

EXPORT CONTROLS GUIDANCE BIOLOGICAL AGENTS AND TOXINS

Export control regulations govern the transfer of certain biologicals, pathogens and toxins. These regulations also control proprietary information or non-publicly available technology on the know-how to grow, maintain, quality check or dispose a controlled biological agent. Biologicals can be controlled under the Bureau of Industry and Security Export Administration Regulations (EAR), Commerce Control List (CCL) or under the Department of State International Traffic in Arms Regulations (ITAR), U.S. Munitions List (USML).

EAR-Controlled Biologicals

Several relevant export control classification numbers (ECCN) from the CCL are:

- ECCN 1C350 - Chemicals that may be used as precursors for toxic chemical agents;
- ECCN 1C351 - Human and animal pathogens and “toxins”. The export controls list of biological is broader than the Select Agent list. Some examples are: viruses like the Western equine encephalitis, Yellow fever virus, Lyssaviruses, bacteria like *Brucella abortus*, *Salmonella typhi*, and toxins like Shiga toxin;
- ECCN 1C353 - Genetically modified organism that contains, or genetic element that codes for any of the following: any gene or genes specific to any controlled virus, any gene or genes of controlled bacterium or fungus and which: represents a significant hazard to human, animal or plant health or could enhance pathogenicity; or any controlled toxins, or their subunits;
- ECCN 1C354 - Plant pathogens (including, but not limited to, bacteria such as *Xanthomonas albilineans*, fungi such as *Magnaporthe oryzae*);
- 1E001- Technology for the development or production of the controlled biological agents;
- ECCN 1E351 - Technology for the disposal of controlled biologicals;
- ECCN 1C991 - Vaccines, immunotoxins, toxin based products (includes medical products, diagnostic and food test kits with toxins). Vaccines need to be approved by the FDA or the USDA to be considered a vaccine under export control regulations;
- ECCN 2B352 - Biological Processing Equipment (including, but not limited to, certain centrifugal separators cable of the continuous separation of pathogenic microorganisms, certain equipment designed for fixed installation in containment facilities).

Faculty and staff planning to transfer biological agents outside the U.S. or to a foreign person in the U.S. are encouraged to seek guidance from the Export Controls Office before engaging in such activities. There is a worldwide license requirement for controlled biological agents listed in ECCN’s 1C351, 1C353 and 1C354.

ITAR-Controlled Biologicals

Category XIV: Toxicological Agents Including Chemical, Biological Agents and Associated Equipment, of the United States Munitions List). Foreign nationals and entities in the United States may not access ITAR- controlled biologicals or technology without authorization from the government.

- If a biological agent or biologically derived substance is specifically developed or modified to increase its capability to produce casualties in humans or livestock or to degrade equipment or damage crops it may fall under the ITAR regulations.
- Equipment and its components, parts, accessories, and attachments specifically designed or modified for military operations and compatibility with military equipment may be controlled under the ITAR regulations.

Fundamental Research and Published Information Exclusions

Generally, in the United States, a foreign person may use EAR export controlled pathogens and toxins for fundamental research so long as the technology being shared with the foreign national or entity is publicly available and part of fundamental research (see below). It is important to keep in mind that unlike EAR controlled pathogens and toxins, foreign persons and entities in the United States may not access ITAR controlled biological agents/substances (see Category XIV: Toxicological Agents Including Chemical, Biological Agents and Associated Equipment, of the United States Munitions List (USML)).

Fundamental research is defined as research in science, engineering, or mathematics, the results of which ordinarily are published and shared broadly within the research community, and for which the researchers have not accepted restrictions for proprietary or national security reasons.

- The fundamental research exclusion does not apply to export controlled items or information used in connection with fundamental research (i.e. models, instruments, equipment devices, biologicals).
- It is not fundamental research if publication/dissemination restrictions are accepted or if the research is proprietary.
- Published information or information that will be published is not subject to the EAR.
- Information that is already in the public domain is not subject to the ITAR.

Examples of Potentially Export-Controlled Activities

- A foreign person working in a laboratory that conducts research related to export-controlled biologicals or vaccines, could pose a deemed export concern, if they have access to controlled technology or proprietary information.
- Sharing controlled, proprietary or non-publicly available information, including how to grow, maintain, quality check, or dispose of biological agents or genetic elements with a foreign person or entity anywhere.
- Shipping an export-controlled biological agent or genetic element internationally (“hand carried” is considered an export). A license is required to ship controlled biologicals to

any country outside the U.S.

Common Misconceptions

- Some people believe attenuated strains are not controlled. This is false. Attenuated strains can still be controlled.
- Some people believe minimal quantities are not controlled. This is false. Any quantity of a controlled biological is still controlled.
- Some people believe their research materials and equipment are not controlled if the project is fundamental research. This is false. Fundamental research exclusion does not apply to physical/tangible items.
- Some people believe that if the biological is no longer subject to the Department of Health & Human Services Center for Disease Control and Prevention – Federal Select Agent Program (<https://www.selectagents.gov/>), it is also not export controlled. This is false. These are separate concerns controlled by separate governmental departments. Material that may no longer be regulated under the Select Agent Regulations may nonetheless be regulated under export control regulations.

Export control laws are complex and fact specific. Regulations, rules and lists for specifying who or what is considered export sensitive and where export controls apply are subject to change. The outline above is intended to provide a very brief outline of basic export control information. It should not be relied upon exclusively nor should it be construed as legal advice.

Also, please be mindful that every export from the United States is an import to another country. That country may also have import regulations, duties and taxes that must be followed.

For more information contact:

[Export Controls/Conflict of Interest/Responsible Conduct of Research Office](#)

Email: exportcontrols@tamu.edu

Phone: 979-862-6419

Useful Links:

Bureau of Industry and Security

[Export Administration Regulations \(EAR\)](#)

[FAQs - Deemed Exports and Fundamental Research for Biological Items](#)

Code of Federal Regulations

[eCFR :: 15 CFR 734.8 -- “Technology” or “software” that arises during, or results from, fundamental research.](#)

[eCFR :: 22 CFR 120.11 -- Public domain.](#)

[eCFR :: 22 CFR Part 121 -- The United States Munitions List](#)

Texas A&M University

[TAMU Hazardous Material Shipping](#)

[TAMU International Shipping Guidance](#)

[TAMU International Shipping Review Form](#)