Organisms and Vectors
Protecting America’s Agriculture

Dr. Scott Epperson
Veterinary Medical Officer
Animal Products Imports and Exports
USDA, APHIS, Veterinary Services
Organisms and Vectors Permitting: Protecting American Agriculture

Scott Epperson, DVM, MPH
Veterinary Medical Officer
U.S. Department of Agriculture
Animal and Plant Health Inspection Service
Veterinary Services
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Who We Are

• 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

• 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

• **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

• 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.)
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

• 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.
eFILE

- eFile is a new APHIS permitting system replacing ePermits [https://efile.aphis.usda.gov/s/](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

• 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

UNITED STATES VETERINARY PERMIT FOR IMPORTATION AND TRANSPORTATION OF CONTROLLED MATERIALS AND ORGANISMS AND VECTORS

NAME AND ADDRESS OF SHIPPER(S)
Varicella shippers within the UNITED STATES

NAME AND ADDRESS OF PERMITTEE INCLUDING ZIP CODE AND TELEPHONE NUMBER
Transport - BSL3
XYS University
Museum of Vertebrates
111 Oak Street
Anytown, Georgia 11111

DATE ISSUED
Unknown (DRAFT)
DATE EXPIRES
Unknown (DRAFT)

PERMIT NUMBER
Unassigned (DRAFT)
Research
The current duration period selected for this permit is 1 year

AS REQUESTED IN YOUR APPLICATION, YOU ARE AUTHORIZED TO IMPORT OR TRANSPORT THE FOLLOWING MATERIALS

Wild avian samples (previously imported)

RESTRICTIONS AND PRECAUTIONS FOR TRANSPORTING AND HANDLING MATERIALS AND ALL DERIVATIVES

This permit is issued under authority contained in 9 CFR Chapter 1, Parts 58 and 121. 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.

1. Adequate safety precautions shall be maintained during shipment and handling to prevent dissemination of disease.

2. With the use of this permit, 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 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.

3. Each shipment shall be accompanied by an ORIGINAL signed document from the producer/manufacturer/shipper(s) 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
Website

Questions?

Scott Epperson, DVM, MPH and Troy Bigelow, DVM
Veterinary Medical Officers
U.S. Department of Agriculture
Animal and Plant Health Inspection Service
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Email: APIE@usda.gov