

FREQUENTLY ASKED QUESTIONS FOR IMPORTATION AND TRANSPORTATION OF ORGANISMS AND VECTORS (OV)

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Q1. Why do you need to obtain a permit for importing or transporting organisms and vectors?

The [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*”.

Q2. Who controls importation or transportation of organisms and vectors?

The Organisms and Vectors (OV) unit of the Agricultural Select Agent Services (AgSAS) staff regulates the importation and transportation of pathogenic organisms and vectors.

Q3. 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.

Q4. Who should obtain the OV permit, sender or the recipient?

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

Q5. What are considered as “pathogenic organisms” that OV regulate?

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

Q6. What are considered as “vectors” that OV regulate?

OV regulates arthropods (e.g. insects, flies, fly larva, ticks, worms, mosquitoes, mites) that can effectively serve as the carriers of pathogens. Cultures and specimens of all animals (including

laboratory animals and pets) are also considered as “vectors” if infected or likely exposed to pathogens

Q7. 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, their extracted nucleic acids, inactivated and killed products, 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 or transportation:**

1. Pathogens that can initiate or disseminate disease in livestock and poultry
2. Vectors that can serve as the carrier of or have been exposed to an infectious disease of livestock or poultry
3. Animal specimens including tissue, fluids, or blood collected from animals infected with pathogens or exposed to pathogens or vectors
4. Cell cultures exposed to organisms that cause disease in livestock or poultry
5. Human viruses and human vaccines intended for research use in livestock or poultry.
6. Attenuated live viruses and vaccine strains
7. Fish pathogens: infectious salmon anemia virus, spring viremia of carp virus, and viral hemorrhagic septicemia virus

Q8. When is an OV permit not needed?

Review the “Animal Products that Do Not Require an Import Permit (Guidelines)” posted on the APHIS website ([USDA Import Guidelines](#)). 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 and listed as:

[1100](#) *Human Pharmaceuticals and Human Vaccines Containing Animal Components*

[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*

Q9. 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 ePermits 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.

Q10. 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).

Q11. 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 \(PPQ\)](#).

Q12. Does OV regulate human pathogens?

No. 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. For importation of pathogens that are concern of human and non-human primates, please contact [Centers for Disease Control](#) (CDC).

Q13. Does OV regulate veterinary biological products?

No. The regulation 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](#) (PDF 17KB).

Q14. 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.

Q15. Your OV permit expired. Do you need to submit an application 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.

Q16. 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 VS 16-3 application form.

Q17. Your OV permit expired, can you still possess 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.

Q18. 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.

Q19. Whom do I contact if I have questions for OV?

Please email your questions to: ov@aphis.usda.gov ; call 301-851-3300, option 3; or fax your inquiry to: 301-851-2239. For additional information please visit our website at: www.aphis.usda.gov/animal-health/organisms-vectors

Q20. How do I submit a VS 16-3 application for VS 16-6 permit for a microorganism or vector?

VS 16-3 permit applications may be obtained:

1. On-line at http://www.aphis.usda.gov/animal_health/permits/
2. By writing to:
USDA, APHIS, VS
National Import Export Services
4700 River Road, Unit 2
Riverdale, MD 20737
Telephone: 301-851-3300, Option 3
Fax: 301-851-2239

For faster processing, please submit your application using the online permitting system “[ePermits](#)”

Q21. What is the processing fee for a VS 16-3 application?

For current fee structure please visit:

[Organisms and Vectors Permitting](#)

Q22. 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 ePermits 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 (link) and “Animal Products that Do Not Require an Import Permit (Guidelines)” posted on the APHIS website ([USDA](#))

[Import Guidelines](#)). 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.

Q23. 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.

Q24. How do I receive inactivated and excluded Select Agents?

1. Inactivated or excluded select agents can be received using a VS 16-6 permit. For importation, the inactivation method should be supplied.
2. 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). If the virus has already been excluded, OV may require the exclusion letter is submitted before a issuing a permit.

Q25. 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.

Q26. Does OV regulate toxins?

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

Q27. Fish and shrimp are types of livestock. Which aquatic pathogens are regulated by OV?

OV regulates three aquatic pathogens: Viral hemorrhagic septicemia, Infectious salmon anemia virus, Spring viremia of carp