Introduction

The Office of Occupational and Environmental Safety (OES) has developed this guideline to assist in the shipment of biological materials and dry ice. This document includes information about how to properly classify, package, mark and label your shipment. This section also describes the training requirements necessary to ship biological materials and dry ice.

Shipped biological specimens, infectious agents and other biological materials are regulated by governmental and non-governmental, consensus development organizations. Penalties for non-compliance with the rules could result in the following significant fines:

- Up to $250,000 and up to a year jail sentence for individuals.
- Up to $500,000 per incident for organizations.

Several agencies regulate the shipment of biological materials including:

- International Air Transport Association (IATA).
- US Department of Transportation (DOT).
- US Public Health Service (PHS).
- Occupational Health and Safety Administration (OSHA).
- United States Postal Service (USPS).

Infectious substances and other dangerous goods must always be transported according to the appropriate regulations. Carrying dangerous goods by hand, for example, in a vial in your pocket or in luggage, is strictly prohibited. IATA/DOT regulations cover your checked luggage, materials you carry on, or materials you carry in your pockets when you board an airplane. Persons who violate IATA regulations are subject to fines and criminal prosecution.

IATA regulations are commonly encountered since they regulate materials transported by air and are generally the most restrictive. For these reasons, this guide pays special attention to IATA protocols.

Training Requirements

Federal rules require that anyone wishing to ship biological materials or dry ice must first have shipping training. If you are going to package biological materials or dry ice for shipment, or fill out a Declaration for Dangerous Goods form, you must follow the training certification requirements outlined below.

1. ***Read this guideline.*** This guideline will provide familiarity with the general provisions relating to the regulations and detailed training in the requirements applicable to shipping infectious materials and dry ice.

2. ***Have a current bloodborne pathogen training certification from OES.*** This training ensures that you are familiar with the hazards presented by infectious materials, proper handling, and emergency response procedures.
3. ***Submit to OES an*** Intent to Ship Hazardous Materials ***form*** (Appendix B)**.** OES will review this form with you, and upon successful completion, will certify you to ship only those materials that are listed on your Intent form.

Shipping regulations change frequently so it is necessary to repeat training certification every two years. Training sessions reviewing the material in this guideline are available from OES. Call OES at 578 8507 to schedule training or to ask questions regarding the shipment of biological materials and dry ice.

Shipping Overview

Follow these steps when shipping biological materials and dry ice.

Classify your materials for shipment. See Shipment Types.

1. Package, mark and label your material(s) appropriately. See Packaging
2. Fill out the Declaration for Dangerous Goods form. Available from Carrier
3. If you are shipping Select Agents, special regulations apply.
4. If you plan on importing or exporting biological materials, special regulations apply.

Shipment Types

For shipment purposes, biological materials are categorized into one of the following categories:

- Unregulated biological material;
- Category A infectious substances;
- Category B infectious substances;
- Patient specimens; or
- Genetically modified organisms and microorganisms.

Read each material section carefully to determine how to classify a material. If you are shipping a biological material that *cannot cause disease*, infectious substance regulations do not apply, unless sent by mail. **Note:** All specimens or packaging containing dry ice or liquid nitrogen must be shipped properly (see Other Packaging Requirements). All samples preserved with flammable or toxic materials, such as ethanol or formalin, must be shipped appropriately. If you are still not sure how to classify a material for shipment after reviewing the following sections, contact OES at 578-8507.

A. Unregulated Biological Material

The materials listed below are not subject to IATA or DOT infectious substance shipping regulations. However, these materials may require a permit for shipment abroad. Please check with the OES if you have questions about these materials. All shipments of blood and blood products must be labeled with a biohazard symbol.

- Substances which do not contain infectious substances or which are unlikely to cause disease in humans or animals;
- Non-infectious biological materials from humans, animals, or plants. (non-infectious cells, tissue cultures, blood or plasma from individuals not suspected of having an infectious disease, DNA, RNA, or other genetic elements)
- Substances containing microorganisms, which are non-pathogenic to humans or animals;
- Substances that have been neutralized or inactivated such that they no longer pose a health risk;
- Environmental samples which are not considered to pose a significant risk of infection;
- Dried blood spots;
- Fecal occult blood screening tests;
- An infectious substance, other than a Category A infectious substance, contained in a patient sample being transported for research, diagnosis, investigation activities, or disease treatment and prevention, or a biological product, when such materials are being transported by a private or contract carrier in a motor vehicle used exclusively to transport such material;
- Blood or blood components which have been collected for the purpose of transfusion or the preparation of blood products to be used for transfusion or transplantation;
- Tissues or organs intended for use in transplantation;
- A material with a low probability of containing an infectious disease or where the concentration of the infectious substance is at a level naturally occurring in the environment so it cannot cause disease when exposure to it occurs.
- A biological product, subject to federal approval, permit, review or licensing such as by the FDA or USDA.

B. Infectious Substances

Infectious substances are materials known to be, or are reasonably suspected to contain, an animal or human pathogen. A pathogen is a virus, microorganism (including its viruses, plasmids, or other genetic elements), pertinacious infectious particle (prion) or recombinant microorganism (hybrid or mutant) that is known or reasonably expected to cause infectious disease in humans or animals. Microorganisms that are unlikely to cause human or animal disease, i.e. no or very low, individual or community risk, do not have to be shipped as infectious substances.

1. Category A Infectious Substances

Category A infectious substances are capable of causing permanent disability, life threatening or fatal disease in humans or animals when exposure occurs. Category A infectious substances are shipped as infectious substances, affecting humans (UN2814 or animals (UN2900)

a. Packaging

The triple packaging concept, explained below applies to infectious substances. Purchase packaging approved for use with infectious substances. These packages must comply with IATA Packing Instruction 602. See Appendix A for a list of packaging suppliers. Make sure to specify if you are shipping a refrigerated sample (ice packs or dry ice). The maximum quantity of infectious substance that can be shipped by air cargo in one package is 4 L or 4 kg. The maximum quantity that may be shipped via passenger aircraft is 50 ml or 50 g.

b. Labeling

The outer container of a category A infectious substance shipment must display the following information:

- sender and recipient's full name and addresses.
- Infectious Substance label
- UN2814 and net quantity
- UN2900 and net quantity
- The text "Person responsible: " and 24 hour phone number.
- If packaged with dry ice, a Class 9 diamond label
- When shipping over 50 mL or 50 g of infectious substance, you must also put a Cargo Aircraft Label on the outer container

Figure 1. **Figure 2.** **Figure 3.**


9


INFECTIOUS SUBSTANCE
IN CASE OF DAMAGE OR LEAKAGE
IMMEDIATELY NOTIFY
PUBLIC HEALTH AUTHORITY
IN U.S.A.
NOTIFY DIRECTOR-CDC
ATLANTA GA
404-633-5313
6


DANGER
DO NOT LOAD IN PASSENGER AIRCRAFT

2. Category B Infectious Substances

Category B infectious substances are materials that are infectious, but do not meet the standard for inclusion in Category A. Category B infectious substances are assigned to UN3373.

a. Packaging

The triple packaging concept, explained below applies to infectious substances. Purchase packaging approved for use with infectious substances. These packages must comply with IATA Packing Instruction 602. See Appendix A for a list of packaging suppliers. Make sure to specify if you are shipping a refrigerated sample (ice packs or dry ice). The maximum quantity of infectious substance that can be shipped by air cargo in one package is 4 L or 4 kg.

b. Labeling

The outer container of a category A infectious substance shipment must display the following information:

- sender and recipient's full name and addresses.
- The words "Biological Substance, Category B"
- UN3373 label
- The text "Person responsible: " and 24 hour phone number.
- If packaged with dry ice, a Class 9 diamond label

3. Patient Specimens

Patient specimens that have a minimal likelihood of containing pathogens are exempt from many shipping requirements. Professional judgment is used to determine if a specimen contains pathogens and should be based on the patient's medical history, symptoms, etc.

If there is more than a minimal likelihood that a patient specimen contains pathogens, it must be shipped as a category A or B substance.

1. Labeling

The outer package must be marked with "exempt human specimen", or "exempt animal specimen".

C. Biological Products

Biological products are defined as biological materials used in the prevention, diagnosis, treatment or cure of diseases in humans or animals and certified by the USDA or FDA. Examples of biological products include certain viruses, therapeutic

serums, toxins, antitoxins, vaccines, blood and blood products. Biological products that meet the definition of an infectious material must be shipped as an infectious substance. Biological products that have no or very low probability to produce disease and those packaged for final distribution for use for personal or animal health care by medical professionals are not subject to special shipping regulations but should be shipped safely.

D. Genetically Modified Organisms and Microorganisms

Genetically modified organisms or microorganisms that are dangerous, infectious, or carried by an animal host are regulated for transportation. For the following guidelines, make sure to distinguish those that apply to *organisms vs. microorganisms*.

A genetically-modified *microorganism* which meets the definition of an infectious substance must be classified as an infectious substance for transportation. For these materials, follow instructions for shipping an infectious substance.

Genetically-modified *microorganisms* which are not infectious substances but which are capable of altering animals, plants or microbiological substances in a way that is not normally the result of natural reproduction can be transported when classified as a Miscellaneous Hazard (Class 9). These materials are packed for shipment in the same way as infectious substances, except there are no specific testing requirements for the packaging; this packaging variation is IATA Packing Instruction 913. You may not be able to purchase packages designed for Packing Instruction 913. In this case, use packages designed for infectious substances (Packing Instruction 605) and use a Class 9 label (Figure 1). These materials are shipped with the proper shipping name, "Genetically modified micro-organisms" and UN 3245. The maximum allowable quantity per primary receptacle is 100 mL or 100 g. There is no maximum net quantity per package.

Genetically modified *organisms* that are known or suspected to be dangerous to humans, animals or the environment cannot be transported by air. Animals which contain, or are contaminated with, genetically-modified *microorganisms* or *organisms* that meet the definition of an infectious substance cannot be shipped by air.

A. Other Packaging Requirements

Overpacks. An overpack can be used to combine several triple packages into one large package. This may be done to save freight charges when shipping multiple samples. Each triple package inside the overpack must be properly marked and labeled. The outside of the overpack must bear the same markings and labels as the triple packages within. If packed with dry ice, the total net quantity of dry ice must be listed on the outer container. The overpack must also be marked with the statement:

"Inner Packages Comply with Prescribed Specifications."

Ice and Dry Ice. If a shipment includes ice or dry ice, special packaging must be purchased. If shipping with ice, the packaging must be leak-proof. If dry ice is used, the outer packaging must allow for the release of carbon dioxide gas when the solid sublimates. Ice or dry ice must be placed outside the secondary packaging. Interior supports must be provided to secure the secondary container as the refrigerant melts/sublimates. Dry ice is considered a miscellaneous hazard (Class 9) by IATA. Packages containing dry ice must bear a Class 9 label and be marked with the proper shipping name, UN number and net quantity, e.g., Dry Ice, UN1845, 3 KG. Certified packages for dry ice most likely will be pre-labeled and marked. A Declaration for Dangerous Goods is not required for shipments in which dry ice is the only hazardous material. Dry ice is included on the Declarations for shipments which include other hazardous materials such as infectious substances.

Liquid Nitrogen. Biological materials can be shipped in liquid nitrogen or dry shippers, which are insulated packages containing refrigerated liquid nitrogen fully absorbed in a porous material. Special packing regulations apply to shipments containing nitrogen. Contact OES if you need to ship materials with liquid nitrogen.

Shipper's Declaration for Dangerous Goods

A Declaration for Dangerous Goods form must be completed when shipping infectious substances or genetically modified micro-organisms. A Declaration is not required for shipments in which dry ice is the only hazardous material. Dry ice should be listed on Declarations for shipments containing infectious substances or genetically modified micro-organisms. A Declaration is not required if you are shipping diagnostic specimens (unless it must be classified as an infectious substance, see note). The Declaration is included with purchased shipping materials, or provided by the carrier. For Federal Express, these forms must be typed or computer generated. Improperly completed declarations are the most common cause of package refusal.

Refer to the Shipper's Declaration for Dangerous Goods for an explanation of each section:

A **Shipper**: Enter your full name, address and telephone number.

a. **Consignee**: Enter full name and address of recipient. When shipping infectious substances, some shippers may require you to include the text, "Person responsible for the shipment," followed by your name and phone number.
b. **Transport Details**: Indicate here if your shipment is restricted to cargo aircraft only (if it is more than 50 ml or 50 g of an infectious substance). Airport of departure and airport of destination will be filled out by the carrier, leave blank.
c. **Shipment Type**: Cross out "radioactive" to indicate you are shipping a non-radioactive substance.
d. **Proper Shipping Name**: Enter the proper shipping name exactly as it appears in Table 1.
e. **Class or Division**: Enter appropriate hazard class as found in Table 1.
f. **UN or ID Number**: Enter appropriate UN number as found in Table 1.

g. **Packing Group**: For dry ice, enter "III" in this column. Biological materials are not assigned packing groups.
h. **Subsidiary Risk**: Leave this column blank.
i. **Quantity and Type of Packaging**: Enter the net quantity for each material here. Use only metric units. At the bottom of this column, indicate the number and type of packages used (usually, "all packed in one fibreboard box."). Do not spell like "fiberboard." If using an overpack, indicate here with "Overpack Used."
j. **Packing Instructions**: Enter appropriate packing instruction number. Refer to Table 1.
k. **Authorization**: Leave this column blank.
l. **Additional Handling Instructions**: Three things are required in this section:
    1. The statement "Emergency Contact: (Enter 24 hour contact number for shipper)
    2. The statement "Prior arrangements as required by the IATA Dangerous Goods Regulations 1.3.3.1 have been made."
    3. The statement "Prepared according to ICAO/IATA."
m. **Signature and date**.

Declaration forms must be filled out in triplicate. Keep one copy and supply two to the carrier. Regulations require that you must retain your copy for *375 days*. Feel free to contact OES with any questions on how to fill out the declaration.

Table 1. Summary of Shipping Information

Shipment Type	Proper Shipping Name	UN Number	Hazard Class	Packing Group (PG)	Packing Instruction (PI)	Max. Net qty./pkg. for Passenger Aircraft	Max. Net qty./pkg. for Cargo Aircraft
Infectious substance, affecting humans and possibly animals	Infectious substance, affecting humans (*technical name*)	UN 2814	6.2	-	602	50 ml or 50 g	4 L or 4 kg
Infectious substance, affecting only animals (not humans)	Infectious substance, affecting animals (*technical name*)	UN 2900	6.2	-	602	50 ml or 50 g	4 L or 4 kg
Diagnostic or clinical specimen	Diagnostic specimens	UN 3373	-	-	650	4 L or 4 kg	4 L or 4 kg
Dry Ice	Dry Ice or Carbon Dioxide, solid	UN 1845	9	III	904	200 kg	200 kg
Non-infectious, transducing genetically modified *micro-organisms*	Genetically modified micro-organisms	UN 3245	9	-	913	No limit	No limit

CDC Select Agents

The U.S. Department of Health and Human Services and USDA have developed a list of biological agents/toxins (see Appendix D) that have the potential to pose a severe threat to public health. Special regulations apply to the use and transfer of these materials, including registration with the LSU Interinstitutional Biological and Recombinant DNA Safety Committee (IBRDS) and the Centers for Disease Control and Prevention and/or USDA/APHIS. If you are planning to, or currently work with, any of the select agents listed below and have not registered, contact OES. Specific shipping restrictions apply to these agents/toxins.

Importing and Exporting Biological and Infectious Agents

Receiving and sending animals and animal-derived materials, infectious or biohazardous agents, biological toxins, and genetically modified organisms require the approval of federal agencies such as the Centers for Disease Control and Prevention (CDC), the United States Department of Agriculture (USDA), or the US Fish and Wildlife Service (USFWS). Regulations that govern the transfer of biological materials help to minimize or eliminate the possible threats to public health and agriculture.

A. Importation of Infectious Agents

For agents infectious to humans, CDC permit applications are found online at: http://www.cdc.gov/od/ohs. These agents include any infectious agent known or suspected to cause disease in humans, unsterilized specimens of human or animal tissues (including blood and other fluids), or vectors including infectious animals, bats, insects, arthropods and snails (see Appendix D for *HHS Select Infectious Agents*).

B. Importation of Plant/Animal Pests

A USDA/APHIS permit is required to import or domestically transfer a plant pest, plant or animal biological agent, or any material that might contain them. Some items that are included are bees, biological control organisms, butterflies and moths, genetically engineered plants and microorganisms, certain fruits and vegetables, noxious weeds, snails and slugs, soil, and wood products (see Appendix D for *APHIS Plant Pathogens* or *USDA High Consequence Livestock Pathogens or Toxins*). Consult the following web page for more information and permit applications: http://ups.com/using/services/export/prohibited.html

C. Importation of Fish and Wildlife

For transporting fish, wildlife, or endangered species, use the USFWS form 3-177 and 3-177A found at: http://forms.fws.gov/display.cfm?number1=100.

D. Export Guidelines for Infectious Agents of Humans, Animals, Plants, and Related Materials

The export of infectious agents and related materials is governed by the following federal regulation: 15 CFR Parts 730 to 799. An export license is required from the Department of Commerce, when exporting infectious agents of human, plant, and animal diseases, including genetic material, and products which might be used for culture of large amounts of agents. Consult the following web page for specific items and procedures: http://www.bxa.doc.gov.

Appendix A – Manufacturers of Certified Shipping Containers for Infectious Substances, Diagnostic Specimens & Dry Ice

Air Sea Atlanta
1234 Logan Circle
Atlanta GA 30318
Phone: 404-351-8600
http://www.airseaatlanta.com

All-Pak, Inc.
Corporate One West
1195 Washington Pike
Bridgeville, PA 15017
Phone: 800-245-2283
http://www.all-pak.com

Casing Corporation
P.O. Box 820369
Dallas, Texas 75382
Phone: 800-358-6866
http://www.casingcorp.com

CARGOpak Corporation
3215-A Wellington Court
Raleigh, NC 27615
Phone: 800-266-0652
http://www.cargopak.com

DG Supplies, Inc.
5 Boxal Drive
Cranbury, NJ 08512
Phone: 800-347-7879
http://www.dgsupplies.com

EXAKT Technologies, Inc.
7416 N Broadway Ext., Suite E
Oklahoma City, OK 73116
Phone: 800-923-9123
http://www.exaktpak.com

HAZMATPAC, Inc
5301 Polk St., Bldg 18
Houston, TX 77023
Phone: 800-347-7879
http://www.hazmatpac.com

Inmark, Inc.
220 Fisk Drive S.W.
Atlanta, GA 30336-0309
Phone: 800-646-6275
http://www.inmarkinc.com

Polyfoam Packers Corporation
2320 S. Foster Avenue
Wheeling, IL 60090
Phone: 888-765-9362
http://www.polyfoam.com

SAF-T-PAK, Inc.
10807 - 182 Street Edmonton,
Alberta, Canada, T5S 1J5
Phone: 800-814-7484
http://www.saftpak.com

Source Packaging of New England, Inc.
405 Kilvert St.
Warwick, RI 02886
Phone: 800-200-0366
http://www.sourcepak.com

Appendix B – Intent to Ship Hazardous Materials

After reading the *LSU Shipment of Biological Materials and Dry Ice Guideline*, fill out this form to qualify to ship dangerous materials at LSU. OES will review this completed form and upon successful completion and demonstration of knowledge of applicable regulations you will be certified to ship those materials designated on this form.

1. What regulated material(s) might you ship via mail or courier service? List all hazardous materials that you intend to ship. Also, list the mailing service you intend to use.

2. What packaging will you use to ship your material(s)? Include company name and product number for chosen packaging for each material you intend to ship.

3. Check those that should appear on your package:
   - ☐ Class 6.2 label
   - ☐ Class 9 label
   - ☐ Cargo Aircraft label
   - ☐ Dry ice, UN 1845, net weight _____ kg
   - ☐ Infectious substance, affecting humans (*technical name*), UN 2814, net quantity _____
   - ☐ Infectious substance, affecting animals (*technical name*), UN 2900, net quantity _____
   - ☐ Name, Address and Phone Number of Shipper
   - ☐ Name and Address of Consignee
   - ☐ Name and Phone Number of Person Responsible for Shipment
   - ☐ "Inner Packages Comply with Prescribed Specifications."
   - ☐ Genetically modified micro-organisms, UN 3245, net quantity _____
   - ☐ "Diagnostic Specimen Packed in Compliance with IATA Packing Instruction 650"

4. Fill out attached Declaration for Dangerous Goods form (if your shipments require one). I understand the hazards associated with the materials noted above. Also, I understand the shipping requirements for those materials, as outlined in this guideline.

Print name:	
Signature:	
Date:	
Please return - in campus mail – to OES , 126 Public Safety Building.	

Appendix C Declaration of Dangerous Goods

Declaration of dangerous goods forms can be found on the carrier's website. An example is FedEx at:
http://www.fedex.com/us/services/options/dangerousgoods/declarationforms.html

Appendix D – APHIS Plant Pathogens, HHS Select Infectious Agents & USDA High Consequence Livestock Pathogens/Toxins

Viruses

1. African horse sickness virus [3]
2. African swine fever virus [3]
3. Akabane virus [3]
4. Avian influenza virus (highly pathogenic) [3]
5. Blue tongue virus (exotic) [3]
6. Camel pox virus [3]
7. Cercopithecine herpesvirus 1 (Herpes B virus) [2]
8. Classical swine fever virus [3]
9. Crimean-Congo haemorrhagic fever virus [2]
10. Eastern equine encephalitis virus [4]
11. Ebola viruses [2]
12. Foot and mouth disease virus [3]
13. Goat pox virus [3]
14. Japanese encephalitis virus [3]
15. Lassa fever virus [2]
16. Lumpy skin disease virus [3]
17. Malignant catarrhal fever virus [3]
18. Marburg virus [2]
19. Menangle virus [3]
20. Monkeypox virus [2]
21. Newcastle disease virus (VVND) [3]
22. Nipah and Hendra complex viruses [4]
23. Peste des petits ruminants virus [3]
24. Plum pox potyvirus [1]
25. Rift Valley fever virus [4]
26. Rinderpest virus [3]
27. Sheep pox virus [3]
28. South American haemorrhagic fever viruses [(Junin, Machupo, Sabia, Flexal, Guanarito)] [2]
29. Swine vesicular disease virus [3]
30. Tick-borne encephalitis complex (flavi) viruses [Central European Tick-borne encephalitis, Far Eastern Tick-borne encephalitis (Russian Spring and Summer encephalitis, Kyasanur Forest disease, Omsk Hemorrhagic Fever)] [2]
31. Variola major virus (Smallpox virus) and Variola minor (Alastrim) [2]
32. Venezuelan equine encephalitis virus [4]
33. Vesicular stomatitis virus (exotic) [3]

Prion

1. Bovine spongiform encephalopathy agent [3]

Toxins

i. Abrin [2]
ii. Botulinum neurotoxins [4]
iii. *Clostridium perfringens* epsilon toxin [4]
iv. Conotoxins [2]
v. Diacetoxyscirpenol [2]
vi. Ricin [2]
vii. Saxitoxin [2]
viii. Shigatoxin and Shiga-like ribosome inactivating proteins [4]
ix. Staphylococcal enterotoxins [4]
x. Tetrodotoxin [2]
xi. T– 2 toxin [4]

Bacteria

1. *Bacillus anthracis* [4]
2. Botulinum neurotoxin producing species of *Clostridium* [4]
3. *Brucella abortus* [4]
4. *Brucella melitensis* [4]
5. *Brucella suis* [4]
6. *Burkholderia mallei* [4]
7. *Burkholderia pseudomallei* [4]
8. *Coxiella burnetii* [4]
9. *Cowdria ruminantium* (Heartwater) [3]
10. *Francisella tularensis* [4]
11. *Liberobacter africanus, Liberobacter asiaticus* [1]
12. *Mycoplasma capricolu/M.* F38/*M. mycoides capri* (contagious caprine pleuropneumonia agent) [3]
13. *Mycoplasma mycoides mycoides* (contagious bovine pleuropneumonia agent) [3]
14. *Ralstonia solanacearum* race 3 biovar 2 [1]
15. *Rickettsia prowazekii* [2]
16. *Rickettsia rickettsii* [2]
17. *Xanthomonas oryzae* pv. oryzicola [1]
18. *Xylella fastidiosa* (citrus variegated chlorosis strain) [1]
19. *Yersinia pestis* [2]

Fungi

1. *Coccidioides immitis* [4]
2. *Coccidioides posadasii* [2]
3. *Peronosclerospora philippinensis* [1]
4. *Phakopsora pachyrhizi* [1]
5. *Sclerophthora rayssiae var zeae* [1]
6. *Synchytrium endobioticum* [1]

Exemptions

The following agents or toxins are exempt if the aggregate amount under the control of a principal investigator does not, at any time, exceed:

- 0.5 mg of botulinum neurotoxins
- 5 mg of *Staphylococcal* enterotoxins
- 100 mg of abrin, *Clostridium perfringens* epsilon toxin, conotoxin, ricin, saxitoxin, shigatoxin, shiga-like ribosome inactivating protein, and tetrodotoxin
- 1,000 mg of diacetoxyscirpenol and T-2 toxin

The following agents or toxins are also exempt:

- Any agent or toxin that is in its naturally occurring environment provided it has not been intentionally introduced, cultivated, collected, or otherwise extracted from its natural source.
- Non-viable select agent organisms or nonfunctional toxins.
- The vaccine strains of Junin virus (Candid #1), Rift Valley fever virus (MP-12), Venezuelan Equine encephalitis virus vaccine strain TC-83.

The medical use of toxins for patient treatment is exempt.

Genetic Elements, Recombinant Nucleic Acids, and Recombinant Organisms

1. Select agent viral nucleic acids (synthetic or naturally derived, contiguous or fragmented, in host chromosomes or in expression vectors) that can encode infectious and/or replication competent forms of any of the select agent viruses.
2. Nucleic acids (synthetic or naturally derived) that encode for the functional form(s) of any of the listed toxins if the nucleic acids: a) are in a vector or host chromosome; b) can be expressed *in vivo* or *in vitro*; or c) are in a vector or host chromosome and can be expressed *in vivo* or *in vitro*.
3. Listed viruses, bacteria, fungi, and toxins that have been genetically modified.

Other Restrictions

1. Experiments utilizing recombinant DNA that involve the deliberate transfer of a drug resistance trait to the listed agents that are not known to acquire the trait naturally, if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture.
2. Experiments involving the deliberate formation of recombinant DNA containing genes for the biosynthesis of listed toxins lethal for vertebrates at an LD50 < 100 ng/kg body weight.

[1] APHIS Plant Pathogen [2] HHS Select Infectious Agent [3] USDA High Consequence Livestock Pathogen or Toxin [4] USDA-HHS Overlap Agent