

(b) The collagen is derived from hides and skins, provided the collagen has not been commingled with materials ineligible for entry into the United States.

(c) The collagen is derived from the bones of bovines that originated from a region of negligible risk for BSE.

(d) The collagen is derived from the bones of bovines that originated from a region of controlled or undetermined risk for BSE and meets the requirements of paragraphs (d)(1) through (d)(4) of this section:

(1) The bones from which the collagen was derived were derived from bovines that passed ante-mortem and post-mortem inspection;

(2) The bones from which the collagen was derived did not include the skulls of bovines or the vertebral column of bovines 30 months of age or older;

(3) The bones were subjected to a process that includes all of the following steps, or to a process at least as effective in reducing BSE infectivity:

(i) Degreasing;

(ii) Acid demineralization;

(iii) Acid or alkaline treatment;

(iv) Filtration; and

(v) Sterilization at 138 °C (280.4 °F) or greater for a minimum of 4 seconds; and

(4) The collagen has not been commingled with materials ineligible for entry into the United States.

(e) The collagen is accompanied to the United States 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 that the requirements of paragraph (b), (c), or (d) of this section, as applicable, have been met and, for collagen other than that described in paragraph (b) of this section, must indicate the BSE risk classification of the exporting region.

(f) The Administrator determines that the collagen will not come into

contact with ruminants in the United States and can be imported under conditions that will prevent the introduction of BSE into the United States, and the person importing the collagen has obtained 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/). The application for such a permit must state the intended use of the collagen and the name and address of the consignee in the United States.

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[78 FR 73003, Dec. 4, 2013]

§ 95.8 Tallow derived from bovines.

(a) The importation of bovine-derived tallow is prohibited unless:

(1) The requirements of either paragraph (b), (c), or (d), as well as the requirements of paragraph (e) of this section are met; or

(2) The requirements of paragraph (f) of this section are met.

(b) The tallow is composed of a maximum level of insoluble impurities of 0.15 percent in weight; or

(c) The tallow originates from a region of negligible risk for BSE; or

(d) The tallow originates from a region of controlled risk for BSE, is derived from bovines that have passed ante-mortem and post-mortem inspections, and has not been prepared using SRMs as defined for regions of controlled risk for BSE in § 92.1 of this subchapter.

(e) The tallow is accompanied to the United States 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

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to do so. The certificate must state that the requirements of paragraph (b), (c), or (d) of this section, as applicable, have been met and, for tallow other than that described in paragraph (b) of this section, must indicate the BSE risk classification of the exporting region.

(f) The Administrator determines that the tallow will not come into contact with ruminants in the United States and can be imported under conditions that will prevent the introduction of BSE into the United States, and the person importing the tallow has obtained 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/). The application for such a permit must state the intended use of the tallow and the name and address of the consignee in the United States.

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§95.9 Derivatives of tallow derived from bovines.

(a) The importation of derivatives of tallow from bovines is prohibited unless the commodity meets the conditions of either paragraph (b), (c), (d), or (e) of this section as well as paragraph (f) of this section, or, alternatively, meets the conditions of paragraph (g) of this section.

(b) The commodity meets the definition of tallow derivative in §95.1.

(c) The derivative is from tallow composed of a maximum level of insoluble impurities of 0.15 percent in weight.

(d) The derivative is from tallow that originates from a region of negligible risk for BSE.

(e) The derivative is from tallow that originates from a region of controlled risk 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 §92.1 of this subchapter.

(f) The tallow derivative is accompanied to the United States 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 that the requirements of paragraph (b), (c), (d), or (e) of this section, as applicable, have been met and, for tallow derivatives other than those described in paragraph (b) or (c) of this section, must indicate the BSE risk classification of the exporting region.

(g) The Administrator determines that the tallow derivative will not come into contact with ruminants in the United States and can be imported under conditions that will prevent the introduction of BSE into the United States, and the person importing the tallow derivative has obtained 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/). The application for such a permit must state the intended use of the tallow derivative and the name and address of the consignee in the United States.

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§95.10 Dicalcium phosphate derived from bovines.

(a) The importation of dicalcium phosphate derived from bovines is prohibited unless:

(1) The requirements of either paragraph (b), (c), or (d) and the requirements of paragraph (e) of this section are met; or