GUIDE FOR FEED MANUFACTURERS TO COMPLY WITH THE FDA FINAL RULE PROHIBITING MAMMALIAN PROTEIN IN RUMINANT FEED

Introduction

On June 5, 1997, FDA published a final rule prohibiting the use of mammalian protein (i.e. animal protein products, such as meat and bone meal) in ruminant feeds. Mammalian protein is defined as protein from mammals, but excludes porcine (pork) and equine (horse) protein from single-species slaughter plants.

There are exemptions from this prohibition for proteins derived from blood, milk, gelatin and processed meat products which have been cooked and offered for human consumption and further heat processed for feed (such as plate waste and cellulosic food casings). Fat, tallow, amino acids, and dicalcium phosphate produced as a by-product of gelatin manufacturing, are not covered by this rule and may be used in ruminant feeds. Similarly, poultry and fish meals are not included in this rule and may continue to be used.

The rule took effect August 4, 1997. This means the required warning statements and written recordkeeping and cleanout procedures should have been in place on this date. FDA is allowed an additional 60 days to exhaust labeling and products from the marketplace for products and labels produced before June 5, 1997. Therefore, all products and labels were to be in compliance with this rule by October 3, 1997.

This guide is designed to assist you in complying with this new rule in a timely manner. However, it is difficult to design a broad-based guide of this type for all situations and scenarios in the feed industry. Much of the guide will be devoted to discussing the end-point for complying, so a firm can design compliance procedures to reach that endpoint in a manner appropriate for its particular operations.

Areas of Concern

Three principal areas are detailed in this guide. These are labeling, recordkeeping, and the main point of this guide, equipment cleanout. Each of these areas has specific requirements as part of the final rule. For the purpose of this guide, it is assumed your firm manufactures feed for more than one species, and likely uses meat and bone meal or other animal protein products from mammalian sources.

If your firm utilizes only animal protein products from exempt sources, such as pork or horse, no equipment cleanout is required, nor is special labeling required. However, you may wish to acquire a letter of certification, such as the one appearing in Appendix A.

Source — AFIA
http://199.73.36.105/Afia/Files/BAMN-%20BSE-%20DDGS-%20Biosecurity%20Awareness/BSE%20Guidelines.pdf

Labeling

The rule requires ail feed labeling, including brochures and other leaflets distributed with feed products containing (or likely to contain) prohibited mammalian protein, to have the statement "**Do not feed to cattle or other ruminants**" in a prominent place on the label or other printed material. FDA suggests the statement be distinguished by different type size or color or other means of highlighting the statement. Pet foods for retail sale and feed for non-ruminant laboratory animals are exempt from the labeling requirement.

For existing Labeling, some firms may find it helpful to use a rubber stamp with the required statement, thus saving reprinting costs. Use of such a stamp should not obliterate or make unreadable other required labeling information. Similarly, printed bags may be labeled with a rubber stamp of the statement, stick-on labels, or other means of printing the statement prominently on the bag. For bulk shipments, the required statement may be stamped or otherwise printed on invoices or other shipping documents.

PLEASE NOTE: The rule does not require the use of the words "Caution" or "Warning". Only the statement highlighted above is required.

According to FDA, feed not bearing the required label statement are assumed to be in compliance with the rule, and the feed does not contain prohibited substances. FDA and state investigators will likely review animal protein product records of firms listing no cautionary statements on product labels. In other words, failing to use the cautionary statement implies compliance with the rule and means a firm is not using prohibited mammalian proteins.

Feed produced by integrated operators for distribution to on-farm producers is not exempt from the labeling requirement unless the firm is using only exempt protein substances. This should be documented by adequate records.

The Association of American Feed Control Officials (AAFCO) model feed regulations allow use of collective terms, such as "animal protein products." Nearly all states (except California and Hawaii) allow such terms in lieu of the individual ingredient name, such as, "meat and bone meal." This allowance makes it easier to utilize least-cost or best-cost formulation programs without reprinting labels each time an ingredient is changed.

The final rule does not change the ability to use collective terms. Firms may continue to use "animal protein products" on feed labels, where one or more animal protein ingredients from the AAFCO list are utilized.

Firms may voluntarily choose to utilize more specific ingredient names than "meat and bone meal" in ingredient listings by utilizing such specifically named ingredients like pork and bone meal. (Please note the use of a specific species name in the meat and bone name. The usual rule is to utilize the meat name, i.e. pork, beef, lamb, etc. followed by "... and bone meal.") It is unclear if feed control agencies will allow use of terms, such as "non-ruminant meat and bone meal." However, AFIA can petition such if needed.

Protein From Single Species Slaughter Facilities

The rule allows certain exemptions from labeling and recordkeeping for firms purchasing and utilizing exempt products. For example, if your firm chooses to utilize only pork and bone meal, this ingredient must he obtained from a single-species slaughter facility. If such single species ingredients are utilized, neither recordkeeping nor the cautionary label statement is required.

While not required to do so by the FDA regulations, ASIA strongly recommends that such a facility certify to the feed manufacturer that only porcine (or equine) species are slaughtered in its facility. Appendix A is an example of a certification letter (or such a statement may be included on invoices or other shipping document).

Recordkeeping

The rule requires records sufficient to track ingredients and finished products throughout receipt, processing and distribution for firms utilizing mammalian ingredients prohibited in ruminant feeds. These records must be available for inspection and copying by state and federal investigators, and must be maintained for one year after distribution. Normal business records may be used to document compliance with the rule during inspections by state and/or federal investigators.

Most firms should have existing records sufficient to be in compliance with this rule. Any voluntary certification statements, detailed in the "Protein From Single Species Slaughter Facilities" section above and the "Ingredient Receiving" section below, should be maintained with ingredient invoices or other shipping documents. Labels of such products should be maintained as well.

FDA advises that the recordkeeping requirement can be satisfied by an invoice or similar document reflecting receipt or purchase, and sale or delivery of the product. The information normally included in these documents includes: 1) Date of receipt or purchase, or sale or delivery; 2) seller's name and address; 3) consignee's name and address; 4) identification of the product, and 5) quantity. FDA notes invoices or similar sales documents may serve as labels for bulk products.

Customer Recordkeeping

Your customers may request information about recordkeeping required to comply with the rule, or you may wish to advise them about their recordkeeping requirements, especially dairy and beef cattle customers. AFIA offers the following suggestions for your customers:

- Records to document compliance with the rule for customers feeding ruminants must be available for FDA or state inspection and maintained for one year.
- Such records are similar to those described above for feed manufacturers and include the labeling for all feed products containing animal protein products.
- If a customer further mixes feeds for use at other facilities, these feeds must be labeled with the required cautionary statement if the feeds contain prohibited animal protein products.

Facilities and Equipment Cleanout

For facilities which choose to separate mammalian and non-mammalian materials, FDA suggests that all equipment which comes in contact with feeds containing mammalian and nonmammalian product follow all reasonable and effective procedures to prevent contamination of manufactured feed.

The agency notes that only equipment and storage facilities that are used for proteins derived from both mammalian and nonmammalian tissues are subject to the clean-out requirement. FDA will consider the use of clean-out procedures to be adequate for the purposes of this final rule if the procedures are based on the equipment clean-out procedures in 21 CFR 225.65 (CGMPs for medicated feed manufacturers). Federally licensed, medicated feed mills are required to comply with these CGMP requirements, including having predetermined, written compliance procedures for each facility.

Many feed manufacturers that do not hold a feed mill license (formerly MFAs or 1900s) may not have written procedures. These firms also must have written procedures to prevent unsafe carryover of prohibited mammalian protein into either ruminant feeds and/or ingredients used in ruminant feeds. These procedures may include physical clean-out, flushing, or sequencing.

Ingredient Receiving

In most instances, sequencing of received ingredients will enhance- operating efficiencies. For example, after unloading rendered mammalian protein, the area around the receiving pit should be swept, and the conveying system operated until it is completely cleaned out. Next, depending upon the operating capacity of the receiving system, an adequate amount of a high volume, routinely received ingredient, such as soybean meal, should be received to clean the receiving pit and conveying equipment of rendered mammalian protein residue. Ideally, this material should be directed to a second soybean meal bin, for example, and not used in ruminant feeds.

In cases where the preferred sequence of ingredients cannot occur, then flushing is an option. In such a case, an adequate amount of soybean meal should be transferred to a bulk load out bin, loaded onto a truck, received to clean the receiving pit and conveying system, and directed to the soybean meal bin designated for non-ruminant use.

The amount of sequenced or flushed material deemed adequate to clean the receiving system of rendered protein residue should he decided by someone knowledgeable in plant operations and/or FDA compliance. If inspected, FDA investigators will review your written procedures for receiving rendered protein, verify your plant personnel are following the procedures, and make an assessment as to whether the amount of material used for sequencing and/or flushing is adequate to prevent carryover of rendered protein.

In order to document cleanout and minimize carryover from ingredient suppliers and carriers, each firm may request from ingredient haulers certification (Appendix B) that transport vehicles have been flushed with non-prohibited ingredients and/or sequenced in a manner adequate to prevent carryover or prohibited substances. Although certificates are not required by FDA, AFIA strongly recommends this approach.

Processing

Similar to CGMPs for medicated feed, the manufacture of feed formulated with mammalian protein can be properly sequenced. For example, prior to the production of ruminant feed, a non-ruminant feed, not formulated with mammalian protein, can be produced after feed containing mammalian protein. In most cases, this sequence should continue through each process in the plant, up to and including bulk load-out: and packaging, to prevent unsafe carryover of feed containing mammalian protein into any ruminant feeds.

In cases where feed sequencing is not practical, then flushing is an option. In such a case, prior to ruminant feed production, an adequate amount of flush material, such as a high-volume ingredient like soybean meal, should be transferred through the plant processes to remove residues of feed containing mammalian protein. Typically, this amount will range between 200 pounds and 1,000 pounds, depending -upon the size of the operating systems. This flush material can be sacked or held in a bulk tote, must be properly identified as "mammalian protein flush", and can be reused into feed production containing mammalian protein by replacing the same ingredient pound for pound.

The amount of flush material deemed adequate to clean the mixing and other plant systems of residue from feed containing rendered protein should be determined by someone knowledgeable in plant operations and/or FDA compliance. If inspected, FDA investigators will review your written procedures for production of rendered protein feeds, verify your plant personnel are following the procedures, and make an assessment as to whether the amount of material used for flushing is adequate to prevent unsafe carryover of feed containing rendered protein.

Remember, written procedures must be developed for each site. Moreover, any procedures developed must be used consistently in the facility for which the procedures were developed.

Summary

In order to comply with this rule, feed manufacturers choosing to utilize non-mammalian and mammalian protein ingredients in she same facility must do the following:

- Label all products containing or which nay contain prohibited mammalian protein with the required warning statement.
- Maintain adequate records for one year to document compliance with the FDA rule on mammalian protein.
- Develop, maintain and utilize written procedures adequate to prevent the carryover of prohibited mammalian ingredients into ruminant feed.
- Allow state and/or federal investigators access to records and procedures concerning the rule.

Feed manufacturers choosing to utilize non-prohibited mammalian proteins are not required to label products with the cautionary statement. However, they should maintain records sufficient to document compliance with the rule, including any certification statement from suppliers. Questions on compliance with this rule may be addressed to either Brian Bursiek or Richard Sellers at AFIA.

Appendix A

Letter Certifying Pure Porcine/Equine Protein Product Compliance

I/We certify that our product _____
sold to _____at the
following location _____
contains only porcine/equine protein product and is therefore an exempt mammalian protein under FDA regulation 21 CFR 4 589.2000. I/We certify this product was produced at a single-species slaughter facility. I/we further certify that this letter will cover all future shipments until I/We provide written notification that this letter is no longer in effect.

_____
Name

_____
Signature

_____
Title

_____
Address

_____
Firm

_____
City/State/ZIP

_____
Phone Number

_____
Date

Source: AFIA

Appendix B

Letter Requesting Adequate Cleanout of Conveyance Vehicles In Compliance with FDA Regulation 21 CFR 589.2000

This is to notify you that (Firm Name) _____
requires your firm (shipper's name) _____
to be in compliance with FDA regulation 2] CFR 589.2000 cleanout procedures. Your cleanout procedures should be adequate to prevent any carryover of mammalian protein products from one load to the next. Such procedures may be by flushing, physical cleanout or by sequencing your loads.

You must provide this firm with written concurrence of this request. If there are any questions about this request, please contact the person in the office listed below.

_____
Name

_____
Signature

_____
Title

_____
Address

_____
Firm

_____
City/State/ZIP

_____
Phone Number

_____

Source: AFIA

I/We concur with this request and certify our/my firm is in compliance with the stated rule and adequately clean out my/our vehicles after transportation of mammalian protein products. I/We further certify that this letter will cover all future shipments until I/we provide written notification that this letter is no longer in effect.

_____

Name

_____

Signature

_____

Title

_____

Address

_____

Firm

_____

City/State/ZIP

_____

Phone Number

_____

Date

Source: AFIA