

DEPARTMENT OF FOOD AND AGRICULTURE

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fisher Lane, Room 1061
Rockville, MD 20852

Docket No. 02N-0273

To Whom It May Concern:

The following comments are offered on behalf of the California Department of Food and Agriculture (CDFA) regarding the Advance Notice of Proposed Rulemaking (ANPR), Substances Prohibited from Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed, dated November 4, 2002. The Department's Agricultural Commodities and Regulatory Services Branch (ACRS) has primary responsibility for administration and enforcement of the California Commercial Feed Law to help ensure a clean and wholesome supply of animal products for the consumer.

Bovine spongiform encephalopathy (BSE) has resulted in devastating and significant impacts to animal agriculture and related industries in countries where the disease has occurred. The Department views BSE as a serious threat to the beef, dairy, and other ruminant animal production industries and supports the federal rule as specified in Title 21, Code of Federal Regulations, Part 589.2000. California has adopted the federal BSE Rule by reference in the state feed regulations and provides the majority of on-site inspection of feed manufacturing facilities, transporters, and livestock production operations for compliance with the regulation.

ACRS provides the following information and responses to questions listed in the Federal Register published under Docket No. 02N-0273:

1. Excluding Brain and Spinal Cord from Rendered Animal Products.

Question: Should high-risk materials, such as brain and spinal cord from ruminants two years of age and older, be excluded from all rendered products?

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Comment: If scientifically factual information supports prohibiting these high-risk materials from human foods, then it is also appropriate to exclude them from the diet of food-producing animals.

Not doing so would result in the public perception that FDA is not taking every reasonable action to reduce the risk of BSE in the United States. If central nervous system material is banned in both human and animal food, it is important that reliable testing methodology be available to effectively monitor compliance.

Question: How feasible would it be for the rendering industry to implement such an exclusion?

Comment: This must be answered by the rendering industry.

Question: What will be the adverse and positive impacts (economic, environmental, health, etc.) resulting from a brain and spinal cord exclusion?

Comment: The Harvard Risk Assessment indicates that banning the inclusion of these high-risk materials has the potential to positively impact both animal and human health. Should FDA amend the regulations to ban the inclusion of brain and spinal cord from feed, there must be specific guidance for industry and state regulators to assure proper disposal of such materials.

2. Use of Poultry Litter in Cattle Feed

Question: How extensive is the use of poultry litter in cattle feed in the United States?

Comment: In California, poultry litter is utilized for production of calf feed and dry cow rations. California feed regulations prohibit the feeding of poultry waste or litter to lactating dairy animals. There is up to eight thousand tons of processed poultry waste and litter used in ruminant feed annually.

Question: What is the level of feed spillage in poultry litter?

Comment: Specifics regarding feed spillage will need to be provided by the poultry industry. Microscopic examination of dried poultry litter by the ACRS Feed Inspection Program has detected bone and hair in some samples.

Question: What are the methods used to process poultry litter before inclusion in animal feed?

Comment: All manufacturers of poultry waste and poultry litter must be licensed and permitted in California pursuant to the California Feed Law. Poultry waste and poultry litter is processed by dehydration utilizing natural or artificial heat up to 230 degrees Fahrenheit to destroy pathogens and other microorganisms, and to remove moisture. The majority of dried poultry waste and litter is pelleted before use.

Question: What will be the adverse and positive impacts (economic, environmental, health, etc.) resulting from banning poultry litter in ruminant feed?

Comment: The poultry industry is taking steps to minimize, prevent or eliminate feed spillage to litter. These materials are closely monitored and regulated in California. Banning poultry litter or waste from ruminant feed would significantly reduce the potential for prohibited protein to be fed to ruminants from these sources.

A feed ban on litter from poultry operations receiving prohibited material would be consistent with the current zero tolerance level for prohibited mammalian protein in ruminant feed. However, this may complicate a disposal problem already critical to the poultry industry. Any change in the disposition of poultry litter and wastes could have important environmental and health impacts, as available land to dispose of such materials is limited.

Poultry litter or poultry waste from operations that only feed plant protein in their rations may still be suitable for use in ruminant feed.

3. Use of Pet Food in Ruminant Feed

Question: Should pet food for retail sale be labeled with the statement "Do not feed to cattle or other ruminants."?

Comment: Yes. This would be consistent with current requirements for the labeling of feed for non-ruminant livestock species that contain prohibited materials. While the feed manufacturing industry is able to recognize product labels containing prohibited material, animal producers and purchasers of animal feed, including pet food, may not recognize prohibited materials in labeled ingredients and inadvertently, or intentionally, feed them to ruminants.

Question: What would be the adverse and positive impacts (economic, environmental, health, etc.) of such a labeling requirement?

Comment: This will need to be addressed by the pet food industry.

4. Preventing Cross-Contamination

Question: Are there practical ways, other than dedicated facilities, for firms to demonstrate that the level of carry-over could not transmit BSE to cattle or other ruminants? If so, what is the safe level of carry-over in a feed mill and what is the scientific rationale used to establish this safe level?

Comment: Dedicated facilities and equipment is the most effective and reliable way for feed manufacturers, distributors, and transporters to eliminate carry-over or cross-contamination. The majority of firms in California that handle prohibited materials have taken steps to use dedicated equipment.

An acceptable level of carry-over cannot be established without sufficient knowledge of the amount of infective prion in the diet necessary to cause BSE. Without the development of a tolerance level based upon reliable scientific data, clean-out procedures are only adequate if prohibited materials are completely undetectable. At the present time, any amount of prohibited material in ruminant feed would cause the feed to be adulterated.

A zero tolerance dictates dedicated equipment, as typical clean-out procedures utilized in conformance with Good Manufacturing Practices (GMPs) are not designed to result in zero carry-over from one batch of feed to another.

Question: What steps are firms currently taking to prevent cross-contamination of prohibited protein into ruminant feed, and what are the costs of those steps?

Comment: This needs to be answered by the feed industry.

5. Elimination of the Plate Waste Exemption

Question: To what extent is plate waste used in ruminant feed?

Comment: There are substantial tonnages of food processing waste, and outdated or damaged human food products collected as plate waste distributed in ruminant feed.

Question: What is the composition of plate waste, and what are its sources?

Comment: Plate waste contains anything served to people and also materials from food processing facilities such as pizzas, tacos, burritos, prepared meats, etc.

Question: How is plate waste processed before inclusion in ruminant feed?

Comment: Plate waste is typically dehydrated and pelleted for mixing in ruminant feed. Processing to reduce or eliminate any potential contamination by the BSE prion should not be an issue since plate waste has already been sufficiently processed for use as human food. If the food comprising plate waste was deemed suitable and safe for human consumption, then it should be suitable for use in ruminant feed.

Question: What would be the adverse and positive impacts (economic, environmental, health, etc.) from excluding plate waste from ruminant feed?

Comment: Eliminating plate waste would aid in the Department's ability to monitor for compliance with the regulation since interference with feed testing procedures by these sources of bovine protein would be removed. However, interference from other sources of bovine protein exempted from the feed ban, such as blood meal, must also be considered. Exclusion of plate waste from ruminant feed may also result in greater challenges for the disposal of these materials.

California is a state with a large animal agriculture industry that is very concerned about the potential for diseases like BSE to impact our ability to produce safe food. We would like to thank the Food and Drug Administration for the opportunity to provide comments for your consideration. If we can provide additional assistance, please let us know.

Sincerely,



SD Wong
for S. Wong

Steven D. Wong, Branch Chief
Agricultural Commodities and Regulatory
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