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I. Introduction

This manual has been developed to assist laboratory personnel in complying with requirements of the federal Toxic Substances Control Act (TSCA). The main objective of TSCA is to identify and address the potential effects of new chemical substances to human health and the environment prior to their introduction into commerce.

The UNH TSCA Compliance Guide focuses on those activities taking place in research laboratories where chemical substances may be imported, exported, or shipped domestically. This document is specifically designed to provide a mechanism for evaluating the applicability of the TSCA rules to laboratory activities. It also provides guidance for adhering to federal requirements under TSCA.

The purpose of the UNH TSCA Compliance Guide is to:

- Provide information for determining the applicability of TSCA in laboratories at UNH;
- Explain the TSCA Research & Development exemption; and
- Provide guidelines for importing, exporting, and making domestic shipments.

A glossary of terms has been provided in Appendix A. All questions regarding the TSCA Compliance Guide should be directed to the UNH Office of Environmental Health and Safety.

II. Roles and Responsibilities

The roles and responsibilities of those who may be involved in TSCA-regulated research activities are listed below.

A. Principal Investigators/Researchers/Laboratory Staff

Principal investigators, researchers, and all laboratory personnel are responsible for:

- Reviewing the UNH Laboratory Safety Plan and complying with best management practices;
- Completing all applicable documentation (e.g., import forms, export forms) for chemical substances brought into, shipped out of, or delivered to another organization, person, or facility.
- Reporting all adverse health effects and seeking medical treatment when necessary; and
- Notifying the UNH Office of Environmental Health and Safety if non-compliance is discovered.
- Maintain copies of required documentation for three years.

B. Laboratory Safety Officer

The Laboratory Safety Officer is responsible for ensuring that:

- The prudent practices requirement of the TSCA research and development exemption is satisfied through the Laboratory Safety Plan;
- The required documentation for chemical use and transfer is maintained; and
- The corrective action is taken when a deficiency is identified.

C. Office of Environmental Health and Safety

The UNH Office of Environmental Health and Safety shall:
• Place the UNH TSCA Compliance Guide on the UNH website and distribute the link to all affected laboratory personnel;
• Provide assistance and guidance as necessary for compliance with this document;
• Review allegations of adverse health and/or environmental effects and make a determination as to whether or not the U.S. EPA should be notified; and
• Maintain and update the UNH TSCA Compliance Guide.

III. Regulatory Requirements

The U.S. Environmental Protection Agency’s (U.S. EPA) Office of Pollution Prevention and Toxics (OPPT) administers the TSCA regulations. Unlike other federal statutes which regulate a chemical risk after the chemical has been introduced into commerce, the major objective of TSCA is to characterize and understand the risks a chemical poses to humans and the environment before it is introduced into commerce. TSCA applies to persons, facilities, and companies that manufacture, process, distribute, use or dispose regulated chemicals. Chemical substances regulated by TSCA include:

“All 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.”

**Note:** All organic and inorganic substances used in research laboratories meet this definition.

The U.S. EPA compiles and maintains a list or “inventory” of chemical substances manufactured, imported, or processed in the United States for commercial purposes. The TSCA inventory contains more than 82,000 chemicals and is updated semi-annually by adding and/or delisting chemicals. Any chemical that is not listed on the EPA’s inventory of chemical substances is considered a “new chemical” and therefore is regulated under TSCA. The UNH Office of Environmental Health and Safety should be contacted to determine if a chemical is on the TSCA inventory.

Any chemical substance, which is manufactured or processed only in small quantities solely for purposes of scientific experimentation, is specifically excluded from the TSCA inventory. Scientific experimentation includes analysis or chemical research on, or analysis of, such substance or another substance, including such research or analysis for the development of a product.

IV. TSCA Research and Development Exemption

EPA regulations set forth in 40 CFR 730.36 provide an exemption from certain notification and “new use” requirements. This exemption only applies when small quantities of new chemicals are imported, exported, and/or used solely for Research and Development (R&D) purposes while under the supervision of a technically qualified individual.

According to the U.S. EPA, the following may be considered R&D activity:

• Chemical synthesis and physical/chemical properties testing in the laboratory;
• Health and environmental effects testing;
• Tests or demonstrations of equipment or production processes; or
• Efficacy and performance tests.

Laboratory activities meet the requirements for the R&D exemption when the following conditions are met:

1. R&D chemicals must be used in small quantities only.
2. R&D chemicals must be used under the supervision of a technically qualified individual.
3. All new chemicals for which little or no environmental, health, or safety data exists must be presumed a hazardous substance. All individuals within the laboratory with the potential to come into contact with the chemical must be notified of its risks. This notification may be communicated verbally but should be documented to demonstrate compliance with TSCA requirements.

4. R&D chemicals may be sold or distributed for further R&D without losing the R&D exemption status. However, it is critical that the recipient use the substance solely for R&D.

5. Material Safety Data Sheets (MSDS) must be available in UNHCEMS™ for all new chemicals brought into the laboratory. Copies of all MSDS’s, along with any vendor safety data, must be submitted to the UNH Office of Environmental Health and Safety if available.

6. If a new chemical, for which little or no environmental, health or safety data exists, will be transferred to another laboratory, the researcher must inform the recipient, in writing, of any known or potential risks associated with the substance.

7. Adverse reactions to human health or the environment are documented (see Section IX).

8. Import, export, and domestic transfer procedures for R&D chemicals must be followed (see Sections VI, VII, and VIII).

9. Relevant documents are kept on file for a minimum of three (3) years.

UNH researchers must be able to demonstrate that their activities are eligible for the R&D exemption.

The TSCA R&D Exemption does not provide research laboratories with a complete exemption from compliance with these regulations. Refer to the following sections to determine compliance issues related to chemical shipments and adverse reactions.

V. Domestic Shipments of TSCA-Regulated Chemicals

Shipments of TSCA-regulated chemicals to locations within the United States must be accompanied by documentation that informs the recipient of potential or actual hazards. This includes transfers to other laboratories for R&D purposes.

A. Applicability Determination

Domestic shipment of chemical substances within the U.S. includes the following:

- Carrying the chemical on your person or in your baggage. This practice is not recommended, and may violate domestic or international law, contact OEHS for more information; or
- Shipping the chemical through the mail or express delivery service (e.g., FedEx, UPS, etc.).

A completed and signed TSCA Domestic Shipment Form provided in Appendix B must accompany all such shipments.

B. TSCA Domestic Shipment Form

This form includes text required by TSCA stating that the chemicals to be transferred must be used for R&D purposes only. If the chemical to be transferred is not to be used for R&D only, please contact the UNH Office of Environmental Health and Safety for guidance as there may be additional requirements.
1. **Shipment Contents**

Attach additional sheets that identify the structure of the compound(s), formula and name Chemical Abstract Service (CAS) numbers if available, and any other additional information available regarding the composition of the material.

2. **Health or Physical Hazards**

If little or no known environmental, health, or safety data exists, at a minimum, the researcher must provide in writing any known hazards or risks associated with the substance as indicated on the TSCA Domestic Shipment Form, including:

- Material Safety Data Sheet (MSDS), if available;
- Physical properties of the chemical, if known;
- Classes of compounds with similar properties, if known;
- Suspected hazards as applicable; and
- Indication that the hazards associated with the chemical have not been fully evaluated.

3. **Shipper/Recipient Information**

Complete the shipper’s information as well as the recipient’s contact information. This section includes:

- Shipper’s name;
- Shipper’s telephone number;
- Ship date; and
- Recipient’s name and contact number.

C. **Labeling and Recordkeeping**

1. If little or no known environmental, health, or safety data exists, label the chemical container as follows:

   “The hazards associated with this chemical have not been fully evaluated. This chemical is to be used for research and development purposes only, under the supervision of a technically qualified individual.”

2. Label the outside of the shipping package with the words, “Contents to be used for Research and Development Purposes Only.” Follow U.S. Department of Transportation (DOT) and International Air Transport Association (IATA) requirements as appropriate.

3. Maintain a copy of the signed TSCA Domestic Shipment Form and copies of any environmental, health, or safety data/information provided, in the laboratory for three (3) years.

VI. **Importation of Chemical Substances**

Shipments of TSCA-regulated chemicals into the United States from foreign countries must be accompanied by information that informs the recipient of potential or actual hazards. This includes transfers from other laboratories for R&D purposes.
A. Applicability Determination

The TSCA Import Certification Form (see Appendix C) must be completed for any chemical that is brought into the U.S. by any means, including:

- Chemicals brought into the U.S. through Customs;
- Chemicals shipped to the U.S. from a foreign location (including materials shipped by a colleague, friend, coworker, etc.);
- Chemicals that are hand carried or are in personal baggage (not recommended); or
- Independent imports (i.e., arrangements with a foreign vendor to send a chemical from outside the U.S.).

Note: In cases where a chemical is imported through a vendor/supplier/distributor (i.e., VWR, Fisher, etc.), the importer will complete the TSCA Import Certification Form. No action from the researcher is required.

B. Imports not regulated under TSCA

The following substances are not regulated for import under TSCA:

- Food, drugs, cosmetics, medical devices, or other materials regulated by the Food and Drug Administration or chemicals that are manufactured exclusively for these uses;
- Firearms, ammunition, and other materials, regulated under the Bureau of Alcohol, Tobacco, and Firearms including Tobacco/tobacco products;
- Nuclear or other radioactive material that is regulated by the Nuclear Regulatory Commission;
- Pesticides that are registered under the Federal Insecticide, Fungicide, and Rodenticide Act (pesticide intermediates and individual components of a pesticide are covered);
- Items containing a chemical substance or mixture that is not intended to be removed from the item and that has no end use or commercial purpose separate from the item (fluids and particles are not considered articles).

When importing a substance that is not regulated by TSCA, contact the Office of Environmental Health and Safety.

C. Completion of the Import Certification Form

The researcher must forward a completed Import Certification Form with a Purchase Order to the foreign vendor/shipper. The Purchase Order must include the following text:

“This chemical substance will be used for research and development purposes only.”

The Purchase Order must also include:

- The identity of the substance;
- The Chemical Abstract Service (CAS) number if available; and
- The quantity of the substance ordered.

The vendor/shipper must be instructed to include the Import Certification Form with the shipment so that it will be available to the Customs officer when it enters the country. The researcher must keep the import certification and the Purchase Order on file for three (3) years.
A copy of the Import Certification Form should also be forwarded to the UNH Office of Environmental Health and Safety.

VII. Exportation of Chemical Substances

Chemicals listed in the U.S. EPA’s Chemicals on Reporting Rule (CORR) Database that are shipped from the United States to foreign countries must be accompanied by a UNH TSCA Export Notification Form. This includes transfers to laboratories abroad for R&D purposes.

A. Applicability Determination

The TSCA Export Notification Form in Appendix D must be completed when a chemical to be exported is listed in the TSCA CORR Database. Contact OEHS to query the CORR Database. A chemical is considered to be exported when:

- Chemicals are shipped to a foreign location (including materials shipped to a colleague, friend, coworker, etc.); or
- Chemicals are hand carried or are transported in personal baggage (not recommended).

B. TSCA Export Notification Form

1. OEHS will find your chemical in the TSCA CORR Database and notify you which is the appropriate TSCA Section for your chemical:

   - Section 4, which pertains to new chemical Test Rules and is a one time notification for the destination country; or
   - Sections 5, 6, or 7, which pertain to new chemical Pre-Manufacture and Significant New Uses regulations and is an annual notification to the destination country.

2. Specific information must be listed on the form, including:

   - Chemical structure and formula;
   - CAS number, if applicable;
   - Name and address of exporter;
   - Country of import;
   - Name and address of recipient; and
   - Date of export.

   **Postmark Note:** OEHS will mail the Export Notification Form; it must be postmarked within seven (7) days after accepting a definite contractual obligation or reaching a final decision to export. When the actual export occurs less than seven (7) days after the export obligation or agreement has been executed, the notice must be submitted to the U.S. EPA no later than the same day as the export.

3. Contact information for the sender and recipient must be included on the form. This information includes:

   - The name and contact information for the person submitting the chemical substance for export;
   - The name and contact information for the recipient.
C. Recordkeeping

The researcher must keep one copy of the Export Notification Form and submit a second copy to OEHS. OEHS will submit the form. Copies of all export notifications must be kept on file for three (3) years.

VIII. Adverse Reactions and Risks Notifications

A. Allegations of Adverse Reactions

Allegations of significant adverse reactions to health and the environment alleged to have been caused by a chemical substance used for R&D purposes in the laboratory must be kept on file and submitted to OEHS immediately.

Types of reactions considered significant by the U.S. EPA include, but are not limited to:

1. Human Health Reactions
   - Long-lasting or irreversible damage, such as cancer or birth defects;
   - Partial or complete impairment of bodily functions, such as reproductive disorders;
   - An impairment of normal activities experienced by all or most of the persons exposed at one time; or
   - An impairment of normal activities that is experienced each time an individual is exposed.

2. Environmental Reactions
   - Gradual or sudden changes in the composition of animal or plant life, including fungal or microbial organisms in the area;
   - Abnormal number of deaths by organisms (e.g., fish kills);
   - Reduction of the reproductive success or the vigor of a species;
   - Reduction in agricultural productivity, whether crops or livestock;
   - Alterations in the behavior or distribution of a species; or
   - Long lasting or irreversible contamination of components of the physical environment, especially in the case of groundwater, and surface water, and soil resources that have limited self-cleansing capability.

B. Substantial Risk Notification

The U.S. EPA must be informed if there is information that reasonably supports the conclusion that a chemical substance presents a significant risk of injury to health or the environment. The person reporting allegations of significant adverse reactions must document it in writing, sign it, and forward a copy to the Office of Environmental Health and Safety. If warranted, OEHS will submit a report to the U.S. EPA within 30 calendar days and will include:

- The name and address of the site which received the allegation;
- The date of the allegation;
- The implicated substance, mixture, article, process or operation, or site discharge;
- A description of the “alleger” (e.g., employee, student). If the allegation involves a health effect, the sex and year of birth of the individual should be recorded, if ascertainable;
- A description of the alleged health effect(s). The description must relate how the effect(s) became known and the route of exposure, if explained in the allegation; and
• A description of the nature of the alleged environmental effect(s), identifying the affected plant and/or animal species, or contaminated portion of the physical environment.

Allegations concerning the health of any employee arising from any employment-related exposure must be maintained for 30 years from the date the report is submitted to the U.S. EPA. All other allegations must be maintained for five (5) years.

IX. Research and Development Grants and Material Transfer Agreements

UNH receives more than $100 million in research by government, non-government, and private sector organizations. The Office of Sponsored Research uses the “Request for Internal Approval of Grant or Contract Application to External Sponsor,” or “Yellow Sheet,” to manage the acquisition and distribution of the majority of those funds. This form is available on the UNH website at http://unh.edu/research/get-approvals.

Additionally, Material Transfer Agreements (MTA) are required for materials used in research in instances where no third party controls transfer by an existing agreement. The MTA serves as supporting documentation for R&D activities that are regulated under TSCA to certify that the material will be used for R&D only. The MTA is administered and processed through the UNH Office of Research Partnerships and Commercialization (ORPC). This form is available on the UNH website at http://unh.edu/research/material-transfer-agreements-mtas.
Appendix A - Glossary

**Allegation**: A statement, made without formal proof or regard for evidence, that a chemical substance or mixture has caused a significant adverse reaction to health or the environment.

**Article**: A manufactured item (1) which is formed to a specific shape or design during manufacture, (2) which has end use function(s) dependent in whole or in part upon its shape or design during end use, and (3) which has either no change of chemical composition during its end use or only those changes of composition which have no commercial purpose separate from that of the article and that may occur as described in 40 CFR 720.36(g)(5), except that fluids and particles are not considered articles regardless of their shape or design.

**Byproduct**: A chemical substance produced without a separate commercial intent during the manufacture, processing, use or disposal of another chemical substance or mixture.

**Chemical substance**: 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;
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; or
6. Any food, food additive, drug, cosmetic, or device, when manufactured, processed, or distributed in commerce for use as a food additive, drug, cosmetic or device.

**Dispose**: To get rid of something.

**Distribute**: To sell, introduce or deliver a chemical substance for introduction into commerce.

**Importer**: Any person who imports a chemical substance, including a chemical substance as part of a mixture or article, into the customs territory of the United States. “Importer” includes the person primarily liable for the payment of any duties on the merchandise or an authorized agent acting on his or her behalf. The term also includes, as appropriate:

1. The consignee;
2. The importer of record;
3. The actual owner if an actual owner’s declaration and superseding bond has been filed in accordance with Subpart C of 19 CFR Part 144.

**Impurity**: A chemical substance, which is unintentionally present with another chemical substance

**Intermediate**: Any chemical substance that is consumed, in whole or in part, in chemical reactions used for the intentional manufacture of another chemical substance(s) or mixture(s), or that is intentionally present for the purpose of altering the rates of such chemical reactions.

**Manufacture**: To produce or manufacture in the United States or import into the customs territory of the United States. TSCA jurisdiction over manufacturers is limited to persons who manufacture a chemical substance “for commercial purposes”.
Manufacture or Import for Commercial Purposes: To import, produce, or manufacture with the purpose of obtaining an intermediate or eventual commercial advantage for the manufacturer or importer, and includes, among other things, “manufacture” of any amount of a chemical substance or mixture:

1. For commercial distribution, including test marketing;
2. For use by the manufacturer, including use for product research and development or as an intermediate.

Mixture: Any combination of two or more chemical substances if the combination does not occur in nature and is not, in whole or in part, the result of a chemical reaction, except “mixture” does include:

1. Any combination which occurs, in whole or in part, as a result of a chemical reaction if the combination could have been manufactured for commercial purposes without a chemical reaction at the time the chemical substances comprising the combination were combined, and if all of the chemical substances comprising the combination are not new chemical substances, and
2. Hydrates of a chemical substance or hydrated ions formed by association of a chemical substance with water, so long as the non-hydrated form is itself not a new chemical substance.

New Chemical Substance: Any chemical substance not included on the TSCA inventory.

Process: The preparation of a chemical substance or mixture, after its manufacture, for distribution in commerce.

Significant Adverse Reactions: Reactions that may indicate a substantial impairment of normal activities or long lasting or irreversible damage to health or the environment.

Small Quantities Solely for Research and Development: Quantities of a chemical substance manufactured, imported, or processed or proposed to be manufactured, imported, or processed solely for research and development that:

1. Are not greater than reasonable necessary for such purposes; and
2. Are used by, or directly under the supervision of, a technically qualified individual(s).

Technically Qualified Individual: A person or persons who:

1. 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. Is responsible for enforcing appropriate methods of conducting scientific experimentation, analysis, or chemical research to minimize such risks, and
3. 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.

Test Marketing: The distribution in commerce of no more than a predetermined amount of a chemical substance, mixture or article containing that chemical substance or mixture, by a manufacturer or processor, to no more than a defined number of potential customers to explore market capability in a competitive situation during a predetermined testing period prior to the broader distribution of that chemical substance, mixture, or article in commerce.

Use: The act or practice of employing something.
Appendix B – TSCA Domestic Shipment Form
Appendix C – TSCA Import Certification Form
Appendix D – TSCA Export Notification Form