TAB 47

AAFCO

October 31, 2001

Federal Register Notice
Friday October 5, 2001
21 CFR Part 589
Docket Management Branch [HFA-305]
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852
Docket No. 01N-0423
Substances Prohibited From Use in Animal Food or Feed
Animal Proteins Prohibited in Ruminant Feed

To Whom It May Concern:

On behalf of the Association of American Feed Control Officials (AAFCO), I wish to comment on the current rule to help prevent the establishment and amplification of bovine spongiform encephalopathy (BSE) in the U. S. cattle herd as requested in the notice of federal register (volume 66, No. 194, dated Friday, October 5, 2001). 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.

AAFCO recognizes that Bovine Spongiform Encephalopathy (BSE) is a serious health threat to ruminant animals in North America. BSE has had devastating effects in Europe on both animal and human health, as well as the livestock industries and economies of those countries. 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 certain animal protein products to cattle and other ruminants. State members of our association have conducted approximately 80 percent of the inspections reported by the Food and Drug Administration since the adoption of the above regulations. AAFCO presents the following responses to questions listed in the Federal Register identified under Docket No. 01N-0423:

1. *What additional enforcement activities, if any, regarding the present rule are needed to provide adequate public health controls? Are there other suggestions for ways to improve compliance with the rule?*

   To improve compliance with the rule, more frequent inspection and coordinated re-inspection is recommended for the feed manufacturing sector. Inspection and compliance with the current rule should be expanded to include allied industries. The agency must expand compliance inspections to the livestock producer level. This could be accomplished with the assistance and coordination of the state

01N-0423

CH4

animal health officials. Border inspections need to be strengthened to prevent the importation of feeds or feed ingredients not complying with 21 CFR 589.2000. Although it is important to continue to educate, it is time to start increasing enforcement activities. State and federal application of enforcement activities using the AAFCO Enforcement Guidelines should be considered. Infraction severity and associated regulatory action should be evaluated and applied consistently.

2. *Is the present rule at §589.2000 adequate to meet its intended objectives? If not, what are its inadequacies? Are there additional objectives that this rule should now address? If so, what are these new objectives?*

   The current rule is a labeling and record-keeping regulation. The agency should consider adopting Good Manufacturing Practices (GMPs) that could encompass all potential contaminants including the BSE agent for all animal feed and feed ingredients. The rule should provide adequate guidance to all involved parties and accommodate other potential contaminants.

3. *Should the present FDA ban on the use of certain mammalian proteins in ruminant feed be broadened? If so, what should the new parameters of use be? Should the rule be broadened beyond ruminant feed? Beyond mammalian protein?*

   This requires a science-based response. Again, some of the current exclusions deserve further scientific review. There is considerable debate concerning blood products, plate-wastes, tallow, and poultry litter.

4. *Should FDA require dedicated facilities for the production of animal feed containing mammalian protein to decrease as much as possible the possibility of commingling during production?*

   Yes. The intent and the objectives of the rule are better achieved when dedicated facilities or dedicated mixing and conveyance equipment within facilities are utilized. When a facility making ruminant feed does not handle prohibited material, the chance of commingling, contamination and accidental mixing or human errors may be minimized.

   The above statement is based on our facility inspection experience. The current rule (21 CFR 589.2000) specifies that materials containing any amount of prohibited mammalian protein or that could contain must be labeled with the cautionary statement. It is difficult to assure that current flushing and sequencing procedures are adequate to eliminate with 100% certainty "any amount" of the BSE causative agent(s). We are not aware that the agency has established an acceptable tolerance for prohibited protein in ruminant feed. The potential for accidental mixing warrant the consideration that ruminant feeds and ingredients intended for ruminant feeds be processed and assembled in a facility or by

equipment within a facility dedicated to only handling non-prohibited materials for ruminant feed production. This requirement is viewed as a positive step in preventing the occurrence and amplification of BSE in the United States.

5. *Should FDA require dedicated transportation of animal feed containing mammalian protein to decrease as much as possible the possibility of commingling during transport?*

Requiring dedicated transportation of animal feed containing prohibited mammalian protein is viewed as another positive step in preventing the occurrence and amplification of BSE in the United States. State feed regulatory agencies have very limited authority over the transportation system. The cleaning of transportation equipment between delivery of various commodities and feed ingredients appears to get limited attention.

Feed production facilities advise that transportation providers sequence loads of animal feed within reason when distributing production. In addition, feed manufacturers flush their distribution equipment when sequencing is not possible, however, this could be a prohibitive, resource intensive activity to observe and police to determine if distribution equipment was actually being cleaned to eliminate "any amount" of BSE causative agent(s). The Agency should consider the development of GMPs for the transportation sector to provide regulatory authority, not only for the BSE issue but for all potential contaminants in animal feed.

At a minimum, the agency should develop and mandate a validated cleanout method and record-keeping system for transporters to use. If feed manufacturers use dedicated facilities to manufacture ruminant feed, many of the trucks operated by the feed manufacturers will essentially become dedicated. However, trucks *and* rail cars used by the commercial transportation firms that haul many ingredients to the manufacturers may not be dedicated. The transportation providers, their equipment and employees may be difficult to find, educate and regulate and will require a coordinated effort with federal Department of Transportation.

6. *In order to improve production practices and increase assurance of compliance with the rule, should FDA require FDA licensing of renderers and other firms/facilities engaged in the production of animal feed containing mammalian protein?*

Yes, if the intent of a licensing requirement is to utilize the license as an enforcement tool, like withdrawal of FDA license for violation of 21 CFR 589.2000, and this additional enforcement tool will be used in a timely and

appropriate manner, then this issue may have merit. Without adequate regulatory tools and resources, the agency may not be able to enforce this provision.

We are not aware of specific examples where this requirement would provide assurance for the prevention and amplification of BSE in the United States. Amendment of the rule (21 CFR 589.2000) to require FDA licensing of renderers and other firms/facilities engaged in the production of animal feed containing mammalian protein may not be necessary since most, if not all firms are licensed by a state or federal agency.

Many, if not most, of the states currently require licensing or facility registration of firms/facilities engaged in the production of animal feeds. Many states also require licensing or permits for rendering establishments. It would appear that with continued cooperation between FDA and the states that these firms/facilities are identified. However, if FDA could identify renderers and feed facilities that are not currently licensed and inspected by a governmental agency for compliance with the BSE rule, we would support FDA licensing those firms.

7. *Should FDA revoke or change any/all of the current exclusions for certain products allowed in the current rule at §589.2000 (a) (1)?*

   This question requires a science-based response. As previously mentioned, blood products, plate-wastes, tallow, and poultry litter deserve further scientific review.

8. *Should FDA add to the list of prohibited material in ruminant feed (i.e., add to the definition of "protein derived from mammalian tissues") poultry litter and other recycled poultry waste products?*

   This question requires a science-based response. The concerns of poultry litter is not only the prohibited protein that goes through the digestive tract of the bird, but also the unconsumed feed containing prohibited protein that is found in the litter through feed spillage.

9. *Should FDA remove the exemption for pet foods from labeling with the precautionary statement?*

   Yes. The exemption of the "caution" statement, required by 21 CFR 589.2000, on pet food products can and does lead to confusion and misunderstanding in certain segments of the feed and feeding industry. This statement is made based on several concerns. The first concern is in regard to use of salvage pet food product. Broken bag product is being picked up from establishments handling pet products. This product is being further processed and may be used in other animal diets. Although much of this product is making its way into swine feed, on occasion there is concern that some product is being diverted for distribution to ruminant animals. The second concern is in regard to the storage of package dry pet food at

feed manufacturing establishments and on-farm. Animal producers, employees of feed manufacturing establishments and purchasers of animal feed have been educated to recognize prohibited protein materials on the basis of the labeled caution statement. Since packaged pet food is not required to contain the caution statement established in 21 CFR 589.2000 there is concern that material from broken bags, left over materials or even intact pet food containers are not being recognized as prohibited material and could be incorporated into ruminant feed. In addition, pet food may be a source of imported animal proteins.

The agency should reconsider the current exemption for pet food to be labeled with the caution statement.

10. *Should FDA extend its present recordkeeping requirements beyond 1 year? If so, how many years?*

At the current time, the 1 year record requirement appears to be adequate to do trace forward and trace back inspections. However, should there be a reported case of BSE in the United States, the 1 year record requirement may be inadequate to determine the source of the causative agent.

In most situations where food producing animals are fed for a limited amount of time before slaughter, a reduced record keeping requirement of 1 year may be adequate. However, in cow/calf operations or dairy operations where animals are retained for a number of years before slaughter and clinical signs of the disease may appear before slaughter, a longer record retention schedule may be appropriate.

11. *Should FDA change its rule to required labeling of protein-containing feed to specify what types(s) of mammal was used in the production of the protein, e.g. "porcine MBM", "bovine MBM".*

Yes, requiring listing of the type of mammal along with specific ingredient would be of value in preventing the occurrence and amplification of BSE in the United States. This requirement would assist the purchaser to know clearly what the ingredients and sources are contained in a feed ingredient or mixed feed product. The current use of collective terms in regard to the "animal protein products" also creates unclear situations and inadequate label information for the purchaser.

12. *In order to make the statement clearer, should the required cautionary statement on the label of products that contain protein derived from mammalian tissues and that are intended for use in animal feed be changed to read: "Do not feed to cattle, sheep, goats, bison, elk, or deer."?*

No. In order to make the statement more clear and still be comprehensive, we suggest changing the required cautionary statement to read: "Do not feed to cattle,

sheep, goats, deer, or other ruminants". The statement would list the common ruminants and would still leave it open to include other ruminants as well.

13. *What new information is available on potential efficient, accurate analytical methods that may be used in detecting mammalian proteins, especially the prohibited mammalian proteins, in feed and what should the sampling parameters of such a program be?*

    No comment. This is a question that will need to be addressed by the scientific community and experts working in the area.

14. *Regarding enforcing compliance with the rule, what further authorities, if any, would be desirable in order to enforce the rule adequately (civil monetary penalties?, others?)*

    We believe that in general the states have adequate authorities available to enforce the rule. Currently it appears that the agency could use additional enforcement authority and tools. We suggest that the agency may be interested in reviewing the AAFCO Enforcement Guidelines and craft their enforcement authorities to parallel those stated. Civil penalties and withdrawal from distribution should be considered for adoption at the federal level.

15. *Regarding helping to increase compliance with the rule, what role, if any, should public or private certification programs play?*

    We believe that public *agencies* and private entities should continue to be a leader in providing education pertaining to the requirements of 21 CFR 589.2000 to their members and the public. We do not believe that public or private certification programs should be utilized to judge compliance of a firm. Adequate state and federal resources *are* available to make a determination of a firm's compliance with 21 CFR 589.2000.

    State and federal inspection conclusions should be shared with inspected establishments to demonstrate that the establishment is operating within or outside of compliance with 21 CFR 589.2000. This will enable the industry the ability to provide the necessary assurances to their customers. Compliance with 21 CFR 589.2000 is mandatory and should not be a component of a marketing program.

16. *Regarding the import of feed, what should the restrictions on such import be (country specific? comparison between domestic and foreign controls?)*

    We believe they should be both. The restrictions should be country specific and a determination should be made that the country has in place restrictions that are equal to or greater than those in the United States.

17. *Are there any other additional measures necessary to guard against BSE and vCJD in the United States?*

If the state feed regulatory agencies, FDA and other federal agencies achieved 100% compliance from all sectors of the animal feed industry and the allied industries, and the other involved federal agencies achieved their objectives to prevent BSE from occurring in the U. S., would this prevent the likelihood of an occurrence in this country? TSE's are naturally occurring diseases in many animal species and are occurring in some populations, including our own. We must attempt to minimize the potential impact of an occurrence of BSE. The intent of the current BSE rule is to prevent the spread and amplification of this disease. The agency must attempt to minimize the potential impact of an occurrence of BSE on the agricultural community and the consuming public.

The agency and states must have an enforceable rule and provide adequate resources to enforce it. Reaction to mishaps that have already occurred must be dealt with, however, proactive approaches must be reviewed and then implemented. Enforcement tools must be in place and used at the federal level that are of significant consequences to the parties involved that do not comply with the rule.

The agency should encourage and support all state feed control officials to incorporate a BSE inspection component into their routine feed inspections and share the results of those state inspections with FDA to be entered into a national database tracking BSE compliance.

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,

John W. Breitsman
President, AAFCO