification form, the customs officer will do one of the following:
 - **If the package is not regulated by TSCA**, the customs officer will attach their own certification statement of validation stating that the shipment is not subject to the TSCA regulations (i.e, regulated under FIFRA, ATF, NRC, or FDA) and mark it as a negative import certification.
 - **If the package is regulated by TSCA**, the customs officer will check to verify that the package is compliant with the R&D exemption. If the shipment is exempted, then the officer will check the [EPA's ChemView database](#) to determine if the chemicals are subject to notification to the EPA.
 - If no notification is required then the package will receive a positive import certification and continue in the delivery process.

These procedures are for non-commercial scientific experimentation, analysis, or research chemicals only. Chemicals used for commercial purposes require additional steps.

If you suspect that your operation does not meet the R&D exemption; please contact the EH&S office at 495-2060 for assistance.

TSCA regulations are very complex and compliance can be a significant challenge for those laboratories at Harvard engaged in activities subject to TSCA jurisdiction.

Under some circumstances, the record-keeping, notifications, reporting, and other TSCA required practices can represent a significant administrative burden. Unlike hazardous waste handling and most other environmental laws, TSCA compliance activities are focused on specific laboratory operating practices. For this reason, compliance responsibility rests almost entirely with the laboratory. EH&S and other administrative units can provide only limited support.

Exporting Chemicals

TSCA requires the completion of the [TSCA Export Notification Form](#) prior to the exportation of chemical substances that are identified in the Current List of Chemical Substances Subject to [TSCA Section 12\(b\) Export Notification Requirements](#) maintained on the TSCA website. Copies of this form must be kept in lab records for three years.

Harvard also requires notifying the [Export Controls Office](#) when materials, and sometimes even equipment or data, are exported to another country. Please engage with the Export Controls Office before shipping outside of the United States.

Procedure:

1. Refer to [TSCA 12\(b\) list](#) maintained on the EPA's webpage and attempt to locate the chemical(s) you will be exporting.
2. If the chemicals to be exported on the TSCA 12(b) list, complete the TSCA Export Notification Form and submit it to the EPA. Ensure that the appropriate box is checked off indicating which Section of TSCA (4,5,6,7) is listed for the chemical to be exported. This notice must be postmarked within seven days after accepting a definite contractual obligation or reaching a final decision to export. Where the actual export occurs less than seven days after the export obligation or agreement has been executed, the notice must be submitted to EPA no later than the same day as the export.
3. If the chemicals are NOT listed in the TSCA 12(b), an export notification is not required.
4. Maintain copies of all TSCA Export Notification Forms in laboratory records for past three years and forward a copy of each form to the EHS office. EPA requires these forms to be maintained in lab for their review as proof of compliance.

Domestic Shipment or Transfer of Materials

Shipments of any imported or synthesized chemicals or samples regulated by TSCA, to locations within the U.S. Customs Territory, must be labeled "Content To Be Used For Research And Development Purposes Only," and accompanied with information that informs the recipient of environmental, health, and safety hazards. This information must also be provided when transferring chemicals to other laboratories not under the direct control of the researcher who created the chemical.

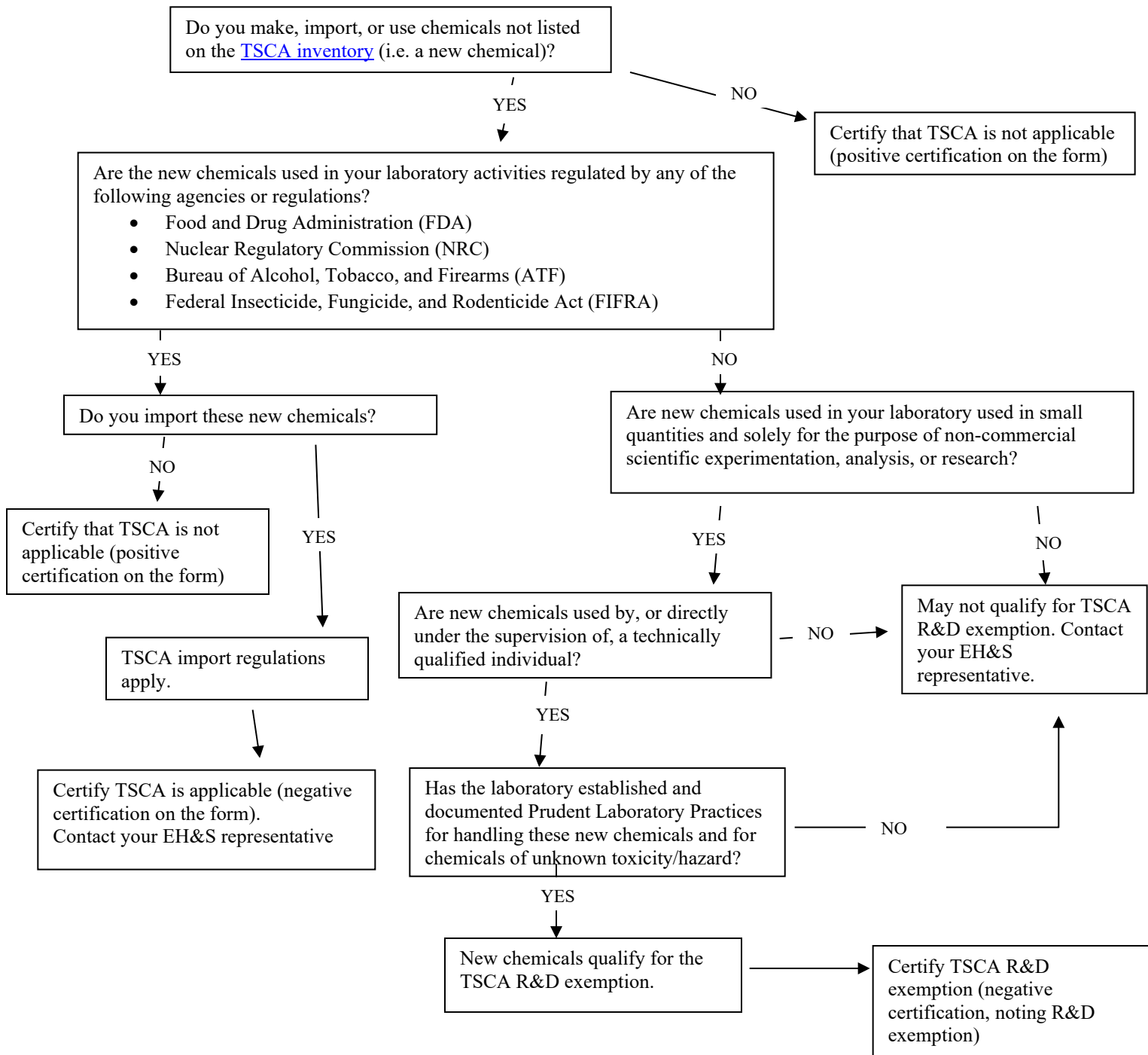
Completion of the [TSCA Domestic Shipment Form](#) for each shipment and inclusion with the shipment will ensure compliance. If the chemicals or samples are excluded from TSCA because they are already regulated by the Food and Drug Administration (FDA), Nuclear Regulatory Commission (NRC), Bureau for Alcohol, Tobacco and Firearms (ATF), or the Federal Insecticide, Fungicide, Rodenticide Act (FIFRA), a TSCA Domestic Shipment Form is not required.

Procedure:

1. For all domestic shipments of chemicals or samples within the US Customs Territory, complete TSCA Domestic Shipment Form and include a signed copy with the shipment. Forward a copy of the form and all associated information to the receiving address before mailing the chemicals or samples.
2. Mark the words "Contents To Be Used For Research And Development Purposes Only" on the outside of the shipping package.

3. Maintain copies of this Form in your laboratory records for three years and forward a copy of each form to the EHS office. EPA requires these forms to be maintained in lab for their review as proof of compliance.

TSCA Import Decision Making Tool



REQUIREMENTS FOR TSCA R&D EXEMPTION. You and your research group can be held liable for failure to comply with TSCA if any of these requirements are not met.

- Certify TSCA status of imported chemicals
- Document exports of chemicals
- Label and document all shipments of new chemicals regarding TSCA risk evaluation and communication
- Document allegations of adverse reactions to human health or environment
- Document and report discovery of substantial risk to human health or environment.