Export Restricted Biological Items



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General Overview

There are two sets of regulations for export restricted biological items:

- International Traffic in Arms Regulations (ITAR) from Department of State and,
- Export Administration Regulations (EAR) from Department of Commerce.

Restricted items require export licenses to all countries. Licensing takes at least 8 weeks. Fines are \$284,000 to \$1,094,010 per violation.

These listed items (and any vaccines against these 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.

All biological agents listed in this document, and their biologically derived substances meeting the specific technical parameters that are controlled by the ITAR are listed in CATEGORY XIV—TOXICOLOGICAL AGENTS, INCLUDING CHEMICAL AGENTS, BIOLOGICAL AGENTS, AND ASSOCIATED EQUIPMENT.

(See Category XIV in ITAR Part 121.1)

Certain precursor chemicals, Biosafety gear, and lab equipment are also export restricted by the EAR. (See Categories 1 & 2 of the Commerce Control List)

Additionally, there are economic and trade sanctions for all transactions under:

• Office of Foreign Assets Control (OFAC) from the Department of the Treasury.

(See OFAC Sanctions Lists)

Want more information? Here are a few helpful links:

<u>CITI Program Training</u> – This program includes self-paced, online trainings about export control. There is a specific section dedicated to export control and biologicals.

<u>CSU Secure and Global Research</u> – Check out our website for more details!

Alphabetical Listing of Export Restricted Biological Items

Λ	hrin	1.	2	3

Aflatoxins 1, 2, 3

African horse sickness virus

African Swine fever virus

Andean potato latent virus (Potato Andean latent tymovirus)

Andes virus

Avian influenza (AI) viruses with high pathogenicity (HP):

- AI viruses that have an intravenous pathogenicity index (IVPI) in 6-week old chickens greater than 1.2; or
- AI viruses that cause at least 75% mortality in 4- to 8-week old chickens infected intravenously.

Note: Avian influenza (AI) viruses of the H5 or H7 subtype that do not have either of the characteristics described in above should be sequenced to determine whether multiple basic amino acids are present at the cleavage site of the haemagglutinin molecule (HA0). If the amino acid motif is similar to that observed for other HPAI isolates, then the isolate being tested should be considered as HPAI and the virus is export restricted

Bacillus anthracis 4

Bluetongue virus

Botulinum toxins 1, 2, 3, 4

Brucella abortus

Brucella melitensis

Brucella suis

Burkholderia mallei (Pseudomonas mallei)4

Burkholderia pseudomallei (Pseudomonas pseudomallei)4

Chapare virus

Chikungunya virus

Chlamydophila psittaci (formerly Chlamydia psittaci)

Choclo virus

Cholera toxin1,2,3

Classical swine fever virus (Hog cholera virus).

Clavibacter michiganensis subspecies sepedonicus (syn. Corvnebacterium michiganensis subspecies sepedonicum or Corynebacterium sepedonicum); Clostridium argentinense (formerly known as Clostridium botulinum Type G) botulinum neurotoxin producing strains

Clostridium baratii, botulinum neurotoxin producing strains

Clostridium botulinum4

Clostridium butyricum, botulinum neurotoxin producing strains4

Clostridium perfringens, epsilon toxin producing types

Clostridium perfringens alpha, beta 1, beta 2, epsilon and iota toxins¹,

Coccidioides immitis

Coccidioides posadasii

Cochliobolus miyabeanus (Helminthosporium oryzae)

Colletotrichum kahawae (Colletotrichum coffeanum var. virulans)

Conotoxins 1, 2, 3

Coronavirus, SARS-associated (SARS-CoV)

Coxiella burnetii

Crimean-Congo hemorrhagic fever

Diacetoxyscirpenol toxin1,2,3

Dobrava-Belgrade virus

Eastern Equine Encephalitis virus Ebolavirus (includes all members of the Ebolavirus genus)4

Encephalitis:

Eastern equine, Japanese, Murray Valley, St. Louis, Tick-borne, Venezuelan equine, Western equine

Enterohaemorrhagic Escherichia coli (E Coli), Shiga toxin producing Escherichia coli (STEC) of serogroups 026, 045, 0103, 0104, 0111, 0121, 0145, 0157, and other shiga toxin producing serogroups

Note: Shiga toxin producing Escherichia coli (STEC) is also known as enterohaemorrhagic E. coli (EHEC) or verocytotoxin producing E. coli (VTEC).

Equine Morbillivirus (Hendra Virus)

Foot-and-mouth disease virus4

Francisella tularensis⁴

Goatpox virus

Guanarito virus

Hantaan virus

Hendra virus (Equine morbillivirus)

Herpes virus (Aujeszky's disease) Hog cholera virus (Swine fever virus)

HT-2 toxin1,2,3

Influenza virus, Reconstructed

Note: This includes reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments.

Japanese encephalitis virus

Iunin virus

Kyasanur Forest disease virus

Laguna Negra virus

Lassa virus

Louping ill virus

Lujo virus

Lumpy skin disease virus Lymphocytic Choriomeningitis virus (LCV)

Lyssa virus (aka Rabies)

Machupo virus

Magnaporthe oryzae (Pyricularia oryzae)

Marburgvirus (includes all members of the Marburgvirus genus)4

Microcyclus ulei (syn. Dothidella

Microcystins (Cyanginosins) 1, 2, 3

Modeccin toxin1,2,3

Monkeypox virus

Murray Valley encephalitis virus Mycoplasma capricolum subspecies capripneumoniae ("strain F38").

Mycoplasma mycoides subspecies mycoides SC (small colony) (a.k.a. contagious bovine pleuropneumonia);

Newcastle disease virus

Nipah virus

Omsk hemorrhagic fever virus

Oropouche virus

Peronosclerospora philippinensis (a.k.a. Peronosclerospora sacchari);

Peste-des-petits ruminants virus Phoma glycinicola (formerly

Pyrenochaeta glycines)

Porcine herpes virus (Aujeszky's disease)

Porcine Teschovirus

Potato Andean latent tymovirus (Andean potato latent virus)

Potato spindle tuber viroid.

Powassan virus

Puccinnia graminis ssp. graminis var. graminis/Puccinia graminis ssp. graminis var. stakmanii (Puccinia graminis [syn. Puccinia graminis f. sp. tritici])

Puccinia striformis (syn. Puccinia glumarum)

Rabies virus and all other members of the Lyssavirus genus

Ralstonia solanacearum, race 3, biovar 2

Rathavibacter toxicus;

Reconstructed 1918 influenza virus

Note: This includes reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments.

Ricin ³ (including Ricin D and Ricin E)

Rickettsia prowazekii

Rift Valley fever virus

Rinderpest virus 4

Rocio virus

Sabia virus

Salmonella enterica subspecies enterica serovar Typhi (Salmonella typhi)

Severe acute respiratory syndrome-related coronavirus (SARS-related coronavirus)

Saxitoxin 3

Sclerophthora rayssiae var. zeae;

Seoul virus

Sheeppox virus

Shiga toxin producing Escherichia coli (STEC) of serogroups 026, 045, 0103, 0104, 0111, 0121, 0145, 0157, and other shiga toxin producing serogroups;

Note: Shiga toxin producing
Escherichia coli (STEC) includes,
inter alia, enterohaemorrhagic E.
coli (EHEC), verotoxin producing
E. coli (VTEC) or verocytotoxin
producing E. coli (VTEC) 1, 2, 3

Shigella dysenteriae

Sin Nombre virus

St. Louis encephalitis virus

Staphylococcus aureus enterotoxins, hemolysin alpha toxin, and toxic shock syndrome toxin (formerly known as Staphylococcus enterotoxin F) 1,2,3

Suid herpesvirus 1 (Pseudorabies virus; Aujeszky's disease)

Swine fever virus (Hog cholera virus)

Swine vesicular disease virus

Synchytrium endobioticum;

T-2 toxin1,2,3

Tetrodotoxin (TTX) 1,2,3

Tick-borne encephalitis complex viruses (Russian Spring-Summer encephalitis virus aka Far Eastern subtype) and (Siberian subtype, formerly West Siberian virus)

Thecaphora solani

Tilletia indica

Vaccines against items in this alphabetical list (ECCNs1C351, 1C353, or 1C354)

Variola virus (major - Smallpox virus; minor – Alastrim) ⁴

Venezuelan Equine Encephalitis virus

Verotoxin & Verocytotoxins: other Shiga like ribosome inactivating proteins^{1, 2, 3}

Vesicular stomatitis virus

Vibrio cholerae

Viscum Album Lectin 1 (Viscumin)

Volkensin toxin^{1, 2, 3}

Western equine encephalitis virus

Xanthomonas albilineans

Xanthomonas axonopodis pv. citri (Xanthomonas campestris pv. citri A) (Xanthomonas campestris pv. citri)

Xanthomonas oryzae pv. oryzae (syn. Pseudomonas campestris pv. oryzae); proteobacteria

Yellow fever virus

Yersinia pestis 4

Genetic elements, as follows:

- Genetic elements that contain nucleic acid sequences associated with the pathogenicity of microorganisms on this list,
- Genetic elements that contain nucleic acid sequences coding for any of the "toxins" on this list or "sub-units of toxins" thereof.

Genetically modified organisms, as follows:

- Genetically modified organisms that contain nucleic acid sequences associated with the pathogenicity of microorganisms on this list;
- Genetically modified organisms that contain nucleic acid sequences coding for any of the "toxins" on this list or "sub-units of toxins" thereof.
- "Genetic elements" include, inter alia, chromosomes, genomes, plasmids, transposons, and vectors, whether genetically modified or unmodified, or chemically synthesized in whole or in part.

 1 Any diagnostic & food testing kits containing these agents are controlled under the Commerce Control List

 $^2\mbox{\sc Any}$ immunotoxins containing these agents are controlled under the Commerce Control List

³Any medical products containing these agents are controlled under the Commerce Control List

⁴These biological agents, and any biologically derived substances and genetic elements thereof meeting the specifications of ITAR category XIV are controlled by the ITAR-Part 121. Category XIV also includes certain listed antibodies, recombinant protective antigens, polynucleotides, biopolymers, or biocatalysts (including their expression vectors, viruses, plasmids, or cultures of specific cells modified to produce them), and equipment for the dissemination, dispersion, or testing of these controlled agents.

Biological International Shipments or Hand Carry Guidance

(Items 1-3) Prepare information and submit via the International Shipping Checklist.

- 1. To which country is it shipping? Does it fall under a comprehensive or targeted sanction? Review at Export Controlled or Embargoed Countries.
 - a. If yes, this may be a prohibited export or an export license or general license may be required.
- 2. Who is the intended recipient? Enter the intended recipient's name, address and institution in the Receiving Party portion of the checklist to screen whether they are a listed as a restricted or denied party. Is there a match on the name or address?
 - a. If yes, this may be a prohibited export or an export license or general license may be required. Results of the screening will be emailed to you after the automatic screen completes. If the response is red, you will need to work with Export Control for further review.

Note: For your reference, consolidated screening lists are also available via <u>US Government</u> <u>Consolidated Export Control Lists</u> (be sure to include all available sources from the dropdown)

- 3. (i) Are you sending any items, software, or technical data outside the U.S. that is restricted for export?
 - a. If yes, this may require an export license. If you know the export classification of the item/technology, please include it in the shipping checklist.
 - b. If unsure, just describe the item as clearly as possible, and include the intended end-use and/or take a look here:

Review Category XIV in <u>ITAR Part 121.1</u>; Review <u>Categories 1 & 2 of the Commerce</u> Control List

Note: Products and services restricted by ITAR are designed for and/or directly applied to military purposes. Items on the CCL are considered dual-use, meaning "items that have both commercial and military or proliferation applications" as well as some purely commercial items.

- 3. (ii) Will this item be for a prohibited end-use like creation of weapons of mass destruction or use by a foreign military?
 - a. If yes, the transaction must stop. Alert Export Control.

What happens if the resulting review determines that your item will require an export license?

Export Control will follow up to verify details about the anticipated shipment. Export Control will then file licenses and advise you on any available exceptions. Licensing takes a minimum of 8 weeks to obtain from the US government and must be in place prior to the export.

Note: Any of the listed items in this document or on the ITAR USML will require an export license to all countries.

Reach out to <u>vpr export control @mail.colostate.edu</u> with questions!



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