

back end; increased sensitivity to noise and sudden movement; tremor, “star gazing,” head pressing, recumbency, or other signs of neurological disease or chronic wasting.

*Tallow derivative.* Any chemical obtained through initial hydrolysis, saponification, or transesterification of tallow; chemical conversion of material obtained by hydrolysis, saponification, or transesterification may be applied to obtain the desired product.

*United States* means the several States, the District of Columbia, Guam, the Northern Mariana Islands, Puerto Rico, the Virgin Islands of the United States, and all other territories and possessions of the United States.

*Veterinary Services* means the Veterinary Services unit of the Animal and Plant Health Inspection Service, United States Department of Agriculture.

[28 FR 5981, June 13, 1963, as amended at 56 FR 19796, Apr. 30, 1991; 56 FR 63869, Dec. 6, 1991; 62 FR 56024, Oct. 28, 1997; 66 FR 42600, Aug. 14, 2001; 70 FR 551, Jan. 4, 2005; 70 FR 71218, Nov. 28, 2005; 74 FR 66226, Dec. 15, 2009; 78 FR 73001, Dec. 4, 2013; 79 FR 71007, Dec. 1, 2014]

#### § 95.2 Region of origin.

No products or materials specified in the regulations in this part shall be imported unless there be shown upon the commercial invoice, or in some other manner satisfactory to the Deputy Administrator, Veterinary Services, the name of the region of origin of such product or material: *Provided*, That the region of origin shall be construed to mean (a) in the case of an animal by-product, the region in which such product was taken from an animal or animals, and (b) in the case of other materials, the region in which such materials were produced.

[28 FR 5981, June 13, 1963, as amended at 62 FR 56024, Oct. 28, 1997]

#### § 95.3 Byproducts from diseased animals prohibited.

The importation of any animal by-product taken or removed from an animal affected with anthrax, foot-and-mouth disease, highly pathogenic avian

influenza, Newcastle disease, or rinderpest is prohibited.

[28 FR 5981, June 13, 1963, as amended at 79 FR 71007, Dec. 1, 2014]

#### § 95.4 Restrictions on the importation of processed animal protein, offal, tankage, fat, glands, certain tallow other than tallow derivatives, and serum due to bovine spongiform encephalopathy.

(a) Except as provided in paragraphs (c), (d), (e), (f), or (g) of this section or in § 95.15, any of the materials listed in paragraph (b) of this section derived from animals, or products containing such materials, are prohibited importation into the United States if paragraph (a)(1), (a)(2), or (a)(3) of this section applies:

(1) The animals have been in any region listed in paragraph (a)(4) of this section;

(2) The materials have been stored, rendered, or otherwise processed in a region listed in paragraph (a)(4) of this section; or

(3) The materials have otherwise been associated with a facility in a region listed in paragraph (a)(4) of this section.

(4) Albania, Andorra, Austria, Belgium, Bosnia-Herzegovina, Bulgaria, Canada, Croatia, the Czech Republic, Denmark, the Federal Republic of Yugoslavia, Finland, France, Germany, Greece, Hungary, the Republic of Ireland, Israel, Italy, Japan, Liechtenstein, Luxembourg, the Former Yugoslav Republic of Macedonia, Monaco, Norway, Oman, the Netherlands, Poland, Portugal, Romania, San Marino, Slovakia, Slovenia, Spain, Sweden, Switzerland, and the United Kingdom.

(b) *Restricted materials:* (1) Processed animal protein, tankage, offal, and tallow other than tallow derivatives, unless in the opinion of the Administrator, the tallow cannot be used in feed;

(2) Glands, unprocessed fat tissue, and blood and blood products;

(3) Processed fats and oils, and derivatives of processed animal protein, tankage, and offal; or

(4) Derivatives of glands and blood and blood products.

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(c) The import prohibition in paragraph (a) of this section does not apply if the following conditions are met prior to importation:

(1) The material is derived from one of the following:

(i) A nonruminant species and the material is not ineligible for importation under §95.13 or §95.14;

(ii) Cervids or camelids;

(iii) Bovines, and the material is not ineligible for importation under the conditions of §95.5, §95.6, §95.7, §95.8, §95.9, §95.10, or §95.12; or

(iv) Ovines or caprines that have never been in any region listed in paragraph (a)(4) of this section.

(2) In any region other than Canada that is listed in paragraph (a)(4) of this section, all steps of processing and storing the material are carried out in a facility that has not been used for the processing and storage of materials derived from ovines or caprines that have been in any region that is listed in paragraph (a)(4) of this section.

(3) In Canada, all steps of processing and storing the material are carried out in a facility that has not been used for the processing and storage of materials derived from ovines and caprines that have been in any region other than Canada that is listed in paragraph (a)(4) of this section.

(4) The facility demonstrates to APHIS that the materials intended for exportation to the United States were transported to and from the facility in a manner that would prevent cross-contamination by or commingling with prohibited materials.

(5) If the facility processes or handles any material derived from mammals, inspection of the facility for compliance with the provisions of this section is conducted at least annually by a representative of the government agency responsible for animal health in the region, unless the region chooses to have such inspection conducted by APHIS. If APHIS conducts the inspections required by this section, the facility has entered into a cooperative service agreement executed by the operator of the facility and APHIS. In accordance with the cooperative service agreement, the facility must be current in paying all costs for a veterinarian of APHIS to inspect the facility (it is an-

anticipated that such inspections will occur approximately once per year), including travel, salary, subsistence, administrative overhead, and other incidental expenses (including excess baggage provisions up to 150 pounds). In addition, the facility must have on deposit with APHIS an unobligated amount equal to the cost for APHIS personnel to conduct one inspection. As funds from that amount are obligated, a bill for costs incurred based on official accounting records will be issued to restore the deposit to the original level, revised as necessary to allow for inflation or other changes in estimated costs. To be current, bills must be paid within 14 days of receipt.

(6) The facility allows periodic APHIS inspection of its facilities, records, and operations.

(7) Each shipment to the United States is accompanied by an original certificate signed by a full-time, salaried veterinarian of the government agency responsible for animal health in the exporting region certifying that the conditions of paragraphs (c)(1) through (c)(5) of this section have been met.

(8) The person importing the shipment has applied for and obtained from APHIS a United States Veterinary Permit for Importation and Transportation of Controlled Materials and Organisms and Vectors by filing a permit application on VS Form 16-3. (VS Form 16-3 may be obtained from APHIS, Veterinary Services, National Center for Import and Export, 4700 River Road Unit 38, Riverdale, MD 20737-1231, or electronically at [http://www.aphis.usda.gov/animal\\_health/permits/](http://www.aphis.usda.gov/animal_health/permits/).)

(d) Except as provided in paragraph (e) of this section and in §95.15, serum from ovines or caprines that have been in any region listed in paragraph (a)(4) of this section is prohibited importation into the United States, except for scientific, educational, or research purposes if the Administrator determines that the importation can be made under conditions that will prevent the introduction of BSE into the United States. Such serum must be accompanied by a permit issued by APHIS in accordance with §104.4 of this chapter

and must be moved and handled as specified on the permit.

(e) The importation of serum albumin, serocolostrum, amniotic liquids or extracts, and placental liquids derived from ovines or caprines that have been in any region listed in paragraph (a)(4) of this section, and collagen and collagen products that are derived from ovines or caprines and that would otherwise be prohibited under paragraphs (a) and (b) of this section, is prohibited unless the following conditions have been met:

(1) The article is imported for use as an ingredient in cosmetics;

(2) The person importing the article has obtained a United States Veterinary Permit for Importation and Transportation of Controlled Materials and Organisms and Vectors by filing a permit application on VS Form 16-3 (VS Form 16-3 may be obtained from APHIS, Veterinary Services, National Center for Import and Export, 4700 River Road Unit 38, Riverdale, MD 20737-1231, or electronically at [http://www.aphis.usda.gov/animal\\_health/permits/](http://www.aphis.usda.gov/animal_health/permits/)); and

(3) The permit application states the intended use of the article and the name and address of the consignee in the United States.

(f) Insulin otherwise prohibited under paragraphs (a) and (b) of this section may be imported if the insulin is for the personal medical use of the person importing it and if the person importing the shipment has applied for and obtained from APHIS a United States Veterinary Permit for Importation and Transportation of Controlled Materials and Organisms and Vectors. To apply for a permit, file a permit application on VS Form 16-3 (available from APHIS, Veterinary Services, National Center for Import and Export, 4700 River Road Unit 38, Riverdale, MD 20737-1231, or electronically at [http://www.aphis.usda.gov/animal\\_health/permits/](http://www.aphis.usda.gov/animal_health/permits/)). The application for such a permit must state the intended use of the insulin and the name and address of the consignee in the United States.

NOTE TO PARAGRAPH (f): Insulin that is not prohibited from importation under this paragraph may be prohibited from importation under other Federal laws, including the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321 *et seq.*

(g) Offal that is otherwise prohibited under paragraphs (a) and (b) of this section because it is derived from ovines or caprines that have been in a region listed in paragraph (a)(4) of this section may be imported into the United States if the offal is derived from ovines or caprines from Canada that have not been in a region listed in paragraph (a)(4) of this section other than Canada, and the following conditions are met:

(1) The offal:

(i) Is derived from ovines or caprines that were less than 12 months of age when slaughtered and that are from a flock or herd subject to a ruminant feed ban equivalent to the requirements established by the U.S. Food and Drug Administration at 21 CFR 589.2000;

(ii) Is not derived from ovines or caprines that have tested positive for or are suspect for a transmissible spongiform encephalopathy;

(iii) Is not derived from animals that have resided in a flock or herd that has been diagnosed with BSE; and

(iv) Is derived from ovines or caprines whose movement was not restricted in the BSE minimal-risk region as a result of exposure to a transmissible spongiform encephalopathy.

(2) Each shipment to the United States 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 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 that the requirements of paragraph (g)(1) of this section have been met; and

(3) The shipment, if arriving at a U.S. land border port, arrives at a port listed in §94.25(c) of this subchapter.

(Approved by the Office of Management and Budget under control numbers 0579-0015, 0579-0234, and 0579-0393)

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