

EXPORT CONTROL BASICS BIOLOGICAL AGENTS AND TOXINS February 2019

The United States (U.S.) Department of Commerce, and the State Department, along with various other government agencies control certain technology, items, etc. Authorization from one or more government agencies may be required to transfer export-controlled items internationally. Additionally, foreign national (i.e. F-1, J-1, H1-B, B-1 visa holder or foreign entity) access or use of export-controlled items, in the U.S. may be restricted unless authorized by the federal government.

EAR-Controlled Biologicals

The Bureau of Industry and Security Export Administration Regulations (EAR) controls certain biological pathogens, toxins, and chemical agents through the Commerce Control List (CCL). Faculty and staff planning to transfer biological agents outside the U.S. or to a foreign national in the U.S. are encouraged to seek guidance from the Export Controls Office before engaging in such activities. Several relevant export control classification numbers (ECCN) from the CCL¹ are:

- ECCN 1C350 - Chemicals that may be used as precursors for toxic chemical agents;
- ECCN 1C351 - Human and animal pathogens and “toxins” (including, but not limited to, viruses like the Western equine encephalitis, bacteria like the Brucella abortus, and toxins like Shiga toxin);
- ECCN 1C353 - Genetic elements (including, but not limited to chromosomes, genomes, plasmids, transposons, and vectors) and genetically modified organisms associated with the pathogens and toxins;
- ECCN 1C354 - Plant pathogens (including, but not limited to, bacteria such as Xanthomonas albilineans, fungi such as Magnaporthe oryzae);
- ECCN 1E351 - Technology for the disposal of the listed biologicals;
- ECCN 1C991 - Vaccines, immunotoxins, toxin based products (includes medical products, diagnostic and food test kits with toxins);
- ECCN 2B352 - Biological Processing Equipment (including, but not limited to, certain centrifugal separators capable of the continuous separation of pathogenic microorganisms, certain equipment designed for fixed installation in containment facilities²).

¹ <https://www.bis.doc.gov/index.php/documents/regulations-docs/2332-ccl1-10-24-18/file>

² <https://www.bis.doc.gov/index.php/documents/regulations-docs/2333-ccl2-10-24-18/file>

ITAR-Controlled Biologicals

It is important to keep in mind that biological agents may also be controlled under the International Traffic in Arms Regulations (ITAR) (see Category XIV: Toxicological Agents Including Chemical, Biological Agents and Associated Equipment, of the United States Munitions List)³. Foreign nationals and entities in the United States may not access ITAR-controlled biologicals without authorization from the government. ITAR treats any of the following as defense articles:

- “Biological agent or biologically derived substance specifically developed or modified to increase its capability to produce casualties in humans or livestock or to degrade equipment or damage crops.”
- "Equipment and its components, parts, accessories, and attachments specifically designed or modified for military operations and compatibility with military equipment. . . ." Note that equipment used with biological materials may be included under this category.

Fundamental Research and Published Information Exclusions

Generally, in the United States, a foreign national 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 nationals 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))³.

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 reasons⁴.

- 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 EAR⁵.

³ <https://www.bis.doc.gov/index.php/documents/regulation-docs/412-part-734-scope-of-the-export-administration-regulations/file>

⁴ <https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=70e390c181ea17f847fa696c47e3140a&mc=true&r=PART&n=pt22.1.121>

⁵ <https://www.bis.doc.gov/index.php/documents/regulation-docs/412-part-734-scope-of-the-export-administration-regulations/file>

- Information that is already in the public domain is not subject to the ITAR⁶.

Examples of Potentially Export-Controlled Activities

- Foreign national (i.e. F-1, J-1, H1B, B-1, etc.) visa holder is going to work in a laboratory that conducts research related to export-controlled biologicals or vaccines for diseases in animals, plants and humans.
- Sharing proprietary or non-publicly available information, including how to produce, maintain, quality check, or dispose of biological agents or genetic elements with a foreign national or entity anywhere.
- Shipping an export-controlled biological agent or genetic element internationally (“hand carried” is considered an export).

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 the EAR.

For additional guidance, please contact the Export Controls Office. The Export Controls Office can assist with classification determinations and provide guidance on application of the regulations to your proposed activity.

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.

⁶ ITAR Public Domain 22 CFR 120.11 <https://www.govinfo.gov/content/pkg/CFR-2018-title22-vol1/xml/CFR-2018-title22-vol1-part120.xml>

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.

Texas A&M University Export Controls Office⁷

<http://vpr.tamu.edu/resources/export-controls>

Email: exportcontrols@tamu.edu

Phone: 979-862-6419

Useful Links:

BIS FAQ's – Deemed Exports and Fundamental Research for Biological Items:

<https://www.bis.doc.gov/index.php/policy-guidance/product-guidance/chemical-and-biological-controls/14-policy-guidance/deemed-exports/111-deemed-export-and-fundamental-research-for-biological-items>

BIS Licensing for Biological Commodities and Technologies:

<https://www.cdc.gov/od/eaipp/docs/bis-export-licensing.pdf>

TAMU Hazardous Material Shipping:

<https://ehs.tamu.edu/programs/hazardous-material-shipping/>

TAMU International Shipping Guidelines:

<https://vpr.tamu.edu/initiate-research/export-controls/ShippingGuidelinesFinal101817RevAttachmentA52218.pdf>

⁷ Each System Member has its own Export Control Office (ECO). To the extent there are overlapping export control compliance obligations with other System members, such as when University faculty, researchers, students or exchange visitors are performing under grants or contracts awarded to AgriLife Research and TEES, all System members should coordinate with the applicable Export Controls Office(s).