

# Organisms and Vectors

## Protecting America's Agriculture



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**USDA, APHIS, Veterinary Services**



DETROIT FIELD OFFICE

**IMP**  **ORTATION**  
**OF BIOLOGICALS**  
**WORKSHOP**



United States Department of Agriculture



# Organisms and Vectors Permitting: Protecting American Agriculture

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Animal and Plant Health Inspection Service  
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# Who We Are

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- We moved!! We are no longer part of Select Agents
- Now part of the Animal Product Import and Export (APIE) team
  - APIE Director: Dr. Keith Wiggins
  - Import Director: Dr. Lisa Dixon
  - Veterinary Medical Officers: Dr. Troy Bigelow and Dr. Scott Epperson
  - Veterinary Permit Examiner: Susan Collins
- APIE includes permitting for several different commodity groups:
  - Meat, milk, eggs, and casings
  - Animal consumption
  - Animal byproducts
  - Organisms and vectors

# What do we do

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- 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 authorities

# Definitions

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- 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.

# Types of permits issues

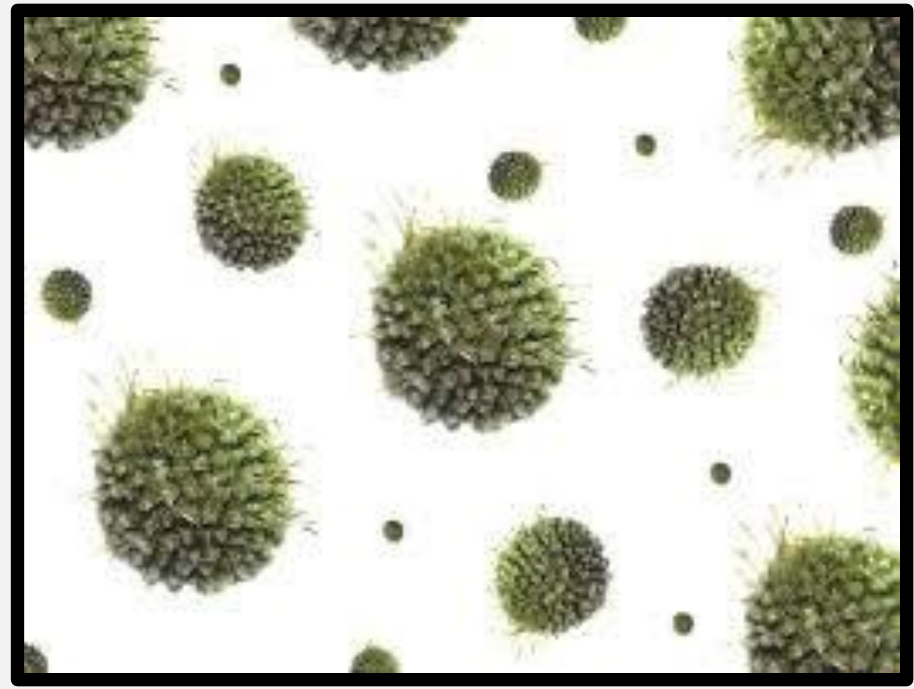
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- Research or Commercial
  - For organisms and vectors, all permits are research
- Import permit or Interstate Transport permit
  - Requirements are slightly different for import vs. interstate transport



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

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- 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

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- 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

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- 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.

# eFILE

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- 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

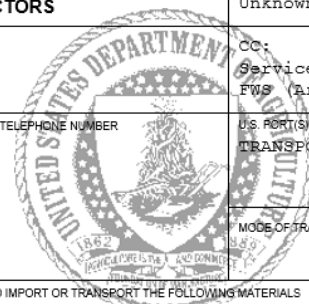
# Application process

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- 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 or originating species/country
  - Disease mitigation protocols reviewed
    - Safety testing or laboratory inspection may be required
- Permit drafted and reviewed
- Process can take 2-3 weeks or longer, plan accordingly

# Example Permit

<p>U.S. DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE VETERINARY SERVICES RIVERDALE, MARYLAND 20737 <small>file:///d:/inetpub/wwwroot/epermits/images/</small></p> <p><b>UNITED STATES VETERINARY PERMIT FOR IMPORTATION AND TRANSPORTATION OF CONTROLLED MATERIALS AND ORGANISMS AND VECTORS</b></p>		<p>PERMIT NUMBER Unassigned (DRAFT) Research <b>The current Duration period selected for this permit is 1 year</b></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>U.S. PORT(S) OF ARRIVAL TRANSPORT PERMIT</p>	
		<p>MODE OF TRANSPORTATION</p>	<p>ANY</p>
<p>AS REQUESTED IN YOUR APPLICATION, YOU ARE AUTHORIZED TO IMPORT OR TRANSPORT THE FOLLOWING MATERIALS</p> <p>Wild avian samples (previously imported)</p>			
<p><b>RESTRICTIONS AND PRECAUTIONS FOR TRANSPORTING AND HANDLING MATERIALS AND ALL DERIVATIVES</b></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"> <li>o Adequate safety precautions shall be maintained during shipment and handling to prevent dissemination of disease.</li> <li>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.</li> <li>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</li> </ul>			







# Website

The screenshot shows the USDA website header with the logo and navigation links. The main content area features a sidebar with a menu of topics, a main heading for 'Organisms and Vectors Guidance & Permitting', a 'Last Modified' date, a 'Print' button, and a paragraph of text. A red 'NEW' banner highlights a 'VS Issues Guideline 1125' effective April 15, 2019. The footer contains a small text reference to a CDC presentation.

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## Organisms and Vectors Guidance & Permitting

Last Modified: Nov 1, 2019 Print

The Veterinary Services, Organisms and Vectors (OV) Permitting Unit regulates the importation into the United States, and interstate transportation, of organisms and vectors of pathogenic diseases of livestock and poultry.

The Code of Federal Regulations, in [9 CFR, §122.2](#), mandates that "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".

**NEW VS Issues Guideline 1125 – Effective April 15, 2019**

Veterinary Services will implement changes to permitting requirements based on Guideline 1125, effective April 15, 2019. The guideline describes allowances for non-regulated interstate movement of

CDC presentation no new guidelines June 2016 - PowerPoint

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



# Questions?

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