National Grain and Feed Association

January 2024

FDA's BSE-Prevention Regulations for Feed and Feed Ingredients

A Compliance Guide for Feed Manufacturers

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Disclaimer

FDA's Ban on Feeding Certain Mammalian Proteins to Ruminant Animals

The U.S. Food and Drug Administration's (FDA) Center for Veterinary Medicine (CVM) on June 5, 1997 published its final rule – 21 Code of Federal Regulations (CFR) Part 589.2000 – prohibiting the feeding of certain mammalian protein to cattle and other ruminant animals.

FDA's rule is intended to prevent the establishment or spread through feed of bovine spongiform encephalopathy (BSE) – commonly referred to as "mad cow disease" – in the United States. BSE belongs to the unusual group of progressively degenerative neurological diseases known as transmissible spongiform encephalopathies (TSEs). TSE diseases are characterized by long incubation periods ranging from several months for transmissible mink encephalopathy, to several years for BSE. During the incubation period there is no visible indication of the disease. In the late 1980's and early 1990s, BSE spread within the United Kingdom and then to other countries through the practice of using rendered bovine origin proteins as an ingredient in cattle feed. Since then, feed restrictions put in place by countries that may have imported infected cattle or contaminated feed ingredients have been highly effective in reducing the number of BSE cases worldwide. Epidemiological studies have concluded there is strong evidence for a causal association between exposure to BSE and the variant form of the fatal degenerative human brain disease known as Creutzfeldt-Jakob disease *(v-CJD).*

To date, six cases of BSE have been detected in the United States. The first case was detected in 2003 in a cow imported from Canada, diagnosed with "typical" BSE, the same strain that caused the outbreak in the United Kingdom. Five more cases have since been detected in U.S. born cattle, but laboratory evidence suggests these cases had atypical strains of BSE, which is not the same strain that caused the large outbreak in the United Kingdom.

Ingredients Exempt from Feeding Ban

Feed ingredients exempt from the mammalian-to-ruminant feeding ban are:

- Protein derived from pure pork or horses (equine) slaughtered at single-species facilities, as well as blood and blood products, gelatin, and milk products (milk and milk proteins);

- Inspected meat products – those inspected by the U.S. Department of Agriculture's Food Safety Inspection Service or a comparable state agency – that have been cooked and offered for human food and further heat-processed for feed (such as plate waste and used cellulosic food casings). The plate waste definition does not include meat trimmings from slaughter operations or butchers;

- Nonmammalian proteins products derived from poultry, fish, and vegetables;

- Fats, oils, grease, amino acids, and dicalcium phosphate – since these products are not proteins.

Classifications of Proteins

FDA's final rule classifies proteins used in feed by three distinct types:

- **Non-Prohibited Mammalian Protein**: Includes such protein as pure pork and horse.

- **Nonmammalian Protein:** Includes protein from nonmammalian animal sources (such as poultry, feathermeal, fish meal, etc.), as well as protein from plant and vegetable origins (soymeal, gluten, etc.).

- **Prohibited Mammalian Material:** Includes protein from ruminants (such as cattle, sheep, goats, deer, elk, buffalo and antelopes), as well as mink.

Specifically identified by the Association of American Feed Control Officials (AAFCO) – an organization of state and federal feed control agencies – as material which, if derived from mammalian sources, is prohibited from being fed to cattle or other ruminants, are:

- Animal By-Product Meal
- Animal Digest
- Animal Liver
- Bone Meal, cooked
- Bone Meal, steamed
- Cooked Bone Marrow
- Distressed Pet Food, if it contains or may contain a prohibited protein product
- Dried Meat Solubles
- Fleshings Hydrolysate
- Food Processing Waste
- Glandular Meal and Extracted Glandular Meal
- Hydrolyzed Hair
- Hydrolyzed Leather Meal
- Meat
- Meat and Bone Meal
- Meat and Bone Meal Tankage
- Meat By-Products
- Meat Meal
- Meat Meal Tankage
- Meat Protein Isolate
- Mechanically Separated Bone Morrow
- Restaurant Food Waste

- Salvage Pet Food, if it contains or may contain a prohibited protein product
- Stock/Broth, when obtained from mammalian bones
- Unborn Calf Carcasses

Also, based upon an April 25, 2008 revision to the final rule – 21 CFR Part 589.2001, tallow (defined as rendered fat of cattle) containing more than 0.15 percent insoluble impurities is classified as a mammalian protein prohibited from use in ruminant feed.

These products, as well as feed that contains or may contain such products, are not to be fed to cattle or other ruminants and are to be labeled with the BSE caution statement: ***"Do not feed to cattle or other ruminants."***

Requirements for Feed Manufacturers and Distributors

FDA's rule applies to both "feed manufacturers" and "distributors" that receive, handle or utilize prohibited mammalian protein.

Importantly, firms that use only nonmammalian protein or non-prohibited mammalian protein (such as pure pork or equine) in their feed rations are exempt from the final rule. FDA defines "feed manufacturers" as on-farm and off-farm (commercial) manufacturers of complete and intermediate feeds intended for use in animals. "Distributors" are defined as those who distribute or transport feeds or feed ingredients intended for animals. This definition encompasses truck, rail and barge transportation, as well as brokers and salvagers.

For feed manufacturers and distributors – as well as renderers, protein blenders and others – that handle prohibited mammalian protein, FDA's final rule has three major potential impacts:

- potential modifications to manufacturing processes and clean-out procedures for establishments that decide to handle both prohibited mammalian and non-prohibited mammalian/nonmammalian protein at the same plant.

- labeling requirements; and

- recordkeeping requirements.

Manufacturing Processes and Clean-Out Procedures

For feed manufacturers and distributors that decide to handle and utilize both prohibited mammalian protein and non-prohibited mammalian/nonmammalian protein in their operations and intend to keep such products separate, FDA's rule requires that they institute procedures to avoid commingling or cross-contamination. Such facilities also are required to comply with certain labeling and recordkeeping requirements.

To prevent commingling or cross-contamination, the final rule allows feed manufacturers and distributors to either:

- **use separate equipment or facilities** for storage, manufacturing, processing or blending prohibited mammalian protein from non-prohibited mammalian/nonmammalian materials; or

- **use clean-out procedures** "or other means adequate to prevent carryover of products that contain or may contain protein derived from (prohibited) mammalian tissues into animal protein or feeds that may be used for ruminants." Only equipment and storage facilities that are used to handle both proteins derived from prohibited mammalian and non-prohibited mammalian/ nonmammalian tissues are subject to the clean-out requirement.

FDA's rule requires that written procedures be maintained specifying the clean-out procedures or other means used to separate prohibited mammalian protein from non-prohibited mammalian/nonmammalian protein.

The verbatim text from ***FDA Guidance for Industry #68*** on cleanout procedures that the agency said it will consider adequate for firms that handle both prohibited mammalian and non-prohibited mammalian/nonmammalian protein in feeds follows:

"Cleanout could be physical cleaning, flushing, sequencing or other means, either alone or in combination with separation measures, that are adequate to prevent carryover of prohibited material into nonprohibited material. Cleanout procedures should be used on all equipment and conveyances that handle both prohibited and nonprohibited material.

Documentation for clean-out should include a description of how cleanout is implemented - who is responsible, how clean-out is monitored and verified; how volume of clean-out flush material was determined; and a description of how cleanout flush material is handled.

Cleaning [may be accomplished] by physical means, e.g., vacuuming, sweeping, washing, etc. Alternatively, flushing, sequencing or other equally effective techniques may be used. Under these methods, the equipment is cleaned through use of a nonprohibited product, e.g., a feed that does not contain prohibited material.

The volume of flushed material should be sufficient to prevent carryover of products that contain or may contain prohibited material. Due to the degree of variability among facilities, feed mills should determine their facilities' individual characteristics and apply appropriate time and volume requirements for flushing material to accomplish the intent of the procedures. The volume used should be stated in the written procedures, and should be based on a documented analysis or test of the firm's system.

Nonprohibited material used in the cleaning [when flushing] should be considered prohibited and should be identified, stored, and handled so that it does not become incorporated in feed for ruminant animals.

Sequencing should be done on a predetermined basis and be designed to prevent unsafe contamination of ruminant feeds. An appropriate example would be producing a swine feed containing prohibited material, followed by a swine or poultry feed containing nonprohibited material, followed by a ruminant feed containing nonprohibited material."

Labeling Requirement

FDA's rule generally requires that labels for all feed that contains or may contain protein from prohibited mammalian tissues contain the phrase: *"Do not feed to cattle or other ruminants."* Exempt from the labeling requirement are:

- feeds containing only non-prohibited mammalian or nonmammalian protein;
- pet food products sold or intended for sale at retail, even though they contain or may contain "prohibited" mammalian protein; and
- feeds for nonruminant laboratory animals.

The term "label" means a display of written, printed, or graphic matter on the immediate container of any product. The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

The labeling requirement applies to all feed that contains or may contain prohibited mammalian protein used in feed intended for nonruminant animals, even if the label already clearly states the nonruminant species for which the feed is intended. For example, feed manufacturers using rendered cattle or other prohibited mammalian protein in rations for hog or poultry feed are required to include the caution statement, *"Do not feed to cattle or other ruminants"* on such labels, even though the feed already clearly is labeled as hog or poultry feed.

FDA's rule requires the labeling statement to be "noticeable" and to appear on product labels, such as those attached to a bag or other container. For bulk feeds, the statement should appear on the placard and invoice that accompany the shipment, and on any other labeling for the product. The labeling statement also should be distinguished by different type size, color or other means so it is noticed easily by a buyer.

FDA guidance states the caution statement, *"Do not feed to cattle or other ruminants,"* also should be included on any other labeling associated with feeds that contain or may contain prohibited mammalian protein. Such labeling may include leaflets, brochures, and other labeling materials whether or not they physically accompany the shipment of the products.

FDA regulations permit feed labels to contain collective terms, rather than common or usual names, in certain circumstances. For example, “animal protein products” can be used where the product contains certain ingredients such as meat and bone meal. FDA does not object to continued use of collective terms, provided that feed intended for ruminants does not contain protein from prohibited material, or the product contains the cautionary statement.

Recordkeeping Requirements

The rule’s recordkeeping requirements generally apply only to feed and feed ingredients that contain or may contain prohibited mammalian protein. It does not apply to feed containing only non-prohibited mammalian/nonmammalian protein, or to grains, grain products and roughage. However, FDA requires that those actually feeding ruminant animals (such as feedlot operators) retain records showing that the protein being used is of non-prohibited mammalian or nonmammalian origin.

Feed manufacturers and distributors handling prohibited mammalian protein are required to retain invoices or other similar records for one year after purchase and distribution so that FDA can track the receipt, processing and distribution of feed containing such materials.

The rule states the recordkeeping requirement can be met by retaining an invoice “or other similar document reflecting the receipt or purchase, and sale or delivery, of the product.” The information FDA expects to find on such documents include:

- the date of receipt or purchase, or sale or delivery, of the product;
- the seller’s name and address;
- the consignee’s name and address;
- the identification of the product (its customary or usual name); and
- the quantity.

For bulk shipments of feed received by ruminant feeders, retaining invoices will be sufficient to comply with the recordkeeping requirement. For bagged feed or feed shipped in containers, the label portion should be removed and retained. It is only necessary to retain one label from each shipment representing a different product. If the label has been removed from the bag or other container, maintaining a representative bag or a transposed copy of the labeling information from a container that cannot be feasibly stored will suffice.

The rule requires renderers to maintain records sufficient to track the receipt, processing and distribution of prohibited mammalian protein.

FDA's Ban on the Use of Certain Cattle Materials in All Animal Feeds

FDA on April 25, 2008 published final regulations – CFR Part 589.2001 – to further enhance its feed rules designed to prevent the establishment or spread of BSE in the United States.

The centerpiece of the final regulations is a requirement that renderers remove brain and spinal cord from all cattle 30 months or older before such animals are allowed to be used in feed for any animal species. For nonambulatory (so-called "downer") and dead cattle, renderers are required to develop and make available for FDA review written protocols for determining the age of cattle and demonstrating that brain and spinal cord from cattle 30 months and older have been removed "or otherwise effectively excluded from animal feed." Such tissues – which FDA classifies in the final rule as "cattle materials prohibited in animal feed (CMPAF)" – are banned from use in all feed for any species.

FDA's new regulations do not replace, but are in addition to, the BSE-prevention feed rule safeguards implemented in 1997 that ban the use in ruminant feed of ruminant-derived mammalian material.

Impact of the Enhanced Feed Ban Regulations

FDA's final regulation establishes that the following cattle materials are prohibited in all animal feed (CMPAF):

- The entire carcass of BSE-positive cattle;
- The brains and spinal cords of cattle 30 months of age and older;
- The entire carcass of cattle not inspected and passed for human consumption 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;
- Mechanically separated beef derived from confirmed BSE-positive cattle or from cattle 30 months or older from which brain and spinal cord have not been removed; and
- Tallow (rendered fat from cattle) containing more than 0.15 percent insoluble impurities derived from: 1) the carcass of BSE-positive cattle; 2) the brains and spinal cords of cattle 30 months of age and older; or 3) the carcass of cattle not inspected and passed for human consumption that are 30 months of age and older from which brains and spinal cords were not effectively removed or otherwise effectively excluded from animal feed.

FDA's regulations continue to allow the use in all animal feed, including ruminant feed, of the following mammalian material: 1) blood and blood products; 2) gelatin; 3) tallow containing 0.15 percent or less insoluble impurities; 4) inspected meat products that have been cooked and offered for human food and further-heat processed for feed (such as plate waste and used cellulosic food casings); 5) milk products (milk and milk proteins); and 6) pork, equine, poultry, fish and vegetable protein.

Requirements for Renderers: Renderers are required under the final rule to develop written procedures available for review and copying by FDA that specify the procedures used to ensure that CMPAF is, in fact, not entering the feed system. These records are to include procedures, if any, being used by renderers to remove brain and spinal cord from cattle 30 months and older, as well as other materials prohibited from use in all animal feed. The final rule states that renderers are to use separate equipment while handling CMPAF or to use separate containers that adequately protect against contact with animal feed, feed ingredients or equipment surfaces. Renderers are to dye or otherwise mark such cattle materials with an agent that readily is detectable during visual inspection. Renderers also are required to label CMPAF as follows: *"Do Not Feed to Animals."*

Further, renderers are required to maintain for at least one year and make available to FDA records sufficient to:

- Demonstrate that material rendered for use in animal feed was not manufactured from, processed with or does not contain CMPAF.

- Demonstrate that establishments that supply cattle material to renderers have implemented adequate procedures to effectively exclude CMPAF. These supplier-related records kept by renderers are to include either: 1) certification or other documentation from suppliers that the cattle material does not include cattle materials prohibited from use in feed, including a description of segregation procedures used; or 2) 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.

- Track CMPAF to ensure they are not used in animal feed.

Requirements for Feed Mills: Although the enhanced feed rule has minimal direct impact on feed mills, feed manufacturers need to be aware of and compliant with the requirements established for tallow.

Pertaining to these requirements, ***FDA Guidance for Industry #195*** provides the following specific information concerning tallow.

- Tallow meeting the regulation's standard of containing no more than 0.15 percent insoluble impurities may be used in feed intended for all animals, regardless of the tallow's origin.

- Tallow that is derived from CMPAF and that contains more than 0.15 percent insoluble impurities is prohibited from use in all animal food and feed.

- Tallow that does not meet the 0.15 percent insoluble impurities standard is prohibited from use in ruminant feed, but may be used in feed for non-ruminant animals if derived from documented sources that are free of CMPAF. Among such prohibited sources are brain and spinal cord from cattle 30 months or older; the entire carcass of BSE-positive cattle; and mechanically separated beef derived from prohibited materials.

- Tallow derived from documented sources that are free of CMPAF and not meeting the impurity standard of no more than 0.15 percent insoluble impurities is to be labeled by renderers prior to distribution with the caution statement: *"Do not feed to cattle or other ruminants."* Such tallow is prohibited from use in feed for ruminant animals.

- The regulation does not require renderers or feed manufacturers to test or certify the impurity level of each load of tallow. However, the rule does require renderers to have written procedures for ensuring that tallow being produced meets the standard if it is to be used in feed for cattle. In addition, FDA's guidance document notes that the ingredient definition established by AAFCO for "animal fat" contains specific information on how tallow is to be labeled, including a guarantee for maximum insoluble impurities.

- FDA's guidance recognizes that settled impurities in an equipment or storage tank may be re-suspended when new tallow is added, which could cause a tallow sample collected from the tank to exceed the limit on insoluble impurities. Therefore, the agency notes that it may not be appropriate to take enforcement action based solely on a sample from a storage tank. Further, FDA states that during inspector training, the agency will emphasize the need to collect tallow samples in a manner reflecting the impurity level of the tallow the renderer offered into commerce. Barring "extenuating circumstances," FDA says it will consider tallow products that are in compliance at the renderer to be in compliance during distribution.

- FDA's BSE-prevention feed regulations do not establish a standard for insoluble impurities in any type of fats or oils derived from cattle other than tallow. The regulations expressly define tallow to mean the rendered fat of cattle. Thus, as examples of products excluded from coverage under the rule, FDA cites fats and oils derived from poultry, pork, sheep, goats, equine, fish and vegetable-based sources, as well as recovered cooking oils from restaurants and food processors (where the tallow is from edible sources from which cattle material prohibited in animal feed already has been removed under U.S. Department of Agriculture supervision).

Concerning blended products, tallow that is to be blended with other fats/oils for use in cattle feed must meet the 0.15% insoluble impurities standard before it is blended. FDA states that blending or dilution may not be used to meet the insoluble impurities standard.

The following table depicts the tallow provisions established within the regulations.

Tallow[1] Provisions – FDA BSE-Prevention Feed Regulations			
Source of Tallow	**Insoluble Impurities Level**	**Feed Use**	**Caution Statement Required**
Any source (CMPAF or non-CMPAF)	< or = 0.15%	Allowed in all animal feeds	None
Non-CMPAF	> 0.15%	Allowed in all but ruminant feeds	"Do not feed to cattle or other ruminants"
CMPAF	> 0.15%	Not allowed in animal feed	"Do not feed to animals"
[1] Tallow means rendered fat from cattle			

FDA's Inspections for Compliance with the BSE-Prevention Feed Rules

FDA has an active program to access compliance with its BSE-prevention regulations. In most cases, BSE inspections are conducted at facilities that handle prohibited material. In addition, unless otherwise directed by FDA, routine surveillance BSE inspections are primarily conducted at facilities that use prohibited materials to manufacture animal food. To target inspections in this manner, FDA field inspection staff assess whether the facility is handling prohibited material to determine whether a BSE inspection is applicable.

Inspection results can be accessed from FDA/CVM's website under the "Ruminant Feed Inspections" section.

A link to "Form FDA 3719 (8/15), Report of Inspection for Compliance with 21 CFR 589.2000 and 589.2001" – FDA's inspection checklist for the BSE regulations – is provided in the Additional Information section of this guidance.

Additional Information

Following are links to additional information and resources from FDA pertaining to its BSE-prevention requirements.

- BSE Ruminant Feed Inspections
- BSE/Ruminant Feed Regulations – 21 CFR Part 589.2000
- BSE/Substances Prohibited from Use in Animal Food or Feed – 21 CFR Part 589.2001
- CVM GFI #68 Small Entities Compliance Guide for Protein Blenders, Feed Manufacturers, and Distributors
- CVM GFI #76 Questions and Answers BSE Feed Regulations
- CVM GFI #195 Small Entities Compliance Guide For Renderers—Substances Prohibited from Use In Animal Food or Feed
- Feed Ban Enhancement: Implementation Questions and Answers
- Form FDA 3719 (8/15), Report of Inspection for Compliance with 21 CFR 589.2000 and 589.2001
- Preventing the Spread of BSE (video)