

27-1028. Animal Proteins Prohibited in Ruminant Feeds.

A. Definitions.

(1) Protein derived from mammalian tissues means any protein-containing portion of mammalian animals, excluding: Blood and blood products; gelatin; 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 protein); 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 product.

(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) Commission means the State Livestock-Poultry Health Commission.

(5) 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.

(6) Nonmammalian protein includes proteins from nonmammalian animals.

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

(8) 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 21 CFR Section 570-17.

C. Requirements for renderers that are not included in paragraph D 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 regulation are not used in the feed of ruminants:

(a) Label the materials and any associated documents (such as bills of lading, invoices, etc.) as follows: "Do not feed to cattle or other ruminants"; and

(b) Maintain records sufficient to track the materials throughout their receipt, processing, and distribution, and make the copies available for inspection and copying by inspectors designated by the commission.

(2) Renderers described in paragraph C(1) of this section will be exempted from the requirements of paragraphs C(1)(a) and C(1)(b) of this regulation if they:

(a) 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;

(b) 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)(a) and C(1)(b) of this regulation. Records of the test results shall be made available for inspection by inspectors designated by the Commission; or

(c) 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.

(d) Notify the Commission in advance of the manufacturing method, the test method utilized and the method of controlling the manufacturing process, as specified in subsections (a), (b), and (c) above. The commission must also be notified in advance of any changes in these required procedures.

(3) Renderers described in paragraph C(1) of this regulation will be exempted from the requirements of paragraph C(1)(b) of this regulation 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.

D. Requirements for persons that intend to separate mammalian and nonmammalian materials.

(1) Renderers 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:

(a) Comply with paragraphs C(1) or D(1) of this regulation 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:

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

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

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

(2) 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

(d) 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 will be exempted from applicable requirements of paragraph C(1) of this section, if they meet the criteria for exemption under paragraphs C(2) or C(3) of this regulation.

E. Requirements for establishments and individuals that are responsible for feeding ruminant animals. Federal regulations require that 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 that copies are available for inspection and copying by inspectors designated by the appropriate federal/state authorities.

F. Adulteration and misbranding.

(1) Animal protein products, and feeds containing such products, that are not in compliance with paragraphs C through E of this regulation, excluding labeling requirements, will be deemed adulterated under section 402(a)(2)(C) or 402(a)(4) of the Food and Drug Administration Act.

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

(3) In either event the material shall be detained and will not be released without the written approval of the commission.

G. Inspection; records retention.

(1) Records that are to be made available for inspection and copying, as required by this regulation, shall be kept a minimum of 1 year.

(2) Written procedures required by this regulation shall be made available for inspection and copying by inspectors designated by the Commission.

27-1029. Preapproval Requirements for Officials Meat & Poultry Establishments.

A. Drawings and Information to be Furnished.

Each applicant for inspection shall submit to the Director a set of complete drawings containing the floor plans of the establishment for which inspection is requested, showing the locations of principal pieces of equipment, floor drains, principal drainage lines, handwashing basins and hose connections for cleanup purposes; a plot plan showing limits of the establishment's premises, locations in outline of buildings on the premises, cardinal points of the compass; and a room schedule showing the finish of walls, floors, and ceilings of all rooms in the establishment.

B. Drawings and Room Schedules to be Furnished in Advance of Construction.

Drawings and room schedules for remodeling any official establishment (or part thereof) and for any new structures to be used as an official establishment must be submitted to the Director. Written approval must be obtained prior to commencing any remodeling, additions or building a new structure. The Director will issue appropriate directives stipulating minimum facility requirements.

C. Equipment and Utensils Approval.

Equipment and utensils used for preparing or otherwise handling any edible product, or ingredient thereof in any official establishment shall be of such material and construction as in the judgment of the Director will facilitate the thorough and adequate cleaning thereof and ensure cleanliness in the preparation and handling of all edible products and otherwise avoid adulteration and misbranding of such products. The Director will issue appropriate directives stipulating minimum equipment and utensil requirements.

D. Grant of Inspection.

Inspection service will not be provided and a grant of inspection issued until the Director has determined that the establishment has been constructed, and facilities and equipment are installed in accordance with the approved drawings and room schedules and facility, equipment and utensils requirements.

E. Labeling Approval.

No label shall be used on any edible product unless the label has been submitted to and approved by the Director in writing. The currently-approved label is the only label authorized to be used on any product, unless authorized by the Director.