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Docket No. 2002N-0273  
Division of Dockets Management [HFA-305]  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

On behalf of the Association of American Feed Control Officials (AAFCO), we wish to comment on the FDA's proposal to amend the agency's regulations to prohibit the use of certain cattle origin materials in the food or feed of all animals. The intent of the amendments is to strengthen existing safeguards that help prevent the spread of bovine spongiform encephalopathy (BSE) in U. S. Cattle.

AAFCO is an international association with membership consisting largely of state feed control officials responsible for administration of state laws and rules, as well as portions of the Food, Drug and Cosmetic Act, which pertain to the distribution of commercial feed and feed ingredients for livestock, poultry and other animals, including pets. AAFCO counts as its members all fifty states, Canada, Puerto Rico, Costa Rica, the United States Department of Agriculture and the Food and Drug Administration. We wish to point out that the FDA has refrained from contributing to these comments in order to avoid any conflict of interest.

AAFCO commends FDA for its careful consideration of comments received from various groups in response to the previous advance notices of proposed rule making. We recognize the attention to detail that FDA has given to risk assessments, reports of the scientific steering committee of the European Union, and recommendations made by the International teams who reviewed the BSE cases in North America, as well as other sources of information, before releasing the current proposal for rule amendment. AAFCO is in support of the removal from the animal food and feed chain of the cattle origin materials specified in the proposal, and would like to state the following concerns and issues.

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AAFCO members conduct the majority of the inspections for compliance with the current rules prohibiting animal proteins in ruminant feed. Therefore, AAFCO would appreciate receiving both educational and enforcement guidance documents to aid in achieving compliance by all responsible parties to include small (mobile or custom) slaughter facilities that are not inspected by USDA or other regulatory agencies.

While one can be reasonably assured that regulatory officials monitoring the removal of Specified Risk Materials (SRM) from human food can verify the effective removal of cattle materials prohibited in animal feed (CMPAF), this is not the case with custom slaughter and other animal processors not continually monitored by USDA or equivalent authorities. An aggressive approach needs to be taken by the authorized regulatory agencies to ensure that the impacted parties will follow the provisions of current proposals, once adopted and in effect. This is particularly important since there are no definitive tests available that would verify cattle that have not been inspected and passed for human consumption and whose brain and spinal cord have not been removed, have not entered the animal feed manufacturing and distribution system.

Consistency and clarity of rule provisions is essential for effective understanding and management. There is a significant volume of younger cattle that are not processed through the continually monitored USDA slaughter facilities. These animals are therefore subject to the proposed rule. Brain and spinal cord from cattle under 30 months of age appear to be of very low, if any, infectivity. As proposed, the brain and spinal cord will have to be removed, from uninspected cattle less than 30 months, if intended for animal feed. This is inconsistent with the removal of SRMs from human foods. Distal ileum, by contrast, from younger cattle (under 30 months) appears to be of higher risk compared to brain and spinal cord but there is no requirement for excluding it from animal feeds. Additionally, the removal of distal ileum or the entire intestine from the younger cattle requires less labor-intensive efforts than removal of brain and spinal cord. We realize there would be a greater volume of tissues requiring disposal, if the entire intestine was to be removed from all cattle of any age not inspected and passed for human consumption. However, the magnitude of the associated risk should be the determining factor. If the character of the regulation is risk, keep risk considerations consistent.

AAFCO is concerned that if the amendment to the rules is adopted CMPAF may be potentially used as fertilizers. If there are risks associated with consumption of CMPAF by cattle through direct crop exposure, this issue needs to be addressed in a coordinated effort with the agencies that have jurisdiction over the distribution and/or use of fertilizers. Prevention of crop contamination is critical as it is now suspected that as little as 0.001g of infected material can transmit BSE to cattle. The agency should provide clear guidance on approved methods for disposal of the CMPAF to ensure that they will not contaminate any animal feed and that they do not accumulate in the environment to become a source of contamination in the future. Miller et al. (2004), on the subject of chronic wasting disease stated that indirect transmission and environmental persistence of prions will complicate efforts to control prion diseases. Their data showed that environmental sources could contribute to maintaining and prolonging local epidemics,

even when all infected animals were eliminated. AAFCO would like to stress the importance of preventing occasions for cross-contamination by the CMPAF.

The Canadian Food Inspection Agency has proposed amendments to the Canadian federal regulations that will strengthen their existing animal feed controls. However, the Canadian definition of Specified Risk Materials is different from FDA's definition of CMPAF. Because of the open trade between the two countries and the similar level of risks associated with BSE, AAFCO would encourage a harmonization of the amendments to the current rules in the United States, as much as possible, with those of Canada.

Furthermore, regarding international distribution of feeds of animal origin, FDA must consider the complications of receiving materials from low BSE risk countries that contain or may contain CMPAFs. While the risk of exposure from these materials is low, the potential for these materials to interfere with compliance verification is high. Until there are valid methodologies to identify CMPAF and other prohibited animal proteins, control officials will have to rely upon physical inspection of processes and records. Not having controls over all materials only makes the burden of compliance monitoring more complicated.

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

Sincerely,



Judy Thompson  
AAFCO President

Sincerely,



Eric M Nelson  
AAFCO President-elect