米国における飼料規制のポイント

連邦政府食品・医薬品・化粧品法 －連邦規則コード 21 part 589.2000（1997年8月施行）－	検討中の追加措置 （2004年1月FDAﾌﾟﾚｽﾘﾘｰｽ）
1．原料不分別業者 (1) レンダリング業者 ① ほ乳動物由来たん白（＊）を含む可能性のある製品を飼料として出荷する場合には、「牛、その他反すう動物に給餌しないこと」のラベルを貼ること。 （＊ 血液及び血液製品、ゼラチン、調理済み食用肉製品で飼料用に加熱処理されたもの、乳製品並びに豚及び馬由来たん白のみを含む製品を除く。以下同じ。） ② 原料となるほ乳動物由来たん白の入手、加工及び販売の過程を追跡するのに十分な記録を保管すること（１年間）。 (2) 飼料配合業者、飼料製造業者、飼料販売業者 ① (1)の①と同じ（小売販売用ペットフード製品又は反すう動物でない実験動物用飼料にはラベルの貼付不要）。	○ ほ乳動物の血液の他の反すう動物への給餌禁止 （プレスリリースにおいては、「科学的知見によれば、血液はＢＳＥ感染因子を伝播する恐れがある。」ことを根拠としている。）
2．原料分別業者（レンダリング業者、飼料配合業者、飼料製造業者、飼料販売業者共通） (1) ほ乳動物由来たん白を含まない製品 ＜分別管理の要件＞ ① 原料の混入又は交差汚染を避けるため、製造、加工及び配合のための装置又は施設を使い分けるか、又は洗浄等が行われること。 ② ほ乳動物由来たん白を入手してから出荷するまでの間、洗浄その他の方法でほ乳動物由来たん白製品と他のたん白製品を区分した手続きを記録し保管すること(1年間)。 ③ １種類の動物のみを取扱うと畜場からのみ入手した非ほ乳動物、豚又は馬のみを原料とすること（レンダリング業者のみ）。 ＜適用規制＞ 原料となるほ乳動物由来たん白の入手、加工及び販売の過程を追跡するのに十分な記録を保管すること（１年間）。 (2) ほ乳動物由来たん白を含む可能性のある製品 1と同様の規制。	○ 交差汚染の可能性を最小限にするための機材、施設、製造ラインに関する規則
3．反すう動物に給餌を行う企業又は個人 動物性たん白を含む全ての飼料の購入伝票ラベルのコピーを保管（１年間）すること。	
	○ 養鶏残渣の反すう動物の餌への使用禁止 ○ 厨房残渣の反すう動物の餌への使用禁止

資料１－３

Electronic Code of Federal Regulations (e-CFR):

BETA TEST SITE

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Title 21: Food and Drugs

PART 589—SUBSTANCES PROHIBITED FROM USE IN ANIMAL FOOD OR FEED

Subpart B—Listing of Specific Substances Prohibited From Use in Animal Food or Feed

§ 589.2000 Animal proteins prohibited in ruminant feed.

Previous

(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 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.

(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.

(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]

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.

Press Release

FOR IMMEDIATE RELEASE
Monday, Jan. 26, 2004

FDA Press Office
301-827-6242

Expanded "Mad Cow" Safeguards Announced to Strengthen Existing Firewalls Against BSE Transmission

HHS Secretary Tommy G. Thompson today announced several new public health measures, to be implemented by the Food and Drug Administration (FDA), to strengthen significantly the multiple existing firewalls that protect Americans from exposure to the agent thought to cause bovine spongiform encephalopathy (BSE, also known as mad cow disease) and that help prevent the spread of BSE in U.S. cattle.

The existing multiple firewalls, developed by both the U.S. Department of Agriculture (USDA) and HHS, have been extremely effective in protecting the American consumer from exposure to BSE. The first firewall is based on import controls started in 1989. A second firewall is surveillance of the U.S. cattle population for the presence of BSE, a USDA firewall that led to the finding of the BSE cow in December. The third firewall is FDA's 1997 animal feed ban, which is the critical safeguard to help prevent the spread of BSE through cattle herds by prohibiting the feeding of most mammalian protein to ruminant animals, including cattle. The fourth firewall, recently announced by USDA, makes sure that no bovine tissues known to be at high risk for carrying the agent of BSE enter the human food supply regulated by USDA. The fifth firewall is effective response planning to contain the potential for any damage from a BSE positive animal, if one is discovered. This contingency response plan, which had been developed over the past several years, was initiated immediately upon the discovery of a BSE positive cow in Washington State December 23.

The new safeguards being announced today are science-based and further bolster these already effective safeguards.

Specifically, HHS intends to ban from human food (including dietary supplements), and cosmetics a wide range of bovine-derived material so that the same safeguards that protect Americans from exposure to the agent of BSE through meat products regulated by USDA also apply to food products that FDA regulates.

FDA will also prohibit certain currently allowed feeding and manufacturing practices involving feed for cattle and other ruminant animals. These additional measures will further strengthen FDA's 1997 "animal feed" rule.

"Today's actions will make strong public health protections against BSE even stronger," Secretary Thompson said. "Although the current animal feed rule provides a strong barrier against the further spread of BSE, we must never be satisfied with the status quo where the health and safety of our animals and our population is at stake. The science and our own experience and knowledge in this area are constantly evolving. Small as the risk may already be, this is the time to make sure the public is protected to the greatest extent possible."

"Today we are bolstering our BSE firewalls to protect the public," said FDA Commissioner Mark B. McClellan, M.D., Ph.D. "We are further strengthening our animal feed rule, and we are taking

additional steps to further protect the public from being exposed to any potentially risky materials from cattle. FDA's vigorous inspection and enforcement program has helped us achieve a compliance rate of more than 99 percent with the feed ban rule, and we intend to increase our enforcement efforts to assure compliance with our enhanced regulations. Finally, we are continuing to assist in the development of new technologies that will help us in the future improve even further these BSE protections. With today's actions, FDA will be doing more than ever before to protect the public against BSE by eliminating additional potential sources of BSE exposure."

To implement these new protections, FDA will publish two interim final rules that will take effect immediately upon publication, although there will be an opportunity for public comment after publication.

The first interim final rule will ban the following materials from FDA-regulated human food, (including dietary supplements) and cosmetics:

- Any material from "downer" cattle. ("Downer" cattle are animals that cannot walk.)
- Any material from "dead" cattle. ("Dead" cattle are cattle that die on the farm (i.e. before reaching the slaughter plant);
- Specified Risk Materials (SRMs) that are known to harbor the highest concentrations of the infectious agent for BSE, such as the brain, skull, eyes, and spinal cord of cattle 30 months or older, and a portion of the small intestine and tonsils from all cattle, regardless of their age or health; and
- The product known as mechanically separated beef, a product which may contain SRMs. Meat obtained by Advanced Meat Recovery (an automated system for cutting meat from bones), may be used since USDA regulations do not allow the presence of SRMs in this product.

The second interim final rule is designed to lower even further the risk that cattle will be purposefully or inadvertently fed prohibited protein. It was the feeding of such protein to cattle that was the route of disease transmission that led to the BSE epidemic in United Kingdom cattle in the 1980's and 1990's.

This interim final rule will implement four specific changes in FDA's present animal feed rule. First, the rule will eliminate the present exemption in the feed rule that allows mammalian blood and blood products to be fed to other ruminants as a protein source. Recent scientific evidence suggests that blood can carry some infectivity for BSE.

Second, the rule will also ban the use of "poultry litter" as a feed ingredient for ruminant animals. Poultry litter consists of bedding, spilled feed, feathers, and fecal matter that are collected from living quarters where poultry is raised. This material is then used in cattle feed in some areas of the country where cattle and large poultry raising operations are located near each other. Poultry feed may legally contain protein that is prohibited in ruminant feed, such as bovine meat and bone meal. The concern is that spillage of poultry feed in the chicken house occurs and that poultry feed (which may contain protein prohibited in ruminant feed) is then collected as part of the "poultry litter" and added to ruminant feed.

Third, the rule will ban the use of "plate waste" as a feed ingredient for ruminants. Plate waste consists of uneaten meat and other meat scraps that are currently collected from some large restaurant operations and rendered into meat and bone meal for animal feed. The use of "plate waste" confounds FDA's ability to analyze ruminant feeds for the presence of prohibited proteins, compromising the Agency's ability to fully enforce the animal feed rule.

Fourth, the rule will further minimize the possibility of cross-contamination of ruminant and non-ruminant animal feed by requiring equipment, facilities or production lines to be dedicated to non-ruminant animal feeds if they use protein that is prohibited in ruminant feed. Currently, some equipment, facilities and production lines process or handle prohibited and non-prohibited materials and make both ruminant and non-ruminant feed -- a practice which could lead to cross-contamination.

To accompany these new measures designed to provide a further layer of protection against BSE, FDA will in 2004 step up its inspections of feed mills and renderers. FDA will itself conduct 2,800 inspections and will make its resources go even further by continuing to work with state agencies to fund 3,100 contract inspections of feed mill and renderers and other firms that handle animal

feed and feed ingredients. Through partnerships with states, FDA will also receive data on 700 additional inspections, for a total of 3,800 state contract and partnership inspections in 2004 alone, including annual inspections of 100 percent of all known renderers and feed mills that process products containing materials prohibited in ruminant feed.

"We have worked hard with the rendering and animal feed production industries to try and achieve full compliance with the animal feed rule," said Dr. McClellan, "and through strong education and a vigorous enforcement campaign, backed by additional inspections and resources, we intend to maintain a high level of compliance."

Dr. McClellan also noted that, in response to finding a BSE positive cow in Washington state December 23, FDA inspected and traced products at 22 facilities related to that positive cow or products from the cow, including feed mills, farms, dairy farms, calf feeder lots, slaughter houses, meat processors, transfer stations, and shipping terminals. Moreover, FDA has conducted inspections at the rendering facilities that handled materials from the positive cow, and they were found to be fully in compliance with FDA's feed rule.

To further strengthen protections for Americans, FDA/HHS intends to work with Congress to consider proposals to assure that these important protective measures will be implemented as effectively as possible.

FDA is also continuing its efforts to assist in the development of better BSE science, to achieve the same or greater confidence in BSE protection at a lower cost. For example, to enhance the ability of our public health system to detect prohibited materials in animal feed, FDA will continue to support the development and evaluation of diagnostic tests to identify prohibited materials. These tests would offer a quick and reliable method of testing animal feeds for prohibited materials and for testing other products for contamination with the agent thought to cause BSE.

FDA has publicly discussed many of the measures being announced today with stakeholders in workshops, videoconferences, and public meetings. In addition, FDA published an Advance Notice of Proposed Rulemaking in November 2002 (available online at http://www.fda.gov/OHRMS/DOCKETS/98fr/110602c.htm concerning possible changes to the animal feed rule.

Comprehensive information about FDA's work on BSE and links to other related websites are available at http://www.fda.gov.

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