



January 27, 2003

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:

On behalf of the Association of American Feed Control Officials (AAFCO), I wish to comment on the potential changes to the existing rule prohibiting the use of protein from certain mammalian tissues to prevent the establishment and amplification of bovine spongiform encephalopathy (BSE) in the United States cattle herd. Solicitation for comment is from the advance notice of proposed rule making dated November 4, 2002, issued under sections 201, 402, 409, and 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, and 371) and under the authority of the Commissioner of Food and Drugs. AAFCO is an international association with membership consisting largely of state feed control officials responsible for administration of state laws, rules, and portions of the Food, Drug and Cosmetic Act pertaining to the distribution of commercial feed and feed ingredients for livestock, poultry and other animals, including pets. All fifty states, Puerto Rico, Canada, Costa Rica, the United States Department of Agriculture, and the Food and Drug Administration are members of AAFCO.

Occurrences of BSE, during the last few years have had devastating effects in other parts of the world where the risk had previously been determined to be relatively low. Members of our association continue to conduct the majority of the inspections of the commercial feed manufacturing establishments in North America for compliance with the requirements of regulations designed to prevent spread of BSE through feed. AAFCO is committed to achieving 100% compliance with the federal rule as defined in Title 21, Code of Federal Regulations, Part 589.2000, prohibiting the feeding of protein from certain mammalian tissues to cattle and other ruminants. AAFCO presents the following responses to questions listed in the Federal Register identified 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 2 years of age and older, be excluded from all rendered products?

**Response:** Yes, we believe FDA should exclude the use of these specific high-risk materials from all rendered products if the decision can be scientifically supported. Additionally, if the United States Department of Agriculture regulations prohibit these high-risk materials from use in human foods, we believe the materials should also be excluded from use in food-producing animals susceptible to BSE.

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

**Response:** The rendering industry should answer this question.

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

**Response:** Banning the inclusion of these high-risk materials has the potential to positively impact on both animal and human health as indicated in the Harvard Risk Assessment.

It is imperative that any regulations developed to ban the inclusion of these materials are practical and enforceable and provide clear guidance to slaughter houses and renderers as to the appropriate disposition of these materials and address other related issues including the rendering of 4-D animals.

## *2. Use of Poultry Litter In Cattle Feed*

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

**Response:** No comment.

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

**Response:** No comment.

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

**Response:** Part of the concern for inclusion of poultry litter in animal feeds arises from its use when minimally processed, if at all. We are not aware of any scientific evidence that current methods of processing

poultry litter would inactivate the BSE agent.

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

**Response:** Banning the inclusion of poultry litter in cattle or other ruminant feed will eliminate another potential source of incidental exposure of ruminant animals to prohibited protein from certain mammalian tissues due to the presence of spilled poultry feed in the litter which contains or may contain prohibited material. While consideration must be given to poultry litter that does not contain prohibited material, it is imperative that any regulations developed to ban the inclusion of this material are practical and enforceable. A partial ban of poultry litter feeding (e.g., allowing feeding of poultry litter, which does not contain prohibited material) would be unenforceable and is not recommended. If poultry litter is banned as a feed ingredient, the impact on the use of poultry litter as a fertilizer/soil amendment must be considered. Currently, poultry litter is typically applied as a source of plant nutrients and organic matter on pastures and agronomic fields, often times at very high rates. Both livestock and wildlife have access to this material as a feed source under this practice. This material is not typically incorporated into the soil because of economic costs, though incorporation would increase plant nutrient benefit from this agronomic practice and reduce the exposure to livestock and wildlife. In States that have significant poultry production, the use of excess poultry litter has become a disposal issue, which has been compounded by nutrient management issues. Additionally, many States also lack the legal authority for on-farm inspections to determine and enforce compliance with regard to the feeding of poultry litter to cattle or other ruminants on-farm.

### *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."?

**Response:** Yes. Employees of feed manufacturing establishments have been educated to recognize prohibited protein from certain mammalian tissues on the basis of the labeled caution statement. Since packaged pet food is exempt from the caution statement established in 21 CFR 589.2000, there is concern that material from broken bags, left over materials and even intact pet food containers are not being recognized as containing or potentially containing prohibited material and could be incorporated into cattle or other ruminant feed. Animal producers and purchasers of animal feed also need the label statement to recognize products which contain or may contain prohibited material and should not be fed to cattle or other ruminants.

The Pet Food Institute has done an excellent job educating their industry members on the proper handling and disposition of salvaged/distressed pet food at the manufacturing level. There still appears to be a concern with the handling and disposition of salvaged/distressed pet food at the retail and wholesale distribution level. A number of pet food manufacturers have stated that once their products leave their distribution system that these products are no longer in their control. The concern is not limited to the retail and wholesale distribution of pet food but all food that contains or may contain prohibited mammalian protein, including salvaged/distressed human food. In general, the retail and wholesale distributors are unaware of federal and state feed labeling requirements, and most likely, not aware of the required cautionary statement for salvaged/distressed pet food. Labeling pet food that contains or may contain prohibited mammalian protein with the BSE caution statement would address some of the issues in the retail and wholesale distribution sector. Additional controls will be needed to address the handling and disposition of salvaged/distressed human food that contains or may contain prohibited mammalian protein in the retail and wholesale distribution sector that may be fed illegally to cattle or other ruminants.

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

**Response:** Requiring the BSE caution statement on pet food that contains or may contain prohibited protein would improve enforcement and compliance. Employees of the feed manufacturing sector, the retail and wholesale distribution sector and on-farm producers would be able to recognize that these products are clearly not intended for cattle or other ruminants. In addition, show cattle may be fed pet food during their show preparation. It is apparently a fairly common practice to feed a high protein, high-energy supplement to "finish" the calf and give it a "slick" coat. Pet food meets the criteria.

The inclusion of a warning statement on pet food could result in a temporary shift from prohibited protein material use in pet food, as consumers move to purchase pet foods without the caution statement and prohibited mammalian protein. This is an educational issue. A BSE regulatory program should not withhold information from distributors, feed manufacturers and customers, especially when some of the customers are livestock producers. Accurately labeling feed that contains or may contain prohibited mammalian protein to reflect that the pet food is not intended for cattle or other ruminants will help ensure that these products are handled and used appropriately in all sectors.

#### *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?

**Response:** The intent and the objectives of the rule are best achieved when dedicated facilities, dedicated manufacturing equipment and dedicated conveyance and transportation equipment are utilized. When a facility making cattle or other ruminant feed does not handle prohibited material, the chance of commingling, contamination and accidental mixing or human errors is minimized. The AAFCO BSE policy statement encourages feed manufacturers and ruminant feeders to review, adopt and implement best management practices, such as those suggested by their trade associations which go above and beyond the current requirements of the rule and can further minimize the potential of BSE becoming established in the United States.

Where dedicated facilities and equipment are not used, the Agency should mandate the validation of written cleanout procedures and record-keeping systems for all segments of the feed manufacturing industry including the distribution and transportation sectors.

If there is adequate scientific support of a safe level of carryover for the BSE causative agent(s) in ruminant feed, an established tolerance should be implemented by the FDA. If there is no adequate scientific support to establish this, there should be zero tolerance for the level of contaminant in the feed.

**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?

**Response:** The animal feed and feed ingredient industries should answer this question.

#### *5. Elimination of the Plate Waste Exemption*

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

**Response:** No comment.

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

**Response:** No comment.

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

**Response:** Plate waste that is intended for swine must be processed by cooking (heat) based on the requirements of the Swine Health Protection Act (7 U.S.C. § 3801, et. al.) 100°C, for 30 minutes, at sea level or equivalent (i.e., higher temperature/reduced time, higher pressure/reduced time, etc.). Generally, equivalency is established by standard methods such as, total cell counts as an indicator of pathogens or spike and recovery counts. Plate waste intended for ruminants and other species have no federal standard except that it must not be adulterated. Some states have expanded their garbage feeding laws to encompass other species but there is minimal enforcement. Companies that are distributing, processing and selling plate waste as commercial feed would have to meet the appropriate AAFCO definitions and federal/state feed requirements.

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

**Response:** Banning the inclusion of plate waste in cattle or other ruminant feed will eliminate another potential source of exposure. While consideration must be given to plate waste that does not contain ruminant material, it is imperative that any regulations developed to ban the inclusion of this material are practical and enforceable. If analytical methodology were developed to accurately detect ruminant protein in ruminant feed, it would be unenforceable if this exemption remains. A partial ban of plate waste feeding to cattle or other ruminants (e.g., allowing feeding of plate waste which does not contain ruminant material) would also be unenforceable and is not recommended.

On behalf of the Association of American Feed Control Officials I would like to thank the Food and Drug Administration for the opportunity to provide these comments for your consideration.

Sincerely,

A handwritten signature in cursive script, appearing to read "Ali Kashani".

Ali Kashani, Ph.D.  
AAFCO President