Export of Restricted Biological Agents

The U.S. Department of Commerce's Bureau of Industry and Security (BIS) administers U.S. laws, regulations and policies governing the export and reexport of commodities, software, and technology (collectively "items") falling under the jurisdiction of the Export Administration Regulations (EAR). The primary goal of BIS is to advance national security, foreign policy, and economic objectives by ensuring an effective export control and treaty compliance system, and promoting continued U.S. strategic technology leadership. BIS also enforces anti-boycott laws and coordinates with U.S. agencies and other countries on export control, nonproliferation and strategic trade issues.

If you work with any of the following or similar agents and/or you intend to send samples or data abroad or plan to collaborate with foreign colleagues either within the United States or in foreign countries, please contact Todd Nielsen, Export Control Officer in the Office or Sponsored Projects. They will help you determine what restrictions apply to the agents in your lab and how to incorporate the export control requirements into your research program.

Note: Penalties are severe for non-compliance, including monetary and criminal punishment.

WHAT BIOLOGICAL AGENTS ARE RESTRICTED?

US export controls impose a requirement to obtain export authorization for shipment to any international destination (including Canada) of certain controlled human, animal, and plant bacteria, viruses, fungi, and toxins. In addition, they restrict the export of genetically modified organisms (GMOs) or genetic elements that contain or code for the genes of controlled pathogens or subunits of controlled toxins, including in some cases where the GMOs or genetic elements are not themselves pathogenic.

A key in determining whether an export license is needed from the Department of Commerce is finding out if the item you intend to export has a specific Export Control Classification Number (ECCN). ECCNs are five-character alpha-numeric designations used on the Commerce Control List (CCL) to identify dual-use items for export control purposes. An ECCN categorizes items based on the nature of the product, i.e. type of commodity, software, or technology and its respective technical parameters. For example:

ECCN 1C351: Human and Animal Pathogens

ECCN 1C354: Plant Pathogens

ECCN 1C353: Genetic Elements and GMOs

Importantly, the controls apply not only to the complete, wild-type organisms listed in the above-referenced ECCNs, but also to any GMO that contains, or any genetic element that codes for, genes of the listed organisms or subunits of the listed toxins. “Genetic elements” is broadly defined to include (without limitation) chromosomes, genomes, plasmids, transposons, vectors, and inactivated organisms containing recoverable nucleic acid fragments, whether genetically modified or unmodified, or chemically synthesized in whole or in part.

Notably, while a GMO that contains, or genetic element that codes for, genes of controlled bacteria and fungi is subject to control if it “[i]n itself or through its transcribed or translated products represents a significant hazard to human, animal or plant health” or “[c]ould endow or enhance pathogenicity,” GMOs that contain, or genetic elements that code for, genes of controlled viruses, or subunits of controlled toxins, are controlled for export even if they are not themselves harmful.

Below is a list of agents restricted for export by the U.S. Department of Commerce. A full list can be found here: https://www.bis.gov/ear/title-15/subtitle-b/chapter-vii/subchapter-c/part-774/supplement-no-1-part-774-commerce-control#1C351. However, always contact the Export Control Officer to confirm that the list is current before exporting biological materials.

These listed items are controlled for export regardless of quantity or attenuation, genetic elements or genetically modified organisms for such agents or “toxins”, including small quantities or attenuated strains of select biological agents or “toxins” that are excluded from the lists of select biological agents or “toxins” by APHIS, CDC, or DHHS.

NOTE: Genetic elements from any of the below are also controlled. Specifically, any nucleic acid sequences which code for biological toxins, any nucleic acid sequences that are a hazard to human health when transcribed or translated, or any nucleic acid sequence that would make any restricted microorganism above more pathogenic. This also covers microorganisms that have been genetically altered to express the above genetic elements.

1. Any agent on the Select Agent List found here: http://www.selectagents.gov/SelectAgentsandToxinsList.html
2. Additionally, any item listed by the Department of Commerce
   A. BACTERIA
   - Bacillus anthracis
   - Brucella abortus
   - Brucella melitensis
   - Brucella suis
   - Burkholderia mallei (Pseudomonas mallei)
   - Burkholderia pseudomallei (Pseudomonas pseudomallei)
   - Chlamydophila psittaci (formerly Chlamydia psittaci)

- Clavibacter michiganensis subspecies sepedonicus (Corynebacterium michiganensis sub species sepedonicum or Corynebacterium sepedonicum)
- Clostridium argentinense botulinum (formerly Clostridium botulinum Type G), neurotoxin producing strains
- Clostridium baratii, botulinum neurotoxin producting strains
- Clostridium botulinum
- Clostridium butyricum, botulinum neurotoxin producting strains
- Clostridium perfringens, epsilon toxin producing types
- Coxiella burnetii
- Francisella tularensis
- Mycoplasma mycoides See Commerce Control List for details
- Ralstonia solanacearum, race 3, biovar 2
- Raythayibactor toxicus See Commerce Control List for details
- Rickettsia prowasecki (Rickettsia prowazekii)
- Salmonella typhi
- Shiga toxin production Escherichia coli (STEC) of serogroups O26, O45, O103, O104, O111, O121, O145, O157, and other shiga toxin producing serogroups NOTE: Shiga toxin producting Escherichia coli (STEC) is also known as enterohaemorrhagic E. coli (EHEC) or verocytotoxin producing E. coli (VTEC)
- Shigella dysenteriae
- Vibrio cholera
- Xanthomonas albilineans
- Xanthomonas axonopodis pv. Citri (Xanthomonas campestris pv. citri A) (Xanthomonas capestrispv. citri)
- Xanthomonas oryzae pv. oryzae See Commerce Control List for details

B. FUNGI

- Coccidioides immitis
- Coccidioides posadasii
- Cochliobolus miyabeanus (Helminthosporium oryzae)
- Colletotrichum kahawae (Colletotrichum coffeanum var. virulans)
- Magnaporthe oryzae (Pyricularia oryzae)
- Microcyclus ulei (Dothidella ulei)
- Peronosclerospora philippinensis (Peronosclerospora sacchari)
- Phoma glycinicola (formerly Pyrenochaeta glycines) – See Commerce Control List for details
- Puccinia striiformis (Puccinia glumarum)
- Purccinnia graminis ssp. graminis var. graminis/Puccinia graminis ssp. graminis var. stakmanii (Puccinia graminis [Puccinia graminis f. sp. tritici])
- Sclerophthora rayssiae var. zeae

- Synchytrium endobioticum
- Thecaphora solani
- Tilletia indica

C. TOXINS

- Abrin
- Aflatoxins
- Botulinum toxins
- Cholera toxin
- Clostridium perfringens toxins
- Conotoxin
- Diacetoxyscirpenol toxin
- HT-2 toxin
- Marine toxins: brevetoxin, gonyautoxin, nodularin, and palytoxin
- Microcystin (Cyanginosin)
- Modeccin toxin
- Ricin
- Saxitoxin
- Shiga toxin
- Staphylococcus aureus enterotoxins, hemolysin alpha toxin, and toxic shock syndrome toxin (formerly Staphylococcus enterotoxin F)
- T-2 toxin
- Tetrodotoxin
- Verotoxin and other Shiga-like ribosome inactivating proteins
- Viscum album Lectin 1 (Viscumun)
- Volkensin toxin

D. VIRUSES

- African horse sickness virus
- African swine fever virus
- Andean potato latent virus (Potato Andean latent tymovirus)
- Andes virus
- Avian influenza (AI) viruses identified as having high pathogenicity (HP) See Commerce Control List for details
- Avian influenza virus
- Bluetongue virus
- Chapare virus
- Chikungunya virus
- Choclo virus
- Congo-Crimean hemorrhagic fever virus (Crimean-Congo hemorrhagic fever virus)
- Coronavirus

- Dobrava-Belgrade virus
- Eastern equine encephalitis virus
- Ebola virus
- Foot and mouth disease virus
- Goat pox virus
- Guanarito virus
- Hantaan virus
- Hendra virus (Equine morbillivirus)
- Influenza virus
- Japanese encephalitis virus
- Junin virus
- Kyasanur Forest virus
- Laguna Negra virus
- Lassa fever virus
- Louping ill virus
- Lujo virus
- Lumpy skin disease virus
- Lymphocytic choriomeningitis virus
- Lyssa virus (a.k.a. Rabies)
- Machupo virus
- Marburg virus
- Middle East respiratory syndrome-related coronavirus (MERS)
- Mpox (Monkey pox) virus
- Morbillivirus
- Murray Valley encephalitis virus
- Newcastle disease virus
- Nipah virus
- Omsk haemorrhagic fever virus
- Oropouche virus
- Peste des petits ruminants virus
- Porcine Teschovirus
- Potato spindle tuber viroid
- Powassan virus
- Pulmonary and renal syndrome hemorrhagic fever viruses (Seoul, Dobrava, Puumala, Sin Nombre)
- Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments
- Rift Valley fever virus
- Rinderpest virus

- Rocio virus
- Sabia virus
- SARS-associated coronavirus (SARS-CoV)
- Seoul virus
- Sheep pox virus
- St. Louis encephalitis virus
- Suid herpesvirus 1 (Aujeszky's disease)
- Swine fever virus (Hog cholera virus)
- Tick-borne encephalitis virus (Far Eastern subtype, formerly known as Russian Spring-Summer encephalitis virus, Siberian subtype, formerly West Siberian virus)
- Variola virus
- Venezuelan equine encephalitis virus
- Vesicular stomatitis virus
- Western equine encephalitis virus
- Yellow fever virus

Adapted from Vanderbilt University Guidance