

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

A Compliance Guide for Feed Manufacturers



National Grain and Feed Association

1250 Eye St., N.W., Suite 1003, Washington, D.C., 20005-3922

Phone: (202) 289-0873 Fax: (202) 289-5388

Web Site: www.ngfa.org

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by National Grain and Feed Association

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

The Food and Drug Administration on June 5, 1997 published its final rule prohibiting the feeding of certain mammalian protein to cattle and other ruminant animals.

FDA's final 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. Epidemiological studies conducted in the United Kingdom have suggested that exposure to BSE may be linked to a new variant form of the fatal degenerative human brain disease known as Creutzfeldt-Jakob disease (*v-CJD*). The United States has experienced only three cases of BSE – the first in December 2003 involving an adult dairy cow imported from Canada, the second involving a 12-year-old cow diagnosed as BSE-positive in June 2005 that had been born and raised in Texas, and the third involving an at least-10-year-old cow in Alabama that was diagnosed in March 2006.

Importantly, **exempt** from the mammalian-to-ruminant feeding ban is 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)**. FDA said it believes these “nonprohibited” products represent a minimal risk of spreading transmissible spongiform encephalopathies (TSEs) to ruminants through feed. “This exclusion is scientifically defensible because swine and horses have not been shown or reported to have a condition that can be linked to a TSE,” FDA has said.

Also **exempt** from the ban on feeding mammalian protein to ruminant animals is “**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).” FDA said such products pose a “lower risk” of spreading TSEs through feed because they are inspected by the U.S. Department of Agriculture's Food Safety Inspection Service or a comparable state agency, and further heat-processed before being fed. The plate waste definition does not include meat trimmings from slaughter operations or butchers.

In addition, **not covered** by the final rule because they are not proteins are such products as: fats; blood or blood products; milk or milk products; oils; grease; amino acids; and dicalcium phosphate (*a byproduct of the gelatin-manufacturing process*).

However, proteins derived from other, prohibited mammalian tissues, such as ruminant meat and bone meal, are classified by FDA to be food additives that are not considered to be “Generally Recognized as Safe” (GRAS) when used or intended for use in feed for cattle or other ruminant animals. Also, based upon an April 25, 2008 revision to the final rule, 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.

The final rule on the mammalian feeding ban took effect on **Aug. 4, 1997**, which was the date feed mills were required to change their formulas to exclude prohibited mammalian protein from ruminant rations. The rule provided another 60 days – **until Oct 3, 1997** – for the pipeline to be cleared of feed manufactured prior to Aug. 4 that contained prohibited mammalian protein intended for use in ruminant feed. **Oct. 3, 1997** also was the deadline for changing printed labels and packaging for feeds that contain or may contain prohibited mammalian protein to include the cautionary statement, *“Do not feed to cattle or other ruminants.”*

Requirements for Feed Manufacturers and Distributors

The FDA final 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, the FDA 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.

This compliance guide focuses on the requirements applicable to feed manufacturers and distributors. The accompanying chart on page 16 visually depicts the applicability of these requirements.

Definitions of Three Types of Protein

The FDA 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 (an organization of state and federal feed control agencies) as material which, if derived from mammalian sources unless specifically exempted by regulation, is prohibited from being fed to cattle or other ruminants¹, are:

- Animal By-Product Meal
- Animal Digest
- Animal Liver
- Bone Meal, cooked
- Bone Meal, steamed
- Cooked Bone Marrow
- 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 Marrow
- Restaurant Food Waste
- Stock/Broth
- Unborn Calf Carcasses

In addition, tallow (rendered fat from cattle) is prohibited from being fed to cattle or other ruminants if its insoluble impurity level is greater than 0.15 percent.

It is these products, as well as feed that contains or may contain such products, that are not to be fed to cattle or other ruminants and are to be labeled with the BSE caution statement.

¹ *Official Publication, 2011. Association of American Feed Control Officials Inc., Oxford, Ind.*

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, the FDA final 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, which are discussed later.

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

- **use separate equipment or facilities** for manufacturing, processing or blending prohibited mammalian protein from non-prohibited mammalian/nonmammalian materials. *[Note: In the preamble to the final rule, FDA states that the requirement that feed mills maintain separate equipment or facilities will be interpreted as also requiring the separate storage of such 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.

The FDA final 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. FDA says that such written procedures should “correspond to the facility’s actual operations.”

In addition, in the preamble to the final rule, FDA accepted a recommendation from the National Grain and Feed Association (NGFA) that it spell out what clean-out procedures the agency considers acceptable. Further, FDA accepted the NGFA’s suggestion that the clean-out procedures rely primarily upon the flushing and sequencing techniques long recognized as effective under the agency’s Current Good Manufacturing Practice (CGMP) regulations for medicated feed mills.

The verbatim text of the FDA’s “guidance” 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:

“Adequate clean-out procedures for all equipment used in the manufacture and distribution of feeds containing mammalian and nonmammalian protein are essential to avoid unsafe contamination of ruminant feeds. Such procedures may consist of cleaning by physical means, e.g., vacuuming, sweeping, etc. Alternatively, flushing or sequencing or other equally effective techniques may be used whereby the equipment is cleaned through use of a nonprohibited

product. After cleaning, the nonprohibited product used in the cleaning should be handled and stored in an appropriate manner.

“FDA suggests that all equipment, including that used for storage, processing, mixing, conveying, and distribution that comes in contact with feeds containing mammalian and nonmammalian protein, follow all reasonable and effective procedures to prevent contamination of manufactured feed. The steps used to prevent contamination of feed often include one or more of the following, or other equally effective procedures: (1) Physical means (vacuuming, sweeping, or washing), flushing, and/or sequential production of feeds; (2) if flushing is utilized, FDA recommends that the flush material be properly identified, stored, and used in a manner to prevent contamination of other feeds. The volume of the flushed material should be sufficient to equal the operating volume of the shared equipment; (3) if sequential production is utilized, FDA recommends that it be on a predetermined basis designed to prevent unsafe contamination of ruminant feeds. An example of appropriate sequencing would be producing a swine feed containing mammalian protein, followed by a swine or poultry feed not using mammalian protein, followed by a ruminant feed containing nonmammalian protein.

“Due to the degree of variability among feed mill systems, a HACCP-based approach of process controls would be helpful in implementing any of the above clean-out procedures. This will enable differences to be addressed on a site-specific basis. Feed mills could follow the clean-out procedures by determining their plant’s individual characteristics and apply appropriate time and volume requirements for flushing material to accomplish the intent of the procedures. Individual clean-out procedures, including time and volume calculations, may be part of the plant’s written procedures specifying the clean-out procedures utilized, and the written procedures are subject to FDA review for compliance purposes.”

The agency said it will consider firms using clean-out procedures “at least as stringent” as those described in the preceding paragraphs to be “adequate.”

Important Note: Subsequent to the issuance of the final rule, FDA clarified the provisions concerning the amount of flush material to be used in clean out for feed mills that handle both prohibited mammalian protein (*such as meat and bone meal from cattle, deer, elk, etc.*) and nonprohibited mammalian protein (*such as pure pork and equine*) and/or non-mammalian protein (*such as poultry, soybean meal, etc.*) FDA’s final rule stated that, “[t]he volume of the flushed material should be sufficient to equal the **operating volume of the shared equipment.**” [Emphasis added.] For many mills, this could result in an enormous quantity of flush material.

However, FDA said that the operative language that the agency wants feed manufacturers to observe is the following portion of the final rule: “**Feed mills could follow the clean-out procedures by determining their plant’s individual characteristics and apply appropriate time and volume requirements for flushing material** to accomplish the intent of the procedures.” [Emphasis added.] This provision provides flexibility to feed mill managers to determine the quantity of flush material necessary to adequately clean out the mill equipment after manufacturing feed that contains prohibited mammalian protein.

Exemptions: Exemptions from the aforementioned requirements would be provided **only** for those purchasing prohibited mammalian protein from renderers that have certified that they:

- exclusively use a manufacturing method validated by FDA to deactivate the agent that causes TSEs (*no such method currently exists*).
- routinely use a test validated by FDA that is effective in detecting the presence of the agent that causes TSEs (*no such test currently exists*); or
- exclusively uses a manufacturing method, such as Hazard Analysis and Critical Control Point (or HACCP) plans, validated by FDA that minimizes the risk of the TSE agent from entering the rendered product (*no such method currently has been approved*).

Labeling Requirement

The FDA final 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 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 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 will be required to include the 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.

In the preamble to its final rule, FDA said it “acknowledges” that it may be unlikely that feed labeled for use in nonruminant livestock would be diverted to ruminants. But the agency maintained that because complete feeds for nonruminants “typically cost only slightly more per ton and often contain more protein than complete ruminant feeds...,” such feeds “may be diverted to ruminant feed.”

FDA’s final rule calls for 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,” FDA said. The agency also “suggests” that the labeling statement be distinguished by different type size, color or other means so it is noticed easily by a buyer.

The only other exemption from the labeling requirement provided in the final rule is for those using mammalian protein purchased from renderers that have certified that they:

- exclusively use a manufacturing method validated by FDA to deactivate the agent that causes TSEs (*no such method currently exists*).
- routinely use a test validated by FDA that is effective in detecting the presence of the agent that causes TSEs (*no such test currently exists*); or
- exclusively uses a manufacturing method (such as HACCP plans) validated by FDA that minimizes the risk of the TSE agent from entering the rendered product (*no such method currently has been approved*).

Recordkeeping Requirements

The 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 receiving and utilizing **prohibited mammalian** protein are required to retain sales invoices or other records for **one year** after purchase so that FDA can track the receipt, processing and distribution of feed containing such materials.

The final rule states that 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 said it would expect 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, FDA said 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, the agency said. It is only necessary to retain one label from each shipment representing a different product, FDA said. 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 agency said.

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

Exemption: The only exemption from the recordkeeping requirement is for feed manufacturers and distributors that purchase animal protein products that contain an FDA-approved distinctive mark on the feed itself (as opposed to the label or packaging) to identify that it consists 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 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**.

When issuing the rule, FDA said the removal of “high-risk materials,” principally brain and spinal cord from cattle 30 months or older, will “further protect against inadvertent transmission” of the protein prion believed to cause BSE as a result of cross-contamination of ruminant feed with nonruminant feed or feed ingredients. FDA noted that such cross-contamination can occur during manufacture and transport, or through misfeeding of nonruminant feed containing such tissues to ruminants on-farm. “FDA believes that the presence of certain cattle-derived risk materials in the non-ruminant feed supply presents a potential source of exposure in the United States” resulting from inadequate cleanout procedures, mislabeling and recordkeeping deficiencies, FDA said in its final rule. “The agency continues to believe that the 1997 ruminant feed rule provides a strong primary line of defense against BSE transmission by prohibiting the use in ruminant feed of all materials with potential BSE infectivity. The added measure of excluding high-risk materials from all animal feeds prevents any accidental feeding of such ingredients to cattle...greatly minimiz(ing) the residual BSE risks not eliminated by the 1997 feed (rule) if cross-contamination of ruminant feed with nonruminant feed, or diversion of non-ruminant feeds to ruminants, were to occur.”

The final regulations were to take effect on April 27, 2009, but that date subsequently was delayed until Oct. 26, 2009 to provide renderers with additional time to comply with the rule’s requirements. FDA’s final regulations generally mirror the recommendations made by the NGFA in comments submitted to the agency in response to its October 2005 proposal. Specifically,

FDA adopted the NGFA's recommendation to permit the use in animal feed of nonambulatory cattle if brain and spinal cord are removed from stock 30 months or older. FDA initially proposed to ban the use of all nonambulatory and dead cattle in all animal feed, regardless of age. However, BSE is not known to manifest itself in younger cattle. In addition, scientific evidence indicates that removing brain and spinal cord from cattle 30 months or older will further reduce – by roughly 90 percent – the already extremely low risk of BSE transmission in the U.S. cattle population.

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 the carcass of BSE-positive cattle **or** the brains and spinal cords of cattle 30 months of age and older **or** 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 final 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 and equine protein. FDA also did not address the feeding of poultry litter to ruminants, thereby continuing to allow that practice.

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 on April 30, 2009 issued final guidance to industry (updated on June 5, 2009) that 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 materials is 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 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.

- Tallow used in animal feed by feed manufacturers after the effective date of the regulations is to meet the new impurity standard. **Importantly**, FDA expressly states that feed manufacturers are **not** required to physically clean tallow tanks to meet this requirement. Rather, FDA states this changeover, if needed, “may be accomplished through physically cleaning the tank, by switching to new product that meets the new impurity standard prior to the effective date, or by some other means.” Further, FDA advises that feed manufacturers document the method they choose to use to bring tallow tanks into compliance to meet the rule’s recordkeeping requirement. Such documentation could include copies of invoices of incoming product that meets the impurity standard, equipment maintenance logs, lab reports, and tank-management plans, FDA advises.
- 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 final guidance document notes that the ingredient definition established by the Association of American Feed Control Officials (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. **Importantly, FDA officials also have told the NGFA that if FDA collects routine samples of tallow for testing, it will be at the rendering plant.** Barring “extenuating circumstances,” FDA says it will consider tallow products that are in compliance at the renderer to be in compliance during distribution. Compliance will be determined on a case-by-case basis, FDA states.
- 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.

Tallow¹ 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”

¹Tallow means rendered fat from cattle

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

FDA on Jan. 29, 1998 issued a “top-priority” assignment to its 21 district offices directing that they develop plans to inspect 100 percent of the nation’s feed mills and rendering plants to enforce the agency’s BSE-prevention rule. About 80 percent of the inspections are being done by state feed control agencies under contract with FDA.

Inspection Priorities: FDA’s current BSE compliance program guidance manual states that inspectional resources for surveillance are to be spent covering those firms or industries potentially having the most adverse affect on BSE prevention efforts should non-compliance with the regulations be encountered. In planning and prioritizing inspections, the guidance states that the following firm/industry types should be considered, in order of descending priority:

- Follow-up to ‘OAI’ inspections
- Firms that have a violative history
- Firms handling prohibited materials (Renderers, Protein Blenders, and Feed Mills)
- Rendering operations
- Protein blenders
- Commercial feed mills (licensed and unlicensed)
- Animal feed distributors/retailers (ruminant feeds involved)
- Pet food/animal feed salvage operations
- On-farm feed mixers (ruminant and non-ruminant animals on farm premises)
- Haulers/transporters of animal feeds (ruminant feeds involved)
- Ruminant feeders (dairy cattle)
- Ruminant feeders (ruminants other than dairy cattle)

- Animal feed distributors/retailers (no ruminant feeds involved)
- Haulers/transporters of animal feeds (no ruminant feeds involved)
- On-farm feed mixers (only ruminant or no ruminant animals on farm premises)

FDA has devised - and subsequently revised on several occasions - an inspection report that is being used by inspectors when inspecting feed mills and other plants to check on compliance with the mammalian feeding ban. [See Pages 17 through 24]. Among other things, feed regulatory officials during inspections will determine if the feed mill: 1) is aware of the BSE-prevention feed regulations; 2) has safeguards in place to assure they do not receive prohibited mammalian proteins, if the mill does not intend to receive feeds or feed ingredients that contain or may contain prohibited materials; 3) uses tallow in animal feed formulations that is in compliance with the regulations; 4) labels feeds containing prohibited mammalian proteins with the caution statement, “Do not feed to cattle or other ruminants;” 5) maintains records that track prohibited mammalian protein products throughout their receipt, processing and distribution; and 6) follows approved clean-out procedures if handling products that contain prohibited mammalian proteins **and** feeds or feed ingredients that may be used for ruminant animals.

Inspection Results: FDA’s Center for Veterinary Medicine (FDA/CVM) on April 19, 2001 began posting on its web site the results of inspections, and currently updates the data on a weekly basis. The information posted, in the form of an Excel spreadsheet and a searchable web-based database, includes: 1) the company name and street address; 2) the type of business (feed mill, renderer, feeder, distributor, etc.); 3) the date of the most recent inspection performed; 4) whether the facility distributes, handles, or does not handle prohibited mammalian protein; 5) whether the facility handles feed for ruminant animals; and 6) the inspection classification results, listed as either “OAI” (official action indicated), “VAI” (voluntary action indicated), or “NAI” (no action indicated). Importantly, FDA has provided the following information concerning its inspection classifications:

- An OAI inspection classification occurs when significant objectionable conditions or practices were found and regulatory sanctions are warranted in order to address the establishment’s lack of compliance with the regulation. An example of an OAI inspection classification would be findings of manufacturing procedures insufficient to ensure that ruminant feed is not contaminated with prohibited material. Inspections classified with OAI violations will be promptly re-inspected following the regulatory sanctions to determine whether adequate corrective actions have been implemented
- A VAI inspection classification occurs when objectionable conditions or practices were found that do not meet the threshold of regulatory significance, but do warrant advisory actions to inform the establishment of findings that should be voluntarily corrected. Inspections classified with VAI violations are more technical violations of the Ruminant Feed Ban provisions such as minor recordkeeping lapses and conditions involving non-ruminant feeds.
- A NAI inspection classification occurs when no objectionable conditions or practices were found during the inspection or the significance of the documented objectionable conditions found does not justify further actions.

When significant violations are detected, FDA states its first action following additional education typically is a warning letter. However, FDA has taken strong legal action against firms for “knowing, egregious or repeated violations.” Several dozen recall orders also have been issued by FDA as a result of noncompliance.

The inspection results can be accessed from FDA/CVM’s website under the “Ruminant Feed Inspections” section.

Conclusion

The NGFA will continue to update this guidance in response to any future changes to FDA’s BSE-prevention regulations. In addition, FDA has published a small business compliance guide concerning the ban on feeding certain mammalian proteins to ruminant animals entitled, ***“Guidance for Industry — Small Entities Compliance Guide for Protein Blenders, Feed Manufacturers and Distributors,”*** which appears on pages 25 through 32. Other compliance guides have been published by FDA for renderers and livestock feeding operations. They are available on FDA/CVM’s web site at: www.fda.gov/cvm. Also included with this NGFA Compliance Guide is a copy of FDA’s ***“Questions and Answers on BSE Feed Regulation”*** found on pages 33 through 48, and a copy of FDA’s ***“Feed Ban Enhancement: Implementation Questions and Answers”*** found on pages 49 through 61.

FDA Final Rule Prohibiting Feeding of Mammalian Protein to Ruminant Animals

Type of Mammalian Protein

<p>Use Only <u>Prohibited</u> Mammalian Protein (includes cattle, sheep, goats, deer, elk, mink, dogs, cats)</p>	<p>Use <u>Both</u> Prohibited and Non-Prohibited Mammalian Protein <u>and</u> Intend to Keep such Products Separate</p>	<p>Use Only <u>Non-Prohibited</u> Mammalian Protein (includes pork and equine) and/or <u>Nonmammalian Protein</u> (includes poultry, fishmeal, plant and vegetable protein, etc.)</p>
<p>Manufacturing Processes and Clean-Out Requirements Do <u>Not</u> Apply (Unless manufacturing feed for cattle or other ruminants¹)</p>	<p>Manufacturing Processes and Clean-Out Requirements</p> <ol style="list-style-type: none"> 1. Use separate equipment or facilities for manufacturing, processing or blending prohibited from non-prohibited mammalian protein <p style="text-align: center;"><u>or</u></p> <ol style="list-style-type: none"> 2. Use clean-out procedures “or other means” to prevent carryover; maintain written procedures that correspond to facility’s actual operations 	<p>Manufacturing Processes and Clean-Out Requirements Do <u>Not</u> Apply</p>
<p>Labeling Requirement</p> <p>“Do Not Feed to Cattle or Other Ruminants”</p> <p>Applicable except for:</p> <ul style="list-style-type: none"> • pet food sold at retail; • feed for non-ruminant laboratory animals 	<p>Labeling Requirement</p> <p>“Do Not Feed to Cattle or Other Ruminants”</p> <p>Applicable to feed containing <u>prohibited</u> mammalian protein unless it is:</p> <ul style="list-style-type: none"> • pet food sold at retail; • feed for non-ruminant laboratory animals 	<p>Labeling Requirements Do <u>Not</u> Apply</p>
<p>Recordkeeping Requirement</p> <p>Retain sales invoice, label, or other records for one year after purchase</p>	<p>Recordkeeping Requirement</p> <p>Retain sales invoice, label, or other records for one year after purchase</p> <p>Applicable only to feed containing <u>prohibited</u> mammalian proteins</p>	<p>Recordkeeping Requirement</p> <p>None, with the following exception:</p> <p>Those actually feeding ruminant animals (e.g., feedlots) are required to retain sales invoice, label or other records for one year documenting that products being fed are non-prohibited mammalian protein or exempt protein</p>

¹ In this situation, flushing or other clean-out procedures would be required to remove prohibited mammalian protein from the system before manufacturing feed for ruminants which must contain only non-prohibited mammalian protein.

REPORT OF INSPECTION FOR COMPLIANCE WITH 21 CFR §589.2000 and §589.2001

FEI NUMBER:

Firm (Legal) Name	Date Current Inspection Ended
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Firm (Physical) Address	Lead Investigator
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Firm City	Lead Affiliation (Check one) <input type="checkbox"/> Federal <input type="checkbox"/> State Agency (Enter name below)
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Firm State	ZIP Code	Telephone Number
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Name and title of person(s) interviewed	GPS Coordinates of Inspected Site
	FDA District Office
	Name and title of most responsible person at this site

<input type="checkbox"/> Information above includes changes to firm's name and/or address	Operational Status (Check only one) (See Instructions) [If firm is OOB, Skip ALL Sections!] <input type="checkbox"/> Operational <input type="checkbox"/> Seasonal <input type="checkbox"/> Inactive <input type="checkbox"/> Out of Business
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Section 1 — Complete for ALL firms

1. a) Type of firm inspected? (Check ALL that apply)

<input type="checkbox"/> Renderer	<input type="checkbox"/> Distributor/Retailer	<input type="checkbox"/> Pet Food Manufacturer	<input type="checkbox"/> Feeder of Ruminants
<input type="checkbox"/> Protein Blender	<input type="checkbox"/> Feed Mill (FDA Licensed)	<input type="checkbox"/> Animal Feed/Pet Food Salvager	<input type="checkbox"/> Human Food Processor
<input type="checkbox"/> Transporter (Hauler)	<input type="checkbox"/> Feed Mill (not FDA Licensed)	<input type="checkbox"/> On-farm Feed Mixer	

Other (Specify): _____

b) Does the firm handle (manufacture, process, blend, distribute, transport or use) feed or feed ingredients that are intended for the feeding of ruminant animals? <input type="checkbox"/> Yes <input type="checkbox"/> No	c) Does the firm handle (manufacture, process, blend, distribute, transport or use) feed or feed ingredients that are intended for the feeding of non-ruminant animals? <input type="checkbox"/> Yes <input type="checkbox"/> No
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d) Is the firm aware of the BSE rule, 21 CFR §589.2000? Yes No

2. If the firm is manufacturing feed, does it use tallow (animal fat from cattle) in animal feed formulations?
 Firm does not manufacture feed. Yes No

a) If yes, does tallow used in ruminant feed contain not more than 0.15% insoluble impurities? Yes No

3. Does the firm receive feeds or feed ingredients that contain or may contain prohibited material (PM)? (Check only one)
 YES, but PM is **Only** in Retail Pet/Lab Feed Yes No

a) If Question 3 is "YES, but PM is only in Retail Pet/Lab Feed" or "NO," check all of the following that describe **voluntary** safeguards the firm has in place to assure they do not receive prohibited material.

<input type="checkbox"/> Written assurance from suppliers that they no longer manufacture/distribute any products containing prohibited materials	<input type="checkbox"/> Written procedures for the label review of incoming materials
<input type="checkbox"/> Written assurance from transporters that they do not transport products containing prohibited materials	<input type="checkbox"/> Uses only vegetable source proteins and uses no animal proteins
<input type="checkbox"/> Written assurance from transporters that they utilize dedicated transport equipment OR utilize clean-out measures that adequately prevent commingling or cross-contamination	<input type="checkbox"/> Uses animal proteins only from exempted sources (Check all that apply) <input type="checkbox"/> Blood <input type="checkbox"/> "Plate waste" <input type="checkbox"/> Equine <input type="checkbox"/> Fish <input type="checkbox"/> Milk <input type="checkbox"/> Porcine <input type="checkbox"/> Poultry <input type="checkbox"/> Gelatin

Testing of incoming materials (Please describe)

Other (Please describe)

If Question 3 is "No" or if Question 1.a) is only "Feeder of Ruminants", skip to Section 4.

b) If Question 3 is either "YES, but PM is ONLY in Retail Pet/Lab Feed" or "YES", is imported prohibited material (not originating in the United States) used? Yes No Unknown

Please list the country/ies of origin for the imported prohibited material.

4. Is the **received** product containing prohibited material intended **ONLY** for further distribution? Yes No

5. Does the firm manufacture or process products containing prohibited materials? Yes No

6. Are the **received** feeds or feed ingredients containing prohibited materials (referred to in #3 above) labeled with the caution statement, "Do not feed to cattle or other ruminants"? (**Check only one**)

PM is **Only** for Rendering PM is **Only** in Retail Pet/Lab Feed Yes No

Section 2 — Complete for ALL firms EXCEPT: Firms that are ONLY Q1a) Firm Type = "Other" OR Firms that are ONLY Q1a) Firm Type = "Feeder of Ruminants"

7. Are the **outgoing** feeds or feed ingredients containing prohibited materials labeled with the caution statement, "Do not feed to cattle or other ruminants"? (**Check only one**)

No Outgoing Feeds/Ingredients containing PM PM is **Only** in Retail Pet/Lab Feed Yes No

8. Describe records the firm maintains in tracking prohibited materials throughout their receipt, processing and distribution.

a) Date of receipt or purchase or sale or delivery..... <input type="checkbox"/> Yes <input type="checkbox"/> No	f) Copies are available for inspection and copying <input type="checkbox"/> Yes <input type="checkbox"/> No
b) Name and address of the seller..... <input type="checkbox"/> Yes <input type="checkbox"/> No	g) Are ONLY retail feed sales involved? <input type="checkbox"/> Yes <input type="checkbox"/> No
c) Name and address of the purchaser <input type="checkbox"/> Yes <input type="checkbox"/> No	h) Are ONLY retail feed sales of pet food involved? <input type="checkbox"/> Yes <input type="checkbox"/> No
d) Identification of the product <input type="checkbox"/> Yes <input type="checkbox"/> No	
e) Quantity <input type="checkbox"/> Yes <input type="checkbox"/> No	

9. a) Does the firm manufacture, process, blend, repackage, or transport **BOTH** products containing prohibited materials **AND** products containing only non-prohibited materials? Yes No

b) Does the firm manufacture, process, blend, repackage, or transport **BOTH** products containing prohibited materials **AND** feeds or feed ingredients that may be used for ruminants? Yes No

10. a) If the answer to **Q9a)** is "NO," then **SKIP to Question 11.**
If the answer to **Q9a)** is "YES", does the firm have a system in place to avoid commingling and cross-contamination? Yes No

b) If the answer to **Q9a)** is "YES," check **ALL** of the following that describe the measures the firm has in place to avoid commingling or cross-contamination.

- Sequencing of feeds
- Flushing the system (Please describe)

- Written sequencing and flushing procedures
- Documentation maintained of sequencing and flushing
- Flushed materials discarded or labeled with the caution statement
- Physical clean-out (e.g. vacuuming, cleaning)
- Dedicated equipment used for prohibited materials
- Product containing prohibited material is always in packaged form when in the firm's possession
- Other (Please describe)

11. Please describe any additional safeguards the firm has in place to assure that **outgoing** feeds or feed ingredients containing prohibited material are not shipped to ruminant feeders (**if none, please enter "None"**).

Section 3 — COMPLETE this section ONLY if the firm is marked as: Q1a) Firm Type = "Renderer"

12. Describe the firm type. (Check one, or more if applicable)

- Independent Renderer (rendering facility not affiliated with a slaughter facility)
- Livestock Slaughter Facility with On-Site Rendering
- Transfer Station, Transporter
- 4-D Processor (non-cooking facility)
- Other (Please describe) _____

13. Does the firm process cattle and/or cattle offal, with or without other livestock species?

- Yes No

If Question 13 is "No", then skip to Section 4.

14. Does the firm collect, receive or process material (including dead stock cattle 30 months of age or older) that contains "cattle material prohibited in animal feed" (CMPAF)?

- Yes No

15. a) Does the firm produce tallow for use in animal feed?..... Yes No
- b) If yes, does the tallow contain not more than than 0.15% insoluble impurities?..... Yes No
- c) If 15(b) is "NO", is outgoing tallow containing more than 0.15% insoluble impurities labeled with the caution statement "Do Not Feed To Cattle Or Other Ruminants"?..... Yes No

16. Does the firm differentiate cattle less than 30 months old from those that are 30 months of age or older? Yes No

a) If yes, check all of the following methods that the firm uses to differentiate cattle by age.

- Dentition (examination of teeth)
- Affidavit from supplier
- Livestock producer herd records
- Other (Please describe) _____

b) Does the firm have written procedures explaining the process(es) used above?..... Yes No

c) Does the firm maintain records for at least one year documenting the methods noted above?..... Yes No

17. Does the firm separate CMPAF from material that may be used in animal feed?

- Yes No

a) If yes, check all of the following methods that the firm uses to separate CMPAF from material that may be used in feed.

- Remove striated muscle and offal from the carcass
- Remove the vertebral column and head from the rest of the carcass
- Remove only the brain and spinal cord
- Other (Please describe) _____

b) Does the firm have written procedures explaining the process(es) used above?..... Yes No

c) Does the firm maintain written records for at least one year documenting the methods noted above?..... Yes No

d) Does the firm have separate equipment for handling CMPAF once removed from the whole carcass?..... Yes No

e) Is the CMPAF labeled "do not feed to animals"?..... Yes No

f) Is the CMPAF marked with an agent that can be seen by visual inspection?..... Yes No

18. Does the firm generate CMPAF?

- Yes No

a) If yes, what method does the firm use to dispose of the CMPAF? (Check all that apply)

- Landfill
- Incineration
- Alkaline or thermal digestion
- Rendering
- Other (Please describe) _____

b) Does the firm have records that document disposition of CMPAF?..... Yes No

c) Do the records demonstrate that CMPAF is not going into animal feed?..... Yes No

Section 4 — SKIP this section when the firm is ONLY marked as: Q1a) Firm Type = "Other" OR Q1a) Firm Type = "Transporter (Hauler)"

19. a) Are any **incoming** feeds or feed ingredients transported in bulk form? Yes No
- b) Are any **incoming** feeds or feed ingredients transported in packaged form? Yes No
- c) Does the firm utilize **its own** transportation vehicles for the delivery of any bulk **incoming** feeds or feed ingredients? Yes No
- d) Does the firm utilize **other firms'** transportation vehicles for the delivery of any bulk **incoming** feeds or feed ingredients? Yes No
- e) If 19(d) is "YES," do **ALL inbound** transporters provide written assurance that they utilize dedicated transport equipment OR utilize measures that adequately prevent commingling or cross-contamination with prohibited material? Yes No
-
20. a) Are any **outgoing** feeds or feed ingredients transported in bulk form? No Outgoing Feeds/Ingredients Yes No
- b) Are any **outgoing** feeds or feed ingredients transported in bagged/packaged form? No Outgoing Feeds/Ingredients Yes No
- c) Does the firm utilize **its own** transportation vehicles for the delivery of any **outgoing bulk** feeds or feed ingredients? No Outgoing Feeds/Ingredients Yes No
- d) Does the firm utilize **other firms'** transportation vehicles for the delivery of any **outgoing bulk** feeds or feed ingredients? No Outgoing Feeds/Ingredients Yes No
- e) If 20(d) is "YES," do **ALL outbound** transporters provide written assurance that they utilize dedicated transport equipment OR utilize clean-out measures that adequately prevent commingling or cross-contamination with prohibited material? Yes No

Section 5 — Complete this section ONLY if the firm is marked as: Q1a) Firm Type = "Feeder of Ruminants"

21. Are ruminant feeders doing the following?
- a) Observing the caution statement on feeds containing prohibited material (**PM**) Yes No No PM-feeds on premises
- b) Maintaining copies of labeling for feeds containing animal protein (**AP**) Yes No No AP-feeds on premises
(**Not including** retail pet food for cats and dogs)
- c) Maintaining copies of purchase invoices for feeds containing animal protein Yes No No AP-feeds on premises
(**Not including** retail pet food for cats and dogs)
- d) Feeding non-ruminant species (**Not including** cats and dogs) Yes No
- e) Feeding non-ruminant species (**Not including** cats and dogs) feeds containing prohibited material Yes No No PM-feeds on premises
- f) Feeding cats and/or dogs Yes No

Section 6 — Complete for ALL Firm Types

22. a) Check all deviations that were noted at the time of inspection. Commingling Labeling No Deviations Noted
 Recordkeeping Feeding Ruminants Prohibited Material
- b) If any deviations were noted above, describe the deviations, and the actions and commitments made to correct each deviation.

23. a) Are you attaching any descriptions, exhibits, records, labeling, reports or supplemental information? Yes No

INSTRUCTIONS — For the Lead Investigator

District BSE Coordinator. The FDA District BSE Coordinator is responsible for communicating and receiving information related to the BSE Checklist/Report. Questions, comments and concerns should be directed to this individual. Completed BSE Reports of Inspection generated by State agencies should be mailed to the District BSE Coordinator, not to CVM. The Districts are responsible for checking the forms for completeness and accuracy, and for entering the information into FACTS.

BSE Checklist/Report Version. Please make sure you are using the **most current** BSE Checklist/Report version. The version date is located at the bottom of the form. Check with your BSE District Coordinator or the FDA/CVM website (<http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM052412.pdf>) to make sure you are using the most recent version. Other versions may not be compatible with the BSE Checklist/Report Database and may invalidate the information collected.

BSE Checklist/Report Alterations. Some agencies may choose to alter the BSE Checklist/Report to better fit their own operations. While CVM does not necessarily object to such alterations, changes **must** be added to the end of the form. No additions, deletions or revisions should be made to the main body of the CVM-version of the BSE Checklist/Report.

Legibility. Illegible writing results in inaccurate data, which compromises the BSE Compliance Program. If you are submitting a handwritten checklist, please print your responses to the questions.

Completing Sections. Sections should be fully completed for each of the firm types indicated in the header of each Section.

Sections inappropriately skipped (based on the firm type) may cause the BSE Checklist/Report to be considered incomplete. Incomplete BSE Reports of Inspection may require follow-up with the investigator and may require a follow-up inspection at the firm.

Completing Questions. The BSE Checklist/Report instructions and flow of questions must be followed. Blank or unanswered required questions may cause the BSE Checklist/Report to be considered incomplete. Incomplete BSE Reports of Inspection will require a follow-up with the investigator and may require a follow-up inspection of the firm.

Descriptive Fields. For those questions that ask for an explanation or description, please be brief and capture the essential elements with as few words as possible. If you feel certain answers require a more lengthy description, consider recording the information on a separate page, which should be attached to the BSE Checklist/Report and so noted in the question at the end of the checklist which asks if additional documents are attached.

Additional Narrative. For those state BSE/Ruminant Feed inspections not being done under federal contract or those state contract BSE/Ruminant Feed inspections that do not include an FDA-481, it is recommended that a brief narrative report accompany the BSE Checklist/Report summarizing the inspection. A brief summary should cover the entire inspection and should include other details not captured in the Checklist/Report.

CHECKLIST QUESTIONS

Firm information - Complete for ALL firms, regardless of the firm type.

FEI Number. The FEI number is **absolutely required**. It is the District's responsibility to provide this information, and you may need to contact your District BSE Coordinator for this information. The District may need to assign an FEI number after the inspection is completed. For example, if the firm has not been inspected before, the District will assign an FEI number when it receives the report.

Firm Name. Use the firm's accurate legal name. Do not use "Doing Business As" (DBA) firm names if at all possible.

Firm Address. The address should reflect the physical location of the firm's activities. Post Office Box numbers are unacceptable. If the firm's mailing address is different than their physical address, please make a note of this information.

Date Current Inspection Ended. If the inspection went more than one day, enter the date of the last day of the inspection.

Lead Investigator. Enter the name of the lead investigator.

Lead Affiliation. If the inspection was done by FDA, check this box. If the inspection was done by a State, check the box and write in the name of the State.

FDA District Office. Enter the name of the FDA District in which the inspected firm is located.

GPS Coordinates. This information is not required by FDA at this time.

Name and Title of the Person(s) Interviewed. Record the name and title of the person(s) interviewed during the inspection.

Name and Title of Most Responsible Person at the Site. Record the name and title of the most responsible person at the facility, for example the firm's President or Manager. This may or may not be the person interviewed during the inspection.

Operational Status. Mark the firm's operational status. Inspection reports should be completed for **Seasonal** and **Inactive** firms since they might begin production at any time. **Out of Business** firms require no more information gathering.

Changes to Firm Name and Address. If the facility/site has a new name and/or address, please check the box indicating this and make sure the address recorded on the inspection report is correct. Please record the firm's former name and/or address somewhere in your inspection report.

Section 1 - Complete for **ALL** firms, regardless of the firm type (with the exception of firms which are Out of Business).

Question 1a) Firm Type. Please understand the firm type categories provided and use these categories whenever applicable. More detail is provided in Compliance Program 7371.009.

Considerations

- A **single firm** can be categorized as **one or more firm types**, so mark all firm types that are appropriate.
- The **BSE Checklist/Report** may not fully describe the activities of certain multiple firm type combinations. Please contact your BSE District Coordinator if additional guidance is needed.
- **Warehouse operations** should be marked as Distributor/ Retailer.
- **Feed mills** should be described on the basis of FDA licensure and NOT on whether the firm produces medicated feeds. A single firm cannot be marked as both a licensed feed mill and an unlicensed feed mill.
- **Ingredient manufacturers** are considered unlicensed feed mills.
- **Ruminant feeders** (e.g. dairy farms, feedlots) might also be On-farm Mixers, but On-farm Mixers might not be ruminant feeders (e.g. swine farms). The "Feeder of Ruminants and Other Species" category has been deleted in this version of the inspection report form. If doing an inspection at a farm that does NOT feed ruminants, but does feed other species of livestock, check the "Other" box and write-in "non-ruminant feeder".
- **On-farm Mixing** applies to mixing that is not performed for the purpose of commercial distribution. Generally the use of on-farm mixed feeds occurs on the same farm premises where the feed is made. However, in some cases feeds mixed on-farm are utilized off-premises and/or outside the direct supervision of the farm manager (e.g., a farm where mixed feeds are delivered for feeding at physically different farm locations, perhaps under a contract arrangement).
- **On-farm Mixers** are subject to the requirements of the BSE/ Ruminant Feed regulation (21 CFR §589.2000) just like commercial feed mills.
- If the firm manufactures human food, mark the **Human Food Processor** box.
- The "**Other**" category should be used only for firm operations that are not described by the other categories listed. Improper use of the "Other" category may cause inaccurate and/or inadequate information to be collected in the remaining Sections.
- **Feed or Feed Ingredients.** These are products intended to be fed to animals or used to manufacture animal feeds. Substances intended solely for other purposes (e.g. fertilizers) are not included in this category.

Question 1 - b) Further defines "handling" for better clarification. **c)** Asks whether the firm makes feed for non-ruminant animals. **d)** Asks whether the firm is aware of the BSE rule or not.

Question 2 - This question is new. Does the firm receive and use "tallow" (animal fat from cattle) in feeds they manufacture? If the firm does not manufacture feed mark the box that says "firm does not manufacture feed". If the firm does not use tallow, mark "NO" and skip 2a). If the firm does use tallow and you marked yes on Q2) then you need to answer Q2a). If the firm manufactures ruminant feed and if they use tallow as an ingredient in ruminant feed, check the label of the tallow to make sure it contains no more than 0.15% insoluble impurities. Mark "YES" if it does, or "NO" if it does not. If the firm is a renderer that processes cattle, mark "YES" to Q2) and answer Q2a). If the firm is a renderer that does not process cattle, mark Q2) "NO".

Question 3 - If you answer "NO" or "YES, but PM is only in Retail Pet/Lab feed" then go through the list of boxes in **3a)** to describe the safeguards the firm is taking to make sure they do not receive prohibited material for use in their manufacturing operation. If the answer to Q3) is "no", or if the firm is only a "feeder of ruminants" , then do not complete question 3b) and skip to Section 4, Question 19, of the inspection report form. **3b)** If imported prohibited material is used, please record the country of origin of that product.

Question 4 - Is the received product that contains prohibited material being held only for further distribution? Mark "Yes" or "No".

Question 5 - Is the firm manufacturing, or otherwise processing, products that contain prohibited material? Mark "Yes" or "No". Note - The answers to questions Q4) and Q5) can both be "No", but they cannot both be "Yes".

Question 6 - Are feeds containing prohibited material properly labeled with the caution statement? Raw animal products destined for a renderer are not required to be labeled. If you are inspecting someone supplying/transporting raw animal products to a renderer, mark "PM is only for rendering". Retail pet foods are exempted from the requirement to have the caution statement on the label, unless the product is salvaged or distressed.

Section 2 - If the firm "handles" (manufacture, process, blend, distribute, transport or use) prohibited materials or feeds which may contain prohibited material, complete section 2.

Question 7 - Asks if outgoing feeds that contain (or may contain) prohibited material are properly labeled with the caution statement. The first option, "No Outgoing Feeds/ Ingredients containing PM", for example, may be used when inspecting a farm that mixes its own feed. The second box, "PM is ONLY in Retail Pet/Lab Feeds" is to be used in those cases where the only prohibited material on the premises is found in pet or lab animal feed.

Question 8 - The purpose of the question is for the Investigator/ Inspector to simply note the types of recordkeeping being utilized and not to indicate their adequacy with respect to the BSE/ Ruminant Feed Regulation (21 CFR §589.2000). Recordkeeping inadequacies should be indicated and described in **Section 6**. Retail sales are sales made to the ultimate consumer — people purchasing feed for their animals. **g)** Mark "yes" if the firm sells feed (any kind of feed, including pet food)

but does not manufacture feed at the site. h) If you marked "yes" on g) and the only type of feed sold at the firm is pet food, mark "yes" on h) as well.

Question 9 - Commingling and cross-contamination can occur when products are processed or handled, such as with manufacturing, blending, repackaging or transporting a product. **a)** Asks if the firm makes a feed product containing prohibited material AND a feed product which does not contain any prohibited material. **b)** Asks if the firm makes a feed product containing prohibited material AND a feed product for ruminants.

Question 10 - If the answer to 9a) is "NO", skip to Question 11. If 9a) is "YES", then answer 10a) by indicating whether or not the firm has a system in place to avoid commingling and cross-contamination. Mark the boxes in 10b) that best describe the measures the firm has adopted to avoid commingling and cross-contamination. Use the narrative fields if necessary.

Question 11 - Briefly describe in writing any additional safeguards the firm may have in place to prevent outgoing feed products that contain prohibited material from being shipped to ruminant feeders.

Section 3 - This section is new and is used only for inspections at rendering establishments. If the firm is not a renderer, skip this section.

Question 12 - Mark the box that best describes the type of rendering firm being inspected. If the first four choices do not seem to describe the firm's principal activity, then mark "other" and very briefly describe the type of firm being inspected. We prefer that you mark only one box, but the question will allow you to mark more than one box if necessary.

Question 13 - If the firm processes cattle, cattle offal, or beef scraps (regardless of whatever else they do) mark "YES" and continue with section 3. If the firm does not process cattle or any cattle origin material mark "NO" and skip to Section 4.

Question 14 - Does the firm collect, receive or process cattle material prohibited in animal feed (CMPAF)? CMPAF is the brain and spinal cord of cattle 30 months of age and older, or material which may contain the brain and spinal cord of cattle 30 months of age and older. Mark "YES" or "NO".

Question 15 - Q15a) Does the firm produce tallow (animal fat from cattle) and market it for use in animal feed? If so, mark "YES". If Q15a) is "YES", go to Q15b) and answer whether the tallow contains 0.15% insoluble impurities or less (meaning it may be used in ruminant feeds) or not. If Q15b) is "NO" then continue to Q15c) and answer the question about whether the caution statement "do not feed to cattle or other ruminants" is being used on the label of the tallow product.

Question 16 - This question asks if the firm differentiates cattle by age, and then if they do, what methods do they use to differentiate cattle 30 months and over from cattle under 30 months of age. If the firm does not differentiate cattle by age, mark "NO" and skip to Q17). Q16a) lists three common options, and provides a space to describe any "other" method. Mark the boxes next to those methods the firm uses. You may mark multiple boxes. If you mark "other", please briefly describe the firm's method. Q16b) asks if the firm has written procedures explaining the process(es) used above, and Q16c) asks if they

have records documenting these activities for the last year. Mark "YES" or "NO".

Question 17 - This question asks about the methods the firm uses to separate CMPAF from material that may be used in feed, how the firm handles it once it is separated, and whether they have written procedures and records in place. If the firm does not separate CMPAF from material that may be used in feed, mark "NO" and skip to Q18). Q17a) lists three common options, and provides a space to describe any "other" method. Mark the boxes next to those methods the firm uses. You may mark multiple boxes. If you mark "other", please briefly describe the firm's method. Q17b) asks whether the firm has written procedures describing their processes, and Q17c) asks whether the firm has records documenting what they have done. Mark "YES" or "NO". Q17d) asks whether the firm has separate equipment for handling CMPAF once it has been removed, Q17e) asks whether the CMPAF is marked with the "do not feed to animals" caution statement, and Q17f) asks if the CMPAF has been dyed or stained with an agent that can be seen by visually inspecting the product. Mark "YES" or "NO" to all of these questions.

Question 18 - This question asks about the methods the firm uses to dispose of any CMPAF they may be generating. If the firm does not generate CMPAF mark "NO" and skip to Section 4. Q18a) lists four common options, and provides a space to describe any "other" method. Mark the boxes next to those methods the firm uses. You may mark multiple boxes. If you mark "other", please briefly describe the firm's method. Q18b) asks whether the firm has records that document how the CMPAF is being disposed of, and Q18c) asks if these records demonstrate that CMPAF is not going to someone who is going to make feed with that material. Mark "YES" or "NO" to these two questions

Section 4 - This section of the checklist deals with the transportation of feeds and feed ingredients in and out of manufacturing facilities and feeding operations, including feed mills, ingredient manufacturers, and ruminant feeders. This section is not intended to be used during the inspection of firms engaged only in transportation. Transportation equipment is treated like mixing equipment, for example, and when inspecting a transportation firm you would ask the same questions about recordkeeping and cleanout asked of feed mills, renderers and other facilities that may handle prohibited material.

Question 19 - Deals with the transport of feeds and ingredients into the firm. On **19 e)** only answer "yes" if EVERY inbound transporter provides written assurance that they use dedicated equipment or have adequate cleanout procedures, otherwise the answer is "no".

Question 20 - Deals with the transport of feeds and ingredients from the firm. On **20 e)** only answer "yes" if EVERY outbound transporter provides written assurance that they use dedicated equipment OR have adequate cleanout procedures, otherwise the answer is "no".

Section 5 - This section is to be used only when the firm feeds ruminant animals.

Question 21 - Contains six questions to be answered when inspecting a ruminant feeder. **a)** Mark "No PM-feeds on premises" only if you found NO feed on the premises containing prohibited material, not including retail pet food intended for cats

and dogs. **b)** Mark "No AP-feeds on premises" only if you found NO feed on the premises containing animal protein, not including retail pet food intended for cats and dogs. **c)** Mark "No AP-feeds on premises" only if you found NO feed on the premises containing animal protein, not including retail pet food intended for cats and dogs. **d)** Are they feeding animals other than ruminants and dogs/cats? "Yes" or "No". **e)** Mark "No PM-feeds on premises" if the feed for the non-ruminant species does not contain prohibited material, not including retail pet food intended for cats and dogs. **f)** Does the firm have pet cats and/or dogs? Please answer.

Section 6 - This section should be completed for all firms, unless the firm was found to be Out of Business (OOB).

Question 22 - **a)** Mark the boxes for any deviations of 21 CFR §589.2000 and §589.2001 identified during the inspection. **b)** Is

to be used to further describe any deviations identified, and to record action taken, or commitments made, by the firm in response. Issues related to 21 CFR §589.2000 and §589.2001 may be noted for firms that are not handling prohibited material. An example would be the use of the caution statement when the firm is not handling prohibited material.

Question 23 - Are you attaching any descriptions, exhibits, records, labels or supplemental information? If so, check the box and do not forget to attach the other documents.

INSTRUCTIONS — For the District BSE Coordinator

The District BSE Coordinator has a key role and overall responsibility for ensuring that BSE Reports of Inspection are completed fully and accurately, which is vital to the success of BSE compliance efforts. The District BSE Coordinator should pay particular attention to ensuring the following:

- Familiarity with the Instructions for the Lead Investigator.
- The most recent version of the BSE Checklist/Report and accompanying instructions are distributed and utilized.
- The BSE Checklist/Report has not been unacceptably altered.
- All required sections are completed. All questions within a required section are completed.
- Handwritten forms are legible.
- The FEI number is provided.
- The FDA District Office identity is provided.
- Response inconsistencies are resolved.

All completed BSE Reports of Inspection generated by State agencies should be sent to the District BSE Coordinator, not to CVM. The Districts are responsible for checking the forms for completeness and accuracy, and for entering the information into FACTS.

Any questions, concerns or comments regarding the BSE Checklist/Report or the BSE/Ruminant Feed Inspection Compliance Program should be directed to the BSE Coordinator in the appropriate District. The following individuals are additional BSE/Ruminant Feed Inspection Compliance Program contacts:

CVM: Shannon Jordre
shannon.jordre@fda.hhs.gov
240-276-9229

ORA: Jim Dunnie
james.dunnie@fda.hhs.gov
301-827-5652

FDA GUIDANCE FOR INDUSTRY 68

This guide replaces those parts of Guidance for Industry 60, June 17, 1997, that applied to protein blenders, feed manufacturers, and distributors.

SMALL ENTITIES COMPLIANCE GUIDE FOR PROTEIN BLENDERS, FEED MANUFACTURERS, AND DISTRIBUTORS

(October 19, 2010, this guidance document was revised to update contact information and to correct broken internet links)

This document is intended to provide guidance for “ANIMAL PROTEINS PROHIBITED FROM USE IN RUMINANT FEED,” Title 21, Code of Federal Regulations, Part 589.2000, Effective Date: August 4, 1997.

Submit comments on this guidance at any time. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. Comments may also be submitted electronically on the Internet at <http://www.regulations.gov>.

For questions regarding this guidance document, contact Division of Compliance (HFV-230), U.S. Food and Drug Administration, Center for Veterinary Medicine, 7519 Standish Place, MPN-4, Rockville, MD 20855, (240) 276-9200.

Additional copies of this guidance document may be requested from the Communications Staff, HFV-12, Center for Veterinary Medicine, U.S. Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855, and may be viewed on the Internet at <http://www.fda.gov/AnimalVeterinary/default.htm>.

The Food and Drug Administration (FDA) has prepared this guide in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act. This guidance document represents the agency's current thinking on compliance with the regulation 21 CFR 589.2000 "Animal Proteins Prohibited from Ruminant Feed." It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations or both.

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Veterinary Medicine
February 1998**

WHAT IS THE PURPOSE AND SCOPE OF THIS REGULATION?

This regulation is designed to prevent the establishment and amplification of Bovine Spongiform Encephalopathy (BSE), sometimes referred to as “Mad Cow Disease,” through animal feed. The regulation prohibits the use of certain proteins derived from mammalian tissue in feeding ruminant animals. An example is meat and bone meal made from cattle. However, certain products are exempt from the regulation:

- The following protein products derived from mammals are **exempt**:
 - Blood and blood products
 - Milk products (milk and milk proteins)
 - Gelatin
 - Pure porcine (pork) or pure equine (horse) protein
 - Inspected meat products, such as plate waste, which have been cooked and offered for human food and further heat processed for animal feed
- The following nonmammalian protein products are **exempt**:
 - poultry
 - marine (fish)
 - vegetable
- The following are also exempt because they are not protein or tissue:
 - Grease
 - Fat
 - Amino acids
 - Tallow
 - Oil
 - Dicalcium phosphate

If you receive and process **ONLY** the above exempted products (or only products containing the exempted products) you are not required to comply with this regulation. We refer to this material as “**nonprohibited material.**”

All other mammalian protein will be referred to as prohibited material throughout this guide. If you receive and process this material or products containing this material, you must comply with this regulation.

Ruminant animals are any animals with a four-chambered stomach including cattle, sheep, goats, buffalo, elk, and deer.

IS MY FIRM AFFECTED BY THIS REGULATION?

This regulation defines blenders, feed manufacturers, and distributors as follows -

- "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 product. "Blenders" under the regulation are protein blenders, which are intermediaries between renderers and feed manufacturers.
- "Feed manufacturer" includes manufacturers and mixers of complete and intermediate feeds intended for animals. It includes on-farm feed mixing operations; however, those with on-farm mixers should refer to the separate guide for feeders of ruminant animals with on-farm feed mixing operations (FDA Guidance for Industry 69). The term includes pet food manufacturers.
- "Distributor" includes persons who distribute or transport feeds or feed ingredients intended for animals. **This includes retailers of feed and feed products; the distribution activities of blenders and feed manufacturers; and independent haulers.**

*** Even if you fall within the definition of blender, feed manufacturer, or distributor, you are not subject to the regulation if you do not receive, process and distribute any prohibited material or products containing prohibited material.**

If you know or have reason to know that an incoming product contains or may contain prohibited material, you are subject to the regulation. Renderers may not be able to determine the species of incoming material; rendered product from such material is considered "prohibited material" because it "contains or may contain" prohibited material. You may wish to have assurance from your raw material supplier about the product's contents. This could include a certification from the supplier, or specification of source in a business contract.

The regulation provides procedures for two general categories of blenders, feed manufacturers, and distributors that are subject to the regulation: those that do **NOT** separate prohibited material from nonprohibited material, and those that do.

HOW DO I COMPLY WITH THE NEW REGULATION?

A. Firms That Handle Only Prohibited Material, or Handle Both Prohibited and Nonprohibited Material But Do Not Separate Them Need to:

1. Label all outgoing products that contain or may contain prohibited material with the following cautionary statement:

"Do not feed to cattle or other ruminants."

2. Maintain records sufficient to track the materials throughout their receipt, processing, and distribution, and make the records available for inspection and copying. Invoices or similar documents for incoming and outgoing products will satisfy this requirement. The records should contain information normally expected to be included in such documents -

- Date of the receipt or purchase and sale or delivery
- Name and address of the seller
- Name and address of the consignee

- Identification of the product
- Quantity

3. Maintain the records for a minimum of one year.

B. Firms That Do Separate Prohibited from Nonprohibited Materials Have Two Additional Requirements:

4. Provide for measures to avoid commingling or cross-contamination of prohibited and nonprohibited materials.

5. Maintain written procedures that document the measures you adopt to prevent commingling or cross-contamination.

WHAT DO I NEED TO KNOW ABOUT THE CAUTIONARY STATEMENT?

- 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 cautionary statement is required only if the products contain or may contain prohibited material.
- This requirement does **NOT** apply to **pet food products** that are sold or intended for sale at retail or to feeds for **nonruminant laboratory animals**. If the pet food products or laboratory animal feeds are sold or are intended for sale as distressed or salvage items, then the cautionary statement is required. Distressed or salvage items may be fed to or become components of feed for other animals including ruminants.
- Labeling for all other animal feeds is required to contain the cautionary statement, **including feeds intended for nonruminant animals**.
- The statement must be placed prominently on the label or labeling. It should be conspicuous compared with other statements on the labeling. It should be placed on the labeling so that it is likely to be read and understood by the ordinary individual under usual conditions of purchase and use.
- FDA suggests that the cautionary statement have a different type size or color from other labeling, or that you use some other means of highlighting the statement so that it is easily noticed by the purchaser.
- For products shipped in bulk, the cautionary statement should appear on the invoice or other document, and placard or any other labeling that physically accompanies the shipment.
- For products that are shipped in bags or other small containers, the cautionary statement should appear on the product labels. The labels can be attached to or be part of the bag or other container.
- The statement should be included on any other labeling for the products. This can include leaflets, brochures, and other labeling materials whether or not they physically accompany the shipment of the products. An example might be a sales brochure that you mail to current and potential customers.

WHAT DO I NEED TO KNOW ABOUT THE RECORD KEEPING REQUIREMENT?

- You are not required to create a new set of records. The information should be available in normal and customary business records maintained by you and/or your company.
- The information could be maintained in several different documents including invoices, receiving tickets, receiving logs, disbursement records, weight tickets, purchase orders, or other business records or documents.
- The records can be maintained for a shipment as a whole and do not have to be maintained for each individual container within a shipment.
- Records need to identify the product:
 - Use of the product's common or usual name on the invoice or similar sales document will satisfy, in part, the "records" requirement of the regulation as well as the legal requirement that the product label bear its common or usual name. The common or usual names of rendered products typically are those included in definitions published by the Association of American Feed Control Officials (AAFCO), such as "meat and bone meal."
 - 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. The agency will 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.
- The records must be maintained so that they are available for inspection and copying. They should be maintained in a condition that keeps them legible and readily retrievable.
- Records must be maintained for one year, which means one year from the date of shipment of the product.

HOW CAN I AVOID COMMINGLING OR CROSS-CONTAMINATION?

1. Separation

- You could have separate equipment or facilities for the manufacture, processing, blending, or storage of prohibited and nonprohibited product. This could be entirely separate buildings, rooms, or other locations; or separate storage containers for incoming material and finished product, and separate mixers and handling equipment.
- Separate equipment for prohibited material should be clearly identified to help ensure that prohibited material is not mistakenly added to product intended to contain nonprohibited material only. **OR**

2. Cleanout

- 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. **OR**

3. Combination of Separation and Cleanout

An example would be use of some separate and some common equipment (clean-out would be required for the latter).

You need **written procedures**, whether you use separation, cleanout, or a combination:

- Written procedures should include the procedures followed from the time of receipt of incoming material until the time of shipment of finished product. They should reflect what actually happens in your operation.
- Written procedures should have enough detail to provide a clear understanding of your actual procedures. An inspector should be able to easily identify operations that are described in the written procedures.

WHAT ARE SOME CLEAN-OUT MEASURES THAT I COULD USE?

Include one or more of the following, or other equally effective procedures. These procedures are adapted from the Current Good Manufacturing Practice for Medicated Feed regulations, Title 21, Code of Federal Regulations, Part 225.

- Use cleaning 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, feedmills 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 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.

WHAT OTHER INFORMATION DO I NEED TO KNOW TO HELP ME COMPLY WITH THIS REGULATION?

- Products containing only nonprohibited material have no requirements under this regulation.
- The Association of American Feed Control Officials (AAFCO) has identified the following ingredients listed in their Official Publication as prohibited material:
 - Meat
 - Meat By-Products
 - Animal Liver
 - Dried Meat Solubles
 - Fleshings Hydrolysate
 - Meat Meal
 - Meat and Bone Meal
 - Animal By-Product Meal
 - Meat Meal Tankage
 - Meat and Bone Meal Tankage
 - Hydrolyzed Hair
 - Hydrolyzed Leather Meal
 - Glandular Meal and Extracted Glandular Meal
 - Unborn calf Carcasses
 - Animal Digest
 - Cooked Bone Marrow
 - Leather Hydrolysate
 - Meat Protein Isolate
 - Mechanically Separated Bone Marrow
 - Bone Meal, cooked
 - Bone Meal, steamed
 - Stock
 - Dehydrated Garbage
 - Dehydrated Food-Waste

PRODUCTS FOR IMPORT

- All mammalian protein products imported into the U.S. are subject to the same requirements under this regulation as mammalian protein obtained from domestic sources. Persons responsible for importing mammalian protein should determine the origin and species of the imported product to be assured any prohibited material is handled in compliance with this regulation. NOTE: Importation of certain animal protein products from certain countries is prohibited by USDA regulations.

PRODUCTS FOR EXPORT

- Product containing prohibited material that is destined for export should be marked **“FOR EXPORT ONLY”** on the shipping containers if appropriate and on documents accompanying the shipment. No other labeling would be required for purposes of this regulation but there may be additional labeling requirements imposed by the country of destination.
- Any product containing prohibited material that is destined for export and is diverted back to domestic commerce for any reason (salvage, quality, etc.), will be subject to all of the requirements of the regulation. This will include the requirement to label the product with the cautionary statement **“Do not feed to cattle or other ruminants.”**
- Responsibility for these products containing prohibited material rests with the owner of the goods (holder of the title to the goods). The owner is responsible for assuring that they are not diverted back to domestic commerce unless they meet the requirements of the regulation, including the cautionary labeling statement.

ARE THERE ANY PROVISIONS FOR PROHIBITED PRODUCTS TO BE EXEMPTED FROM THIS REGULATION?

The regulation provides for two kinds of exemptions for prohibited products from the cautionary statement or records requirements:

NOTE: The FDA has not validated any methods that would meet the requirements for any of the above exemptions. If and when the agency does so, it will provide additional guidance as needed for the implementation of such exemptions.

1) Protein blenders, feed manufacturers, and distributors can be exempted from both the cautionary statement and records requirements if, among other things, they:

a) Purchase animal protein products from renderers that certify compliance with a validated manufacturing method to deactivate the agent that causes transmissible spongiform encephalopathy (TSE) (BSE is a TSE), who routinely use a validated test method to detect the presence of the agent that causes TSEs, or who use exclusively a validated method for controlling the manufacturing process that minimizes the risk of the TSE agent entering the product; or

b) Comply themselves with these exempting provisions.

2) Protein blenders, feed manufacturers, and distributors can be exempted from the records requirement alone if, among other things, they:

a) Purchase animal protein products that are marked by a permanent method, approved by FDA, indicating the presence of the prohibited materials; or

b) Comply themselves with this marking requirement.

GUIDANCE FOR INDUSTRY

QUESTIONS AND ANSWERS BSE FEED REGULATION

21 Code of Federal Regulations (CFR) 589.2000

This document answers questions about “Animal Proteins Prohibited from Animal Feed”, the BSE feed regulation. It is intended to supplement the Small Entity Compliance Guides for the regulation, specifically the following FDA Guidance for Industry documents:

67 - Renderers

68 - Protein Blenders, Feed Manufacturers, and Distributors

**69 - Feeders of Ruminant Animals With On-Farm Feed Mixing
Operations**

**70 - Feeders of Ruminant Animals Without On-Farm Feed Mixing
Operations**

This guide represents the agency's current thinking on compliance with these regulations. It does not create or confer any rights for or on any person and does not operate to bind the FDA or public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations or both.

Comments and suggestions regarding the document should be submitted to Shannon Jordre, Center for Veterinary Medicine, (HFV-230), Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855, 240-276-9229, E-mail: shannon.jordre@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Veterinary Medicine
July 1998

QUESTIONS AND ANSWERS BSE FEED REGULATION

21 Code of Federal Regulations (CFR) 589.2000

U.S. FOOD AND DRUG ADMINISTRATION (FDA)
Center for Veterinary Medicine (CVM)
July, 1998

Introduction:

This document answers questions about “Animal Proteins Prohibited from Animal Feed”, the BSE feed regulation. It is intended to supplement the Small Entity Compliance Guides for the regulation, specifically the following FDA Guidance for Industry documents:

67 - Renderers

68 - Protein Blenders, Feed Manufacturers, and Distributors

69 - Feeders of Ruminant Animals With On-Farm Feed Mixing Operations

70 - Feeders of Ruminant Animals Without On-Farm Feed Mixing Operations

The Small Entity Compliance Guides are available through the Internet at (<http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/ComplianceEnforcement/BovineSpongiformEncephalopathy/default.htm>)

Inquiries:

Q1. Where can I direct any questions on the BSE regulation that are not answered by this document or the Small Entity Compliance Guides?

A. Please direct your questions to Shannon Jordre, Center for Veterinary Medicine, Division of Compliance, HFV-230, 7519 Standish Place, Rockville, Maryland 20855 (240-276-9229). The questions can be faxed

to (240-276-9241) or sent by email to shannon.jordre@fda.hhs.gov.

Effective Dates:

Q2. When was the regulation effective?

A. It was effective August 4, 1997. Printed packaging, labels, labeling and finished products manufactured before the publication of the final regulation (June 5, 1997) were allowed to be used until October 3, 1997.

Q3. I have seen several products that appear to be covered by the regulation. Should they have the required label statement “Do not feed to cattle or other ruminants” even if they were manufactured before June 5, 1997?

A. Yes. If they are available for sale or distribution, such products should be relabeled with the cautionary statement and fed only to nonruminants, or disposed of in a way that ensures they will not be fed to ruminants.

Records:

Q4. It appears that mammalian proteins that have been exempted do not have to be labeled with the cautionary statement “Do not feed to cattle or other ruminants.” But what about the recordkeeping requirements?

A. In general, exempted mammalian proteins are not subject to the recordkeeping or any other requirements of the rule. There is one exception, however. Ruminant feeders are required to keep invoices and labeling for all feed they receive that contains animal protein products, whether or not the animal protein is prohibited material.

Q5. If certain products are received in multiple container shipments in a plant that separates prohibited from nonprohibited materials, must records be kept documenting the final disposition of each container

versus the entire shipment?

A. You are not required to document the final disposition of the contents of each incoming container. The regulation requires records sufficient to track the materials through their receipt, processing and distribution. Invoices or similar documents for incoming and outgoing products will satisfy this requirement. Since your firm separates prohibited and nonprohibited materials, however, you are required to provide for measures to avoid commingling and cross-contamination of prohibited and nonprohibited materials. Neither the regulation nor the Small Entity Compliance Guides provide for specific procedures, because of the variation in facilities and the number of different procedures that would be acceptable. However, your measures to avoid commingling and cross-contamination (which need to be documented in written procedures) need to be adequate to prevent commingling of individual containers that hold prohibited and nonprohibited materials and cross-contamination from their contents.

Q6. If a Hazard Analysis Critical Control Point (HACCP) plan is adopted for the facility, would this reduce the recordkeeping requirement?

A. No. The Agency has indicated it would evaluate the use of HACCP at a later date. We do encourage the use of HACCP plans, however, to assist the agency in its evaluation.

Q7. My feed mill receives prohibited material, and the material is used to produce feed for nonruminant animals. Am I required to annotate the master and batch production records with a statement identifying the ingredients added as prohibited material?

A. The regulation does not specifically require that entries be made in the production records. Nor does the Small Entity Compliance Guide for feed manufacturers suggest that this be done. However, if your firm also manufactures feed for ruminant animals using nonprohibited materials, you are required to provide for measures to avoid commingling and cross-contamination of prohibited materials. Your measures to avoid commingling and cross-contamination (which need to be documented in written

procedures) could include entries in production records along with other separation and/or clean-out procedures that would be adequate to prevent commingling and cross-contamination.

Q8. My feed mill has a small retail sales section where feed is sold in both bagged and bulk form. Should I record complete sales information for feeds containing prohibited material in order to facilitate a recall if one should be needed?

A. The regulation requires recordkeeping (and the cautionary statement) for retail sales of all feeds containing prohibited product. This requirement can be met through copies of sales invoices or similar documents. The records should contain the following information:

- **Date of the sale**
- **Name and address of the seller**
- **Name and address of the purchaser**
- **Identification of the product**
- **Quantity**

Although this information is not intended specifically for recalls, it would be useful for that purpose.

Q9. Do all feed retailers need to keep the records described in answer to the previous question?

A. Yes. The regulation applies throughout the manufacturing and distribution chain. Therefore, it applies to feed retail operations, whether or not the facility is part of a feed manufacturing operation.

Q10. Do ruminant feeders have to maintain records of feeds they receive if the feeds include only nonprohibited protein products such as milk products and feather meal?

A. Yes. The rule states that you must maintain invoices and labeling for all

feeds you receive containing animal protein products. So, these records must be maintained of all feed containing protein products derived from animals including non-prohibited animal protein products. However, you do not need to keep records of feed containing only protein products derived from plants, such as soybean meal.

Labeling:

Q11. My company collects inedible offal products, including beef, sheep and pork offal, and sells them to other companies. Does my company have to keep records and label these products?

A. If you sell the offal to traditional renderers, the regulation does not require that you keep records or label the products. However, renderers may impose their own requirements on you so that they can assure compliance with the regulation. FDA has suggested that renderers who separate prohibited from nonprohibited material may wish to have assurance from their supplier of nonprohibited material about the product's contents. This could include a certification from the supplier, or specification of source in a business contract.

However, if you sell the offal to feed manufacturers or others who are not traditional renderers, you are considered a "renderer" under the regulation and are subject to the recordkeeping and labeling requirements. This is true whether you subject the materials to minimal processing or do not process the materials in any way.

Q12. I produce a product containing mostly hog hair but also a small amount of beef hair. The product has been cooked at 260°F for at least 30 minutes, then screened out in the milling process and hydrolyzed. Am I required to put the statement "Do not feed to cattle or other ruminants" on the label?

A. Yes. There is no exemption for the beef hair, which is a mammalian protein. FDA does not consider the processing you describe to be adequate to inactivate the agent that causes BSE.

Q13. Can damaged and distressed pet food be salvaged by feeding it to food-producing animals?

A. Damaged and distressed pet food may be salvaged as **nonruminant** feed but because it contains or may contain prohibited material, it must be labeled with the caution statement “Do not feed to cattle or other ruminants,” and records of its distribution maintained.

Non-Prohibited or Prohibited Product:

Q14. Are paunch and paunch products prohibited?

A. The paunch is the cow’s stomach excluding the contents. The paunch, itself, is considered an animal protein subject to the rule. The paunch contents (ingested feed and water) are not subject to the rule and therefore are not prohibited. The Agency understands that in the process of removing the contents a very small amount of paunch tissue may be introduced into the contents. The Agency does not believe this poses enough concern to prohibit the use of the contents at this time.

Q15. If “specified bovine offal” (SBO) is removed from the carcass, will the rest of the carcass be considered exempt?

A. No. All protein from bovine tissue is prohibited except blood and blood products, milk products, gelatin and inspected meat products which have been cooked and offered for human food and further heat processed for animal feed.

Q16. Are bone meal and bone byproducts mammalian tissues, and are they prohibited material?

A. Both bone meal and bone byproducts contain proteins from mammalian tissue. They are prohibited material unless they are pure swine or horse products. The regulation prohibits the feeding to ruminants of all proteins from mammalian tissue unless specifically exempted.

Q17. Do all exempt materials have the same status? It seems that

mammalian protein tissue from pigs or horses could be more of a concern to the Agency than milk processing waste.

A. All exempt materials have the same status. They are all exempt and not subject to the requirements of the rule.

Q18. My company processes fresh pork and other processed pork items. My company also renders pork byproducts. In the past we have rendered a tiny portion of rejected beef items that are returned to us from the marketplace. Does this subject us to the rule?

A. Not if the beef products meet the requirement of the regulation. Beef products such as hot dogs and ready-to-eat deli meats which have been inspected, cooked, and offered for human food may be rendered and are exempt from the rule after rendering. This is covered by the exemption for inspected meat products which have been cooked and offered for human food and then further heat processed.

Q19. Does the exemption for products that have been cooked, offered for human food and then further heat processed require that the products be sent to the marketplace and then returned in order to be exempt?

A. No, it is sufficient that the products have been cooked in anticipation of entering the marketplace. Those products such as hot dogs, which have been cooked, and completely prepared for entering the marketplace, and then rejected from the marketplace for quality control reasons, will be considered exempt.

Q20. What does “further heat processed,” as used in the previous question, mean?

A. The regulation does not specify what constitutes acceptable heat processing because of the variety of commercial processes and the variations

in temperature which could be used for heat processing.

Following are examples of acceptable “further heat processing”:

- Traditional rendering processes;
- Extrusion and cooking at 212 degrees Fahrenheit for 30 minutes, as required for garbage under the Swine Health Protection Act;
- Pelleting, if the plate waste in the pellet conditioner reaches an internal temperature of at least 190 degrees Fahrenheit, and the retention time is such that the total heat energy applied is similar to that achieved in the extrusion processes or required by the Swine Health Protection Act;
- Pelleting at temperatures similar to those used in traditional rendering or the holding of pellets at temperatures to comply with the Swine Health Protection Act.

Other methods could meet the “further heat processing” requirement; information on other methods would need to be submitted to CVM.

Q21. A USDA-inspected facility processes edible beef stock or broth from edible and inspected beef bones, making a meat and bone meal product. Does the meat and bone meal product require the labeling “Do not feed to cattle or other ruminants”?

A. Yes. A “meat and bone meal” product by definition contains protein, and is not exempt unless manufactured from pure pork or horse material. Bone contains protein in the form of the marrow and collagen.

Q22. Does this mean that every product whose name includes “bone” is prohibited?

A. No. Products meeting the Association of American Feed Control Officials (AAFCO) definitions of Bone Ash, Bone Phosphate, Bone Charcoal and Bone Charcoal, Spent are exempt because by definition they do not contain protein.

Q23. Is “gel bone” prohibited material?

A. Yes, unless it is from pure pork or horse material. Gel bone is bone that has been coarsely crushed, rinsed and degreased. It is usually intended for use in making gelatin.

Q24. Is collagen exempt under the BSE rule since it is “unprocessed” gelatin?

A. Collagen is not exempt, unless it is obtained from pure pig or horse material. However, gelatin is exempt under the BSE regulation. Data available to the FDA suggests that gelatin does not transmit the transmissible spongiform encephalopathy (TSE) agent. The conventional manufacturing process for gelatin has been demonstrated to inactivate, in a significant way, any residual activity that may have been present in source tissues. But see the answer to the next question.

Q25. If I use collagen to formulate a deer feed, do I have to comply with the rule?

A. Collagen is a protein found in all mammals and is not specifically exempt from the BSE rule. Furthermore, collagen is not a recognized feed term, and its listing in the ingredient list could cause the product to be misbranded. Collagen protein is a starting material for gelatin; however, unprocessed collagen is not gelatin and does not categorically qualify for the gelatin exemption. Products in the market referred to as “hydrolyzed collagen” or similar type names may be a “feed grade” gelatin, since the term “feed grade” can be used to indicate products suitable for animal consumption. Whether these types of “hydrolyzed collagen” products qualify for the gelatin exemption are handled on a case-by-case basis. The decision is based on the starting material and the process. Information on the starting material and the process should be submitted to CVM for comment.

Q26. Can chicken litter be fed to cattle if the poultry might have been fed prohibited material?

A. Yes. The FDA has no evidence that the agent that causes BSE would survive the chicken intestinal tract. FDA expects the states to require recycled animal waste to conform to the definitions promulgated by the

Association of American Feed Control Officials (AAFCO) as published in its official publication and as described in its "Model Regulations for Processed Animal Waste Products as Animal Feed Ingredients." Under the AAFCO Model Regulation, in order for this product to be used in a commercial feed, it must be registered/licensed within a State, and be assayed periodically for *Salmonella* and *E. coli* bacteria, heavy metals, pesticides, drugs, parasitic larva or ova, and mycotoxins.

Q27. Can uncooked pizza dough that may contain beef materials be fed to ruminants?

A. No. The pizza would have to have been inspected, cooked and offered for human consumption, and further processed before it would qualify for the "plate waste" exception.

Single Species Slaughter Facilities:

Q28. I am a renderer and I intend to separate prohibited material from nonprohibited material. Why must I obtain my exempt material from a single species slaughter facility as long as I comply with the separation requirement?

A. FDA has no regulatory authority over the slaughterhouses, so the agency could not require them to have the separation or cleanout procedures which would be necessary to provide adequate protection.

Q29. My company slaughters pigs and lamb in separate facilities. We render the pig offal, but send the lamb offal to another facility for rendering. Waste water from the separate facilities is collected in a common area and then flocculated to suspend the solids from the separate kill floors. The solids, a mud-like material, are returned to the pork rendering operation. May we treat the rendered pork products as if it came from a single species slaughter facility?

A. No. The solid material which you return to the pork rendering operation contains some portion of lamb offal from the kill floor. The addition of this

prohibited mammalian product to the pork materials requires that you label the material “Do not feed to cattle or other ruminants,” and comply with the other requirements of the rule.

Separation of Prohibited and Nonprohibited Materials:

Q30. May prohibited and non-prohibited products be stored in the same cooler so long as each product is in a separate container, is properly labeled, and there are established procedures to prevent commingling and cross-contamination of products?

A. Yes. It is likely that any method will be acceptable to FDA as long as it achieves its intended purpose -- prevention of commingling or cross-contamination.

Q31. Is it necessary to control dust on bin tops to prevent prohibited product particles from entering nonprohibited product?

A. Yes. The rule states that you must use procedures adequate to prevent cross-contamination. If your firm has a dust problem that results in prohibited material contaminating nonprohibited product, then you have not met the requirements of the rule.

Clean-out:

Q32. What procedures are considered acceptable by FDA for cleaning loadout bins?

A. Clean-out could be accomplished by physical clean-out, flushing, sequencing or other means that are adequate to prevent carryover of prohibited materials into nonprohibited materials. The Small Entity Compliance Guides provide additional guidance on clean-out methods. Upon request, CVM’s Division of Compliance (see address and phone number on page 1) will comment on specific clean-out procedures that a firm is planning is to use.

Q33. The Small Entities Compliance Guide for Renderers states that

flushing volume of nonprohibited material should be equal to one complete change of operating volume. My operation has a 10-ton capacity. Does this mean I have to run 10 tons of nonprohibited material through my operation?

A. Not necessarily. The rule itself requires only that procedures be in place to avoid cross-contamination. The Small Entity Compliance Guide for Renderers states that flushing with a complete change of operating volume will satisfy this condition. If you have established a different volume and/or procedure that will also prevent cross-contamination, you may use it. For feed manufacturing operations, off-farm or on-farm, the guide states that the volume of flushed material should be sufficient to prevent carryover of products that contain or may contain prohibited material. Feed mill operators should determine their feed mills' individual characteristics and apply appropriate time and volume requirements for flushing materials. Additional guidance appears in the Small Entity Compliance Guides.

Q34. Is it permissible to load nonprohibited protein in the same loadout bay as prohibited material when separate conveyance systems are used?

A. Yes, as long as the clean-out procedure that you establish is adequate to prevent cross-contamination.

Q35. In addition to providing rendered, non-prohibited product for feeding to ruminants, my firm grinds 4-D meat (meat from dead, dying, diseased or disabled animals) primarily for pet food markets. The 4-D meat is usually ground and frozen but not heat processed. What are the clean-out guidelines for processing these products?

A. We assume that the 4-D meat includes prohibited material, that is, it is not pure horse or pig material. If the two operations share common equipment, your firm needs to follow the clean-out guidelines in the Small Entity Compliance Guide for Renderers. Washing the grinders with soap is an acceptable example. "4-D" processing operations are subject to the same rules as renderers since the regulation defines "renderer" to include any firm or operation that processes animals unfit for human consumption. Whether or not the two operations share common processing equipment, your firm needs

to take steps to avoid commingling of the prohibited and nonprohibited materials.

Q36. Will washing be considered adequate clean-out for small Rubbermaid containers, barrels, totes and/or combo bins?

A. Yes.

Imports:

Q37. Who has the responsibility for assuring that imported meat and bone meal is in compliance with the rule?

A. The firm or individual that enters or intends to enter the product into domestic commerce should determine the origin and species of the imported product to be assured that any prohibited material is handled in compliance with the regulation. Import of all mammalian protein products from certain countries is prohibited by U.S. Department of Agriculture (USDA) regulations.

Q38. What is necessary to establish whether an imported mammalian protein product intended for animal feed use contains prohibited material and therefore must comply with the rule?

A. At this time, we are suggesting that the importer request certification from the exporting country that the product does or does not contain prohibited product.

Exports:

Q39. Are prohibited products that are ordinarily subject to the rule required to comply with the labeling requirements if the products are intended for export?

A. No. However, prohibited protein products destined for export, like all other exported food products, must be marked "For Export Only" on the shipping containers, if appropriate, and on documents accompanying the

shipment. Other legal requirements for exported products must also be met.

Any prohibited product destined for export which is diverted into domestic commerce will be subject to all the requirements of the regulation.

Responsibility for assuring that the products are not diverted into domestic commerce rests with the owner of the product.

Science:

Q40. Can the TSE causative agent affect humans or animals exposed to airborne prohibited materials and dust from these products?

A. No. There is no evidence for direct transmission from animal to animal, or animal to human, by incidental contact. Studies to date indicate that the causative agent must be injected or ingested, or contaminated tissue must be implanted, for transmission to occur.

Feed Ban Enhancement: Implementation Questions and Answers

Updated June 5, 2009

The 2008 Regulation

1. Q: What changes were made to FDA’s animal feed regulations?

A: The changes to the regulations provide additional protections against bovine spongiform encephalopathy (BSE, “mad cow disease”). **FDA added a new section 589.2001 to the regulations** which prohibits the use of high-risk cattle material in feed for all animal species. This section builds on the 1997 BSE feed regulation at 589.2000, which remains in effect but which applies only to feed for cattle and other ruminants. Specifically, the new section 589.2001 defines the following as cattle material prohibited in animal feed (CMPAF):

- the entire carcass of BSE-positive cattle
- the brains and spinal cords from cattle 30 months of age and older
- the entire carcass of cattle not inspected and passed for human consumption, unless the cattle are less than 30 months of age or the brains and spinal cords have been effectively removed
- tallow derived from BSE-positive cattle
- tallow derived from CMPAF that contains more than 0.15% insoluble impurities
- mechanically separated beef derived from CMPAF

2. Q: Were any changes made to section 589.2000?

A: Yes. The definition of protein derived from mammalian tissue was changed to exclude tallow containing no more than 0.15% insoluble impurities. This means that tallow containing more than 0.15% insoluble impurities may no longer be fed to cattle and other ruminants. [See Comment 33 and 589.2000(a)(1) page 22756]

3. Q: What is the impact of the new regulation on feed manufacturers?

A: The primary impact of the 2008 rule will be on the rendering industry due to a number of specific requirements for renderers. However, feed manufacturers may be impacted by the requirement in the new rule that animal feed and feed ingredients shall not be manufactured from, processed with, or otherwise contain CMPAF. In addition, the change to section 589.2000 means that feed manufacturers will need to make sure that tallow used in ruminant feed contains not more than 0.15% insoluble impurities.

4. Q: Will the FDA provide a period of time after the effective date (like that given for the 1997 rule) to educate renderers about new requirements under the 2008 rule?

A: The 12-month implementation period prior to the effective date of April 27, 2009 was intended to provide sufficient time for the industry to become familiar with the requirements of the rule. An additional 6-months, until October 26, 2009, was provided for firms to come into compliance in response to concerns raised over carcass disposal issues in some areas of the country.

5. Q: Does the definition of CMPAF apply to material derived from livestock other than cattle?

A: The new rule applies only to cattle (*bos taurus*, *bos indicus*) and buffalo (*bison bison*) and not to other livestock species such as sheep, swine, or horses. The rule may have an indirect impact on how renderers handle other species, depending on how individual rendering companies respond to the rule.

Exclusions

6. Q: Will FDA list specific exclusions from the rule such as poultry fat, pork fat, recycled restaurant grease (from food offered for human consumption), and blood products to help prevent market disruptions?

A: No. This rule is clear in defining CMPAF and does not restrict the use of any other products in animal feed.

Implementation

7. Q: When does the new regulation go into effect?

A: The regulation became effective on April 27, 2009, one year after publication in the Federal Register. On April 9, 2009 FDA proposed delaying the effective date by 60 days and opened a 7-day comment period requesting comments on whether the effective date should be delayed. After reviewing the comments, FDA confirmed the original April 27, 2009 effective date, and established an October 26, 2009 compliance date. The additional six months is intended to allow more time for affected parties to address compliance and implementation concerns.

8. Q: What about feed manufactured before October 26, 2009 that contains CMPAF?

A: After October 26, 2009 FDA will begin enforcement of this regulation that prohibits introducing into interstate commerce feed or feed ingredients containing CMPAF. Because the rule does not provide a grace period for using up feed made with CMPAF, it is expected that renderers and feed manufacturers will discontinue use of materials containing CMPAF in time to ensure that feed in distribution after the compliance deadline is free of CMPAF.

9. Q: When will more detailed guidance be available for renderers, feed manufacturers and livestock producers?

A: Additional guidance can be found in Guidance for Industry #195, which can be found on the CVM website.

Disposal of CMPAF

10. Q: Can older dead stock cattle and byproducts from meat packing plants that slaughter older cattle still be used in animal feed for non-ruminants?

A: Yes, as long as the material is free of CMPAF.

11. Q: What is going to happen to the CMPAF that can no longer be used in animal feed?

A: A number of methods are currently available for disposing of CMPAF, including landfill, incineration, composting, alkaline hydrolysis, and burial. Another disposal option is to first render CMPAF to stabilize the material and reduce the volume, and then dispose of the rendered material by means other than use in animal feed. Whatever methods are used to dispose of CMPAF, they must comply with state and local requirements.

12. Q: Can ash from the incineration of CMPAF be used in feed?

A: No. The rule prohibits the use of CMPAF in animal feed and does not contain any provisions allowing for inactivation of BSE infectivity.

13. Q: Can CMPAF be rendered for use as fertilizer?

A: This rule does not place any restrictions on the use of CMPAF as fertilizer.

By-products from slaughter establishments

14. Q: How will renderers be assured that cattle offal received from slaughter facilities does not contain CMPAF?

A: Renderers must have records that demonstrate that establishments supplying cattle material to the renderer have adequate procedures in place to exclude CMPAF. These records will be considered sufficient if they include certification or other documentation from the supplier that material supplied to the renderer does not contain CMPAF, or documentation of another method acceptable to FDA, such as third-party certification. [See Section C page 22735]

15. Q: What does an acceptable certification consist of?

A: Certification is acceptable, provided it includes a description of the supplier's segregation procedures, documentation that the supplier confirms that its segregation procedures were in place prior to supplying any cattle material to the renderer, and records of the renderer's periodic review of the suppliers' certification or documentation of another method acceptable to FDA, such as a third party certification, for verifying that suppliers have effectively excluded CMPAF. [Section C page 22735]

16. Q: The rule requires periodic review of the suppliers' certification. How often is periodic?

A: The rule does not specify a frequency.

17. Q: A firm's written procedures are typically proprietary, so how extensive does the description of procedures need to be?

A: The rule does not specify how detailed the description must be. However, with respect to cattle materials obtained from establishments which have segregated CMPAF, such records must demonstrate that those establishments supplying cattle materials to the renderer have adequate procedures in place to effectively exclude CMPAF.

18. Q: How does FDA expect renderers to review the suppliers' certification or other documentation? Will certification renewal be adequate? Does FDA expect renderers to audit supplier documents and procedures – such access will most likely be denied and FDA has limited authority over such suppliers?

A: The rule does not specify the requirements of a review.

19. Q: Who is responsible if it is determined that CMPAF was not excluded from slaughter offal used to produce MBM for animal feed use?

A: Although all parties are expected to exercise due diligence in excluding CMPAF, the rule places the responsibility on the renderer.

20. Q: Will a renderer be responsible for a recall if a supplier of raw material did not remove CMPAF?

A: If it is determined that material rendered for animal feed use contains CMPAF and a recall is necessary, the renderer would be responsible for conducting the recall. However, establishing liability for the cost of the recall should not be different than for other customer/supplier business relationships.

21. Q: How will the new rule be enforced at small slaughtering facilities?

A: Inspections will not be conducted at any slaughter establishments, regardless of size. Inspections will be conducted at rendering facilities to verify that the renderer has determined that CMPAF is being excluded from inedible raw materials supplied by slaughter establishments.

22. Q: Are all specified risk materials (SRMs) required to be separated, or just the brains and spinal cords from cattle over 30 months?

A: The rule requires separation of those materials defined by the rule as CMPAF. In a slaughter facility, this means the brain and spinal cord from any animal over 30 months of age. As explained in the preamble to the 2008 rule, FDA does not believe it is necessary to prohibit from

use in feed for non-ruminants any other tissues defined elsewhere (e.g. by OIE or USDA) as SRMs.

23. Q: Does the rule require suppliers of raw material to renderers to be trained and certified on handling their CMPAF?

A: No. FDA intends to provide outreach explaining the requirements of the rule, but does not intend to provide training to the private sector.

24. Q: What items specifically will not be accepted by renderers as a result of this new rule?

A: The rule does not prohibit a renderer from accepting any of the items they may currently be accepting; the rule prohibits the rendering of CMPAF for use in animal feed. Individual rendering establishments will determine what they choose to accept for further processing. A renderer may choose to collect CMPAF for disposal, as a service to slaughter establishments.

25. Q: Will the FDA develop a standard report to be used in recording CMPAF and/or non-CMPAF material from various sources? It would be helpful if all suppliers and all renderers use the same form for supplier certification.

A: No. FDA will not be developing a standard form, but the rule does not prevent a standard form from being used if industry chooses to develop one.

State-Inspected and Custom Slaughter Facilities

26. Q: Are cattle that are slaughtered in state-inspected facilities eligible for rendering for feed use?

A: Yes. 21 FR 589.2001(b)(2) defines “cattle not inspected and passed for human consumption” as cattle that did not pass antemortem inspection by the appropriate regulatory authority. In a state-inspected slaughter facility the state is the appropriate regulatory authority and animals that pass antemortem inspection may be rendered for use in animal feed provided that other requirements of the rule, such as removal of brain and spinal cord from animals over 30 months of age, are met.

27. Q: Can cattle offal from uninspected (custom) slaughter be rendered for feed use?

A: Yes. Cattle slaughtered under custom slaughter meet the definition of “cattle not inspected and passed for human consumption”. Therefore, offal from custom slaughter operations may be rendered for feed use if the brain and spinal cord from cattle older than 30 months are excluded from the offal. Just as they would for an inspected slaughter establishment, renderers receiving material from a custom slaughter operation would need records that demonstrate that the establishment has adequate procedures in place to exclude CMPAF. [See comments 38 and 57]

Determining Age of Cattle

28. Q: How will renderers determine and document the age of cattle not inspected and passed for human consumption (e.g., dead stock cattle) that are collected to be rendered for feed use?

A: Renderers are required to maintain written procedures for specifying how they either remove brain and spinal cord from cattle not inspected and passed for human consumption, or how they separate such animals based on whether they are 30 months of age or older. Written procedures must be made available for FDA inspection. [See 589.2001(c)(2)(ii) and comments 30 and 40]. Additional information is available in Guidance for Industry #195.

29. Q: What are acceptable procedures for determining the age of cattle?

A: As discussed in the preamble to this rule, FDA received a number of suggestions for ways to determine the age of cattle, including animal identification systems, dairy herd records, dentition, body weight, or feedlot origin. The rule requires only that renderers have written procedures explaining how they determine the age of cattle they process as well as records documenting their compliance with the requirement. It does not mandate the use of a specific method of determining the age of the cattle. [See 589.2001(c)(2)(ii) and comments 30 and 40]. Additional information is available in Guidance for Industry #195.

30. Q: Can renderers accept farmer statements based on production records?

A: Yes, as long as the records meet the requirements in 589.2001(c)(3)(i) (A) or (B).

31. Q: What kinds of written documentation for age verification will be acceptable? Will a handwritten note, signed and dated by the owner, suffice?

A: Nothing in the rule prevents this form of documentation if it meets the requirements in 589.2001(c)(3)(i) (A) or (B).

32. Q: Will renderers be held liable for mistakes in statements of age?

A: Although all parties are expected to exercise due diligence in complying with the rule, the rule places the responsibility on the renderer. The renderer is expected to have procedures in place that will minimize the potential for mistakes. For example, a renderer may wish to use dentition to confirm that the producer's statement is correct. [See comment 28, comment 40; also 589.2001(c)(2)(ii) and 589.2001(c)(3)(i)]

33. Q: Will dentition be accepted as a determinant of age of cattle?

A: Nothing in the rule prevents the use of dentition as a method for determining the age of cattle. We are aware that under USDA procedures for using dentition, cattle are considered to be 30 months of age or older if at least one of the second set of permanent incisors has erupted through the gum line. [See Comment 40]

34. Q: Will renderers be required to provide training on using dentition to determine the age of cattle?

A: No.

35. Q: Can a renderer accept an annual statement of age (such as an affidavit) from a feedlot certifying that dead stock coming from their facility are all under 30 months of age?

A: Nothing in the rule prevents this type of documentation if it meets the requirements in 589.2001(c)(3)(i) (A) or (B).

Removing brain and spinal cord from dead stock cattle

36. Q: How will FDA determine that renderers are adequately removing brain and spinal cord, and will FDA have a zero tolerance for central nervous system tissue?

A: FDA has a variety of means for determining whether renderers are in compliance with the requirements in the 2008 rule, including reviewing renderers' written procedures, and observing the procedures being used while the facility is operating. With respect to adequacy of brain and spinal cord removal, the rule contains no provision allowing residual brain and spinal cord tissue in material from cattle 30 months of age or older. [See 589.2001(c)(2)(ii), 589.2001(c)(3)(i), 589.2001(e)]. Additional information is available in Guidance for Industry #195.

37. Q: What methods are acceptable for removing brain and spinal cord from dead cattle over 30 months of age?

A: The rule does not specify what method or methods may be used. [See Comment 18]. Additional information about methods of removing the brain and spinal cord can be found in Guidance for Industry #195.

38. Q: Does the definition of CMPAF include the dorsal root ganglia?

A: No.

39. Q: Can the vertebral column be rendered for animal feed use if the spinal cord is removed?

A: Yes. [See Comment 31]

40. Q: Can renderers that harvest skeletal muscle and hides from dead cattle (4-D operations) continue to remove skeletal muscle from cattle carcasses to supply to mink farms and/or greyhound kennels?

A: Yes. Skeletal muscle contains no CMPAF and therefore could be removed from the carcass and used in feed for non-ruminant animals, including food for pets or mink. However, under the rule 4-D operations meet the definition of a renderer and are therefore required to ensure that CMPAF from the remainder of the carcass is properly excluded from animal feed. Such operations are also required to have written procedures in place describing the processes they use to comply with the rule. [See Comment 30]

41. Q: What does “or otherwise effectively excluded from animal feed” mean?

A: The phrase was intended to describe operations where the animal feed (e.g., skeletal muscle for pets or mink) is removed from the CMPAF (i.e. the remainder of the carcass containing the brain and spinal cord), as opposed to operations that remove the CMPAF (brain and spinal cord) so that the remaining material may be used in animal feed. “Removal of brain and spinal cord” does not accurately describe the first type of operation. [See 589.2001(c)(2)(ii) and comments 30 and 40.]

42. Q: Can renderers collect offal from 4-D operations and other renderers?

A: Yes. Both parties would have the same obligations to ensure that CMPAF is excluded from animal feed. [See Comments 30 and 57]

Dedicated equipment/transportation

43. Q: Can the same receiving and processing equipment be used for CMPAF and non-CMPAF materials?

A: No. The rule requires the use of either separate equipment or separate containers for CMPAF that has been separated from non-CMPAF materials. [See 589.2001(c)(2)(iii)(A) & (B)]

44. Q: On a truck, do dead cattle over 30 months of age have to be physically separated from dead cattle under 30 months of age?

A: No. The rule only requires separate equipment or containers once the CMPAF has been separated from non-CMPAF.

45. Q: Can CMPAF be hauled on the same truck as slaughter offal intended to be used in animal feed if it is in a separate container or compartment?

A: Yes, provided there is no cross-contamination between containers or compartments.

Tallow

Table1

Source of Tallow	Insoluble Impurities Level	Feed Use	Caution Statement Required	Regulation
any source (non-CMPAF or CMPAF)	< or = 0.15%	allowed in all animal feeds	None	21 CFR 589.2000 and 589.2001
non-CMPAF	> 0.15%	allowed in all but ruminant feeds	“do not feed to cattle or other ruminants”	589.2000
CMPAF	> 0.15%	not allowed in animal feed	“do not feed to animals”	589.2001

46. Q: Where did the 0.15% insoluble impurity standard come from?

A: The 0.15% level is an internationally recognized standard for trade in tallow. The World Organization for Animal Health (OIE), in the BSE Chapter of the Terrestrial Animal Health Code, has defined protein free tallow as tallow containing no more than 0.15% insoluble impurities.

47. Q: Does all tallow need to contain no more than 0.15% insoluble impurities to be used as a feed ingredient?

A: Tallow containing more than 0.15% insoluble impurities may not be used in ruminant feed but may be used in feed for non-ruminants. However, tallow is prohibited in all animal feed if it contains more than 0.15% insoluble impurities and is derived from rendering CMPAF. See Table 1.

48. Q: Is the caution statement needed on tallow containing more than 0.15% insoluble impurities?

A: Yes. Tallow must bear the caution statement “do not feed to cattle or other ruminants” if it contains more than 0.15% insoluble impurities. If it is derived from rendering CMPAF and contains more than 0.15% insoluble impurities, it must bear the caution statement “do not feed to animals”. See Table 1.

49. Q: Does the 0.15% impurity standard apply to recycled restaurant grease?

A: The impurity standard applies only to tallow. See Guidance for Industry #195 for additional information.

50. Q: Can tallow derived from CMPAF containing more than 0.15% insoluble impurities be blended to meet the 0.15% insoluble impurities limit?

A: There is no provision in the rule to allow blending to be used to meet the 0.15% insoluble impurity limit.

51. Q: Some beef processors produce “edible” tallow. Does edible tallow need to meet the 0.15% insoluble impurities standard if it is intended for use in ruminant feeds?

A: Edible tallow needs to meet the 0.15% insoluble impurities standard if it is intended for use in ruminant feed.

52. Q: Will clean-out/flush-out or sequencing procedures be required if common pipelines are used to load-out fats having levels of impurities above and below 0.15% at a rendering or fat-processing facility?

A: Tallow obtained from rendering CMPAF is itself CMPAF if it contains more than 0.15% insoluble impurities. Equipment or containers for such tallow must therefore be separate from equipment or containers used for ingredients for animal feed. In addition, the change to section 589.2000 means that tallow containing more than 0.15% insoluble impurities is mammalian protein prohibited for use in ruminant feed. Section 589.2000 requires that renderers provide for measures to avoid commingling or cross-contamination by either maintaining separate equipment or facilities, or by using cleanout procedures or other means adequate to prevent carryover. Therefore, separation or other means such as cleaning, flushing, or sequencing is needed between tallow containing more than 0.15% insoluble impurities, and tallow that may be used in feed for ruminants.

53. Q: Is there an analytical method for determining the amount of insoluble impurities in tallow?

A: Yes. The rule specifies that insoluble impurities must be measured by the method entitled “Insoluble Impurities” (AOCS Method Ca 3a-46), American Oil Chemist’s Society (AOCS), 5th Edition, 1997, or another method equivalent in accuracy, precision, and sensitivity to this method. A copy of the method may be obtained from the AOCS (<http://www.aocs.org>), or viewed at the FDA Center for Food Safety and Applied Nutrition’s Library or at the National Archives and Records Administration. [See 589.2001(b)(1)(vi)(B)]

54. Q: What is the analytical variation (AV) for samples analyzed using the AOCS method? AAFCO does not list an acceptable analytical variation (AV) for insoluble impurities. Will acceptable variation for comparing results from different labs be developed? Will FDA verify suitability of labs, methods used, and results?

A: FDA has not established an AV for this analytical method. FDA welcomes any information indicating that variation in test results is presenting difficulties in establishing that tallow meets the impurity standard. Firms using methods other than the AOCS method must have data or other information showing that the method is equivalent in accuracy, precision, and sensitivity to the AOCS method.

55. Q: If a facility receives a load of tallow that is labeled with the “do not feed to cattle or other ruminants” caution statement, but then tests it and find that it contains 0.15% or less insoluble impurities, can the facility use this tallow in ruminant feed?

A: No. While the impurities may settle out to the point where the tallow meets the standard, we do not believe that this is a reliable approach for facilities to use to comply with the requirements of the regulation. We therefore expect the caution statement on the label to be followed.

56. Q: Is there an insoluble impurities standard for blended fats/oils?

A: FDA regulations do not establish a standard for insoluble impurities in any other types of fats or oils except tallow (animal fat from cattle). However, some of the ingredient definitions adopted by the Association of American Feed Control Officials (AAFCO) do establish a maximum amount of insoluble impurities that may be present in a product. 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. Blending or dilution may not be used to meet the insoluble impurities standard.

57. Q: Does a renderer need to supply a Certificate of Analysis (COA) for every load of tallow delivered to a customer?

A: The regulation does not require that a certificate of analysis accompany every load of tallow. A label must accompany every load, however. The AAFCO ingredient definition for “animal fat” contains more specific information on how tallow is to be labeled.

Import and Export of Animal Proteins

58. Q: Are animal proteins being imported into the US from other countries required to have CMPAF removed?

A: Yes, unless the exporting country has been designated as exempt from the requirement. The rule contains a provision allowing countries to apply for such an exemption. Any country seeking such a designation would have to provide sufficient scientific evidence to support its claimed BSE risk status. [See 589.2001(b)(1)(vi)(C) and 589.2001(f)]

59. Q: Will CMPAF removal also be required for ruminant protein meals destined for export?

A: Feed containing CMPAF intended for export is not deemed to be adulterated or misbranded if it complies with the requirements of section 801(e)(1) of the Federal Food, Drug, and Cosmetic Act.

Compliance

60. Q: What are the consequences for failure in age determination or brain/spinal cord removal?

A: FDA’s enforcement response for failing to comply with this rule will be consistent with enforcement responses used for non-compliance with other FDA regulations. These consequences could include opportunity to make immediate correction, warning letter, seizure, injunction and criminal penalties.

61. Q: Will FDA continue to use the designations NAI, VAI and OAI to categorize renderer compliance with the new rule?

A: Yes.

Recall

62. Q: Will a recall be required if it is determined that a renderer did not properly remove brain and spinal cord from dead cattle, or a slaughter establishment did not properly segregate CMPAF from slaughter offal, even if all parties involved made good faith efforts to comply?

A: Decisions to require recalls will be determined on a case-by-case basis, as the Agency does with all other regulated products.

63. Q: Would recalls concerning CMPAF be Class II or Class III?

A: Classification of a recall depends on the circumstances of an individual case.

Records

64. Q: How long are records required to be kept?

A: The rule requires that records be kept for one year. [See 589.2001(e)]

65. Q: Are electronic records acceptable for meeting the one year record-keeping requirement, or is it necessary to maintain the original documents?

A: Documents may be stored electronically. However, as with hard copies, electronic records must still be made available for inspection and copying, if necessary, at the time and location of the inspection.

66. Q: What does “track CMPAF to ensure the materials are not introduced into animal feed” mean? Are renderers responsible beyond giving up control of the material?

A: The renderer is responsible for marking the CMPAF and disposing of it directly, or arranging for its non-feed disposal. See Guidance for Industry #195 for further details.

Marking

67. Q: What are the marking requirements in the new rule?

A: The rule requires that once CMPAF has been separated from other cattle materials, renderers mark CMPAF with an agent that can be readily detected on visual inspection. This requirement is intended to prevent cross-contamination, and as explained in the preamble to the 2008 rule, is also intended to provide a readily detectable method by which all persons in the animal feed chain can be made aware that the product is prohibited material or contains prohibited material. [See Requirements B(1) page 22735]

68. Q: If CMPAF is rendered to obtain tallow, shouldn't the finished meal be marked/dyed rather than the raw CMPAF? Marking the raw CMPAF will cause the tallow to be marked as CMPAF when, if it contains less than 0.15% insoluble impurities, it is not CMPAF.

A: The marking requirement has been addressed in more detail in Guidance for Industry #195.

Cleanout of equipment at feed manufacturing facilities

69. Q: Do feed mills have to clean out their tallow tanks before the compliance date?

A: Although the rule does not require tallow tanks to be cleaned out prior to the compliance date, tallow must meet the new requirements that go into effect on that date. Whether this is accomplished through physical cleaning, by switching to new product that complies with the 2008 revision to 21 CFR 589.2000 in advance of the effective date, or by some other means, the method used for bringing tallow tanks into compliance should be documented to meet the record keeping requirement of the new rule.

70. Q: Do feed mills need to steam-clean or power-wash the inside of their tallow tanks before putting in new product that complies with the 0.15% insoluble impurities standard?

A: As stated above, the rule does not require tallow tanks to be cleaned prior to the compliance date. However, as mentioned above, physical cleaning such as steam-cleaning or power-washing the inside of the tanks prior to putting new product into the tanks may be one way of bringing tallow tanks into compliance. If such cleaning is performed, the date and method should be recorded to meet the recordkeeping requirements of the rule to demonstrate compliance.

71. Q: If a feed mill uses tallow that exceeds the 0.15% insoluble impurities standard to make swine or poultry feeds, but wants to make ruminant feed that doesn't contain tallow, is cleanout of the mixer or other manufacturing equipment required?

A: Tallow (from non-CMPAF material) that exceeds 0.15% insoluble impurities is now considered "prohibited material" and subject to cleanout requirements under 21 CFR 589.2000. Therefore, if common equipment is used to receive tallow that exceeds 0.15% insoluble impurities and ingredients that may be used in ruminant feeds, then facilities should adopt cleanout procedures for that equipment. However, we expect that it may be possible to minimize the amount of tallow carried-over in the mixing equipment and downstream from the mixer. Therefore, extra cleanout procedures may not be needed if other procedures are in place to address carry over.