Guidelines: Animal Products That Do Not Require An Import Permit

Last Modified:

These materials DO NOT require a USDA APHIS VS permit, but they will be reviewed at the U.S. port of entry.

Guideline 1100: Human And Veterinary Pharmaceuticals and Vaccines

This guideline applies to:

- Human pharmaceuticals, approved active pharmaceutical ingredients*, over-the-counter (OTC) drug monographs, human vaccines, human medical devices (including 510k and empty blood collecting tubes), veterinary pharmaceuticals, and veterinary medical devices (including 510k and empty blood collecting tubes) approved by the Food and Drug Administration (FDA) containing animal derived components.

**FDA approved active pharmaceutical ingredients (API) only derived from or containing gelatin and/or lactose.*

FOR VETERINARY MEDICAL DEVICES such as, but not limited to, empty blood collecting tubes and 510k medical devices:

- FDA has regulatory oversight over veterinary devices and can take appropriate regulatory action if a veterinary device is misbranded or adulterated. It is the

responsibility of the manufacturer and/or distributor of these articles to assure that these animal devices are safe, effective, and properly labeled prior to importation to the United States. The labels of all veterinary devices should clearly indicate that they are for animal use only.

Information pertaining to veterinary devices may be accessed at the following FDA websites:

- How FDA Regulates Animal Devices
- CPG Sec. 607.100 - Adequate Directions for Use (Species Designation) - Animal Drugs and Veterinary Devices
- CPG Sec. 655.100 - Devices for Use in Animals

To learn more about the importation process, you may reference the FDA Regulatory Procedures Manual, Chapter 9, Import Operations and Actions.

This guideline does NOT apply to:

- Veterinary vaccines or veterinary diagnostic test kits, Anti-venom, dietary supplements, non-empty veterinary blood collecting tubes, nutraceuticals, FDA approved test kits, test kit reagents, test kit components, in vitro reagents including but not limited to bovine serum, monoclonal antibodies, cell lines, media, transport media, porcine blood, sodium heparin, heparin, ox bile, deoxycholic acid, deoxycholate and non-FDA approved bulk pharmaceutical and vaccine active ingredients.

(Last updated January 2023)

Introduction

Material derived from any animal is potentially subject to U.S. Department of Agriculture (USDA) regulations and must be cleared by Department of Homeland Security, Customs and Border Protection (DHS, CBP) Agriculture Specialists/Inspectors at the U.S. port of arrival before entry into the United States is authorized. A USDA import permit is required for animal material that may pose a risk of introducing foreign livestock and poultry diseases into the United States. However, human pharmaceuticals, human medical devices, approved active pharmaceutical ingredients (usually shipped in bulk), human vaccines, veterinary

pharmaceuticals and veterinary regulated medical devices, containing animal derived ingredients and approved by the Food and Drug Administration (FDA) may enter the United States without USDA, Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) restrictions.

The U.S. Food and Drug Administration and U.S. Public Health Service both may have primary jurisdiction over human pharmaceuticals, approved active pharmaceutical ingredient (usually shipped in bulk), human vaccines, veterinary pharmaceuticals and medical devices. They should be contacted for their importation requirements at the following locations:

U.S. Food and Drug Administration
Division of Import Operations and Policy
10903 New Hampshire Avenue
Silver Spring, MD 20993
1-888-INFO-FDA (1-888-463-6332)
Website address https://www.fda.gov

U.S. Public Health Service
Centers for Disease Control and Prevention, Office of Biosafety
1600 Clifton Road Atlanta, GA 30329-4027 USA
800-CDC-INFO (800-232-4636), TTY: 888-232-6348
CDC Biosafety Resources and Tools

FDA has authority over “devices,” as defined in the Federal Drug & Cosmetic Act, for animal use.

The USDA, Center for Veterinary Biologics, Policy, Evaluation & Licensing (CVB, PEL), may have primary jurisdiction over veterinary biologics, including vaccines, and veterinary medical devices imported for any purpose. For additional information, see the CVB web site, email cvb@aphis.usda.gov and/or call (515) 337-6100.

Procedures

A USDA APHIS VS import permit (VS Form 16-6), will **not** be required for **FDA approved** human pharmaceuticals, approved active pharmaceutical ingredients (usually shipped in bulk), over- the-counter (OTC) drug monographs, human vaccines, human medical devices, veterinary pharmaceuticals, and veterinary

medical devices shipped in bulk (fully manufactured to be packaged) and/or in final-use packaging.

In order to facilitate correct identification of the shipment and to ensure timely delivery, USDA, APHIS, VS recommends that the following documentation or information accompanies each shipment and be presented for review by the Department of Homeland Security, Customs and Border Protection (CBP) Agriculture Specialist/Officers at the U.S. port of arrival. **For FDA approved human and/or veterinary pharmaceuticals, human vaccines and human and/or veterinary medical devices: or**

1. A written statement supplied on foreign producer/shipper letterhead which:
    1. Confirms that the product being imported is approved by the FDA; and/or
    2. Includes a copy of the FDA-approved commercial drug product label.
    OR
2. Based on information contained in shipping documents including, invoices, manifests or products labels, CBP will use information provided in the Orange Book to verify FDA approved pharmaceuticals for human use or the Green Book to verify FDA approved pharmaceuticals for veterinary (animal) use or refer to the FDA website to verify FDA approved human medical devices that contain animal origin ingredients.
    As a reminder, for FDA approved human vaccines:
    A written statement supplied on foreign producer/shipper letterhead which:
    1. Confirms that the product being imported is approved by the FDA; and
    2. Confirms the human vaccine in bulk (fully manufactured in final dosage to be packaged) and intended for human use only.
    3. Confirms that the product does not contain live livestock and poultry viral agents; and
    4. Includes a copy of the FDA-approved commercial vaccine label.

USDA, APHIS, VS recommends that this document be supplied on foreign producer/shipper letterhead. USDA, APHIS, VS further recommends that the documentation accompany each shipment, and be presented as a separate document for review by the DHS, CBP Agriculture Specialists/Inspectors at the U.S. port of arrival. We do not recommend that the foreign producer/shipper place this document inside the shipping containers. We further recommend that you provide a copy of this guideline to your producer/shipper.

For FDA regulated Veterinary Medical Devices

FDA has regulatory oversight over veterinary devices such as 510k medical devices and/or empty blood collecting tubes. The FDA can take appropriate regulatory action if a veterinary medical device is misbranded or adulterated. Imported FDA regulated products are expected to comply with all applicable regulations at the time of entry.

The labels of all veterinary devices should clearly indicate that they are for animal use only.

Guidance pertaining to veterinary devices may be accessed at the following FDA websites:

- How FDA Regulates Animal Devices
- CPG Sec. 607.100 - Adequate Directions for Use (Species Designation) - Animal Drugs and Veterinary Devices
- CPG Sec. 655.100 - Devices for Use in Animals

If the pharmaceutical, medical device or vaccine to be imported cannot meet these criteria, then a USDA import permit may be required. Permit applications may be obtained several ways:

Import Permit

USDA APHIS VS Permit applications can be submitted by any of the following ways:

- Online via eFile: https://efile.aphis.usda.gov/s/
- By e-mail: Submit a completed VS 16-3 (found on Animal Health Permits) to apie@usda.gov
- Contact us at apie@usda.gov or 301-851-3300 with questions/concerns.

Guideline 1101: Non-Human Primate Material (excluding cell cultures)

This guideline applies to:

- **Non-Human Primate Material/Specimens** such as tissues, blood/blood fractions, proteins, DNA, enzymes, feces, fluids, hormones, peptides, RNA, semen, urine, extracts, etc.

This guideline does not apply to:

- Cell cultures, tissues in culture, hybridomas, and their products – refer to Guideline #1120
- Human specimens - the regulation of imported human specimens is deferred to the Centers for Disease Control (CDC)

Effective May 2014

Introduction

U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) has jurisdiction over animal origin material. Material derived from any animal is potentially subject to USDA, APHIS, VS regulations and must be cleared at the U.S. port of arrival by Department of Homeland Security, Customs and Border Protection (DHS, CBP) Agricultural Specialists before entry into the United States is authorized. If the imported non-human primate material has not been inoculated with or exposed to any livestock or poultry foreign animal disease agent, then a VS import permit will not be required and the shipment should be deferred to CDC. The CDC can be contacted by telephoning: (404) 639-3311.

Procedures

A USDA, APHIS, VS import permit will not be required for the importation of material derived from non-human primates, provided the material has not been inoculated with or exposed to any livestock or poultry foreign animal disease agent. DHS, CBP Agricultural Specialists/inspectors must be provided documentation to determine this, which may include: manifests, invoices, foreign producer/shipper statements on letterhead, or other shipping documents which provide the following information:

1. A detailed and accurate description of the material, with species identification.
2. A written statement confirming that the material was not obtained from non-human primates that have been inoculated with or exposed to any livestock or poultry foreign animal disease agent.

VS recommends that this information is available for review by the DHS, CBP Agricultural Specialists upon arrival of the shipment at the U.S. port of arrival. We do not recommend that it be placed inside the shipping container.

We further recommend that you provide a copy of this guideline to your foreign producer/shipper.

If the non-human primate material to be imported cannot meet these criteria, then a USDA import permit may be required.

Import Permit

An import permit issued by USDA, APHIS, VS is required for non-human primate material if the material has been inoculated with or exposed to any livestock or poultry foreign animal disease agent.

USDA APHIS VS Permit applications can be submitted by any of the following ways:

- Online via eFile: https://efile.aphis.usda.gov/s/
- By e-mail: Submit a completed VS 16-3 (found on Animal Health Permits) to apie@usda.gov
- Contact us at apie@usda.gov or 301-851-3300 with questions/concerns.

Guideline 1102: Feline and Canine Material

Including:

- Semen for research purposes, blood, tissues, serum, feces, extracts, fluids.

Not including:

- Semen for reproductive purposes, cell cultures, tissue cultures, cell culture products. (Refer to Guideline #1120 for cell/tissue cultures and their products)

Effective April 14, 1998 (revised July 2006)

Introduction

Material derived from any animal is potentially subject to U.S. Department of Agriculture (USDA) regulations and must be cleared by Department of Homeland Security, Custom and Border Protection (DHS, CBP) Agricultural Specialists at the U.S. port of arrival before entry into the United States is authorized. A USDA import permit is required for animal material that may pose a risk of introducing exotic animal diseases into the United States. However, material from feline and canine

species that have not been inoculated with or exposed to any livestock* or poultry disease agents may enter the country without USDA, Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) restrictions.

Procedures

A USDA import permit will not be required for feline or canine origin material that has not been inoculated with or exposed to any livestock or poultry disease agent. In order to facilitate correct identification of the shipment and to ensure timely delivery, USDA, AHPIS, VS recommends that the following documentation accompany each shipment:

1. A written statement identifying the material and naming the animal species,
2. A written statement confirming that the material does not contain any other animal derived material (i.e., does not contain any livestock or poultry origin material).
3. A written statement confirming that the material was not derived from feline or canine species which were inoculated with or exposed to any infectious agents of USDA agricultural concern.

USDA, APHIS, VS recommends that this document be supplied on foreign producer/shipper letterhead, with the letterhead containing the physical address of the foreign producer/shipper. USDA, APHIS, VS further recommends that the document, written in a clear and concise manner, accompany each shipment, and be presented as a separate document for review by the DHS, CBP Officers at the U.S. port of arrival. We do not recommend that the foreign producer/shipper place this document inside the shipping containers.

We further recommend that you provide a copy of this guideline to your foreign producer/shipper.

If the feline or canine material to be imported cannot meet these criteria, then a USDA import permit may be required.

USDA APHIS VS Permit applications can be submitted by any of the following ways:

- Online via eFile: https://efile.aphis.usda.gov/s/

- By e-mail: Submit a completed VS 16-3 (found on Animal Health Permits) to apie@usda.gov
- Contact us at apie@usda.gov or 301-851-3300 with questions/concerns.

*The term livestock includes any bovine, ovine, caprine, porcine, equine, cervid, fish, or shellfish.

Guideline 1103: Live Laboratory Mammals and Their Material (for research purposes)

This guideline applies to the following:

- Transgenic/knock-out mice and rats, hamsters, gerbils, guinea pigs, rabbits, ferrets, and their blood, tissue, DNA, extracts, antibodies, feces, sera, and antisera for research purposes. (blood, sera, antibodies, and antisera is limited to less than 1 liter)

This guideline does not apply to the following:

- Primates, dogs, cats, livestock*, poultry, hedgehogs, tenrecs, minipigs, monoclonal antibodies, hybridomas, cell lines, and material for commercial purposes. (Refer to Guideline #1120 for cell/tissue cultures and their products)

(Last Updated July 2020)

Introduction

Material derived from any animal is potentially subject to U.S. Department of Agriculture (USDA) regulations and must be cleared by Department of Homeland Security, Customs and Border Protect (DHS, CBP) Agricultural Specialists at the port of arrival before entry into the United States is authorized. However, the USDA does not have regulatory authority over the importation of live laboratory animals or laboratory mammal material that have not been inoculated with or exposed to any livestock or poultry disease agents exotic to the United States.

The Centers for Disease Control and Prevention (CDC) has jurisdiction over live laboratory mammals and their material that may be infectious. Contact the Division of Select Agents and Toxins Importation Permit Program at 404-718-2077 or importpermit@cdc.gov regarding any documentation or other import requirements CDC may have.

USDA, Animal and Plant Health Inspection Service (APHIS), Plant Protection and Quarantine (PPQ) regulates the importation of plants and other vegetable matter. If the transport cage contains any plant or vegetable matter, including but not limited to potatoes, carrots, stray or hay, the importer must contact the PPQ Permit Unit at (301) 734-8758 to determine if it can be allowed entry. PROHIBITED VEGETABLE MATTER MUST BE REMOVED FROM THE CAGE AT THE PORT OF ARRIVAL BY A DHS, CBP AGRICULTURAL SPECIALIST.

Material derived from rodents and other small mammals which: (a) have not been inoculated with, or exposed to any exotic livestock or poultry disease agents, and (b) do not originate from facilities where work with exotic disease agents affecting livestock or avian species is conducted, may be imported without USDA, APHIS, Veterinary Services (VS) restrictions.

Procedures

A USDA permit will not be required for the importation of live laboratory mammals provided the mammals have not been inoculated with, or exposed to any exotic livestock or poultry disease agents, and do not originate from facilities where work with exotic disease agents affecting livestock or avian species is conducted. In order to facilitate correct identification of the shipment and to ensure timely delivery, USDA, APHIS , VS recommends that the following documentation accompany each shipment:

1. A written statement confirming that the live laboratory mammals have not been exposed to or inoculated with any livestock or poultry disease agents exotic to the United States, and
2. A written statement confirming that the live laboratory mammals do not originate from a facility where work with exotic disease agents affecting livestock or poultry is conducted.

A USDA permit will not be required for the importation of laboratory mammal material provided the material is obtained from laboratory mammals that have not been inoculated with, or exposed to any exotic livestock or poultry disease agents, and do not originate from facilities where work with exotic disease agents affecting livestock or avian species is conducted. In order to facilitate correct identification of the shipment and to ensure timely delivery, USDA, APHIS , VS recommends that the following documentation accompany each shipment:

1. A written statement identifying the material and naming the animal species,
2. A written statement confirming that the material was derived only from laboratory mammals that have not been inoculated with or exposed to any livestock or poultry disease agents exotic to the United States,
3. A written statement confirming that the material was derived only from laboratory mammals that did not originate from a facility where work with exotic disease agents affecting livestock or avian species is conducted, and
4. A written statement which identifies the immunogen for antibodies/antiserum, if applicable.

USDA, APHIS, VS recommends that this document be supplied on foreign producer/shipper letterhead, with the letterhead containing the physical address of the foreign producer/shipper. USDA, APHIS, VS further recommends that the document, written in a clear and concise manner, accompany each shipment, and be presented as a separate document for review by the DHS, CBP Agricultural Specialist at the U.S. port of arrival. We do not recommend that the foreign producer/shipper place this document inside the shipping containers.

We further recommend that you provide a copy of this guidance to your foreign producer/shipper.

If the live laboratory mammals or laboratory mammal material to be imported cannot meet these criteria, then a USDA import permit may be required.

USDA APHIS VS Permit applications can be submitted by any of the following ways:

- Online via eFile: https://efile.aphis.usda.gov/s/
- By e-mail: Submit a completed VS 16-3 (found on Animal Health Permits) to apie@usda.gov
- Contact us at apie@usda.gov or 301-851-3300 with questions/concerns.

*The term livestock includes any bovine, ovine, caprine, porcine, equine, cervid, fish and shellfish.

Guideline 1104: Amphibians, Fish, Reptiles, Shellfish and Aquatic Species (includes venom)

This guideline applies to:

- Amphibians, fish, reptiles, shellfish, aquatic species and/or their materials such as: blood, chondroitin, collagen, emulsions, extracts, feces, fluids, gelatin,

glucosamine, oils, tissues, serum, urine, and venom, from these species.

This guideline does not apply to:

- Bloodworms, antivenom, hydrosylates, processed animal proteins (PAPs) (e.g. rendered fats), meals (e.g. fish meal), monoclonal antibodies, hybridomas, cell lines (Refer to Guideline #1120 for cell/tissue cultures and their products), and live fish species susceptible to Spring Viremia of Carp (SVC) from all countries. For the list of regulated SVC species and import requirements (including permit application) please visit the following web site: Import Live Animals

(revised September 2019)

Introduction

Materials derived from all animals are potentially subject to U.S. Department of Agriculture (USDA) regulations and must be cleared by Department of Homeland Security Customs and Border Protection (CBP) Agricultural Specialists/Inspectors at the port of arrival before entry into the United States is authorized. A USDA, APHIS, Veterinary Services (VS) Import Permit is required for animal material that may pose a risk of introducing foreign livestock and poultry diseases into the United States. However, material from the above listed animals that have not been inoculated with or exposed to any livestock or poultry disease agents or antigens may enter the United States without USDA restrictions.

NOTE: The U.S. Fish and Wildlife Service has jurisdiction over the importation of Convention on International Endangered Species of Wild Fauna and Flora (CITES) listed animals. Please contact their Office of Management Authority at 800-358-2104. The National Oceanic and Atmospheric Administration (NOAA) provides information regarding import of both marine mammals and seafood at https://www.fisheries.noaa.gov/topic/international-affairs.

Procedures

A USDA VS Import Permit will not be required for these types of animal products if DHS, CBP Agricultural Specialists/Inspectors are provided documentation which may include: manifests, invoices, foreign producer/shipper statements on letterhead, or other shipping documents which provide the following information:

1. Identification of the material, and
2. The species of origin.

VS recommends that this information is available for review by the DHS, CBP Agricultural Specialists/Inspectors upon arrival of the shipment at the U.S. port of arrival. We do not recommend that it be placed inside the shipping container.

We further recommend that you provide a copy of this guideline to your foreign producer/shipper.

If the amphibians, fish, reptiles, shellfish, aquatic species and/or their materials cannot meet these criteria, then a USDA import permit may be required.

IMPORT PERMIT FOR PRODUCTS AND BYPRODUCTS (For live animal applications, please visit the website listed above)

USDA APHIS VS Permit applications can be submitted by any of the following ways:

- Online via eFile: https://efile.aphis.usda.gov/s/
- By e-mail: Submit a completed VS 16-3 (found on Animal Health Permits) to apie@usda.gov
- Contact us at apie@usda.gov or 301-851-3300 with questions/concerns.

Guideline 1105: Chemically Synthesized Materials

This guideline applies to:

- Biochemicals/materials that do not contain, were not derived from, and were not exposed to an animal, microorganism, or cell culture product at any step in the production process.

This guideline does not apply to:

- Nucleic acids that contain sequences homologous to genes of livestock or poultry animals or organisms or vectors which are known to cause or transmit disease in livestock or poultry. This exclusion from the guideline applies to nucleic acids produced through polymerase chain reaction (PCR) or by another nucleic acid amplification method/protocol.
- Biochemicals/materials that contain, were derived from, or were exposed to an animal, microorganism, or cell culture product at any step in the production process.

Effective April 14, 1998 (Revised November 2023)

Introduction

Biochemicals/materials derived from any animal, including those materials produced with an animal, microorganism, or cell culture product, are potentially subject to U.S. Department of Agriculture (USDA) regulations and must be cleared by Department of Homeland Security, Customs and Border Protection (DSH, CBP) Agricultural Specialists at the U.S. port of arrival before entry into the United States is authorized. A USDA import permit is required for animal material that may pose a risk of introducing exotic animal diseases into the United States. However, chemically synthesized biochemicals/materials that do not contain, were not derived from, and were not exposed to an animal, microorganism, or cell culture product at any step in the production process may enter the country without USDA, Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) restrictions.

Procedures

A USDA import permit will not be required for chemically synthesized biochemicals/materials that do not contain, were not derived from, and were not exposed to an animal, microorganism, or cell culture product at any step in the production process. In order to facilitate correct identification of the shipment and to ensure timely delivery, USDA, APHIS, VS recommends that the following documentation accompany each shipment:

1. A written statement identifying the biochemicals/materials (name).
2. A written statement confirming the biochemicals/materials are chemically synthesized.
3. A written statement confirming the biochemicals/materials do not contain any animal, microorganism, or cell culture product.
4. A written statement confirming the biochemicals/materials were not derived from and were not exposed to any animal, microorganism, or cell culture product at any step in the production process.

USDA, APHIS, VS recommends that this document be supplied on foreign producer/shipper letterhead, with the letterhead containing the physical address of the foreign producer/shipper. USDA, APHIS, VS further recommends that the

document, written in a clear and concise manner, accompany each shipment, and be presented as a separate document for review by the DHS, CBP Agricultural Specialists at the U.S. port of arrival. We do not recommend that the foreign producer/shipper place this document inside the shipping containers.

We further recommend that you provide a copy of this guideline to your foreign producer/shipper.

If the chemically synthesized biochemicals/materials to be imported cannot meet these criteria, then a USDA import permit may be required.

USDA APHIS VS Permit applications can be submitted by any of the following ways:

- Online via eFile: https://efile.aphis.usda.gov/s/
- By e-mail: Submit a completed VS 16-3 (found on Animal Health Permits) to apie@usda.gov
- Contact us at apie@usda.gov or 301-851-3300 with questions/concerns.

Guideline 1107: Importation of Lactose and Lactose Derivatives

This guideline applies to:

- Products for human and animal consumption including but not limited to pharmaceuticals, nutraceuticals, dietary/nutritional supplements, culture media, medical devices, placebos, and investigational pharmaceuticals that contain lactose (milk sugar) and the following lactose derivatives, galactose and lactulose, as the ONLY animal origin ingredient. This would include bulk amounts of lactose or galactose or lactulose.

This guideline does not apply to:

- Products that contain other animal origin ingredients besides lactose or galactose or lactulose

(revised September 2016)

Introduction

Material derived from any animal is potentially subject to U.S.Department of Agriculture (USDA) regulations and must be cleared by Department of Homeland

Security, Customs and Border Protection (DHS, CBP) Agricultural Specialists/Officers at the U.S. port of arrival before entry into the United States is authorized. A USDA import permit is required for animal material that may pose a risk of introducing foreign livestock and poultry diseases into the United States. However, the USDA has assessed the risk of lactose (milk sugar) and the following lactose derivatives, galactose and lactulose, and determined that they are not a viable vectors for Foot and Mouth Disease (FMD), and the risk of entry of FMD via products containing lactose or galactose or lactulose is negligible. Therefore, products that contain lactose or galactose or lactulose as the **ONLY** animal origin ingredient may enter the United States without USDA, Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) restrictions.

The U.S. Food and Drug Administration have primary jurisdiction over these materials.

They should be contacted for their importation requirements at the following locations:

U.S. Food and Drug Administration (FDA)
Division of Import Operations and Policy, HFC-170
5600 Fishers Lane, Rockville, MD 20857
Tel. (301) 796-0356

Procedures

A USDA, APHIS, VS import permit will not be required for pharmaceuticals, nutraceuticals, dietary/nutritional supplements, culture media, and products for human and animal consumption that contain lactose or galactose or lactulose as the ONLY animal derived ingredient. In order to facilitate correct identification of the shipment and to ensure timely delivery, USDA, APHIS, VS recommends that the following documentation or information accompanies each shipment, and be presented for review by the DHS, CBP Agricultural Specialists/Inspectors at the U.S. port of arrival.

- A document on company letterhead prepared by the producer/manufacturer, shipper, or seller identifying lactose or galactose or lactulose as the **only** animal origin ingredient; OR

- An official government certificate identifying lactose or galactose or lactulose as the only animal derived ingredient

We do not recommend that the foreign producer/shipper place this documentation inside the shipping containers. A copy of this Guideline for Importation should be provided for your producer/shipper.

If the pharmaceuticals, nutraceuticals, dietary/nutritional supplements, culture media, and products for human and animal consumption, etc. to be imported cannot meet the criteria, then a USDA import permit may be required. Permit applications may be obtained several ways:

Import Permit

USDA APHIS VS Permit applications can be submitted by any of the following ways:

- Online via eFile: https://efile.aphis.usda.gov/s/
- By e-mail: Submit a completed VS 16-3 (found on Animal Health Permits) to apie@usda.gov
- Contact us at apie@usda.gov or 301-851-3300 with questions/concerns.

Applicable Federal Regulation

- 9 CFR 94.16

Guideline 1110: Microbially Produced Materials

This guideline applies to:

- Microbially produced materials such as: enzymes, plasmids, proteins, hormones, extracts, phages and/or DNA.

(revised May 2014)

Introduction

Materials derived from any animal, or produced with animal products or extracts of microorganisms, are potentially subject to U.S. Department of Agriculture (USDA) regulations and must be cleared by Department of Homeland Security, Customs and

Border Protection (DHS, CBP) Agricultural Specialists/Inspectors at the port of arrival before entry into the United States is authorized. A USDA import permit is required for animal material that may pose a risk of introducing foreign livestock and poultry diseases into the United States. However, microbes (usually E. coli or yeasts) that do not express material of a foreign livestock and/or poultry disease agent may enter the United States without USDA restrictions.

Procedures

A USDA VS Import Permit will not be required for microbially produced biochemicals if DHS, CBP Agricultural Specialists/Inspectors are provided documentation which may include: manifests, invoices, foreign producer/shipper statements on letterhead, or other shipping documents which provide the following information:

1. An accurate description of the material.
2. A declaration, (if applicable), indicating that the material is produced by microbial fermentation.
3. A declaration stating the preparation does not contain any animal derived additives, such as albumin, OR, if the preparation does contain animal derived additives, a declaration identifying the additives and stating that the product will be used only in vitro.

This information must be available for review by the DHS, CBP Agricultural Specialist/Inspector at the port of arrival.

- Do not put documents INSIDE shipping containers.
- Please instruct your shippers to provide this information.
- If the above information is not supplied, the shipment will be subject to delays. If the material to be imported cannot meet these criteria, then a USDA import permit may be required.

Import Permit

USDA APHIS VS Permit applications can be submitted by any of the following ways:

- Online via eFile: https://efile.aphis.usda.gov/s/
- By e-mail: Submit a completed VS 16-3 (found on Animal Health Permits) to apie@usda.gov
- Contact us at apie@usda.gov or 301-851-3300 with questions/concerns.

Guideline 1114: Recombinant Microbes and Their Products

Including:

- Microbes (bacteria, viruses, yeasts/fungi), proteins, hormones, extracts, plasmids, DNA, RNA.

Not Including:

- Materials produced by cell culture techniques.

Effective October, 1998 (revised June 2007)

Introduction

Materials derived from any animal or produced with animal products or extracts of microorganisms are potentially subject to U.S. Department of Agriculture (USDA) regulations and must be cleared by USDA inspectors at the port of arrival before entry into the United States is authorized. A USDA permit is required for any material that may pose a risk of introducing epizootic livestock diseases exotic to the United States . However, recombinant non-pathogenic bacteria/yeasts (such as E. coli & Saccharomyces cerevisiae) and their products that are not related to livestock or avian species or disease causing agents and that do not contain animal products such as albumin or serums may be brought into the country without USDA veterinary restrictions.

Procedures

A USDA veterinary import permit will not be required for recombinant microbes or their products if the following is provided in the shipping documents:

1. A detailed name or description of the microbe/recombinant product, including genetic insert.
2. For recombinant products, a declaration with the shipment confirming that the material is produced by recombinant microbial expression (vector must not be considered pathogenic for livestock* or avian species) AND that the organism does not contain genes or express antigens of livestock or poultry disease agents.

3. A declaration stating the preparation does not contain any animal derived additives, such as albumin, OR, if the preparation does contain animal derived additives, a declaration identifying the additives and stating that the product will be used only in vitro.

The above information should be supplied with each shipment in a clear and concise manner and be available for review by the USDA Inspector at the port of arrival. We recommend that a separate memorandum or letter be included with the shipping documents, such as U.S. Customs declaration and invoice.

Please instruct your shippers to provide this information.

If the above information is not supplied, the shipment will be subject to delays. If the material to be imported cannot meet these criteria, a USDA import permit may be required.

USDA APHIS VS Permit applications can be submitted by any of the following ways:

- Online via eFile: https://efile.aphis.usda.gov/s/
- By e-mail: Submit a completed VS 16-3 (found on Animal Health Permits) to apie@usda.gov
- Contact us at apie@usda.gov or 301-851-3300 with questions/concerns.

**The term, livestock, includes any bovine, ovine, caprine, porcine, and equine animal*

Guideline 1116: Non-Pathogenic Microorganisms (and their extracts)

Including:

- Environmental or water organisms, such as algae.

Effective November 7, 2014

Introduction

Microorganisms are potentially subject to U.S. Department of Agriculture (USDA) regulations and must be cleared by CBP inspectors at the port of arrival before entry into the United States is authorized. A USDA permit is required for any microorganism that is known to cause infectious, contagious, or communicable diseases of livestock or poultry. However, non-pathogenic bacteria, viruses, algae,

or yeast (fungi) may be imported into the country without USDA veterinary restrictions.

Import requirements for plant pathogens may be obtained by contacting Biological Assessment and Taxonomic Support:

USDA, APHIS, PPQ
4700 River Road, Unit 133
Riverdale, MD 20737
Main: 301-851-2046
Fax: 301-734-8700

Procedures

A USDA veterinary import permit will not be required for specimens if the following is provided in the shipping documents:

1. A detailed description of the microorganism (genus and species),
2. A written declaration indicating that the microorganism is not considered to be pathogenic for livestock or poultry.

This information should be supplied as statements on producer/shipper letterhead in a clear and concise manner and be available for review by the USDA Inspector at the Portof Arrival. We recommend that a separate memo or letter be included with the shipping documents, such as U.S. Customs declaration and invoice. Do not put documents INSIDE shipping containers.

Please instruct your shippers to provide this information.

If the above information is not supplied, the shipment may be subject to delays. If the material to be imported cannot meet these criteria, then a USDA import permit may be required.

How to Submit a Permit Application

USDA APHIS VS Permit applications can be submitted by any of the following ways:

- Online via eFile: https://efile.aphis.usda.gov/s/
- By e-mail: Submit a completed VS 16-3 (found on Animal Health Permits) to apie@usda.gov

- Contact us at apie@usda.gov or 301-851-3300 with questions/concerns.

Guideline 1119: Pet Chews and Treats Made of Antlers or Rawhide

Effective March 31, 2016

Introduction

Material derived from any animal is potentially subject to U.S. Department of Agriculture (USDA) regulations and must be cleared by Department of Homeland Security, Customs and Border Protection (DHS, CBP) Agricultural Specialists at the U.S. port of arrival before entry into the United States is authorized. A USDA import permit is required for animal material that may pose a risk of introducing foreign animal diseases into the United States.

Rawhide and antlers intended for use as pet chews/treats may be imported without a USDA VS Import Permit provided the conditions of this guideline are met.

Entry

1. **Rawhide:** Plain rawhide intended for use as pet chews/treats (may be cut, molded, or in sheets) which has not been ground, flavored, basted, colored, or otherwise processed is allowed entry without a VS Import Permit. All shipments are subject to inspection by CBP personnel at the U.S. port of arrival.

   Rawhide which does not meet the above requirement must be accompanied by a USDA VS Import Permit.
   *Note: Rawhide is defined as untanned cattle skin made into leather by dehairing, drying, liming, and other processes. Products which do not meet this description, such as pork hides labelled as "rawhide" require a VS Import Permit.

2. **Antlers:** Plain, naturally shed antlers intended for use as pet chews/treats which have not been ground, powdered, or flavored, originating from a region free of FMD and Rinderpest are allowed entry without a VS Import Permit when accompanied by an original health certificate, signed by a full-time salaried veterinarian of the agency responsible for animal health in the exporting region which states the following:

    - The name of the FMD/Rinderpest free country of origin of the antlers; and
    - That the antlers are clean, dry, and free of soil, clay, sand, tissue, and un-dried pieces of hide, flesh, sinew, and other related material.

Antlers originating from a region affected by FMD and/or Antlers in Velvet must be accompanied by a VS Import Permit unless consigned to an approved establishment.

To view the USDA list of regions considered to be free of FMD please visit the USDA APHIS web site at; www.aphis.usda.gov scroll down and click on the “import animal or animal product” link, scroll down on the next page and click on “country animal disease status”, and then click on the “Countries/Regions Free of Foot-and-Mouth Disease” (FMD).

USDA APHIS VS Permit applications can be submitted by any of the following ways:

- Online via eFile: https://efile.aphis.usda.gov/s/
- By e-mail: Submit a completed VS 16-3 (found on Animal Health Permits) to apie@usda.gov
- Contact us at apie@usda.gov or 301-851-3300 with questions/concerns.

Guideline 1120: Cell Cultures/Lines, Recombinant Cell Cultures/Lines, and Their Products (for in vitro use)

Including:

- Monoclonal antibodies, cell culture supernatants, ascitic fluid, cell extracts, hybridomas, cell cultures/lines which are not derived from livestock*.

Not including:

- Cell lines of livestock* and their products, microbial cultures and their products.

Introduction

Materials derived from all animals are potentially subject to U.S.Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) regulations and must becleared by USDA inspectors at the port of arrival before entry into theUnited States is authorized. A USDA, APHIS, VS permit is required formaterial derived from animals that may pose a risk of introducing

livestock diseases exotic to the United States.

Cell lines and other products of cell lines, including monoclonal antibodies, which:

1. Are not derived from livestock or avian species;
2. Are for in vitro use;
3. Have not been exposed to livestock or avian disease agents exotic to the United States; and
4. Do not produce antigens or contain genes of livestock or avian disease agents or do not produce monoclonal antibodies directed against livestock or avian disease agents.

May be imported without a USDA permit.

In addition, monoclonal antibodies intended for in vivo human use do not require a permit.

However, (1) cell lines derived from livestock or avian species, (2) cell lines derived from any species which will be used for in vivo use, and (3) cell lines of any species which may have been exposed to exotic livestock or avian disease agents will require a USDA, VS import permit.

Procedures

A USDA, VS import permit will NOT be required for cell lines other products of cell lines, including monoclonal antibodies if the shipment is accompanied by:

A statement from the shipper/producer which clearly states or identifies:

a. the material as a cell line or another product of a cell line (including monoclonal antibodies);
b. the immunogen (what the monoclonal antibody is directed against), as applicable;
c. the material is for in vitro use OR the material is for in vivo human use;
d. the material does not come from a facility where work with exotic viruses affecting livestock and avian species is conducted; and
e. the material is not recombinant OR the material is recombinant but contains no genes and expresses no products of exotic livestock or poultry disease agents.

This information must be supplied as statements and made available for review by the USDA Inspector at the port of arrival.

- Do not put the documents INSIDE the shipping container.
- Please instruct your shippers to provide this information.

If the above information is not supplied, the shipment will be subject to delays. If the material cannot meet these criteria, a USDA import permit may be required.

USDA APHIS VS Permit applications can be submitted by any of the following ways:

- Online via eFile: https://efile.aphis.usda.gov/s/
- By e-mail: Submit a completed VS 16-3 (found on Animal Health Permits) to apie@usda.gov
- Contact us at apie@usda.gov or 301-851-3300 with questions/concerns.

**The term, livestock, includes any avian/poultry, bovine, caprine, fish, ovine, porcine, and equine animal.*

Guideline 1121: Self-Contained Test Kits Containing Animal-Derived Ingredients

(revised) February, 2013

Introduction

Test kits may contain small amounts of animal-derived components. Most test kits are consigned to universities, diagnostic laboratories, or pharmaceutical companies which dispose of them by autoclaving and/or incineration. Therefore, applicable imported test kits present a negligible risk of exposure of U.S. animal populations to exotic disease agents and do not require a USDA, Veterinary Services (VS) import permit.

Procedures

Test Kits Not Requiring a USDA Import Permit:

A USDA Import Permit is not required for test kits if the shipment meets the following conditions and it is recommended that the shipment be accompanied by:

1. A statement on manufacturer's letterhead, or other information used as proof that: the test kits cannot diagnose infectious diseases of animals; and
2. The test kits are pre-packaged and ready for use.

If the material to be imported cannot or does not meet the criteria outlined above on this Guideline, then a USDA, VS or USDA, CVB Import Permit is required.

USDA, VS Import Permit

Test Kits and material(s) that require a USDA, VS import permit:

1. Test Kit Components shipped in bulk: i.e. reagents, calibrators, controls, etc.;
2. Media (such as selective media), petri dishes, filtration units;
3. Kits that do not contain everything for use and/or that are not pre-packed for ready for final sale

USDA APHIS VS Permit applications can be submitted by any of the following ways:

- Online via eFile: https://efile.aphis.usda.gov/s/
- By e-mail: Submit a completed VS 16-3 (found on Animal Health Permits) to apie@usda.gov
- Contact us at apie@usda.gov or 301-851-3300 with questions/concerns.

USDA, CVB Import Permit

Test Kits that can diagnose infectious diseases of animals, imported for any purpose, or for any type of research require a Research and Evaluation Permit from USDA, VS, Center for Veterinary Biologics, Policy, Evaluation and Licensing (CVB, PEL).

1. The telephone number for CVB in Riverdale, Maryland is (301) 851-3609
2. The CVB ePermits portal can be found at the following website: CVB ePermits portal

Please include the information recommended/required by this Guideline along with the shipping documents for each shipment and ensure that it is available for review by USDA authorized inspectors at the port of entry. DO NOT put documents INSIDE the shipping container. If the above information is not available, the shipment may be subject to delays and import compliance fees.

Other Agencies

The Food and Drug Administration and/or the Centers for Disease Control should be contacted for information regarding the import of kits that diagnose human disease.

[1]A self-contained test kit includes everything needed to use the kit assembled in a pre-packaged kit ready for final use.

Guideline 1122: Vitamins and Minerals

(revised July 2017)

Introduction

Materials derived from animals, or produced with animal-origin ingredients, are potentially subject to U.S. Department of Agriculture (USDA) regulations and must be cleared by Department of Homeland Security (DHS) Customs and Border Protection (CBP) personnel at the port of arrival before entry into the United States is authorized.

***IMPORTANT**

Imported products containing plant materials may be subject to regulations enforced by:

- USDA Plant Protection and Quarantine (PPQ), Analysis and Support. Please contact USDA APHIS PPQ Quarantine Policy, Analysis and Support at (301) 851-2220 for more information.
- The U.S. Food and Drug Administration (FDA) also regulates the importation of foods for human consumption and animal feeds and ingredients intended for incorporation into animal feeds. FDA should be contacted regarding their import requirements:

  FDA, Division of Import Operations and Policy, HFC-170
  5600 Fishers Lane, Rockville, MD 20857
  Telephone: (301) 796-0356
  Web address: http://www.fda.gov

Background

Most commercially derived vitamins and minerals are synthetically produced from non-animal origin ingredients. Exceptions include vitamin D3, vitamin A, and dicalcium phosphate.

Procedures

1. A USDA VS Import Permit will NOT be required for bulk shipments or articles containing vitamin A derived from porcine gelatin, vitamins coated with porcine gelatin, and/or vitamin D3 derived from sheep wool grease as the **only** animal origin ingredients (i.e., bulk shipment of animal-derived vitamin D3). Excluding those commodities that meet the terms of #2 or #3 below, bulk shipments or articles containing the above referenced materials will be allowed entry without a USDA VS Import Permit only when the shipment is accompanied by an original certificate issued by a full-time, salaried veterinarian of the national government of the country of export certifying the vitamin A derived from porcine gelatin, vitamins coated with porcine gelatin, and/or vitamin D3 derived from sheep wool grease as the **only** animal-origin ingredients.

2. A USDA VS Import Permit or Government Certification will NOT be required for fully finished food products for human consumption containing vitamin A derived from porcine gelatin, vitamins coated with porcine gelatin, or vitamin D3 as the only animal origin ingredients, or in combination with other exempted animal origin ingredients or non-exempted animal origin ingredients such as milk and eggs when all applicable APHIS import requirements for those other animal origin ingredients have been met. The fully finished food product must be commercially labeled and shelf-stable (not requiring refrigeration).

   Food products or articles containing vitamin A derived from porcine gelatin, vitamins coated with porcine gelatin, or vitamin D3 derived from sheep wool grease (lanolin) listed as animal origin ingredients will be allowed entry without a USDA VS Import Permit and without Government Certification only when meeting the description listed above.

   Examples of fully finished food products include the following as a partial, not all-inclusive list: candy and/or confectioneries, baking mixes, cocoa mixes, drink

mixes, instant cake mixes, instant pudding mixes, liquid drink mixes containing reconstituted dry mix or dry milk products (including those containing sugar), pancake mixes, potato flakes, powdered infant formula, cookie fillings, fully baked goods (excluding moon cakes), egg protein shampoos, mayonnaise, dry plain pasta, dry plain noodles, salad dressings, sauces, pancake mixes, and cake mixes.

3. A USDA VS Import Permit will NOT be required for vitamin D3 derived from **non-animal origin** sources (e.g., recombinant yeast, lichen, or mushrooms).

   Articles other than fully finished food products for human consumption (as described above in #2) containing the aforementioned materials will be allowed entry without a USDA VS Import Permit only when the shipment is accompanied by a manufacturer's declaration stating the vitamin D3:
   1. was produced 1) from lichen, or 2) from mushrooms, or 3) by a fermentation process using a genetically modified yeast, or 4) using a manufacturing process that does not include animal derived material [describe the process]; and
   2. was not derived from any animal origin ingredients, including sheep wool grease (lanolin).
4. A USDA VS Import Permit will NOT be required for dicalcium phosphate.

Articles containing dicalcium phosphate will be allowed entry without a USDA VS Import Permit only when the shipment is accompanied by an original certificate signed by a full-time salaried veterinary officer of the national government of the exporting region, or issued by a veterinarian designated by the national government of the exporting region and endorsed by a full-time salaried veterinary officer of the national government of the exporting region, representing that the veterinarian issuing the certificate was authorized to do so.

The certificate must state the name and BSE risk classification of the exporting region and:

a. The dicalcium phosphate contains no trace of protein or fat, OR
b. The dicalcium phosphate originates from a region of negligible risk (name of the region) for BSE, OR
c. The dicalcium phosphate originates from a region of controlled risk (name of the region) for BSE, is derived from bovines that have passed ante-mortem and

post-mortem inspections, and does not contain SRMs as defined for regions of controlled risk for BSE in 9 CFR § 92.1. SRMS include: (a) Brain skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and the dorsal root ganglia from animals aged 30 months and older; (b) The tonsils and distal ileum of the small intestine from cattle.

If the material cannot meet the criteria outlined in this guideline, then a USDA, APHIS, VS import permit may be required.

Import Permit

USDA APHIS VS Permit applications can be submitted by any of the following ways:

- Online via eFile: https://efile.aphis.usda.gov/s/
- By e-mail: Submit a completed VS 16-3 (found on Animal Health Permits) to apie@usda.gov
- Contact us at apie@usda.gov or 301-851-3300 with questions/concerns.

Guideline 1123: Histopathological Fixed Slides

This guideline applies to histopathological fixed slides that contain:

1. Uninfected animal material
2. Animal material that is infected with microorganisms known to cause infectious, contagious, or communicable diseases of livestock or poultry which are fixed in 10% formalin; or
3. Animal material that is infected with Bovine Spongiform Encephalopathy (BSE) prions, Scrapie prions, or Chronic Wasting Disease (CWD) prions fixed in formic acid.

Does not include:

- This guideline does not apply to histopathological slides or other fixed slides which contain Foot and Mouth Disease virus or Rinderpest virus.

Introduction

Microorganisms are potentially subject to U.S. Department of Agriculture (USDA) regulations and must be cleared at the port of arrival before entry into the United States. A USDA permit is required for any microorganisms that are known to cause infectious, contagious, or communicable diseases of livestock or poultry.

However, specimen slides that are fixed with 10% formalin for a minimum of 24 hours; or BSE, Scrapie, or CWD prion agents fixed in 96% absolute formic acid solution for a minimum of 30 minutes, followed by emersion in fresh 10% formalin for a minimum of 45 hours, may be imported into the US without a USDA Veterinary permit.

In the case of histopathological slides which contain Foot and Mouth Disease virus or Rinderpest virus, importers must apply for a USDA import permit and include the method of inactivation.

Procedures

A USDA import permit will not be required for the importation of histopathological slides if the following is provided in the shipping documents:

A statement from the shipper/producer which clearly states:

1. Detailed and accurate description of the materials.
2. Confirming that the slides were fixed for a minimum of 24 hours in a 10% formalin solution; or slides with BSE, Scrapie, or CWD prions were fixed in 96% absolute formic acid solution for a minimum of 30 minutes, followed by emersion in fresh 10% formalin for a minimum of 45 hours.
3. The slides do not contain Foot and Mouth Disease virus or Rinderpest virus.

USDA, APHIS, VS recommends that this document be supplied on foreign producer/shipper letterhead, with the letterhead containing the physical address of the foreign producer/shipper. USDA, APHIS, VS further recommends that the documentation, written in a clear and concise manner, accompany each shipment, and be presented as a separate document for review by the DHS, CBP Agricultural Specialists at the U.S. port of arrival. We do not recommend that the foreign producer/shipper place this document inside the shipping containers.

Please instruct your shipper to provide this information. We further recommend that you provide a copy of this guideline to your foreign producer/shipper.

If the above information is not supplied, the shipment may be delayed. If the material to be imported cannot meet these criteria, then a USDA permit may be required.

USDA APHIS VS Permit applications can be submitted by any of the following ways:

- Online via eFile: https://efile.aphis.usda.gov/s/
- By e-mail: Submit a completed VS 16-3 (found on Animal Health Permits) to apie@usda.gov
- Contact us at apie@usda.gov or 301-851-3300 with questions/concerns.

Guideline 1125: Guideline for NO INTERSTATE TRANSPORT Permit Required

This guideline applies to:

Materials such as pathogenic microorganisms and vectors - including tissues and blood - which are infectious or contagious to livestock, poultry, or aquatic animals; or are treated, inoculated, or exposed to such pathogens. See VS-Regulated Livestock and Poultry Pathogens (Partial List).

These materials are regulated under alternate Guidelines or regulatory authorities:

- Agents and Toxins regulated by the Federal Select Agent Program.
- Materials imported from outside the United States.
- Materials transported intrastate (within a State).

Effective Date: April 15, 2019

Introduction

The U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS), per Title 9, Code of Federal Regulations (CFR) Part 122, may require a permit for the interstate transport of certain organisms and vectors to protect American agriculture. VS issues such permits for the interstate transport of organisms, vectors, or derivatives thereof – including tissues and blood – which are infectious or contagious to livestock, poultry, or

aquatic species or are treated, inoculated, or exposed to such pathogens. However, VS does not require an interstate transport permit for materials such as organism and vectors, and derivatives thereof, meeting the criteria described below (i.e., which are not infectious, contagious, or treated, inoculated or exposed to any livestock, poultry or aquatic pathogen).

Whether VS requires a permit or not, the material may be regulated by other authorities, including local, State, or Federal regulatory agencies. The shipper and receiver are responsible for identifying and gaining approval from all applicable regulatory and oversight agencies.

Materials and Conditions Where an Interstate Transport Permit is Not Required:

VS does not require an Organisms and Vectors permit (VS Form 16-6A, United States Veterinary Permit for Importation and Transportation of Controlled Materials and Organisms and Vectors) for the interstate transportation of:

1. Non-pathogenic microorganisms not able to spread communicable disease to livestock, poultry, or aquatic animals.
2. Biological agents (such as vaccines, bacterins, blood and blood components, allergenics, somatic cells, antibodies, gene therapy, tissues, and recombinant therapeutic proteins) not capable of introducing or disseminating infectious diseases to livestock, poultry, or aquatic animals.
3. Toxins or toxoids that are not infectious (able to multiply) or able to spread communicable disease to livestock, poultry, or aquatic animals.
4. Samples from animals or aquaculture systems not confirmed as infected by laboratory testing, not exposed to or suspected of illness caused by an infectious pathogen, and not experimentally infected with organisms or vectors.
5. Inactivated forms of pathogens.
6. Viable or dead insect vectors – excluding screwworms and other arthropods such as ticks – of livestock, poultry, or aquatic animal pathogens reared in a U.S. laboratory colony, not known to have been exposed to or to carry pathogens on the VS Pathogen List.

Procedures

Shipping Materials Without an Interstate Transport Permit

VS recommends that shippers sending materials for which VS does not require an interstate transport permit provide the recipient a written statement describing the material, including genus and species (if applicable). The statement should also affirm the material is not a pathogen of livestock, poultry, or aquatic animals; and (if applicable) describe the inactivation or extraction method for any deactivated materials.

Obtaining a Permit Application

If the material does not meet the above conditions, the recipient may need a permit. The recipient may obtain an application for a permit (VS Form 16-3).

USDA APHIS VS Permit applications can be submitted by any of the following ways:

- Online via eFile: https://efile.aphis.usda.gov/s/
- By e-mail: Submit a completed VS 16-3 (found on Animal Health Permits) to apie@usda.gov
- Contact us at apie@usda.gov or 301-851-3300 with questions/concerns.

Additional information on application submission and payment is available at the Organisms and Vectors web page.

Guideline 1127 – Movement Conditions for Certain Swine Products and Swine Byproducts from Puerto Rico & U.S. Virgin Islands to Continental United States

This guideline applies to:

- Swine products and swine byproducts from Puerto Rico (PR) and the U.S. Virgin Islands (USVI) moving interstate to other parts of the United States, including other U.S. territories.

This guideline does not apply to:

- Live swine and swine germplasm, transport of which will continue to be suspended from PR and USVI **to other parts of the United States, including other U.S. territories.**

Introduction

On September 17, 2021, the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) issued Federal Order DA-2021-0002 suspending the interstate movement of all live swine, swine germplasm, swine products, and swine byproducts from Puerto Rico (PR) and the U.S. Virgin Islands (USVI) **to other parts of the United States, including other U.S. territories** until sufficient mitigations could be established to authorize such movement. APHIS took this action out of an abundance of caution to further safeguard the U.S. swine herd and protect the interests and livelihoods of U.S. pork producers from African swine fever (ASF), which was confirmed in the Dominican Republic on July 28, 2021.

APHIS subsequently issued revised Federal Order DA-2021-0003 on December 2, 2021, outlining mitigations to allow certain commercially processed swine products and swine byproducts from PR and USVI to move **to other parts of the United States, including other U.S. territories**, while continuing to provide the necessary protections against ASF.

The September and December 2021 Federal Orders do not restrict the inter-island movement of cooked and raw swine products between PR and the USVI in both passenger baggage (travelers) and cargo (commercial).

Procedures

For commercially labeled processed swine products or swine byproducts from PR or USVI in passenger baggage: Only canned meat/meat products or baked goods that are commercially labeled and packaged, and shelf-stable without requiring refrigeration will be eligible for entry. The passenger must declare swine products and swine byproducts to the USDA inspector at the airport before leaving PR or to the U.S. Customs and Border Protection officer before leaving the USVI.

For commercially labeled processed swine products or swine byproducts from PR or the USVI in cargo (including mail), a USDA Veterinary Services (VS) transport permit will be required unless the commodity has met the cooking and documentation requirements below.

A USDA VS transport permit will not be required if the processed swine products and swine byproducts are accompanied by supporting documentation confirming one of the following heat treatments:

- The swine products or swine byproducts were fully cooked by a commercial method in a container hermetically sealed promptly after filling but before such cooking, so that such cooking and sealing produced a fully sterilized product which is shelf-stable without requiring refrigeration; OR
- The swine products or swine byproducts were heated by other than a flash-heating method to an internal temperature of at least 69 °C (156 °F) throughout after the bones had been removed; OR
- The swine products are pork rind pellets (pork skins) that were cooked in an establishment in one of the following ways:
    - One-step process. The pork skins must be cooked in oil for at least 80 minutes when oil temperature is consistently maintained at a minimum of 114 °C.
    - Two-step process. The pork skins must be dry cooked at a minimum of 260 °C for approximately 210 minutes after which they must be cooked in hot oil (deep-fried) at a minimum of 104 °C for an additional 150 minutes.

Supporting documentation verifying the above requirements must include a signed producer statement on company letterhead. In addition, information on invoices, bills of lading, packing lists, or other verifying documents may also be required to verify compliance with the above requirements. The commodities must be commercially labeled.

VS recommends that the supporting documentation of the above treatments accompany each shipment. VS does not recommend that the documentation be placed inside the shipping container and further recommends that a copy of this guideline be provided to the producer/shipper in PR and/or the USVI.

For fresh frozen/chilled pork/pork meat products from PR or the USVI in commercial cargo – VS transport permits will be required for all commercial cargo shipments of fresh frozen/chilled pork/pork meat products, and other swine products and swine byproducts not meeting the above requirements that are shipped directly from PR or the USVI to other parts of the United States, including other U.S. territories outside of the protection zone (PR and USVI). Please contact USDA APHIS directly at APIE@usda.gov for specific permitting procedures.

Transport Permit for Products and Byproducts

When applying for a USDA VS transport permit, provide documentation such as manifests, invoices, producer/shipper statements on official company letterhead, or other shipping documents which provide the following information:

1. Identification of the material, and
2. The processing treatment.

The permit application and instructions, including information on the user fee and e-authentication, is available on the APHIS web page Animal Health Permits.

The current permit processing fee is $150 and permit duration is one year.

USDA APHIS VS Permit applications can be submitted by any of the following ways:

- Online via eFile: https://efile.aphis.usda.gov/s/
- By e-mail: Submit a completed VS 16-3 (found on Animal Health Permits) to apie@usda.gov
- Contact us at apie@usda.gov or 301-851-3300 with questions/concerns.

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