

University of Wisconsin- Milwaukee Chemical Hygiene Plan- Appendix D

Toxic Substances Control Act (TSCA) Fact Sheet

This fact sheet is designed to provide University of Wisconsin- Milwaukee (UWM) laboratories with an overview of the requirements and impacts of Toxic Substances Control Act (TSCA) with regards to new chemicals. More specific guidance and resources are available on the [EPA TSCA website](#).

Overview of TSCA

The Toxic Substances Control Act (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 properly controlled prior to placing these materials into commerce.

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:

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

Laboratories engaged in research must consider the applicability of the Toxic Substances Control Act (TSCA) to their operation. Most UWM laboratory operations for which TSCA is applicable will fall under the R&D Exemption.

Research and Development (R&D) Exemption:

- (1) Any chemical substance is exempted from many of the requirements of TSCA when it is:
 - imported, produced 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.
- (2) To maintain this exemption status, laboratories engaged in research and development must comply with the following TSCA requirements:
 - Certify the TSCA status of imports of R&D substances, in writing.
 - Notify receiving countries of exports of certain R&D substances, in writing.
 - Document prudent laboratory practices.
 - 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 transfer form with the substance.
 - Create and maintain records of any allegations of effects to human health or the environment potentially caused by R&D substances.
 - 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 University Safety and Assurances at 229-6339 for assistance.

To ensure that your department complies with TSCA's regulatory requirements, each department should complete the following steps:

Step 1: Determine TSCA's applicability to your department

Use the TSCA Applicability Form to evaluate each research laboratory operation and to document the results to the TSCA Coordinator. Laboratory operations should be monitored on an on-going basis for any changes that could affect your TSCA applicability. A new TSCA Applicability Form should be

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prepared whenever such changes take place.

Step 2: Identify a “TSCA Coordinator” for your department

This person may be a Laboratory Supervisor, Principal Investigator, or another technically qualified individual that will manage the research group’s TSCA requirements to ensure compliance. A person who is knowledgeable in the following areas should act as TSCA Coordinator:

- How chemicals are procured and transferred (e.g. direct purchase, import from foreign country, shipped to non-UWM facilities, etc.)
- The type and approximate quantity of chemicals used in the department;
- The nature of the research and operations conducted in the department;
- Grant and funding applications and contracts.

Step 3: Establish a TSCA compliance file

TSCA is primarily an administrative, records-intensive program. TSCA files will be the first stop during an inspector’s visit. TSCA files should contain the following documents:

- TSCA Applicability Form
- * Chemical Hygiene Plan documenting prudent practices
- Import certifications
- Export notifications
- Inter-facility shipping/transfer records
- Significant adverse effect log
- Substantial risk reports

Step 4: Develop a process for ongoing review of TSCA applicability/compliance

Ensure that a process is in-place to conduct ongoing applicability determination and documentation.