

The select agent list and relevant regulatory program information are maintained by the CDC and can be found on the select agent web site <http://www.selectagents.gov/>. The regulations covering select agents include Code of Federal Regulations, *Title 7, Part 331 (agriculture)*, *Title 9, Part 121 (animals and animal products)*, *Title 42, Part 73 (public health)*.

Permissible toxin amounts:

The following toxins are exempt from the full scope of the Select Agent rules provided they are under the control of a principal investigator, treating physician or veterinarian and the aggregate amount does not, at any time, exceed the following amounts:

Abrin 100 mg
Botulinum neurotoxins 0.5 mg
Conotoxin 100 mg
Diacetoxyscirpenol (DAS) 1000 mg
Ricin 100 mg
Saxitoxin 100 mg
Staphylococcal enterotoxins (A, B, C, D and E subtypes) 5.0 mg
T-2 toxin 1000 mg
Tetrodotoxin 100 mg

Use of these toxins requires and number of steps for compliance including

- Receive IBC approval before possession
- Inventory tracking and security, log each use, keep toxin locked and secure
- Document destruction or depletion, disposal must be approved and witnessed
- Develop specific procedures, train staff and document your work
- Report all exposures, spills or theft/suspicious activity

There are a number of other toxins of biological origin which exhibit similar toxicity and risk (i.e. – Bungarotoxin, Digitoxin, Pertussis Toxin, Cholera Toxin, Diphtheria Toxin), but are NOT on the select agent list (see Appendix G for a more comprehensive list of biological toxins). These toxins should be handled with similar precautions as outlined in this policy (security, inventory control, training, documented disposal etc.)

Controlled Substances:

The Federal Drug Enforcement Administration (DEA) requires that research personnel must have their own DEA license. At Dartmouth, the principal investigator is the responsible individual. Special inventory, security and recordkeeping requirements apply. For more information on obtaining a DEA license, contact EHS (646-1762).

TSCA – the Toxic Substances Control Act

TSCA, or the Toxic Substances Control Act (1976), regulates new and existing chemicals for potential environmental and public health effects prior to production or transportation.

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This law requires a basic hazard assessment for all new chemicals offered for transport or sale and requires documentation and communication of this hazard assessment.

Laboratories engaged in research must consider the applicability of the Toxic Substances Control Act (TSCA) on their operation. Most chemicals in our labs are on the TSCA inventory already (referred to as “existing” chemicals) but specialty chemicals or materials synthesized in our labs are likely not on the inventory and are thus “new chemicals”. Documentation and evaluation of adverse health effects is required for both existing and new chemicals. In addition new chemicals must be registered with TSCA or used under the research and development exemption.

You become subject to TSCA when you:

- **Bring chemicals not on the TSCA Inventory (i.e., “new chemicals”) on campus or into the country.**
- **Purchase a “new” chemical, either from a domestic or foreign vendor.**
- **Synthesize a new chemical for use, transfer, shipment or export.**
- **Transfer or ship a new chemical to another lab or institution, in the US or overseas.**
- **Observe an adverse health or environmental effect associated with a new chemical, or a new health effect associated with an existing chemical.**

As EPA becomes aware of activities at colleges and universities, it becomes increasingly important for Dartmouth College to demonstrate that a TSCA compliance program is in place. Most activities at Dartmouth College should be exempt from TSCA provided certain conditions are met but you will need to document that your work meets this exclusion. In rare cases you may need to document your TSCA registration information.

Overview of Research and Development (R&D) Exemption Requirements:

A chemical substance can be exempted from many TSCA requirements when it is imported, manufactured or used in small quantities, solely for purposes of *non-commercial* scientific experimentation, analysis or research and used under the supervision of a technically qualified individual.

- **Laboratory work involving new chemicals must be overseen by a technically qualified individual (such as the Principal Investigator) and be laboratory scale, non-production work.**
- **New chemicals must be appropriately labeled with the chemical name, a statement that the chemical is to be used for research and development purposes only, and information regarding the potential hazards. If you create your own label you must document this. An example label might read: “*chemical name*, for laboratory research and development purposes only, for use by technically qualified individuals only, liver toxin and suspect carcinogen, the physical, chemical and toxicological properties have not been fully investigated, this product is not on the TSCA inventory”.**

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- **New chemicals can be shipped to offsite locations (i.e. – for identification, analysis or collaboration) provided that a hazard assessment is performed (toxicology research) and documented, the container is labeled as above and an MSDS/SDS sheet is developed. You will also need to document the names/addresses of those you distribute the material to, and the date, amount distributed and notices provided to them (container labels, warnings, MSDS/SDS etc.).**
- **All documentation needs to be kept on file in your lab for 5 years minimum.**

Note that laboratories synthesizing, storing or using new chemicals that do not meet the requirements of the R&D exemption are subject to significant additional TSCA requirements. See Appendix D for additional clarification and definitions associated with TSCA. If you suspect that your operation does not meet the R&D exemption; please contact the EH&S office at 646-1762 for assistance.

The US Environmental Protection Agency (EPA) administers TSCA by 1) creating a list of chemicals that are widely available (i.e., “TSCA Inventory”); 2) regulating chemical imports and exports; 3) collecting information on adverse environmental and health effects for new and existing chemicals; 4) screening new chemicals intended for broad manufacture; and 5) banning chemicals with unacceptable environmental and/or health risk from broad circulation in commerce (e.g., PCBs and asbestos).

Chemical Hygiene Plan Evaluation and Recordkeeping:

The Dartmouth College Chemical Hygiene Plan will be evaluated and updated as needed by EHS. Comments and suggestions on the improvement of this document should be directed to the Director of EHS (646-1762).

Training and chemical exposure monitoring records are maintained by EHS. Individuals may request their records by contacting the Director of EHS (646-1762).

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Additional information and definitions under TSCA

Additional Requirements for import, export and shipping chemicals:

- **Imports:** Any chemicals imported from outside the US Customs Territory must be certified as TSCA compliant or not regulated by TSCA at the time of import.
- **Exports:** Any chemicals exported outside the US Customs Territory must be screened against certain EPA chemical lists. Some particular chemicals may require additional actions required by EPA prior to or within several days of export.
- **Shipments:** New chemicals shipped to other institutions or entities must be shipped for R&D purposes only. Containers of these chemicals and shipping documentation must be labeled. The environmental and health risks of these chemicals must also be evaluated and communicated to the receivers by preparing and shipping an MSDS/SDS and/or shipment form with the substance.
- **Reporting:** ALLEGATIONS OF ADVERSE REACTIONS - Create and maintain records and report any allegations of adverse 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.

TSCA Definitions/Clarifications:

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 substance means 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 (*individual components are chemical substances*).
- (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.
- (6) Any food, food additive, drug, cosmetic, or device, when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device.

Commercial Activities

Activities whose results are directly intended to produce commercial gain for those involved in the oversight or performance of the activity.

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Laboratory is a contained research facility where relatively small quantities of chemical substances are used on a non-production basis, and where activities involve the use of containers for reactions, transfers, and other handling of substances designed to be easily manipulated by a single individual.

Prudent and safe handling practices means the implementation of safe chemical handling practices as delineated in the Chemical Hygiene Plan.

Small quantities solely for research and development (or ‘small quantities solely for purposes of scientific experimentation or analysis or chemical research on, or analysis of, such substance or another substance, including such research or analysis for the development of a product’) means quantities of a chemical substance manufactured, imported, or processed or proposed to be manufactured, imported, or processed solely for research and development that are not greater than reasonably necessary for such purposes.

Technically qualified individual means a person or persons (1) who, 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) who is responsible for enforcing appropriate methods of conducting scientific experimentation, analysis, or chemical research to minimize such risks, and (3) who 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.

Chemicals or Activities not Regulated by TSCA:

Foods, food additives, drugs, cosmetics **or** devices regulated by the Food and Drug Administration.

Radioactive materials regulated by the Nuclear Regulatory Commission .

Tobacco, tobacco products and ammunition regulated by Alcohol Tobacco and Firearms

Pesticides regulated by **FIFRA (Federal Insecticide, Fungicide and Rodenticide Act)**-- pesticides officially recognized as pesticides through an experimental use permit or otherwise. FIFRA regulated pesticides.

Individual components of a given pesticide are regulated by TSCA.

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