

FDA GUIDANCE FOR INDUSTRY 70

This guide replaces those parts of Guidance for Industry 60, June 17, 1997, that applied to feeders of ruminant animals without on-farm feed mixing operations.

SMALL ENTITIES COMPLIANCE GUIDE

FOR FEEDERS OF RUMINANT ANIMALS

WITHOUT ON-FARM FEED MIXING OPERATIONS

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 and requests for information to Gloria Dunnavan, Director, Division of Compliance (HFV-230), U.S. Food and Drug Administration, Center for Veterinary Medicine, 7500 Standish Place, Room 405, Rockville, MD 20855, (301) 594-1726.

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 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 derived from cattle. However, certain products are **exempt** from this regulation.

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

- Blood and blood products
- Milk products (milk and milk proteins)
- Pure porcine (pork) or pure equine (horse) protein products
- Inspected meat products, such as plate waste, which have been cooked and offered for human food and further heat processed for animal feed
- Gelatin

■ The following nonmammalian protein products are **exempt**:

- Poultry
- Marine (fish)
- Vegetable

■ The following products are also **exempt** because they are not protein or tissue:

- Grease
- Fat
- Amino acids
- Tallow
- Oil
- Dicalcium phosphate

We refer to the exempted products throughout this guide as “**nonprohibited material**.” We refer to all mammalian protein that is not exempted as “**prohibited material**.”

Prohibited material and/or feeds containing prohibited material cannot be fed to ruminant animals. “**Ruminant animals**” are any animals with a four-chambered stomach including cattle, sheep, goats, buffalo, elk, and deer.

IS MY OPERATION AFFECTED BY THIS NEW REGULATION?

- This provision applies to livestock feeding operations that feed ruminants. The regulation applies to "establishments and individuals that are responsible for feeding ruminants" to make it clear that all responsible persons, in both large and small feeding operations, are subject to the regulation.
- Examples include dairies, cattle feed lots, calf and lamb raising operations, cattle, sheep, and goat grazing operations.
- If a feed is intended for ruminants contains animal protein, the protein can consist only of nonprohibited material.
- The Association of American Feed Control Officials (AAFCO) has identified the following ingredients listed in their Official Publication as prohibited material:

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|---|--------------------------------------|-----------------------|
| ■ 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 Leather Meal | ■ Hydrolyzed Hair |
| ■ Glandular Meal and Extracted Glandular Meal | | ■ Stock |
| ■ Animal Digest | ■ Cooked Bone Marrow | ■ Leather Hydrolysate |
| ■ Meat Protein Isolate | ■ Mechanically Separated Bone Marrow | |
| ■ Unborn Calf Carcasses | ■ Bone Meal, cooked | ■ Bone Meal, steamed |
| ■ Dehydrated Garbage | ■ Dehydrated Food-Waste | |

- Feed and feed ingredients not containing animal proteins are not subject to the regulation.
- Persons who feed prohibited material to ruminants would be subject to regulatory action under the Federal Food, Drug, and Cosmetic Act. Regulatory action could include seizure of inventory, injunction against feeding prohibited material to ruminants, or prosecution.

Note: If you mix your own feed for your ruminant animals, you are subject to additional requirements. Consult the "Small Entities Compliance Guide for Feeders of Ruminant Animals with On-Farm Feed Mixing Operations," FDA Guidance for Industry 69.

HOW DO I COMPLY WITH THE NEW REGULATION?

1. Do not feed products labeled with the caution statement **“Do not feed to cattle or other ruminants”** to your ruminant animals.
2. Maintain copies of all purchase invoices for **ALL** feeds received that contain **animal protein**.
3. Maintain copies of labeling for **ALL** feeds received containing **animal protein** products.
4. Keep invoices and labeling available for inspection and copying.
5. Maintain the records for a minimum of one year.

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

- Renderers, protein blenders, and feed manufacturers are required to label products containing prohibited materials with the cautionary statement “**Do not feed to cattle or other ruminants.**”

- If you intend to feed **only ruminant animals**, products with this caution statement should not be available for use in your operation. If the feed does not bear the caution statement but you suspect that it contains prohibited material, do not use it until you are sure that it does not contain such materials.

- If you intend to use a feed containing prohibited material for nonruminant animals, take steps to ensure that the feed will not be fed to ruminants.

■ LABELING

- Since bulk shipments of feed are commonplace, and labeling information typically is contained in the invoices for bulk shipments, maintenance of the invoice is sufficient documentation.

- If the only labeling for a bulk product is on a placard, the placard **for each shipment** should be retained.

- Feed may also be received in bags or other containers that have attached labeling. In those instances, the labeling should be removed and retained. However, maintenance of only one such labeling piece **from each shipment that represents a different product** is necessary.

- If the labeling cannot be removed from the bag or other container, it is acceptable to retain a representative bag or a transposed copy of the labeling information from a container that cannot feasibly be stored.

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

■ RECORD KEEPING

- The records should be legible and readily retrievable.
- The one year requirement for maintenance of records means one year from the date of the receipt of the product.

■ INSPECTIONS

- On-farm inspections will be limited but will be needed on a selective basis to trace prohibited material to verify that it is not being shipped to ruminant producers and fed to ruminant animals. For example, on-farm inspection might be necessary as a follow up to a feed mill inspection, to verify that feed not labeled with the cautionary statement is in fact being fed to nonruminant animals.