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# Frequently Asked Questions: Importation and Transportation of Organisms and Vectors

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## Why do I need to obtain a permit for importing or transporting organisms or vectors?

The Code of Federal Regulations [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."

## Who controls importation or transportation of organisms and vectors?

APHIS Veterinary Services Organisms and Vectors (OV) unit of the Agricultural Select Agent Services (AgSAS) staff regulates the importation and transportation of

livestock- and poultry-pathogenic organisms and vectors.

APHIS Plant Protection and Quarantine [regulates importation of plant pests](#).

[CDC Import Permit program](#) regulates importation of human infectious disease organisms and vectors.

## **What is the difference between a VS 16-3 and a VS 16-6?**

A [VS Form 16-3](#) "Application for Permit to: Import or Transport Controlled Materials or Organisms or Vectors" is the application form which is submitted to apply for a permit (VS form 16-6A) for Organisms or Vectors. It is also the same application used to apply for a permit (VS form 16-6A) for Animal Products and By-Products. A VS Form 16-6A "United States Veterinary Permit for Importation and Transportation of Controlled Materials and Organisms and Vectors" (usually referred to simply as a VS 16-6) is the actual permit that is issued to the permittee for import or transport of the regulated material.

## **Who should obtain the OV permit: the sender or recipient?**

OV issues VS 16-6 permits to the recipient ("The Permittee") but not to the sender ("The Shipper").

## **What are considered as "pathogenic organisms" that OV regulates?**

OV regulates all cultures or collections of organisms which may introduce or disseminate any contagious or infectious disease of livestock and poultry. For

importation, OV also regulates those organisms and their derivatives (DNA/RNA, recombinants, inactivated/attenuated). These pathogens include bacteria, viruses, fungi, protozoa, transmissible spongiform encephalopathy (TSE) agents, and their extracted nucleic acids.

## What are considered as "vectors" that OV regulates?

OV regulates arthropods (e.g. insects, flies, fly larva, ticks, worms, mosquitoes, mites) that may be infected with or have been exposed to livestock or poultry pathogens. Cultures and specimens of all animals (including laboratory animals and pets) are also considered as "vectors" if infected or likely exposed to pathogens.

## When do you need an OV permit?

Controlled materials that require a VS 16-6 **import** permit include microorganisms (e.g. bacteria, viruses, fungi, protozoa, and TSE agents) that are pathogenic to livestock or poultry, their extracted nucleic acids, inactivated and killed products, and vectors of livestock or poultry pathogens. Importation of non-pathogenic microorganisms that have not been exposed to components derived from animal sources do not require a VS permit.

Controlled materials that require a VS 16-6 interstate **transport** permit include live microorganisms (e.g. bacteria, viruses, fungi, protozoa, and TSE agents) that are pathogenic to livestock or poultry and vectors of livestock or poultry pathogens. Transportation of non-pathogenic microorganisms do not require a VS permit.

Examples of organisms and vectors that require VS permit for **importation and/or transportation**:

- Pathogens that can initiate or disseminate disease in livestock and poultry
- Vectors that are infected with or have been exposed to an infectious disease of livestock or poultry

- Animal specimens including tissue, fluids, or blood collected from animals infected with pathogens or exposed to pathogens or vectors
- Cell cultures exposed to organisms that cause disease in livestock or poultry
- Human viruses and human vaccines intended for research use in livestock or poultry.
- Attenuated live viruses and vaccine strains
- Certain Fish and mollusks pathogens

## When is an OV permit not needed?

Review the [Guidelines for animal products that do not need an import permit](#) and [Guideline 1125: Conditions under which Veterinary Services does not require a transport permit](#). These guidelines describe materials for which a permit **IS NOT** required, and describe documentation to include with your materials to facilitate their import or transport.

## Is there a difference between a VS 16-6 permit for import and a VS 16-6 permit for transport?

Yes. Import and transport permit applications are both processed through the [APHIS eFile system](#) and approved permits populate on the same form (VS 16-6). However, import permit applications require more information than transport permit applications. This is because APHIS classifies countries according to their animal disease status, and prohibits or restricts importation of certain materials from countries based on their disease status.

Examples of the information we need for import permits include:

- A full description of the organism. This includes the genus and species for bacteria and the full name of the virus.
- For bacteria, the applicant must verify that the organism was subcultured for isolation at least four times prior to import.

- The country of origin of the materials. This allows us to determine if there are diseases endemic to that country that we might be concerned about in the imported material.
- A description of any animal or animal-origin nutrients or media that importing materials might have been exposed of.
- The method of inactivation should be provided if the material or components are high risk or if the material comes from a country endemic for select agents.

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### **Does OV regulate pathogens of all animals?**

No. OV only regulates organisms that introduce or disseminate disease in livestock, poultry and certain diseases of aquaculture. Not included under OV restrictions are pathogens of pet animals or laboratory animals such as non-human primates, bats, mice, or rats (unless they have been exposed to an infectious disease of livestock or poultry).

### **Does OV regulate plant and soil organisms?**

No. Plant pathogens and vectors of plant pathogens that do not introduce or disseminate disease in livestock or poultry are not regulated by OV. For importation of plant pathogens and vectors of plant pathogens, please contact [USDA Plant Protection and Quarantine \(PPQ\)](#).

### **Does OV regulate human pathogens?**

OV regulates organisms pathogenic to livestock or poultry, even if the pathogen was isolated from a human.

Human pathogens that do not introduce or disseminate disease in livestock or poultry are not regulated by OV except if they are to be imported and have been exposed to animal materials or animals. OV does not regulate human diagnostic samples (human clinical samples expected to contain pathogen/s).

For importation on human and non-human primate pathogens, and for movement of human diagnostic samples, please contact [Centers for Disease Control \(CDC\)](#).

### **Does OV regulate veterinary biological products?**

No. The regulation for VS 16-6 permit for a microorganism or vector of veterinary biologics (vaccines, bacterins, antisera, diagnostic kits, and other products of biological origin) to ensure that the veterinary biologics available for the diagnosis, prevention, and treatment of animal diseases are pure, safe, potent, and effective is done by APHIS' [Center for Veterinary Biologics \(CVB\)](#) and is centered around enforcement of the [Virus Serum Toxin Act](#) (16.44 KB)(PDF 17KB).

### **You have a CDC permit for a zoonotic pathogen. Do you also need a VS permit?**

Yes. Receipt of zoonotic pathogens of livestock or poultry also requires a permit from VS irrespective of whether a CDC permit was obtained or not.

### **Your OV permit expired. Do you need to apply for renewal?**

Yes. The expiration date listed on the USDA VS 16-6 permit is the last date on which the permittee is allowed to import or transport agents listed on the permit. Renew using the [APHIS eFile system](#).

### **Your address, laboratory information, or regulated material is changing from the details on the permit. Do you need an**

## **amendment to your existing permit?**

Yes. You must amend your existing permit if your details change. Make requests for a change in name, address, laboratory information, or material description through the online permit system where your permit exists: [Animal Health Permits](#)

## **Your OV permit expired. Can you still process imported materials beyond the permit expiration date?**

Yes. Renewal of permit is not required for possession of previously imported materials. However, the permittee is responsible for all materials until possession ends. Permit restrictions remain in effect until the material is used up, destroyed, or discarded following appropriate methods.

## **Does my laboratory or facility require an APHIS inspection before obtaining a VS permit?**

APHIS inspection is required prior to obtaining importation and transportation permits for any BSL-3 pathogens. Additionally, inspection is required for selected BSL-2 pathogens.

## **Who do I contact if I have questions for OV?**

Please email your questions to [apie@usda.gov](mailto:apie@usda.gov) ; call 301-851-3300. For additional information please visit [Organisms and Vectors webpage](#).

## **How do I submit a VS 16-3 application?**

VS 16-3 permit applications may be obtained and submitted online using the [APHIS eFile system](#).

Email [apie@usda.gov](mailto:apie@usda.gov) with any questions.

## **How do I become eAuthenticated to access the online permitting system?**

Online access to the permitting system requires a “Verified Identity” authentication (Previously, this was called “Level 2”). Please visit <https://www.eauth.usda.gov/eauth/b/usda/home> to create or update your account.

## **What is the processing fee for a VS 16-3 application?**

For current fee structure please visit [VS User Fees](#).

## **Are there best practices for applying for and successfully obtaining a VS 16-6 permit for a microorganism or vector?**

OV recommends the following best practices:

1. Apply through [APHIS eFile System](#) (Veterinary Services Permitting Assistant-VSPA) using form VS 16-3. Electronic submissions allow OV to provide you the most efficient service and reduce the time needed to process your application.
2. Review the "[Is a VS 16-6 permit required?](#)" [flowchart](#) (332.04 KB) and [USDA Guidelines for no import permit required](#). These guidelines describe materials that DO NOT require a permit, and describe documentation to include with your materials that will facilitate their import or transport. It is always a good practice to include the printed guideline with the shipping documents.
3. State whether the permit requested is an import permit or a transport permit. An import permit is for movement of materials into the U.S. Transport permits are for interstate transport within the United States.

4. The restrictions are more stringent for import permits. See Q9 for best practices for import permit applications.

## **How do I receive Select Agents?**

1. Select Agents are prohibited from movement under a VS 16-6 permit. A Form 2 transfer issued through the [Federal Select Agent Program](#) is required.
2. Importation of tissues and samples suspected of containing Select Agents is prohibited. Confirmation that the material does not contain Select Agents must be verified at one of the two Veterinary Services Diagnostic Laboratories by safety testing, safety treatment or both. A safety testing /treatment permit to one of the Veterinary Diagnostic Laboratories are generated with the initial application.

## **How do I receive inactivated and excluded Select Agents?**

1. Inactivated or excluded select agents may be imported and received using a VS 16-6 import permit. The inactivation method should be supplied in the application.
2. Excluded select agents that are to be moved between U.S. states and territories also require a VS 16-6 interstate transport permit.
3. Avian influenza is considered highly pathogenic (a Select Agent) until proven to be low pathogenic avian influenza. This means a request for exclusion of the virus from the Federal Select Agent Program must be submitted ( [AgSAS@aphis.usda.gov](mailto:AgSAS@aphis.usda.gov)) and approved prior to permit issuance. If the virus has already been excluded, OV may require the exclusion letter before issuing a permit.

**The materials I am requesting for import were exposed to animals or animal products? Why does this matter? Can the materials be treated before importation?**

1. Materials that have been exposed to animals or animal products from certain countries could act as vectors for certain organisms of concern for U.S agriculture. As examples, organisms such as Highly Pathogenic Avian Influenza could be found in eggs used to grow influenza viruses. Foot and Mouth disease virus or viral RNA (both select agents) could be transmitted through exposure to fetal bovine serum.
2. In many cases, the materials can be treated prior to importation and may not require safety testing/treatment. For example, non-pathogenic bacterial cultures grown in standard autoclaved sterile media will not require a VS permit to import.

### **Does OV regulate toxins?**

No, toxins are not regulated by OV. Some toxins are regulated by the [Federal Select Agent Program](#).

### **Fish, shrimp, and mollusks are types of livestock. Which aquatic pathogens are regulated by OV?**

OV regulates the aquatic pathogens: infectious salmon anemia virus, spring viremia of carp, Tilapia Lake Virus, Epizootic Hematopoietic Necrosis Virus, Salmonid alphavirus, Gyrodactylus salaris, Marteilia refringens, Perkinsus olseni, and Martellioides chungmuensis.

### **Do I need a permit for receipt of transported animal surveillance samples from one State to another State within the United States?**

Do I need an interstate transport permit for receipt of livestock or poultry specimens or by-products not known or suspected to be infected with livestock or poultry pathogens? No. The recipient is not required to obtain an interstate transport permit

for surveillance specimens originated from healthy animals not known or suspected to be infected with livestock or poultry pathogens. An interstate transport permit is required for movement of materials that are known or suspected to contain communicable or contagious livestock or poultry disease agents such as diagnostic samples from sick animals and surveillance samples from outbreak situations.

## **Does Organisms and Vectors issue commercial permits?**

Organisms and Vectors does not issue commercial permits.

## **How do I use guidelines for no permit required?**

Carefully read and follow the instructions on the applicable guideline, as outlined below.

[IMPORT](#): Guidelines to be used for importation into the United States also require original written statements from the producer.

[INTERSTATE MOVEMENT](#): There is an interstate transport guideline that is to be used only for eligible items that are moved from one U.S. state or territory to another (not to be used for importation).

## **Blanket permit - do you have one?**

Do you seek interstate transport of US Origin Livestock and poultry pathogens? If so, Organisms and Vectors permitting has two US ORIGIN LIVESTOCK AND POULTRY PATHOGENS PERMITS that may work for you: 1) allows in-vitro work only on regulated materials received via interstate transport; and, 2) the other allows in-vitro and in-vivo work on regulated materials received via interstate transport. These permits are only applicable for interstate movement of U.S. origin organisms classified as Biosafety level 1 (BSL1) and biosafety level 2 (BSL2) materials that do not require a USDA VS laboratory inspection. The blanket permits are template permits and cannot be changed. If you need specific permit language, or if you seek

organisms that require laboratory inspections, a separate application is required.

The US Origin Livestock and Poultry pathogens in-vitro only interstate transport permit allows receipt by interstate transport of all BSL1 and BSL2 US origin livestock and poultry pathogens except: Low Pathogenic Avian Influenza, Newcastle Disease virus (non-select agent strains, ICPI 0.07 or lower), and Pseudorabies (Aujeszky's disease) that will be propagated. Propagation of these organisms requires a separate permit in which the BSL2 labs are inspected and listed on the permit.

The US Origin Livestock and Poultry pathogen in-vitro and in-vivo interstate transport permit allows transport of all BSL1 And BSL2 US origin livestock and poultry pathogens except:

Organisms when used in ANY animal are excluded from the permit because lab inspections are required : Low Pathogenic Avian Influenza; Newcastle Disease virus (non-select agent strains, ICPI 0.07 or lower); Prion diseases- Scrapie Chronic Wasting Disease, Bovine Spongiform Encephalopathy; Pseudorabies (Aujeszky's disease); Surra (*Trypanosoma evansi*); Trypanosomiasis (*Trypanosoma congolense*, *T. vivax*, *T. brucei brucei*, *T. evansi*) and

Organisms when used in LIVESTOCK OR POULTRY susceptible species are excluded from the permit because lab inspections are required: Contagious equine metritis (*Taylorella equigenitalis*); Cysticercosis (*cysticercus cellulosae* metacestode stage of *Taenia solium*); Dourine (*Trypanosoma equiperadum*); Equine Infectious Anemia virus; Equine piroplasmiasis (Babesiosis)- *Babesia caballi*, *Babesia equi*/*Theileria equi*, *Babesia bovis*; Equine viral arteritis (EVA); Infectious salmon anemia; Japanese Encephalitis virus attenuated vaccine (JEV14-14-2) used in pigs; Porcine Reproductive and Respiratory Syndrome (PRRS); Spring viremia of carp; *Theileria* (*annulata*, *buffeli*, *equi*, *lestouardi*, *lowenshuni*, *mutans*, *orientalis*, *parva*, *sergenti*, *uilenbergi*); Vesicular stomatitis (VSV)

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