

and is subject to an approved application under section 512 of the act or an effective notice of claimed investigational exemption for a new animal drug under part 511 of this chapter.

[61 FR 19544, May 2, 1996]

§ 589.2000 Animal proteins prohibited in ruminant feed.

(a) *Definitions*—(1) *Protein derived from mammalian tissues* means any protein-containing portion of mammalian animals, excluding: Blood and blood products; gelatin; tallow containing no more than 0.15 percent insoluble impurities and tallow derivatives as specified in § 589.2001; inspected meat products which have been cooked and offered for human food and further heat processed for feed (such as plate waste and used cellulosic food casings); milk products (milk and milk proteins); and any product whose only mammalian protein consists entirely of porcine or equine protein.

(2) *Renderer* means any firm or individual that processes slaughter byproducts, animals unfit for human consumption, or meat scraps. The term includes persons who collect such materials and subject them to minimal processing, or distribute them to firms other than renderers (as defined here) whose intended use for the products may include animal feed. The term includes renderers that also blend animal protein products.

(3) *Blender* means any firm or individual which obtains processed animal protein from more than one source or from more than one species, and subsequently mixes (blends) or redistributes an animal protein product.

(4) *Feed manufacturer* includes manufacturers of complete and intermediate feeds intended for animals, and includes on-farm in addition to off-farm feed manufacturing and mixing operations.

(5) *Nonmammalian protein* includes proteins from nonmammalian animals.

(6) *Distributor* includes persons who distribute or transport feeds or feed ingredients intended for animals.

(7) *Ruminant* includes any member of the order of animals which has a stomach with four chambers (rumen, reticulum, omasum, and abomasum) through which feed passes in digestion. The

order includes, but is not limited to, cattle, buffalo, sheep, goats, deer, elk, and antelopes.

(b) *Food additive status*. The Food and Drug Administration has determined that protein derived from mammalian tissues for use in ruminant feed is a food additive subject to section 409 of the Federal Food, Drug, and Cosmetic Act (the act). The use or intended use in ruminant feed of any material that contains protein derived from mammalian tissues causes the feed to be adulterated and in violation of the act, unless it is the subject of an effective notice of claimed investigational exemption for a food additive under § 570.17 of this chapter.

(c) *Requirements for renderers that are not included in paragraph (e) of this section*. (1) Renderers that manufacture products that contain or may contain protein derived from mammalian tissues and that are intended for use in animal feed shall take the following measures to ensure that materials identified in paragraph (b) of this section are not used in the feed of ruminants:

(i) Label the materials as follows: “Do not feed to cattle or other ruminants”; and

(ii) Maintain records sufficient to track the materials throughout their receipt, processing, and distribution, and make the copies available for inspection and copying by the Food and Drug Administration.

(2) Renderers described in paragraph (c)(1) of this section will be exempted from the requirements of paragraphs (c)(1)(i) and (c)(1)(ii) of this section if they:

(i) Use exclusively a manufacturing method that has been validated by the Food and Drug Administration to deactivate the agent that causes transmissible spongiform encephalopathy (TSE) and whose design has been made available to the public;

(ii) Use routinely a test method that has been validated by the Food and Drug Administration to detect the presence of the agent that causes TSE's and whose design has been made available to the public. Renderers whose products test positive for agents that cause TSE's must comply with paragraphs (c)(1)(i) and (c)(1)(ii) of this

section. Records of the test results shall be made available for inspection by the Food and Drug Administration; or

(iii) Use exclusively a method for controlling the manufacturing process that minimizes the risk of the TSE agent entering the product and whose design has been made available to the public and validated by the Food and Drug Administration.

(3) Renderers described in paragraph (c)(1) of this section will be exempted from the requirements of paragraph (c)(1)(ii) of this section if they use a permanent method, approved by FDA, to make a mark indicating that the product contains or may contain protein derived from mammalian tissue. If the marking is by the use of an agent that cannot be detected on visual inspection, the renderer must use an agent whose presence can be detected by a method that has been validated by the Food and Drug Administration and whose design has been made available to the public.

(4) Renderers shall comply with all applicable requirements under § 589.2001.

(d) *Requirements for protein blenders, feed manufacturers, and distributors that are not included in paragraph (e) of this section.* (1) Protein blenders, feed manufacturers, and distributors that manufacture, blend, process, and distribute products that contain or may contain protein derived from mammalian tissues shall comply with paragraph (c)(1) of this section.

(2) Protein blenders, feed manufacturers, and distributors, shall be exempt from paragraphs (d)(1) of this section if they:

(i) Purchase animal products from renderers that certified compliance with paragraph (c)(2) of this section or purchase such materials from parties that certify that the materials were purchased from renderers that certified compliance with paragraph (c)(2) of this section; or

(ii) Comply with the requirements of paragraph (c)(2) of this section where appropriate.

(3) Protein blenders, feed manufacturers, and distributors, shall be exempt from paragraph (c)(1)(ii) of this section if they:

(i) Purchase animal protein products that are marked in accordance with paragraph (c)(3) of this section or purchase such materials from renderers that certified compliance with paragraph (c)(3) of this section, or purchase such materials from parties that certify that the materials were purchased from renderers that certified compliance with paragraph (c)(3) of this section; or

(ii) Comply with the requirements of paragraph (c)(3) of this section where appropriate.

(4) Pet food products that are sold or are intended for sale at retail and feeds for nonruminant laboratory animals are exempt from the labeling requirements in paragraphs (c) and (d) of this section. However, if the pet food products or feeds for nonruminant laboratory animals are sold or are intended for sale as distressed or salvage items, then such products shall be labeled in accordance with paragraph (c) or (d) of this section, as appropriate.

(5) Copies of certifications as described in paragraphs (d)(2) and (d)(3) of this section, shall be made available for inspection and copying by the Food and Drug Administration.

(e) *Requirements for persons that intend to separate mammalian and nonmammalian materials.* (1) Renderers, protein blenders, feed manufacturers, distributors, and others that manufacture, process, blend and distribute both products that contain or may contain protein derived from mammalian tissues or feeds containing such products, and protein products from other animal tissues or feeds containing such products, and that intend to keep those products separate shall:

(i) Comply with paragraphs (c)(1) or (d)(1) of this section as appropriate except that the labeling requirement shall apply only to products that contain or may contain protein derived from mammalian tissues or feeds containing such products;

(ii) In the case of a renderer, obtain nonmammalian or pure porcine or pure equine materials only from single-species slaughter facilities;

(iii) Provide for measures to avoid commingling or cross-contamination;

(A) Maintain separate equipment or facilities for the manufacture, processing, or blending of such materials; or

(B) Use clean-out procedures or other means adequate to prevent carry-over of products that contain or may contain protein derived from mammalian tissues into animal protein or feeds that may be used for ruminants; and

(iv) Maintain written procedures specifying the clean-out procedures or other means, and specifying the procedures for separating products that contain or may contain protein derived from mammalian tissue from all other protein products from the time of receipt until the time of shipment.

(2) Renderers, blenders, feed manufacturers, and distributors will be exempted from applicable requirements of paragraph (e)(1) of this section, if they meet the criteria for exemption under paragraphs (c)(2) or (c)(3) of this section, and (d)(2) or (d)(3) of this section.

(3) Renderers shall comply with all applicable requirements under § 589.2001.

(f) *Requirements for establishments and individuals that are responsible for feeding ruminant animals.* Establishments and individuals that are responsible for feeding ruminant animals shall maintain copies of purchase invoices and labeling for all feeds containing animal protein products received, and make the copies available for inspection and copying by the Food and Drug Administration.

(g) *Adulteration and misbranding.* (1) Animal protein products, and feeds containing such products, that are not in compliance with paragraphs (c) through (f) of this section, excluding labeling requirements, will be deemed adulterated under section 402(a)(2)(C) or 402(a)(4) of the act.

(2) Animal protein products, and feeds containing such products, that are not in compliance with the labeling requirements of paragraphs (c) through (f) of this section will be deemed misbranded under section 403(a)(1) or 403(f) of the act.

(h) *Inspection; records retention.* (1) Records that are to be made available for inspection and copying, as required

by this section, shall be kept for a minimum of 1 year.

(2) Written procedures required by this section shall be made available for inspection and copying by the Food and Drug Administration.

[62 FR 30976, June 5, 1997, as amended at 73 FR 22756, Apr. 25, 2008]

EFFECTIVE DATE NOTE: At 62 FR 30976, June 5, 1997, § 589.2000 was added. Paragraph (e)(1)(iv) of this section contains information collection and recordkeeping requirements and will not become effective until approval has been given by the Office of Management and Budget.

§ 589.2001 Cattle materials prohibited in animal food or feed to prevent the transmission of bovine spongiform encephalopathy.

(a) *Purpose*—The purpose of this section is to prohibit the use of certain cattle origin materials in the food or feed of all animals to further reduce the risk of the spread of bovine spongiform encephalopathy (BSE) within the United States.

(b) *Definitions*—(1) *Cattle materials prohibited in animal feed* include:

(i) The entire carcass of BSE-positive cattle;

(ii) The brains and spinal cords of cattle 30 months of age and older;

(iii) The entire carcass of cattle not inspected and passed for human consumption as defined in paragraph (b)(2) of this section that are 30 months of age or older from which brains and spinal cords were not effectively removed or otherwise effectively excluded from animal feed;

(iv) Mechanically separated beef as defined in paragraph (b)(3) of this section that is derived from materials specified in paragraphs (b)(1)(i), (b)(1)(ii), and (b)(1)(iii) of this section; and

(v) Tallow as defined in paragraph (b)(5) of this section that is derived from materials specified in paragraphs (b)(1)(i), (b)(1)(ii), and (b)(1)(iii) of this section.

(vi) Cattle materials prohibited in animal feed do not include:

(A) Tallow derivatives as defined in paragraph (b)(6) of this section;

(B) Tallow as defined in paragraph (b)(5) of this section that is derived from materials specified in paragraphs (b)(1)(ii) and (b)(1)(iii) of this section