

FDA GUIDANCE FOR INDUSTRY 67

This guide replaces those parts of Guidance for Industry 60, June 17, 1997, that applied to renderers.

SMALL ENTITIES COMPLIANCE GUIDE FOR RENDERERS

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.

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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

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WHAT IS THE PURPOSE 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. However, certain products are **exempt** from the regulation:

The following protein products derived from mammals are **exempt**:

Blood and blood products, Gelatin, Milk products (milk and milk proteins), 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 you are not required to comply with the provisions of this regulation. This material is referred to as "**nonprohibited material**" throughout this guide.

All other mammalian protein will be referred to as "**prohibited material**" throughout this guide. If you receive and process this material, you must comply with the provisions of 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 a renderer** as any firm or individual that processes slaughter byproducts, animals unfit for human consumption, or meat scraps. This definition includes:

establishments traditionally considered to be renderers;

those who collect slaughter by-products, animals unfit for human consumption, or meat scraps, and subject them to minimal processing;

those who collect and distribute slaughter by-products, animals unfit for human consumption, or meat scraps, to firms other than renderers; and

renderers that also blend animal protein products. The "Small Entities Compliance Guide for Protein Blenders, Feed Manufacturers, and Distributors," FDA Guidance for Industry 68, applies to protein blending operations. **The distribution activities of renderers are included in this regulation.**

A slaughterhouse, dealer, hauler, or anyone else who supplies you with product to be rendered is not subject to specific requirements under this regulation. However, if you separate prohibited from nonprohibited material, you may wish to have assurance from your 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.

Even if you fall within the definition of renderer, you are not subject to the regulation if you do not receive and process any prohibited material.

If you obtain raw materials from a variety of sources, and may not be able to determine the species of some incoming material, the material is considered "prohibited material" because it **"contains or may contain"** prohibited products. "Prohibited materials" also includes products sold by renderers that may be able to determine the species of all their incoming materials, but choose not to separate prohibited from nonprohibited materials.

There are two categories of renderers that process prohibited material - 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 Do Not Separate Prohibited and Nonprohibited Material 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 by the FDA. 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 Have Three Additional Requirements:

4. Obtain non-prohibited material (including pure pork and pure equine) only from single species slaughter facilities. Single species slaughter facilities are those that are dedicated solely to the slaughter of a single species of animal.

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

6. 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.

The cautionary 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 cautionary 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?

This requirement does not anticipate the creation of 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."

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 PROVIDE FOR MEASURES TO 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 materials. This could be entirely separate buildings, rooms, or other locations; or separate storage containers for incoming material and finished product, and separate manufacturing lines.

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. Clean-out

Clean-out 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. Clean-out 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 clean-out 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 clean-out flush material is handled. **OR**

3. Combination of separation and clean-out

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, clean-out, 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 products. 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 investigator should be able to easily identify operations that are described in the written procedures.

WHAT ARE SOME EXAMPLES OF MEASURES THAT I COULD FOLLOW TO PREVENT COMMINGLING AND CROSS CONTAMINATION?

EXAMPLE PROCESSING OPTION #1

This example is a single plant with two or more **totally segregated** processing lines. This includes all process functions from raw material receiving through and including finished product load-out.

Suggested Procedures for Processing Option 1

No clean-out procedures are necessary for this processing situation, because the lines are completely separate. This type of plant should have the ability to process prohibited and non-prohibited products from the same plant so long as procedures are in place to assure total segregation. These procedures should be part of the plant's written procedures specifying measures the firm is taking to prevent commingling and cross contamination and should be available for inspection and FDA review for compliance purposes.

EXAMPLE PROCESSING OPTION #2

This example is a single plant which has two or more segregated raw material receiving, grinding, cooking, and pressing lines but shares finished product conveying, grinding, and load-out systems.

Suggested Procedures for Processing Option 2

The suggested procedures to prevent commingling and cross contamination for this type of plant deal specifically with the meal grinding (and screening), storage, and load-out systems. It is assumed that this type of plant would have separate storage facilities for prohibited versus non-prohibited product. It may have separate or common load-out facilities.

STEP #1 - The first step in the clean-out and flushing procedure should be to empty all transport and process equipment from the first point of commonality of products to the final load-out device.

STEP #2 - The system should then be flushed with a sufficient volume of non-prohibited product to accomplish one complete change of operating volume of the entire system (exclusive of separate meal storage facilities). The flush material should be considered prohibited product and treated as such.

STEP #3 - Once the system has been flushed, all subsequent material processed

would be non-prohibited material. Specific operating procedures should be part of the plant's written procedures specifying the procedures to prevent commingling and cross contamination and available for inspection and FDA review for compliance purposes.

EXAMPLE PROCESSING OPTION #3

This example is a single plant with separate raw material receiving and grinding, common cooking and pressing, and common or separate finished product handling.

Suggested Procedures for Processing Option 3

The procedures to prevent commingling and cross contamination for this type of plant deal specifically with the cooking and pressing systems. The meal grinding, storage, and load-out systems should be cleaned and flushed according to the guidance in processing option 2 above. It is also assumed that this type of plant would have separate storage facilities for prohibited versus non-prohibited finished meal. It may have separate or common load-out facilities.

STEP #1 - The first step should be to empty all transport and process equipment (including the cooker) from the first point of commonality of raw material to the meal grinding system.

STEP #2 - The system should then be cleaned and/or flushed with sufficient non-prohibited raw material to accomplish the following changes of the operating volume of the cooker:

In the case of a continuous cooker with a bottom discharge (to provide positive cooker clean-out), raw material equal to at least one half the operating volume of the cooker;

In the case of a continuous cooker without a bottom discharge, raw material equal to at least the operating volume of the cooker; or

In the case of a batch cooker system, raw material equal to at least one half the operating volume of the cooker for each batch cooker.

In general, the volume of material required to flush the cooking system should provide an adequate flush of the meal grinding, storage and load-out system, as well. The flush material should be considered prohibited product and treated as such. All subsequent material processed should be considered non-prohibited product. Specific operating procedures should be documented and verified, should be part of the plant's written procedures specifying the

procedures utilized to prevent commingling and cross contamination, and should be available for inspection and FDA review for compliance purposes.

EXAMPLE PROCESSING OPTION #4

This example is for a single plant with one processing line handling both prohibited and non-prohibited material. This includes all process functions from raw material receiving through and including product load-out.

Suggested Procedures for Processing Option 4

The procedures to prevent commingling and cross contamination for this type of plant deal with the complete plant process. It is assumed that this type of plant would have adequate storage facilities to separate prohibited from non-prohibited finished product. It may have separate or common load-out facilities.

The procedures should include measures to empty and clean and/or flush all transport and process equipment including the raw material receiving hoppers, conveyors, grinders, and cooker from the first point of commonality of raw material through the load-out system. As a guideline, the volume of flushing material should be equal to the operating volume of the process and transport equipment, including the cookers.

The flush material should be considered prohibited product and treated as such. All subsequent material processed should be considered non-prohibited product. Specific operating procedures should be documented and verified, should be part of the plant's written procedures specifying the procedures utilized to prevent commingling and cross contamination, and should be available for inspection and FDA review for compliance purposes.

Due to the degree of variability among rendering systems, a Hazard Analysis and Critical Control Points (HACCP)-based approach of process controls would be helpful in implementing any of the above procedures. This will enable differences to be addressed on a site-specific basis. Renderers could follow the above 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, should be part of the plant's written procedures specifying the procedures utilized to prevent commingling and cross-contamination and should be available for inspection and FDA review for compliance purposes.

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

SINGLE SPECIES SLAUGHTER FACILITIES

Single species slaughter facilities are those that are dedicated solely to the slaughter of a single species of animal. That means any facilities slaughtering different species on different days, different shifts, or on different processing lines, even if done only occasionally, are not "single species" facilities.

Product received from different single species slaughter facilities may be combined or blended at the renderer and it may be commingled with other protein products as long as the requirements of the regulation are met.

PRODUCTS FOR IMPORT

All mammalian protein product imported into the U.S. is 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 regulation.**

PRODUCTS FOR EXPORT

Prohibited protein product 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 for the country of destination.

Any prohibited protein product destined for export which 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 prohibited protein products 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.

Product consisting **only** of nonprohibited protein has no requirements under this regulation.

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

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.

The regulation provides for two levels of exemption from the cautionary statement and records requirements:

- 1) Renderers can be exempted from both the cautionary statement and records requirements if they do any one of three things:
 - a) Use exclusively a manufacturing method that has been validated by the FDA to deactivate the agent that causes transmissible spongiform encephalopathy (TSE) (BSE is a TSE) and whose design has been made available to the public;
 - b) Use routinely a test method that has been validated by the FDA to detect the presence of the agent that causes TSE's and whose design has been made available to the public. Products found by such test to contain the agent that causes TSE's shall be labeled "Do not feed to cattle or other ruminants." Records of the test results shall be made available for inspection by the FDA; or
 - c) Use exclusively a method for controlling the manufacturing process that minimizes the risk of the TSE agent entering the product and whose design has been made available to the public and validated by FDA.
- 2) Renderers can be exempted from the records requirement alone if they use a permanent method, approved by FDA, to make a mark indicating the presence of the mammalian materials. If the marking is by the use of an agent that cannot be detected on visual inspection, the renderer must use an agent whose presence can be detected by a method that has been validated by the FDA and whose design has been made available to the public.