Toxic Substances Control Act (TSCA) Fact Sheet

This fact sheet is designed to provide Auburn University laboratories with an overview of the requirements and impacts of Toxic Substances Control Act (TSCA). More specific guidance and resources are available in Compliance and Implementation Guide and on the EPA TSCA website [http://www.epa.gov/oppt/newchems].

Overview of TSCA

Laboratories engaged in research must consider the applicability of the Toxic Substances Control Act (TSCA) on their operation. 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 adequately addressed prior to production or transport of those substances.

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

Research and Development (R&D) Exemption

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, 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 CHEMCIAL - Certify the TSCA status of imports** 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 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 EHS office at 844-4805 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 AU 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. EHS and other administrative units can provide only limited support.

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

Step 1: Determine TSCA's applicability to your laboratory

Use the TSCA Applicability Determination Form to document your review. This form should be completed annually. Operations should be monitored on an on-going basis for any changes that could affect your TSCA applicability. A new TSCA Applicability Determination Form should be prepared whenever such changes take place. A copy of TSCA Applicability Determination Form information should be forwarded to the EHS Office TSCA Contact.

Step 2: Identify a "TSCA Coordinator" for your laboratory

This person may be a lab's Chemical Hygiene Officer or another technically qualified individual that will manage the lab's TSCA requirements to ensure compliance. A lab 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 countries, shipped to non-AU facilities, etc.)
- The type and approximate quantity of chemicals used in laboratory;
- The nature of the research and operations conducted in lab;
- Grant and funding applications and contracts.

See TSCA Roles and Responsibilities for additional information.

Step 3: Establish a TSCA compliance file

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

- TSCA Applicability Determination
- Import Certifications
- Export Notifications
- Domestic Shipping Notifications
- 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 (at a minimum) annual applicability determination and completion of the Self-Assessment Checklist.