



United States Department of Agriculture



Organisms and Vectors Permitting: Protecting American Agriculture

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Who We Are

- USDA, Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS)
- Animal Product Import and Export (APIE) team
 - APIE Director: Keith Wiggins
 - Import Director: Lisa Dixon
 - Veterinary Medical Officers: Troy Bigelow and Scott Epperson
 - Veterinary Permit Examiner: Susan Collins
- APIE includes permitting for several different commodity groups:
 - Meat, milk, eggs, and casings
 - Products for animal consumption
 - Animal byproducts
 - Organisms and vectors

<https://www.aphis.usda.gov/aphis/ourfocus/importexport/organism-vectors>

What do we do

- Regulate the importation and interstate transport of organisms and vectors of diseases of livestock and poultry:

“No **organisms or vectors** shall be **imported** into the United States or **transported** from one State or Territory or the District of Columbia to another State or Territory or the District of Columbia without a **permit**”
«9 CFR Part 122»

- Intrastate Transport: VS does not permit movement within a state.
Contact state and local animal health authorities

Types of permits issued

- Research or Commercial
 - For organisms and vectors, all permits are research
- Import permits and Interstate Transport permits
 - Requirements are slightly different for import vs. interstate transport

Regulated Materials

- Organisms that can cause disease in livestock (cattle, horses, pigs, sheep, goats) or poultry
- [List of regulated livestock and poultry pathogens requiring a United States Veterinary Permit for Importation and Transportation of Controlled Materials and Organisms and Vectors](#)
- Includes organisms that have been isolated from humans

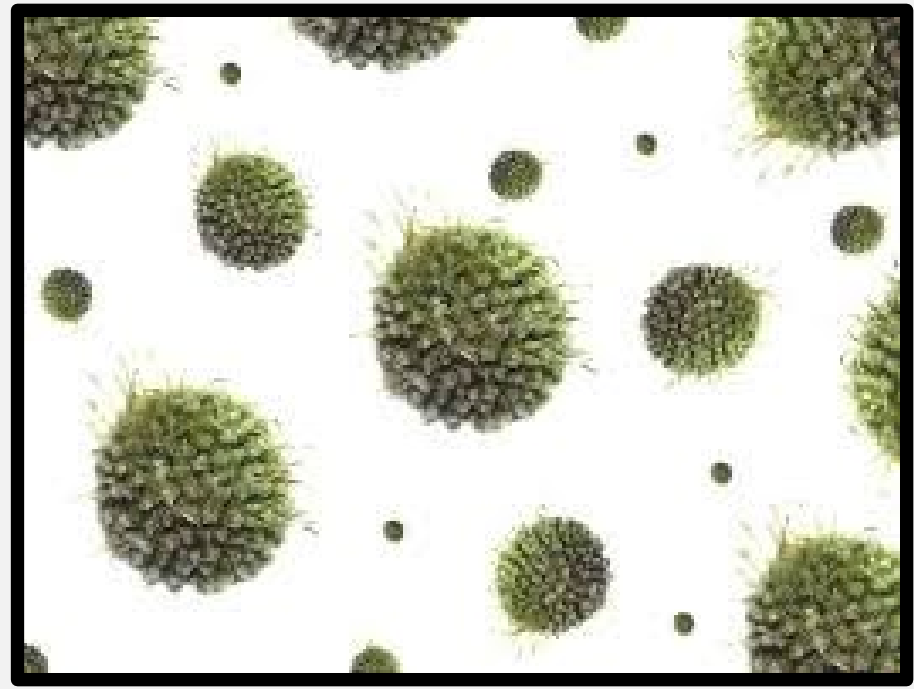
Definitions

- Organisms: all cultures or collections of organisms and their derivatives (DNA/RNA, recombinants, inactivated/attenuated) which may introduce or disseminate any contagious or infectious disease of livestock and poultry. These pathogens include bacteria, viruses, fungi, parasites, protozoa, transmissible spongiform encephalopathy (TSE) agents, and their extracted nucleic acids.

- Vectors: arthropods (e.g. ticks, mosquitoes) that may be infected with or have been exposed to livestock or poultry pathogens. Other material can be considered as "vectors" if infected or likely exposed to pathogens.

For **import**, a Permit is required for movement of lived or killed pathogens, vectors, and their derivatives:

- Antigens
- Vaccine components
- DNA/RNA
- Insect vector (mosquito, ticks, etc.)
- Imported media vector (FBS, trypsin, egg etc.)



Vectors!

VS permit is required
for **importation** into
U.S. of any organism
if exposed to
medium of animal
origin

(example: MMR vaccine with exposure to
fetal bovine serum)



Materials may need additional permission/documentation/permits

- Centers for Disease Control and Prevention (CDC)
- Food and Drug Administration (FDA)
- Fish and Wildlife Service (FWS)
- Plant Protection and Quarantine (PPQ)
- Center for Veterinary Biologics (CVB)
- Food Safety and Inspection Service (FSIS)





Guidelines – no import permit required

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- 1100: Human Pharmaceuticals and Human Vaccines Containing Animal
 - 1101: Non-Human Primate Material (excluding cell cultures)
 - 1102: Feline and Canine Material
 - 1103: Live Laboratory Mammals and Their Material (for research purposes)
 - 1104: Amphibians, Fish, Reptiles, Shellfish and Aquatic Species (includes venom)
 - 1105: Chemically Synthesized Materials
 - 1110: Microbially Produced Materials
 - 1114: Recombinant Microbes and Their Products
 - 1116: Non-Pathogenic Microorganisms (and their extracts)
 - 1119: Pet Chews/Treats Made of Antlers or Rawhide
 - 1120: Cell Cultures/Lines, Recombinant Cell Cultures/Lines, and Their Products (for in vitro use)
 - 1121: Test Kits
 - 1122: Vitamins and Minerals
 - 1123: Histopathological fixed slides

Interstate Transport Permits

- Transport permits are required to move any livestock or poultry pathogen across state/territory/DC lines
- Livestock and poultry pathogens must be infectious or contagious or Guideline 1125 applies
- Live influenza A viruses need a permit, even if human origin, as they can cause disease in livestock.



Guideline 1125: No Interstate Transport Permit Required

- Interstate movement only
- Guideline 1125 is Veterinary Services permission to move non-infectious materials between states/territories/DC that meet the requirements in the guideline.



Import Safety Testing

Materials containing products from countries affected with agricultural diseases of concern are scrutinized to **protect animal agriculture!!!**

*****Review our website for [Animal Health Status](#) as a country's disease status does change*****

Safety testing (FADDL/NVSL) sometimes required

Permit restrictions prevent importation of CSF, ASF, SVD, FMD, HPAI, NDV, AHS

Remember FMD RNA is a select agent!!!



Inspection

Inspections, when required, are for permit issuance.

- Inspections are not certifying labs, they are only for approval to receive regulated material
- Inspections are a tool we use to protect animal agriculture

BMBL is basis for inspection checklists

Inspection valid for 3 years

Approval of labs – based on inspector recommendation

Deficiencies – addressed with applicant

CFR 9, section 130 covers inspection fees

Is Inspection Required?

Depends On the Organism and the Risks

- National/OIE Reportable Disease?
- What country or region is the material from?
- In vitro or in vivo work
- Importance to industry/economic impact
- Level of pathogenicity
- Risk of spread/infectivity/mode of transmission

COVID-19

2019 Novel Coronavirus (COVID-19) – Effective February 21, 2020

USDA regulates the *importation into the United States* of COVID-19 isolates exposed to livestock or poultry products (such as eggs, fetal bovine serum, etc).

- Permits for COVID-19 exposed to fetal bovine serum from countries affected with Foot and Mouth Disease will require BSL3 handling (see [Animal Health Status](#) page)

USDA **DOES NOT REGULATE** the *interstate movement* of COVID-19 isolates. Use Guideline 1125 for No Interstate Transport Permit Required

USDA **DOES NOT REGULATE** the importation or interstate transport of HUMAN DIAGNOSTIC SAMPLES (tissues, blood, etc. suspected to contain organisms).

Application process

- Application submitted by individual/entity receiving the material
- Application reviewed for completeness
- Initial content review by veterinary permitting examiner
 - Questions or follow up with applicant
- Evaluation of risk
 - Disease risk of originating species/country
 - Disease mitigation protocols reviewed
 - Safety testing or laboratory inspection may be required
- Permit drafted and reviewed
- Process can take 2 weeks or longer, depending on the situation

eFILE

- eFile is a new APHIS permitting system replacing ePermits
<https://efile.aphis.usda.gov/s/>
- eFile includes permitting as well as the VS Permitting Assistant (VSPA).
 - VSPA is a self-service online tool to assist with understanding permit requirements
- Permits will not automatically transfer from ePermits to eFile
 - Will have ability to “renew” your ePermits permit in eFile
 - ePermits will move to read only soon. eFile is the permitting system of the future across USDA
 - Quick reference guide: <https://www.aphis.usda.gov/help/eFile/quick-ref-guidance-vs-16-3-permit-app.pdf>

Example Permit

<p>U.S. DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE VETERINARY SERVICES RIVERDALE, MARYLAND 20737 file:///d:/inetpub/wwwroot/permits/images/</p> <p>UNITED STATES VETERINARY PERMIT FOR IMPORTATION AND TRANSPORTATION OF CONTROLLED MATERIALS AND ORGANISMS AND VECTORS</p>		<p>PERMIT NUMBER Unassigned (DRAFT) Research The current Duration period selected for this permit is 1 year</p>	
<p>NAME AND ADDRESS OF SHIPPER(S) Various shippers within the UNITED STATES</p>		<p>DATE ISSUED Unknown (DRAFT)</p>	<p>DATE EXPIRES Unknown (DRAFT)</p>
<p>NAME AND ADDRESS OF PERMITTEE INCLUDING ZIP CODE AND TELEPHONE NUMBER Transport - BSL2 XYZ University Museum of Vertebrates 111 Oak Street Anytown, Georgia 11111</p>		<p>CC: Service Center, NY (Albany, NY) FWS (Arlington, VA)</p>	
<p>AS REQUESTED IN YOUR APPLICATION, YOU ARE AUTHORIZED TO IMPORT OR TRANSPORT THE FOLLOWING MATERIALS Wild avian samples (previously imported)</p>		<p>U.S. PORT(S) OF ARRIVAL TRANSPORT PERMIT</p>	
<p>RESTRICTIONS AND PRECAUTIONS FOR TRANSPORTING AND HANDLING MATERIALS AND ALL DERIVATIVES</p> <p>THIS PERMIT IS ISSUED UNDER AUTHORITY CONTAINED IN 9 CFR CHAPTER 1, PARTS 94.95 AND 122. THE AUTHORIZED MATERIALS OR THEIR DERIVATIVES SHALL BE USED ONLY IN ACCORDANCE WITH THE RESTRICTIONS AND PRECAUTIONS SPECIFIED BELOW (ALTERATIONS OF RESTRICTIONS CAN BE MADE ONLY WHEN AUTHORIZED BY USDA, APHIS, VS).</p> <ul style="list-style-type: none"> o Adequate safety precautions shall be maintained during shipment and handling to prevent dissemination of disease. o With the use of this permit I, Ornithologist ABC, Permittee, acknowledge that the regulated material(s) will be imported/transported within the United States in accordance with the terms and conditions as are specified in the permit. The Permittee is the legal importer/recipient [as applicable] of regulated article(s) and is responsible for complying with the permit conditions. The Permittee must be at least 18 years of age and have and maintain an address in the United States that is specified on the permit; or if another legal entity, maintain an address or business office in the United States with a designated individual for service of process; and serve as the contact for the purpose of communications associated with the import, transit, or transport of the regulated article(s). **Note: Import/Permit requirements are subject to change at any time during the duration of this permit. o ***Each shipment shall be accompanied by an ORIGINAL signed document from the producer/manufacturer/shipper 1) identifying the country of origin and confirming that the wild avian material was NOT collected in a) Canada between November 1, 2014 and September 30, 2015, b) the European Poultry Trade Region (EU-PTR see below) or 		<p>MODE OF TRANSPORTATION ANY</p>	



Website

The screenshot shows the USDA website header with the logo and navigation links. The main content area features a sidebar menu on the left with categories like 'Animal Health', 'Contact Us', and 'Program Overview'. The main article is titled 'Organisms and Vectors Guidance & Permitting' and includes a 'Print' button and a 'Last Modified' date of Nov 1, 2019. A red 'NEW' ribbon graphic highlights a section titled 'VS Issues Guideline 1125 – Effective April 15, 2019', which describes changes to permitting requirements for non-regulated interstate movement of organisms and vectors.

<https://www.aphis.usda.gov/aphis/ourfocus/importexport/organism-vectors>



Questions?

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