

# Frequently Asked Questions

## USDA Permits for Pathogens of Livestock and Poultry



TEXAS A&M  
UNIVERSITY

**Q: What agents require a United States Department of Agriculture (USDA) permit? Is there a list of permitted strains of agents to which investigators can refer?**

A. *Regulation 9 CFR 122-Organisms and Vectors* is under review to actually indicate which agents need an import/transport permit. Currently the USDA requires permits for individuals to receive materials, ranging from prions to macroscopic nematodes, that may represent a health risk to livestock and poultry.

**Q: Who needs a USDA transport permit?**

A. The person receiving the regulated organism is the permit holder. Please note that the regulation applies to interstate or foreign importation of materials. The USDA does not regulate intrastate transport of materials, unless it is a select agent as defined under *9 CFR 121*. The shipper will be identified if needed. Applicants usually have multiple suppliers so the USDA does not list them specifically on the permit, but they may be included in the application (VS Form 16-3).

**Q: Does the transport permit also regulate use or work with the permitted agent?**

A. The USDA regulates the transport and use of the materials. If the material is considered high risk and it is not a select agent (low pathogenicity influenza virus, West Nile virus, porcine reproductive and respiratory syndrome virus, and others) a USDA field inspector may be asked to evaluate the level of containment of the applicant facility. Most laboratory or animal facilities are BSL-2 based upon the recommendations/guidelines of *Biosafety in Microbiological and Biomedical Laboratories*. The USDA will issue the permit once a satisfactory report from the USDA field inspector is received.

**Q: Do agents or pathogens purchased from a commercial source, such as the American Type Culture Collection, require a USDA permit?**

A. Yes. In general, if the material can be classified as a health risk to livestock and poultry, *9 CFR 122* is applicable and a permit is required.

**Q: May the permit holder share the permitted organism(s) with collaborators on campus?**

A. When applying for the permit, the individual should list the collaborators in the importer section. If the material will be shared after the permit is issued, the USDA can amend the permit to allow local movement. The pertinent statement is changed to indicate that the material will be shared provided the permit holder keeps records of the movement and provides documentation to USDA if needed.

**Q: If the permit holder is still working with the permitted strain and the permit is about to expire, must the permit be renewed?**

A. It depends upon the material. If the permit holder is working with high risk materials, such as avian influenza virus low path, a USDA BSL-2 inspection and an active permit are required; for lower risk material the USDA does not consider the permit expired unless the investigator intends to receive more material. The USDA does not search for expired permits. It is not necessary to renew the permit every year unless there are changes to the permit holder section, such as a new address. However, the USDA recommends that permits remain current, in case there is an incident with the permitted strain.

**Q: Is a USDA permit required to receive dead organisms or DNA extracted from regulated organisms?**

A. Yes, the USDA would issue a broad permit stating that the species, as well as derivatives including nucleic acids, are included.

**Q: If the permit holder wishes to receive nucleic acids encoding for select agents or select agent toxins that have been generated synthetically, is a permit required?**

A. Yes, such materials are regulated under *9 CFR 121.3* or *9 CFR 122*.