

Policy No.: BS009	Approved by: Mike Liberty
Title: Shipping Biological Materials and Dry Ice (excerpt) – Import, Export and Shipment checklists	Date: 3/11/2021
Revision No.: 8	Page 1 of 4
Prepared by: Sonia Rosenberger	

Appendices 1 and 5 reformatted to serve as a Quick Reference Guide (QRG) for imports and exports (including to/from Canada)

IMPORTS (biologicals from other countries including Canada; USDA – transfer between states too)

- CDC's [e-Tool](#) decision tree determines if a CDC import permit is required.
 - Permits are free, but require online federal Secure Asset Management System (SAMS) registration (restricts access to permit holder) – this should be the Principal Investigator.
 - If a permit is not required, the tool provides certification statements for help with Customs. Put these on letterhead and provide to the sender for inclusion with the shipment.
- USDA's [Veterinary Services Permitting Assistant](#) determines if a USDA import permit is required (e.g. for animal products such as bovine serum albumin and fetal bovine serum.)
 - USDA requires permit if from other another country e.g. Canada (transfer between states too).
 - Permits are \$150 and require registration with USDA's ePermits/eFile system.
 - If a permit is not required, follow the instructions in the appropriate [guideline](#) for help with Customs (e.g. a written statement supplied on foreign producer/shipper letterhead).
- USDA's [Plant Health Permits](#) website lists when a USDA permit is required for plants, plant products, plant pests, plant pathogens, biological control agents, bees, soil, etc.
- CITES permit - samples from endangered or threatened animals (see [USFW](#)), plants ([see USDA](#)); e.g. a CITES permit is required for all nonhuman primate material, including cell lines (Vero).
- Lists of invasive and injurious species (eggs, invertebrates, plants, fungi, algae, cyanobacteria) help determine when a [USFW permit](#) or [NYS DEC permit](#) is required.

EXPORTS (sending biologicals to other countries including Canada)

The US DOC's Commerce Control List (CCL) changes. Always check www.bis.doc.gov/index.php/regulations/export-administration-regulations-ear for the current CCL. Human and animal pathogens and toxins; plant pathogens; and genetic elements and genetically modified organisms appear in [Category 1](#) of the CCL). If dated 1/14/2021, see help on Page 3.

Any export compliance questions may be submitted to: export@rochester.edu

- Material Transfer Agreements (MTA) implemented through ORPA help with export compliance (submit MTA requests through IORA). ORPA will also take the lead for DOC export licenses.

* See Appendix 5 of BS009 for complete list. A subset of the CCL, of particular note for UR:

Organism (1C351)	Genes* (1C353)	Rationale (Australia Group, CCL Handbook, Federal Register)
LCMV	All	All <i>Arenavirus</i> genus spp. that cause human disease are listed
MERS	All	Homology with SARS-CoV
Pseudorabies	All	Potential for socioeconomic harm
Rabies	All	Some countries are rabies-free
SARS-CoV (not 2)	All	No effective vaccine, limited post-exposure treatment options
<i>Vibrio cholerae</i>	Some	Potential to damage the environment
VSV	All (e.g. VSV-G)	Potential for socioeconomic harm (mimics Foot and Mouth disease in livestock)







* For more on 'genes', see Technical Note 2 at the end of ECCN 1C353 in the Commerce Control List (CCL).

- CITES permit - samples from endangered or threatened animals (see [USFW](#)), plants ([see USDA](#)); e.g. a CITES permit is required for all nonhuman primate material, including cell lines (Vero).
- Import permit for recipient's country – the recipient should get the permit. If not required, recommend you include the same certification statement used for US imports, on UR letterhead. When serum-free media is used, that's helpful information to include.

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SHIPMENT CHECKLIST

Date	*Keep shipping documents for 2 years past ship date
Person shipping	Last trained (within previous 2 years):
Recipient/Consignee	
Material(s) shipped	
Permit or License	<input type="checkbox"/> None or 3 copies with shipment: <input type="checkbox"/> Import or Interstate <input type="checkbox"/> Export
Proper Shipping Name	<input type="checkbox"/> Not applicable for biological component (exempt specimen , etc.) <input type="checkbox"/> Biological substance, Category B <input type="checkbox"/> Infectious substance, affecting humans (liquid, solid) <input type="checkbox"/> affecting animals <input type="checkbox"/> Dry ice <input type="checkbox"/> Genetically modified micro-organism
Chemicals included	<input type="checkbox"/> De minimis (≤ 1 ml per primary/inner receptacle, ≤ 100 ml total) <input type="checkbox"/> Excepted quantities (≤ 30 ml per primary/inner receptacle, ≤ 500 ml total) <input type="checkbox"/> Limited quantities <input type="checkbox"/> “non-infectious” in formaldehyde, ethanol or isopropanol (A180) <input type="checkbox"/> None
Refrigerant	<input type="checkbox"/> Dry ice <input type="checkbox"/> Cold Pack <input type="checkbox"/> Liquid nitrogen <input type="checkbox"/> Dry shipper <input type="checkbox"/> None
Carrier	<input type="checkbox"/> UPS <input type="checkbox"/> FedEx <input type="checkbox"/> World Courier <input type="checkbox"/> US Mail <input type="checkbox"/> Self/MOT <input type="checkbox"/> Other
Document	<input type="checkbox"/> Air Waybill <input type="checkbox"/> Emergency response telephone number <input type="checkbox"/> Substance description: “not restricted, Special Provision A180” <input type="checkbox"/> Handling Information <input type="checkbox"/> “Dangerous Goods as per attached Shipper’s Declaration” <input type="checkbox"/> “Dangerous Goods as per attached DGD-Cargo Aircraft Only” <input type="checkbox"/> Nature and Quantity of Goods <input type="checkbox"/> UN 3373, “Biological Substance, Category B”, number of packages <input type="checkbox"/> UN 3245, “GMMO” or “GMO”, number of packages <input type="checkbox"/> UN 1845, “Dry ice” or “Carbon dioxide, solid”, number of packages, net weight of dry ice in kg <input type="checkbox"/> Shipper’s Declaration for Dangerous Goods and Emergency Response Info (3 copies with shipment, 1 copy for records)
Mark and Label Outer Packaging	      <p>Circle:</p> <input type="checkbox"/> Exempt human specimen or Exempt animal specimen <input type="checkbox"/> Biological substance, Category B <input type="checkbox"/> Infectious substance, affecting humans, UN2814 (... animals, UN2900) <input type="checkbox"/> Dry ice (or “Carbon dioxide, solid”), net weight of dry ice in kg, and “frozen medical specimens” for Category B specimens <input type="checkbox"/> Overpack <input type="checkbox"/> Other:
Pack	<input type="checkbox"/> Packaging per manufacturer instructions; not altered or substituted <input type="checkbox"/> Biohazard label on primary or secondary packaging (latter for US Mail) <input type="checkbox"/> List of contents between secondary and outer packaging <input type="checkbox"/> Exempt human or animal specimen – basic three layer/triple packaging <input type="checkbox"/> Biological substance, Category B/ Packing Instruction 650 (+ biohazard symbol) <input type="checkbox"/> Infectious substance, Category A/ Packing Instruction 620 <input type="checkbox"/> Genetically modified micro-organism/ Packing Instruction 959 <input type="checkbox"/> Dry ice/ Packing Instruction 954

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EXCERPTS FROM THE COMMERCE CONTROL LIST (1/14/2021)

(Notes: The US DOC's Commerce Control List (CCL) changes. Always check www.bis.doc.gov/ for the current CCL.)

The US is a member of international groups that develop harmonized export controls for biologicals and related equipment (Australia Group, Wassenaar Arrangement). Export licenses are required for:

- CDC/USDA's Select Agents and Toxins (including Select Toxin subunits)
- Additional Bacteria, Fungi, Viruses, and Plant pathogens; additional Toxins and subunits
- Genetic elements: all genes-CCL Viruses; some genes from Bacteria, Fungi, Toxins and subunits

CDC/USDA's Select Agents and Toxins (and subunits of Select Toxins), 1C351, 353, 354:

These are potential bioterror agents, listed at www.selectagents.gov/SelectAgentsandToxinsList.html. For Select Toxins, even 'permissible amounts' and subunits have export controls.

Bacteria (in addition to those on the Select Agents list), 1C351:

Chlamydia psittaci (*Chlamyodophila psittaci*)

Clostridium perfringens, epsilon toxin producing types

Salmonella enterica subspecies *enterica* serovar Typhi (*Salmonella typhi*)

Shiga toxin producing *Escherichia coli* (STEC) (see serogroups on the Commerce Control List)

Shigella dysenteriae

Vibrio cholerae

Fungi (in addition to those on the Select Agents list), 1C351:

Coccidioides immitis

Coccidioides posadasii

Viruses (in addition to those on the Select Agents list), 1C351:

Andes virus

Bluetongue virus

Chikungunya virus

Choclo virus

Dobrava-Belgrade virus

Hantaan virus

Japanese encephalitis virus

Laguna Negra virus

Louping ill virus

Lymphocytic choriomeningitis virus

Lyssaviruses (including rabies)

Murray Valley encephalitis virus

Oropouche virus

Porcine Teschovirus

Powassan virus

Rabies virus (and all other members of the Lyssavirus genus)

Rocio virus

Seoul virus

Sin Nombre virus

St. Louis encephalitis virus

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

UNIVERSITY OF ROCHESTER
ENVIRONMENTAL HEALTH & SAFETY

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Vesicular stomatitis virus
Western equine encephalitis virus
Yellow fever virus

Plant Pathogens (in addition to those on the Select Agents list; not by kingdom), 1C354:

Andean potato latent virus (Potato Andean latent tymovirus)
Clavibacter michiganensis subspecies *sepedonicus* (see syn. on the Commerce Control List)
Cochliobolus miyabeanus (*Helminthosporium oryzae*)
Colletotrichum kahawae (*Colletotrichum coffeanum* var. *virulans*)
Magnaporthe oryzae (*Pyricularia oryzae*)
Microcyclus ulei (syn. *Dothidella ulei*)
Potato spindle tuber viroid
Puccinia graminis (see specific subspecies and variants on the Commerce Control List)
Puccinia striiformis (syn. *Puccinia glumarum*)
Tilletia indica
Thecaphora solani
Xanthomonas albilineans
Xanthomonas axonopodis pv. *citri* (*Xanthomonas campestris* pv. *citri*, *X. campestris* pv. *citri* A)

Toxins and subunits (in addition to those on the Select Toxins list), 1C351:

Aflatoxins
Cholera toxin
Clostridium perfringens alpha, beta1, beta2, epsilon and iota toxins
HT-2 toxin
Microcystins (Cyanginosins)
Modeccin
Shiga toxins (shiga-like toxins, verotoxins, and verocytotoxins)
Viscumin (*Viscum album* lectin 1)
Volkensin

Genetic elements, 1C353:

Any genetically modified organism that contains, or any genetic element that codes for:

- 1) genes specific to any virus on the CCL, 2) any toxin (or its subunit) on the CCL, or
- 3) any genes specific to any bacteria or fungus on the CCL that:
 - In itself or through its transcribed or translated products represents a significant hazard to human, animal or plant health; *or*
 - Could endow or enhance pathogenicity*.

Exception: Shiga toxin producing *Escherichia coli* (STEC) genes other than toxins or subunits

*'Endow or enhance pathogenicity' is defined as when the insertion or integration of the nucleic acid sequence or sequences is/are likely to enable or increase a recipient organism's ability to be used to deliberately cause disease or death. This might include alterations to, *inter alia*: virulence, transmissibility, stability, route of infection, host range, reproducibility, ability to evade or suppress host immunity, resistance to medical countermeasures, or detectability.