

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 and that contains no more than 0.15 percent insoluble impurities. Insoluble impurities must be measured by the method entitled “Insoluble Impurities” (AOCS Method Ca 3a-46), American Oil Chemists’ Society (AOCS), 5th Edition, 1997, incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or another method equivalent in accuracy, precision, and sensitivity to AOCS Official Method Ca 3a-46. You may obtain copies of the method from the AOCS (<http://www.aocs.org>), 2211 W. Bradley Ave., Champaign, IL 61821. Copies may be examined at the Food and Drug Administration’s Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(C) Materials as defined in paragraphs (b)(1)(ii), (b)(1)(iii), (b)(1)(iv) (other than mechanically separated beef from the carcass of a BSE-positive cattle), and (b)(1)(v) of this section from cattle from a country that has been designated under paragraph (f) of this section.

(2) *Cattle not inspected and passed for human consumption* means cattle that did not pass antemortem inspection by the appropriate regulatory authority. This term includes nonambulatory disabled cattle. Nonambulatory disabled cattle are cattle that cannot rise from a recumbent position or that cannot walk, including, but not limited to, those with broken appendages, severed tendons or ligaments, nerve paralysis,

fractured vertebral column, or metabolic conditions.

(3) *Mechanically separated beef* means a finely comminuted meat food product, resulting from the mechanical separation and removal of most of the bone from attached skeletal muscle of cattle carcasses and parts of carcasses.

(4) *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 in this paragraph) whose intended use for the products may include animal feed, industrial use, or other uses. The term includes renderers that also blend animal protein products.

(5) *Tallow* means the rendered fat of cattle obtained by pressing or by applying any other extraction process to tissues derived directly from discrete adipose tissue masses or to other carcass parts and tissues.

(6) *Tallow derivative* means any product 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.

(c) *Requirements.* (1) No animal feed or feed ingredient shall be manufactured from, processed with, or otherwise contain, cattle materials prohibited in animal feed as defined in paragraph (b)(1) of this section.

(2) Renderers that receive, manufacture, process, blend, or distribute cattle materials prohibited in animal feed as defined in paragraph (b)(1) of this section, or products that contain or may contain cattle materials prohibited in animal feed, shall take the following measures to ensure that materials prohibited as defined in paragraph (b)(1) of this section are not introduced into animal feed:

(i) Exclude from use in animal feed the entire carcass of cattle not inspected and passed for human consumption as defined in paragraph (b)(2) of this section if:

(A) The brain and spinal cord are not effectively removed from such cattle or

the brain and spinal cord from such cattle are not otherwise effectively excluded from animal feed; and

(B) Such cattle are 30 months of age or older.

(ii) If renderers remove brain and spinal cord from cattle not inspected and passed for human consumption, or separate such animals based on whether or not they are 30 months of age or older, renderers must maintain adequate written procedures specifying how these processes are carried out.

(iii) Once cattle materials prohibited in animal feed have been separated from other cattle materials, provide for measures to avoid cross-contamination;

(A) Use separate equipment while handling cattle materials prohibited in animal feed; or

(B) Use separate containers that adequately prevent contact with animal feed, animal feed ingredients, or equipment surfaces;

(iv) Label the cattle materials prohibited in animal feed and products that contain or may contain cattle materials prohibited in animal feed in a conspicuous manner as follows: "Do not feed to animals";

(v) Mark the cattle materials prohibited in animal feed and products that contain or may contain cattle materials prohibited in animal feed with an agent that can be readily detected on visual inspection; and

(vi) Establish and maintain records sufficient to track cattle materials prohibited in animal feed to ensure such material is not introduced into animal feed, and make the records available for inspection and copying by the Food and Drug Administration.

(3) Renderers that receive, manufacture, process, blend, or distribute any cattle materials shall take the following measures to ensure that materials prohibited as defined in paragraph (b)(1) of this section are not used in animal feed:

(i) Establish and maintain records sufficient to demonstrate that material rendered for use in animal feed was not manufactured from, processed with, or does not otherwise contain, cattle materials prohibited in animal feed and make copies of all records available for inspection and copying by the Food

and Drug Administration. With respect to cattle materials obtained from establishments which have segregated cattle materials prohibited in animal feed, such records must demonstrate that establishments supplying cattle materials to the renderers have adequate procedures in place to effectively exclude cattle materials prohibited in animal feed; and these records shall be considered sufficient to meet this requirement if they include either:

(A) Certification or other documentation from the supplier that material supplied to the renderer does not include cattle materials prohibited in animal feed; such certification or documentation is acceptable, provided that it includes a description of the segregation procedures used, documentation that the supplier confirms that its segregation procedures are in place prior to supplying any cattle material to the renderer, and records of the renderer's periodic review of the suppliers' certification or other documentation; or

(B) Documentation of another method acceptable to FDA, such as third-party certification, for verifying that suppliers have effectively excluded cattle materials prohibited in animal feed.

(ii) Comply with all applicable requirements under § 589.2000 regarding animal proteins prohibited in ruminant feed.

(d) *Adulteration and misbranding.* (1) Failure of a renderer to comply with the requirements in paragraphs (c)(2)(i) through (c)(2)(iii), (c)(2)(v) and (c)(2)(vi), or (c)(3)(i) of this section will render the animal feed or feed ingredients adulterated under section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the act).

(2) Animal feed or feed ingredients that are not in compliance with paragraph (c)(1) of this section are adulter-

ated under section 402(a)(2), 402(a)(3), or 402(a)(5) of the act.

(3) Animal feed or feed ingredients that are not in compliance with the labeling requirements of paragraph (c)(2)(iv) of this section are misbranded under section 403(a)(1) or 403(f) of the act.

(4) Failure of a renderer to comply with the requirements in paragraph (e) of this section will render the animal feed or feed ingredients adulterated under section 402(a)(4) of the act.

(e) *Inspection; records retention.* Records required to be made available for inspection and copying by the Food and Drug Administration, as required by this section, shall be kept for a minimum of 1 year.

(f) *Process for designating countries.* A country seeking designation must send a written request to the Director, Office of the Center Director, Center for Veterinary Medicine, at the address designated in § 5.1100 of this chapter. The request shall include information about that country's BSE case history, risk factors, measures to prevent the introduction and transmission of BSE, and any other information relevant to determining whether the cattle materials from the requesting country do or do not meet the definitions set forth in paragraph (b)(1) of this section. FDA shall respond in writing to any such request and may impose conditions in granting any such request. Any grant by FDA of such a request under this paragraph will be subject to future review by FDA and may be revoked if FDA determines that the granted request is no longer appropriate.

[73 FR 22756, Apr. 25, 2008, as amended at 81 FR 5596, Feb. 3, 2016]

PARTS 590–599 [RESERVED]