

**American Feed Industry Association**

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December 17, 2001

Mr. John Breitsman  
President  
Association of American Feed Control Officials  
2301 N. Cameron St.  
Harrisburg, PA 17110-9408

Dear John:

The undersigned organizations appreciated the opportunity to meet with the Board of Directors and other representatives of the Association of American Feed Control Officials on December 12, 2001 to discuss the recommendations made by AAFCO in response to the Food and Drug Administration's Oct. 5 *Federal Register* notice concerning the agency's existing feeding regulations designed to prevent the establishment or spread of bovine spongiform encephalopathy (BSE) in the United States.

As we said at the meeting, we had two objectives when submitting the attached December 10, 2001 letter concerning the statement submitted by AAFCO in response to FDA's notice. First, we wanted to highlight several areas of mutual agreement we have with AAFCO. Second, we wanted to identify concerns that we have with some of the positions taken by AAFCO, and to respectfully propose some alternative approaches for addressing the issues raised by AAFCO that we believe merit further consideration.

We appreciate the fact that AAFCO is cognizant of the seriousness and complexity of the issues raised, which could result in multiple repercussions, unintended consequences and ripple effects. As expressed during the Dec. 12 meeting, we fully respect AAFCO's right and responsibility to establish and advocate positions on important public policy issues, especially those involving food and feed safety. We also fully recognize that at the end of the day, AAFCO may have a different point of view than does industry.

Our purpose in seeking the meeting was to hold an open, two-way dialogue with AAFCO so that we could better understand AAFCO's concerns and rationale related to BSE policy, and explore together different approaches and ideas that might accomplish the same goals.

We pledge our best efforts to contribute constructively to what we hope will be an ongoing dialogue at a time and place of AAFCO's choosing as we seek to continue the strong food safety partnership that we have enjoyed during the recent past, and to achieve our mutual objective of keeping the United States free of BSE.

Sincerely,

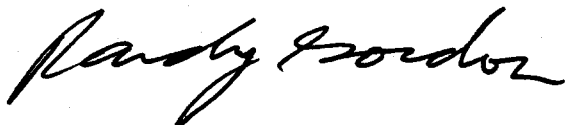
Sincerely yours,



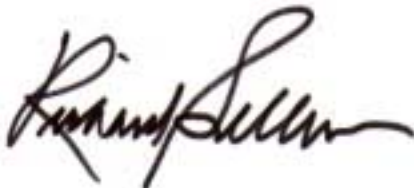
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cc: AAFCO Board of Directors  
Mr. Paul Bachman  
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December 10, 2001

Mr. John Breitsman  
President  
Association of American Feed Control Officials  
2301 N. Cameron St.  
Harrisburg, PA 17110-9408

Dear Mr. Breitsman:

The undersigned organizations want to express our collective concern over several of the responses made by the Association of American Feed Control Officials to the questions posed by the Food and Drug Administration in its October 5, 2001 *Federal Register* notice concerning existing regulations that are designed to prevent the establishment or spread of bovine spongiform encephalopathy (BSE) in the United States.

We want to explain why we take issue with several of AAFCO's responses, and respectfully ask AAFCO to reconsider its position.

But first, we want to commend AAFCO's stated support for FDA continuing to base its decision-making on BSE-related regulations on the best available science and facts – a position that we share. In this regard, it is important that all organizations – industry and AAFCO alike – now also evaluate and take into account the results of the comprehensive, three-year study conducted by the Harvard Center for Risk Analysis, as well the mathematical risk-assessment model it developed. That study documented the effectiveness of the triple-firewall strategy implemented by government and industry, stating that these cooperative efforts have made the United States “highly resistant” to the emergence or spread of BSE, even under worst-case scenarios. In short, we share in the belief that deviating from science-based risk-assessment is fraught with peril, and would undermine the credibility of federal and state regulators in serving their indispensable role in protecting the safety of the food and feed supply.

We also commend states for conducting approximately 80 percent of the inspections that have been done to date of establishments for compliance with FDA's animal feeding restrictions. And we commend AAFCO for including in its BSE Policy Statement a provision that calls on states to make BSE inspections a routine part of their inspections of feed mills.

However, as noted previously and as articulated below, we are concerned about the substance of AAFCO's responses to several of the questions posed by FDA in its notice, and believe that in several instances AAFCO's statements belie its stated support for science-based rulemaking. We also are concerned that several of AAFCO's responses may be based on anecdotal incidents or abnormal inspection experiences. We respectfully submit that these "anecdotal" incidents or infrequent inspectional experiences warrant enforcement action – not major changes to FDA's existing BSE-prevention regulations or additional enforcement authorities.

Finally, we are concerned that the process used by AAFCO to arrive at its statement was not in keeping with the open, deliberative process that has served the organization so well over its history – a process that AAFCO itself recognizes as being important to generating the "sympathy and understanding (of) responsible members of the regulated industries."

The following are specific comments on several of the most important AAFCO responses with which we take issue. These comments are not meant to be all-inclusive. Nor do they address each of the questions posed in the FDA notice to which AAFCO responded.

To facilitate discussion, our comments are organized in the same manner as AAFCO's statement, and are numbered accordingly:

- 1. Additional Enforcement Authorities:** AAFCO argues for more frequent inspections and coordinated reinspections of feed manufacturers. In this regard, **we would like to encourage AAFCO to support the suggestion made by industry that FDA in the future adopt a "trace-forward" inspectional approach**, in which inspections would be prioritized by tracking the movement and use of mammalian protein that is prohibited from use in ruminant feed (restricted-use protein) from its origin to subsequent receivers and handlers. **These inspections could be augmented by states conducting BSE-rule compliance inspections as part of their routine feed mill inspections, as advocated by AAFCO.** We also would appreciate AAFCO's support of the industry's call for FDA to develop an overall strategic plan to guide its future BSE-prevention surveillance and inspection efforts. We have recommended that a trace-forward/trace-back enforcement strategy – augmented by states making compliance with the BSE-prevention rule a part of their routine feed mill inspections – should be considered as a central feature of such a strategy.

However, we believe it is important for AAFCO to recognize that compliance with the existing regulations has been improving steadily since FDA's final rule was issued in 1997. Based upon the most recent data made available by FDA, compliance is ranging from 87 percent for firms handling restricted-use protein to 96.3 percent for all facilities, which includes those not handling the product. Education has – and will continue to be – a key element to improved compliance. **Changing the rules will only lengthen the learning curve, and may incidentally result in increased non-compliance.**

We do seek clarification from AAFCO concerning two statements made in this section of its response to FDA. First, AAFCO states that compliance inspections should be expanded to include all “allied industries,” including at the “livestock producer level.” How does AAFCO propose to obtain the authority to conduct such inspections? Second, what does AAFCO envision when it recommends that enforcement authorities be increased? In this regard, we would urge that AAFCO join the industry in urging FDA to develop a database that documents the frequency of regulatory letters, stop-sale orders and other regulatory actions already being implemented so that there is a clearer picture of the level of enforcement activity that already is occurring.

In addition, the industry seeks AAFCO's support in obtaining consistency in the interpretation from FDA over what constitutes an “illegal” carryover of restricted-use protein in feed manufacturing and rendering operations that use GMP clean-out and/or sequencing procedures that are referenced in the preamble of the agency's existing BSE-prevention regulations. These are the same procedures that address drug residues in medicated feed applications, and are time-tested for effectiveness.

- 2. CGMPs for ‘All Potential Contaminants, Including the BSE Agent’:** We strongly object to AAFCO's statement that FDA should consider adopting good manufacturing practice regulations encompassing “all potential contaminants, including the BSE agent, for all animal feed and feed ingredients.” In this regard, it should be noted again that FDA in the preamble to its existing BSE-prevention regulations recognizes as the legal standard the clean-out and sequencing procedures specified in the agency's existing CGMPs for medicated feed establishments as appropriate for reducing or preventing contamination that may occur in the use of restricted-use protein products.

Further, as we have stated previously on numerous occasions, FDA has no statutory GMP rulemaking authority for feed other than for medicated feed. AAFCO's call for FDA to use this rulemaking as a forum to address non-BSE-related issues (such as to develop GMPs for “other potential contaminants”) is inappropriate.

In addition, we seek clarification from AAFCO as to whether its response to FDA on this question signals its intent to develop CGMPs for non-medicated feed and feed ingredients, contrary to the letter issued by the AAFCO Board of Directors earlier this year directing that the Feed Manufacturing Committee's "*Guidance/Framework for Best Management Practices for Manufacturing, Packaging and Distributing Animal Feeds and Feed Ingredients*" remain a guidance document, rather than a proposed set of CGMPs.

- 4. Dedicated Feed Manufacturing Facilities:** The last sentence of AAFCO's statement implies that it supports a "requirement" that FDA stipulate that restricted-use proteins be used only in facilities that do not manufacture ruminant feed, terming such an action a "positive step." The remainder of AAFCO's comments in this section does not differ greatly from those of AFIA, NGFA and PFI. NGFA and AFIA, in fact, have developed BSE Policy Statements that encourage member companies to consider, as a best management practice where feasible, not using restricted-use proteins in facilities that manufacture ruminant feed, as a way of reducing or eliminating the risk of accidents or cross-contamination.

Many, if not most, feed manufacturers already have adopted such an approach voluntarily where feasible. But for others, the use of dedicated facilities simply is not a realistic option given their location, the lines of feed they manufacture and the customer base they serve. These facilities have chosen to utilize the clean-out and/or sequencing procedures permitted under the existing FDA rule. Ultimately, we believe the decision on whether to adopt a dedicated-facility approach is a management decision best left to the individual facility, rather than a hard-and-fast regulatory requirement.

As an alternative approach, we again encourage AAFCO to support a trace-forward inspection approach to focus future inspection resources on facilities that are subject to the FDA rule's clean-out requirements because they are manufacturing feed for ruminants and other species, and are utilizing both restricted- and non-restricted-use proteins. As noted previously, we also seek AAFCO's support in urging FDA to develop a science-based approach for clarifying what constitutes an "acceptable tolerance" for restricted-use protein to bring more uniformity to the inspection process, rather than using the lack of such a tolerance as a rationale for requiring dedicated facilities through regulation.

In addition, we request that AAFCO provide a summary of inspectional data to support its assertion that a requirement for dedicated facilities is "based on our facility inspection experience." [*Emphasis added.*]

- 5. Dedicated Transportation:** AAFCO recommends that FDA “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.” AAFCO also urges FDA, “at a minimum,” to “develop and mandate a validated cleanout method and recordkeeping system for transporters to use.” Both of these AAFCO proposals fall outside the scope of FDA’s statutory authority. While such authority could fall under the scope of the Department of Transportation under the Safe Food Transportation Act of 1990, regulations to implement this law have yet to be promulgated.

But requiring dedicated transportation equipment would increase delivery costs and present operational challenges to feed manufacturers, ingredient suppliers, rail carriers and truckers in efficiently and cost-effectively transporting feed and feed ingredients.

As an alternative, we encourage AAFCO to support industry efforts to make transportation providers more accountable under the existing regulations. One such effort that is underway involves the development of a voluntary set of “best management practices” for transporting animal and plant protein products that is designed to foster compliance with the aspects of the FDA rule that apply to distributors, including the prohibition on commingling or cross-contaminating ruminant feed or feed ingredients containing restricted-use proteins. These “best management practices” recognize the existing CGMP clean-out procedures for medicated feed, which are designed to prevent cross-contamination. In addition, renderers, feed manufacturers and pet food manufacturers provide educational materials to their transportation providers to acquaint them with the FDA rule, and many request certification letters from common carriers attesting to their compliance.

We would oppose AAFCO’s suggestion that a “validated” cleanout method be required, particularly in the absence of data that this has been a significant problem.

- 6. Licensing of Renderers and Feed Manufacturers:** AAFCO states that it would support licensing if it were used as an enforcement tool, such as the withdrawal of a license for violating the FDA animal feeding restrictions rule. In response to the FDA notice, the rendering industry voiced support for the licensing of its sector of the industry as a way to identify the locations of rendering plants to facilitate the inspection process, not as an additional enforcement tool – even though the locations of renderers have been fully documented under the application of the current rule. Knowing the locations of renderers and packers that produce restricted-use protein – and having access to their sales and distribution records – already makes it possible to implement an effective trace-forward inspectional approach, as has been suggested previously in this correspondence.

Therefore, we believe FDA and states already have sufficient enforcement authority, and that it may be impractical and costly to attempt to license all feed manufacturers (including on-farm mixer-feeders) that utilize restricted-use proteins. For instance, such an approach would involve at least 2,701 licenses of commercial establishments based upon FDA's most recent set of inspection results; and this number does not account for on-farm mixer-feeders.

9. **Require Caution Statements on Retail Pet Food Labels:** We strongly object to AAFCO's recommendation that FDA "reconsider the current exemption for pet food to be labeled with the caution statement" when sold at retail. We support the agency's 1997 decisions, and believe there is no reason to change the exclusion for cautionary labels on pet food sold at retail. The reasoning for excluding pet food sold at retail from the cautionary label requirement was made clear in the agency's preamble to the 1997 rule<sup>1</sup>. Instead, the agency established a requirement that distressed and salvage pet food be labeled with the cautionary statement "Do not feed to cattle or other ruminants." The reasons for the agency's decisions have not changed.

When salvage or distressed pet food is found in commerce or distribution and is labeled as a different product; or is mixed improperly with other ingredients; or is being used as feed for cattle or other ruminants, the agency or appropriate state authorities should take immediate enforcement action to stop the misuse, mislabeling or mishandling of the material. However, the amount of distressed pet food possibly included in ruminant feed, even taking into consideration "anecdotal reports," is very small. Further, PFI continues to develop "best practices" to address distressed product for the retail industry, and has met with the Grocery Manufacturers Association, Food Marketing Institute and the Food Distributors International's Joint Industry "Unsalables" Steering Committee to expand and quantify the steps that they already are taking – and future steps that can be taken – to address these concerns.

Consumer surveys conducted by PFI – and presented to FDA and the White House Office of Management and Budget – have documented and quantified the degree to which consumers would draw incorrect conclusions from such a labeling requirement at the retail level, and the catastrophic economic impact and ripple effects that would result for the pet food, rendering and meat

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<sup>1</sup> "FDA agrees that the cautionary statement serves no useful purpose on pet food and feed for nonruminant laboratory animals and has amended the rule by creating a new Sec. 589.2000(d)(4) to exclude pet food products that are sold or intended for sale at retail to non-food producing animals and feed for nonruminant laboratory animals. These products typically cost substantially more per ton than most complete feeds intended for food-producing animals. Therefore, there is little, if any, risk that pet foods or feeds for nonruminant laboratory animals will be purchased at full price for use in ruminant rations. (62 Federal Register 30955, 06/05/97)." [Emphasis added.]

industries.<sup>2</sup> FDA's rule already requires that distressed pet food resold by retailers be labeled with the caution statement. The responsibility for such labeling rests with the reseller of such pet food, and compliance with the feeding restriction rests with the buyer. Therefore, **the current regulations need to be enforced.**

Another consequence of inserting the caution statement on labels of retail pet foods containing ruminant protein ingredients may be a consumer shift to pet food products that do not contain those ingredients and, therefore, would not carry the cautionary label. This unintended shift could further disrupt the marketplace for ruminant protein ingredients and affect not only pet food manufacturers, but also renderers, meat processors and other related industries.

We ask that AAFCO reconsider its position concerning the caution statement on pet food sold at retail, and urge that as an alternative approach that AAFCO support strong regulatory enforcement of the current requirement to label salvaged or distressed pet food that is being withdrawn from retail sale for subsequent resale, and join ongoing industry efforts to aggressively educate retailers and feeders about the illegality of feeding such pet food products to ruminants.

In addition to distressed pet food being withdrawn from retail sale, AAFCO also states it is concerned over the disposal of pet food from broken bags, left-over materials or even intact pet food containers...not being recognized as prohibited material” at “feed manufacturing establishments and on-the-farm.” We are not aware that this has been a significant problem area. Therefore, we also ask AAFCO to clarify its position concerning disposal of distressed pet food found at feed mills or on-the-farm.

**10. Extending the Recordkeeping Requirement Beyond One Year:** AAFCO's statement refers to the possibility of a longer recordkeeping requirement to permit trace-forward and trace-back inspections. In this regard, we would note that FDA's intent by requiring retention of records for one year is not for investigatory purposes, but to gauge compliance with the rule. We believe that the current one-year recordkeeping requirement is adequate and well understood, and note that requiring multiple years of records could be unmanageable, expensive to store and of dubious benefit to an investigation.

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<sup>2</sup> The research showed, among other things, that: 1) 71 percent of respondents would buy something other than pet food (e.g., formulating their own home-made pet food diets that would be highly unlikely to meet the complex nutritional requirements of pets); 2) 68 percent would be “concerned” or “very concerned” about the safety of pet foods bearing such a label; 3) 57 percent would not know if dogs and cats were ruminants; and 4) 40 percent would be “concerned” or “very concerned” about the safety of humans eating beef or lamb as a consequence of this label appearing on pet foods.

**11. Amending the Label to Require Specie-Specific Identification of Animal Protein Ingredients:** We are alarmed and mystified by AAFCO’s statements that undermine its own “animal protein products” collective term, which also has been recognized by FDA. Contrary to AAFCO’s assertion, we are not aware of any evidence that specie-specific ingredient labeling “could be of value in preventing the occurrence and amplification of BSE in the United States.” It is the presence, or absence, of the BSE caution statement that animal feed manufacturers and feeders widely understand to be the determinative indicator of whether the feed contains or may contain restricted-use protein. Simply put, if the product does not bear the caution statement, the product does not contain restricted-use protein.

We also disagree strongly with AAFCO’s statement that the current use of the “animal protein products” collective term “also creates unclear situations and inadequate label information for the producer.” Even if use of the “animal protein products” collective term were disallowed, inspectors still would be expected to review records as part of their BSE inspections to verify the source of proteins being used in ruminant feeds. For example, if specie-specific ingredient labeling were to be required, and a product were labeled “porcine meat and bone meal,” verification of feed formulas and ingredient records still would be required to document whether, in fact, this was the actual protein source used.

Further, concerning AAFCO’s statement about “inadequate label information for the producer,” it is common practice for feed companies to provide information on the specific animal protein used in feed – either orally or in writing – to producers who request it. We believe it is inappropriate for AAFCO to interject itself into such customer-relations issues that are not food- or feed-safety related.

AAFCO prudently in 1998, with the strong support of the industry, acted to designate individual ingredients found within the “animal protein products” collective term which, if derived from ruminant animals, are prohibited from being used in ruminant feed under FDA’s regulations. In our view, this was the proper policy response.

Additional regulatory changes that undermine the use of the “animal protein products” collective term would negate the substantial benefits this term has to the producer – the industry’s customer. Those benefits result in lower feed costs to the producer/customer, without any sacrifice in safety or nutrition. Such a change also would result in costly labeling changes for the feed industry, without commensurate benefits, particularly in the absence of misuse of the term. Such a change in feed labeling practices also would undermine uniformity in feed labeling and further hamper effective and efficient business practices.

We strongly urge AAFCO to protect the use of the “animal protein product” collective term.

- 12. Changing the BSE Caution Statement to Specify Specific Classes of Ruminants:** We are concerned that AAFCO’s response to this question – suggesting that the caution statement be revised to read, “Do not feed to cattle, sheep, goats, deer or other ruminants” – is based more on anecdotal incidents rather than customary, real-world conditions.

We believe that virtually all commercial feeders of cattle, sheep, goat, bison, elk and deer fully understand that they are feeding ruminant animals, and that changing the BSE caution statement would have costs that far outweigh the benefits.

In addition, there have been extensive educational efforts by FDA, states, industry and producer groups to build awareness and attain compliance with the current rule’s caution statement. In this regard, the principal outgrowth of a change to the caution statement would not be improved compliance with the feeding restrictions, but rather a drain on resources to reeducate renderers, feed manufacturers and feeders about a new label requirement, and extend the learning curve for compliance.

- 15. Role of Public or Private Certification Programs:** While there are differences between our respective organizations on the role of public or private certification programs, we are united in our support of credible, government-based inspection programs that lead to full and fair enforcement of FDA’s existing BSE-prevention rule to ensure compliance throughout the supply chain.

Federal and state regulators also should acknowledge that self- or other certification programs may exist in response to customer demand, and also may serve a useful educational function in encouraging compliance with the FDA rule. We also believe it is unrealistic for AAFCO to expect companies not to use their participation in certification approaches in their marketing programs.

## **Conclusion**

In closing, we urge AAFCO to reconsider its views on the aforementioned issues, based upon the reasons provided herein, when developing its comments in response to FDA’s advance notice of proposed rulemaking expected to be issued early next year covering the same 17 questions concerning the agency’s current BSE-prevention animal feeding rules.

We look forward to discussing these matters with AAFCO on December 12 in the kind of open, deliberative and professional manner that has been the hallmark of AAFCO-industry interaction. Thank you in advance for considering our views.

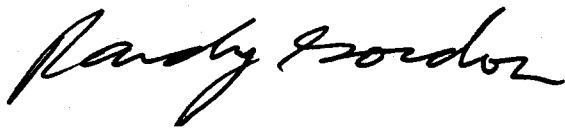
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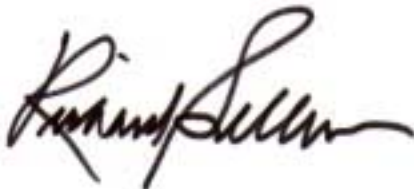
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