

Shipping Animal Pathogens and Select Agents

Regulations regarding the shipment of micro-organisms, toxins, and associated genetic material are complex and frequently change. Therefore, reviewers are encouraged to consult with the NVSL/CVB person designated to oversee compliance with shipping regulations whenever there is a question about shipping procedures. The fines for noncompliance are heavy, and it is the responsibility of each firm to ensure that all shipments are in compliance.

Regulations and guidance regarding shipments are found in:

- 9CFR Parts 121 and 122
- APHIS website for Agricultural Select Agent Program (www.aphis.usda.gov/programs/ag_selectagent)
- CDC website for Select Agent Program (www.cdc.gov/od/sap)

This chapter of the reviewer manual is NOT intended to be a comprehensive discussion of shipping regulations [REDACTED]

1. Shipment of Animal Pathogens to CVB

1.1 Permits issued by the National Center for Import-Export (NCIE) are required in order to **RECEIVE** animal pathogens. Our authorization to move an organism into a production facility does NOT abrogate this requirement. CVB-IC inspects for NCIE permits and compliance with their restrictions.

NCIE permits are needed for *interstate* movement, not intrastate. The exception to the intrastate rule is if the seed was received originally under NCIE permit, in which case a permit may be needed for further shipment, regardless of destination. Exceptions also apply to intrastate shipment of select agents.

The permits may allow additional shipment from the original location but the person at the original location is still responsible for compliance with the restrictions and the extension of the shipping is specifically noted on the permit.

1.2. A copy of the permit has to be included in the package being shipped—firms should not be shipping animal pathogens to third parties unless they have a copy of the recipient's permit.

1.3. If material is being shipped internationally, Department of Commerce rules apply, and firms should be advised that they need to be in compliance with those rules. Also, CVB's "blanket" permit to receive animal pathogens applies only to domestic shipments. Additional permits may be required for international shipments.

1.4. Many Master Seeds are animal pathogens!! These require NCIE permits for movement. Firms should be asking for a copy of our permit when they are shipping pathogenic Master Seeds to use for confirmatory testing. In the letter authorizing shipment of Master Seeds for confirmatory testing, enclose a copy of our NCIE permit to receive the Master Seed, for the firm to include with the Master Seed samples [REDACTED]

2. Procedure for submitting Select Agent Master Seeds to the CVB

See the APHIS agricultural select agent program website for a current list of select agents. It is the responsibility of the reviewer to be aware of the agent status of all Master Seeds!

If the Master Seed is a select agent, contact the Responsible Official for select agents [REDACTED] for the most up-to-date procedures for shipping. Shipping a select agent is a complex process that requires submission of the proper permission forms to the Agriculture Select Agent program before the Seed is shipped. The actual shipment must include proper permit forms and a GPS monitoring device. Proper chain of custody procedures must be followed once the Seed arrives at the NVSL/CVB. [REDACTED]

3. Shipping Serum Samples

If the sera are produced domestically and have not been imported into the U.S., no permit is needed to transport serum samples [REDACTED].

4. Shipping Animal Pathogens from a Licensed Firm to Another Facility

CVB authorization to ship or receive animal pathogens is generally not required unless the firm is bringing a new seed into their production facility, or if the organism is to be tested in animals. Production is considered to be any step in the preparation of the product, as defined in 9 CFR 101.2, and includes processing, testing, packaging, labeling, and storing of the biological product (which includes manufacturing facilities, QC testing facilities, and animal testing facilities). Note that testing is not considered to be a “significant” step in preparation in the context of split manufacturing as described in Veterinary Services Memorandum 800.61. By definition, however, it is a step in preparation in the context of movement of animal pathogens. If the research facilities of

the firm receiving the seed are not separate and apart from the production facility, permission to receive the isolate should be requested, as per 9 CFR 103.1. The firm receiving the isolate also has the responsibility to ensure any applicable NCIE permits to receive the isolate are obtained. General Department of Transportation shipping regulations (e.g. hazardous goods, select agents) apply to all shipments, regardless of destination or use. No CVB notification is required for isolates to be transferred to research facilities separate and apart from licensed production facilities.

Although CVB notification is not required for isolates transferred to facilities separate and apart from licensed production facilities, CVB may be notified by a letter from the firm of intention to transfer. The letter should include details regarding what is to be moved, the amount, locations, the recipient, the preparation, shipping conditions, and purpose of the shipment. In many cases, it may be in the best interest of the firm to tell CVB what is going on, especially for select agents or high profile seeds/killed antigens. It may also be helpful to let the firm know that maintaining an inventory could make it easier to demonstrate compliance with any applicable NCIE permits. Although CVB approval is not required, the recipient is responsible for complying with NCIE requirements regarding the receipt of animal pathogens.

In general, shipment of killed antigens may be handled in a similar way. Verification of inactivation may be required.

5. Conversion of a seed obtained under a NCIE Permit to a Master Seed for use in biologics preparation.

Imported seed material is under the jurisdiction of NCIE and subject to the permit restrictions this program has placed on the material. Some restrictions may make specific reference to CVB and CVB authorizations that would negate them. Some of these restrictions do not make reference to CVB but are not compatible with the use of the seed material to prepare a master seed for biologics production.

If a firm wishes to use the seed material to produce a veterinary biologic, a Master Seed Lot is prepared and the jurisdiction is transferred to CVB. At that time, the restrictions are reviewed to determine which no longer apply or should be modified. Specific wording is usually supplied in the letter supplying the results of confirmatory testing indicating that the seed material may be used for the production of biologics. A firm may request to move the master seed material into production for the purpose of making working seed. Such authorization may be provided but wording in the letter will indicate that the transfer is at their own risk should any extraneous agents be identified.