

Toxic Substances Control Act (TSCA) Fact Sheet

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

Overview of TSCA

Laboratories engaged in research must consider the applicability of the TSCA on their operation. TSCA, administered by the U.S. Environmental Protection Agency (EPA), is intended to ensure that the human health and environmental *effects* of chemical substances are identified and adequately addressed prior to production or transport of those substances.

Chemical substances **regulated** by TSCA include:

"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 chemical reaction or occurring in nature and any element or uncombined radical."

Chemical substances **not regulated or excluded** by TSCA include:

- (1) pesticides regulated by FIFRA
- (2) tobacco and tobacco products regulated by A TF
- (3) radioactive materials regulated by NRC
- (4) foods, food additives, drugs, cosmetics or devices regulated by FDA

Research and Development (R&D) Exemption

Any chemical substance is exempt 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, 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(s) -Certify the TSCA status of imports** of R&D substances, in writing.
- **EXPORT OF CHEMICAL(s) -Notify receiving countries of exports** of certain R&D substances, in writing.
- **SHIPMENT OF CHEMICAL(s) TO LOCATION WITHIN U.S. -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 chemical substances that do not meet this definition or laboratories that do not meet the requirements of the R&D exemption are subject to significant additional TSCA requirements. If you suspect that your operation does not meet the R&D exemption; please contact the OESO EP at 684-2794 for assistance.

Compliance Guidance

The EPA has recently identified TSCA compliance as an area of emphasis for laboratories. Suggested actions based on the lessons learned from EPA inspections include:

- Ensuring that grant and other funding documentation indicates that funding is intended for research activities and not commercial purposes;
- Determining that shipments of chemicals imported from areas outside the U.S. Customs territory are accompanied by a TSCA Import Certification;
- Determining that shipments of exported chemicals to areas outside the U.S. Customs territory are properly notified to receiving governments;
- Ensuring that shipping documentation contains language that indicates that shipped materials are for research purposes only.

TSCA regulations are very complex and compliance can be a significant challenge for those laboratories at Duke engaged in activities subject to TSCA jurisdiction. Under some circumstances, the records 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. OESO EP can provide only limited support.