



GUIDANCE ON THE TRANSFER OF SELECT AGENTS AND TOXINS

42 CFR § 73.16, 7 CFR § 331.16, and 9 CFR § 121.16

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Centers for Disease
Control and Prevention
Division of Select
Agents and Toxins



Animal and Plant Health
Inspection Service (APHIS)
Division of Agricultural Select
Agents and Toxins

Change/Highlight Section

Revisions: This is a living document subject to ongoing improvement. Feedback or suggestions for improvement from entities registered with the Federal Select Agent Program, as well as the general public, are welcomed. Submit comments directly to the Federal Select Agent Program at:

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September 2017: Initial posting

June 2020: Updated to include eFSAP information, updated links, and removed appendices.

February 2021: Updated Packaging and Labeling section based on clarification of Department of Transportation regulations.

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Introduction

This document is intended to provide guidance and assist entities in meeting Federal regulatory requirements when transferring or importing a select agent or toxin ([7 C.F.R. §331.16](#), [9 C.F.R. §121.16](#), and [42 C.F.R. §73.16](#)).

Within the United States (U.S.), other than law enforcement, only entities that are registered with the Federal Select Agent Program (FSAP) are allowed to receive material that has been identified as a select agent or toxin. This includes the importation of select agents and toxins from outside the U.S.

The [APHIS/CDC Form 2: Request to Transfer Select Agents and Toxins](#) can be submitted directly using electronic Federal Select Agent Program (eFSAP) portal , email, fax or mail to the Federal Select Agent Program (FSAP).

The exportation of a select agent or toxin requires an export license issued by the Department of Commerce (DOC). Information may be obtained by contacting the DOC [Bureau of Industry and Security](#).

Determining When an APHIS/CDC Form 2 is Necessary

See the chart below to determine whether a Form 2 is necessary in order to conduct a transfer.

Material to be transferred	Form 2
Inter-entity transfer of select agent or regulated amounts of toxin:	
Between two registered entities	Yes
From an unregistered entity to a registered entity	Yes
Imported into the U.S.	Yes
Exported from the U.S.	No*
Select agent or regulated amounts of toxin transferred (intra-entity):	
Between two registered Principal Investigators at the same institution	No
From an unregistered area to a registered area at the same institution	Yes
Excluded amounts of select toxin:	
Inter- or intra-entity, either registered or unregistered entities	No
Excluded strains of select agents listed on the FSAP website: (Note: Attenuated strains that are not listed as excluded strains are considered select agents.)	
Inter- or intra-entity, either registered or unregistered	No
Specimen that has been presented for diagnosis:	
That has not been identified to contain a select agent or toxin	No
That has been identified to contain a select agent or toxin	Yes
Proficiency samples: (Note: At least 7 days prior to the transfer, the sender must provide a written report to FSAP detailing the select agent or toxin to be transferred and the name and address of the recipient.)	
That do not contain a select agent or toxin	No
That contain a select agent or toxin	No

*Note: The exportation of a select agent or toxin requires an export license issued by the Department of Commerce. For more information, contact the DOC Bureau of Export Administration at the [Bureau of Industry and Security](#).

Packaging and Labeling

Select agents and toxins should be classified as outlined by Department of Transportation ([Reference No. 20-0035](#)) and packaged in accordance with the U.S. Department of Transportation's (DOT's) [Hazardous Materials Regulations \(HMR; 49 CFR Parts 171-180\)](#). Please see the [Guidance for Completing the Shipper's Declaration for Dangerous Goods](#) for more information.

Labeling of Packages Containing Select Agents and Toxins

The outer container of all Category A infectious substance packages must display the following:

- Sender's name and address
- Recipient's name and address
- Infectious substance label
- Proper shipping name as outlined by Department of Transportation ([Reference No. 20-0035](#)), UN number, and net quantity of infectious substance
- Name and telephone number of person responsible for shipment
- Cargo Aircraft Only label (when shipping quantities of infectious substance over 50 ml or 50 g by aircraft)
- Class 9 label, including UN 1845, and net weight if packaged with dry ice and identified as Carbon Dioxide, solid, *or* Dry ice

Packaging of Select Agents and Toxins

The area where the packaging of select agents and toxins occurs must be listed on the entity's certificate of registration and must meet all the requirements outlined in the select agent regulations. An entity's packaging area will be subject to inspection to ensure compliance with the select agent regulations.

If the container of select agents and toxins is packaged by the laboratory and has been classified as outlined by Department of Transportation ([Reference No. 20-0035](#)), the package containing select agents can be placed with other packages in the area that the entity uses for shipment of materials and does not need to be accompanied by "chain of custody" paperwork.

If the select agents and toxins are sent to another area for packaging and shipping, "chain of custody" paperwork is required to document transfer from the laboratory to the area where packaging occurs. The area where packaging and shipping occurs must be listed on the entity's certificate of registration and must meet all the requirements outlined in the select agent regulations. If Tier 1 select agents and toxins will be packaged in the shipping and receiving area, that area must meet all provisions associated with Tier 1 requirements. All individuals who will have access to Tier 1 select agents or toxins must also meet Tier 1 requirements and be enrolled in the entity's suitability assessment program. The area will also be inspected to ensure the entity's compliance with the select agent regulations.

Select agents and toxins must be shipped in a triple package that consists of:

- Leakproof primary receptacle(s)

- Leakproof secondary packaging. For liquid materials, the secondary packaging must contain absorbent material in sufficient quantities to absorb the entire contents of the primary receptacle(s)
- Rigid outer packaging which must be of adequate strength for its capacity, mass, and intended use

The DOT "[Transporting Infectious Substances Safely](#)" pamphlet provides a diagram of how to properly package containing a select agent or toxin.

Shipping Select Agents and Toxins

The transportation in commerce of hazardous materials, including select agents and toxins, is governed by the U.S. Department of Transportation (DOT)'s Hazardous Material Regulations. Transportation in commerce starts when a carrier takes physical possession of a select agent or toxin for the purpose of transporting it and continues until the hazardous material is received by the intended recipient and their the destination indicated on a shipping paper, package marking, or other medium. FSAP maintains oversight of select agents and toxins until the materials are packaged for shipment, in compliance with DOT hazardous materials regulations, by an individual approved to have access to select agents and toxins by FSAP and ready for receipt by a courier.

Commercial carrier or courier

Once the package is ready for shipment, the entity should use their established procedures for providing the package to the commercial carrier. The package must have the carrier's DOT number listed and the carrier must be approved by DOT to ship hazardous material being offered for transport. See the [PHMSA Transporting Infectious Substances Q&A](#) and [DOT Guidance for Transporting Ebola Contaminated Items](#) for more information.

Hand-delivered package

While an entity may choose to hand deliver a package containing a select agent or toxin to a registered entity, the individual who is hand carrying the package must be an individual approved by FSAP to have access to select agents and toxins. The registered entity remains responsible for ensuring that all local, state, and/or federal requirements for the transportation of hazardous materials are followed. The registered entity must ensure that adequate precautions are taken to prevent a theft, loss, or release of the select agents and toxins.

Receiving Packages Containing Select Agents and Toxins

Receipt of Packages by Entity

The entity offering packages containing hazardous materials for transport, including packages containing select agents and toxins, should ensure these packages are provided to the intended recipient without delay to avoid the hazardous materials from being compromised (e.g., thawing of dry ice). For example, the entity can have the shipping and receiving personnel take the package directly to the intended recipient upon package arrival; have a secured location in the shipping area for the intended recipient to retrieve the package; or have the commercial carrier deliver the package directly to the intended recipient. A package containing select agents and toxins is not considered "received" by the entity until the intended recipient takes possession of the package.

Receipt by Intended Recipient

The intended recipient, or his/her designee, must be an individual who is approved by FSAP for access to select agents and toxins. Upon receipt of the shipment, the intended recipient must verify the contents. If there is a discrepancy noted, the entity must immediately notify FSAP.

Loss or Damage to Package

If a package containing select agents or toxins has not been received within 48 hours after the expected delivery time or has been damaged to the extent that a release of a select agent may have occurred, the recipient must immediately report this incident to FSAP. In addition to the initial reporting, the entity must follow up with a written report ([APHIS/CDC Form 3 - Incident Notification and Report](#)) within 7 calendar days of the incident.

In addition to the select agent requirements to report a loss or damaged package, DOT also requires reporting of specific types of transportation incidents that involve hazardous materials. For more information, see 49 CFR 171.15 and 171.16.

Unexpected Shipments

An "unexpected shipment" is when an entity receives a shipment of a select agent or toxin that it had neither requested nor coordinated for and, therefore, was not expected.

The entity should have a written contingency plan for receipt and security for unexpected shipments to ensure that approved personnel gain control of the unexpected shipment of select agents and toxins immediately and secure it in a registered area. The entity should inform FSAP of all unexpected select agent and toxin shipments immediately (within 24 hours of receipt).

Delivery Exception

A delivery exception occurs when a shipment is held by the carrier or returned to the shipper due to inadequate paperwork. If this occurs, the sender should notify FSAP and the recipient entity immediately. The notification should include the following:

- New tracking number(s), if applicable
- The reason and needed action associated with the delivery exception
- Expected new date of arrival

Note: If returned to sender, the sender must notify FSAP and complete Section 2 of Form 2 with the new information and submit it to FSAP or enter into eFSAP at the time of shipment.

Once the delivery exception package is delivered, the recipient must:

- Ensure that the expected shipment was properly packaged, labeled, and shipped in accordance with all federal regulations.
- Verify the contents and shipment information (example: updated tracking number(s)) for the transfer authorization).
- If there is a discrepancy noted, the entity must immediately notify FSAP.