

**PET FOOD INSTITUTE**

2025 M Street, NW, Suite 800 • Washington, DC 20036 • (202) 367-1120 • FAX (202) 367-2120 • www.petfoodinstitute.org

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February 4, 2003

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

Re: Docket No. 02N-0273

Dear Sir or Madam:

On behalf of its members, the Pet Food Institute (PFI) submits the following comments to the Food and Drug Administration in response to its Advance Notice of Proposed Rulemaking entitled "Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed." PFI represents the companies that manufacture over 97 percent of the dog and cat food sold in the United States, as well as affiliated ingredient, packaging and other companies that serve the industry.

PFI joins with other organizations in commending the agency for its efforts to date to prevent the introduction of bovine spongiform encephalopathy (BSE) into the United States. In addition, the FDA should be recognized for its efforts to put in place preventive measures should this disease ever be detected in the US. In particular, the agency's 1997 rule to prohibit the use of certain animal proteins in ruminant feed and to require the labeling of salvage and distressed pet food to prevent its inclusion in ruminant feed has and will continue to be a critical part of the steps taken to protect animal health and, ultimately, the US food supply. The agency has achieved an unprecedented level of compliance with the current rule and should, therefore, make only science-based changes to it rather than expending resources to reexamine

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portions of it that have proven successful and for which there exists no scientific evidence a change is required.<sup>1</sup>

As the US pet food industry's trade association, PFI will focus its comments on the following question contained in the agency's notice:

*Use of Pet Food in Ruminant Feed*

*Under the current regulation, pet food for retail sale is exempt from the labeling requirement and need not bear the caution statement "Do not feed to cattle or other ruminants." However, if the pet food products are sold or are intended for sale as distressed or salvage items, then, under §589.2000(d)(4), such products must state, "Do not feed to cattle or other ruminants." In order to assure that salvage pet food is not used in ruminant feed despite the requirement that it be labeled with the caution statement, FDA is asking for comments on the following questions.*

- *Should pet food for retail sale be labeled with the statement "Do not feed to cattle or other ruminants"?*
- *What would be the adverse and positive impacts (economic, environmental, health, etc.) of such a labeling requirement? (67 Fed. Reg. 67573, 11/06/02)*

PFI's comments to the question will be divided into two sections that address possible consumer reactions to and industry costs as a result of the proposed label "Do not feed to cattle or other ruminants." These comments will also review the efforts on the part of PFI and its members to educate handlers of salvage and distressed pet food of their responsibilities under the law for labeling and handling that product in an appropriate manner is also included.

Before specifically addressing the agency's current request for comments, a brief review of the logic behind the agency's decision in 1997 which originally amended the rule to exclude pet food sold at retail from the labeling scheme is in order. In its June, 1997 Final Rule, the agency stated the following,

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 feeds for nonruminant laboratory animals. (62 Fed. Reg. 30955, 06/15/97)

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<sup>1</sup> FDA Center for Veterinary Medicine officials reported at a recent meeting that less than one percent of facilities inspected under the rule had violations requiring official agency action.

PFI believes the underlying reasons for excluding pet food sold at retail remains unchanged. As FDA further stated in its discussion on labeling retail pet food,

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 Fed. Reg. 30955, 06/15/97)

This price disparity between retail pet food and ruminant feed has not declined but has, in fact, increased since the original rule was issued.

As previously stated, PFI fully supports the requirement of the rule that salvage and distressed pet food products bear the label “Do not feed to cattle or other ruminants” and has engaged in an extensive education program to facilitate overall compliance with the rule. The exemptions, including the cautionary statement only on salvage and distressed pet food, in the current rule are based on sound science. The rule itself has been credited with providing the US with a high level of resistance to BSE, as noted by the Harvard Center for Risk Analysis.

In its study measuring the risk of BSE introduction and spread in the US, the Harvard Center for Risk Analysis cited FDA’s feed rule as the cornerstone of government success in preventing any cases of BSE in the US. The Harvard Report concluded that the US “appears very resistant to a BSE challenge, primarily because of the FDA feed ban.”<sup>2</sup> The Harvard Report went on to cite compliance statistics as the key measure of success and, as confirmed by statistics compiled by the FDA Center for Veterinary Medicine, nearly complete compliance with the current rule is now in reach.

### **Consumer Reaction to the Proposed Label**

In short, PFI can determine no positive consumer effects of the proposed label. The potential economic damage to the industry and the erosion of the positive nutritional gains provided by commercially prepared pet food to companion animals far outweigh any possible gains in public and animal health protections by the labeling of pet food sold at retail. PFI and

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<sup>2</sup> Harvard Center for Risk Analysis, “Evaluation of the Potential for BSE in the United States,” p. 97.

its members strongly believe the use of the caution statement “Do not feed to cattle or other ruminants” would have a devastating effect on the pet food industry, its suppliers, agricultural commodities used in pet food products, and, possibly even, sales of products for human consumption that contain beef, lamb and other animal-derived ingredients.

To determine pet food purchasers’ reactions to the proposed label, PFI commissioned an online survey of pet owners who make pet food purchasing decisions for their animals. The survey was conducted for PFI by Edge Research in Falls Church, Virginia. The survey was conducted in August 2002, and consisted of a detailed questionnaire presented in an online format to a panel designed to be representative of the United States population as a whole. Respondents who did not own a pet or who did not make pet food purchasing decisions were excluded. A total of 663 respondents were included in the data and the survey had a margin of error of +/- 3.8 percent at a confidence level of 95 percent.

The questions in the survey were designed to gauge respondent reactions to the presence of the caution label “Do not feed to cattle or other ruminants” on retail pet food products. It is important to note that no information regarding BSE or “Mad Cow” Disease was provided, resulting in unaided responses based solely on the presence of the label. Consumer perceptions regarding the safety of pet food products would no doubt decline even more if the linkage between the cautionary statement on products and BSE were made. The respondents’ reactions to the label are as follows:

- When asked how they would describe their reaction to the statement “Do not feed to cattle or other ruminants” on dog and cat food sold in the US, 42 percent had a negative reaction while 35 percent reacted neutrally and 16 percent said they were not sure. Only seven percent of respondents had a positive reaction to the label.
- When asked if they would be concerned about the safety of the dog or cat food product bearing such a label, 38 percent would be very concerned and 18 percent would be

somewhat concerned, meaning a combined total of 56 percent of respondents have some level of food safety concerns for a labeled pet food product.

- When the placement of the caution label is attributed to the Food and Drug Administration, those results increase to 57 percent indicating a level of concern about the product's safety. Again, it should be noted that none of these questions provided any reason for the placement of the label and that no mention of BSE or "Mad Cow" disease was included in this or any survey question.
- As a direct result of food safety concerns, when asked what changes to their purchasing behavior would occur if the label was present on pet food, 17 percent reported they would stop buying pet food and feed their animal "something else", which was defined as homemade pet food or table scraps. An additional nine percent would feed an undefined "something else" to their pets, while 18 percent of the respondents were not sure how their purchasing behavior would change as a result of the label. This likely 17 percent reduction in pet food sales would have an estimated annual economic impact of approximately \$2.0 billion to the pet food industry in the United States.<sup>3</sup>
- In addition to the pet food safety concerns survey respondents indicated they would have from the presence of the label on pet food products, 19 percent of the respondents indicated they would have safety concerns about products that they, themselves, consume. Specifically, participants were asked the following question, "As you may know, ruminants are hoofed animals with multi-chambered stomachs, like cows, sheep, goats and deer. Thinking now about the beef and lamb that you might eat, how concerned would you be about eating beef and lamb?" In the context of seeing the "Do not feed to cattle or other

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<sup>3</sup> The possible \$2 billion reduction in pet food sales is determined by subtracting 17 percent from \$12 billion in approximate pet food sales for 2002. If those respondents who said they would no longer feed a commercial pet food maintained that decision for one year, the resulting annual loss to the US pet food industry would total, at least, \$2 billion. As previously stated, an additional loss would also be possible, but cannot be accurately determined, once the use of the caution statement on retail products was linked to BSE or "Mad Cow" disease.

ruminants” statement on pet food, ten percent of respondents would be very concerned and nine percent would be somewhat concerned about the safety of those foods.

- In addition to determining what percentages of the respondents would have safety concerns or change purchasing behaviors, the survey also gave respondents an opportunity to directly comment on the presence of the caution statement on pet food products. A selection of those responses clearly indicates a lack of understanding for the need of the label or an understanding of what it actually means. For example, respondents wrote:

- “That this food makes your dog sick. It might not be good for their system”
- “This really disturbs me. If cattle can’t eat the food then why should my dog.”
- “If a cow cannot eat it then how can it be safe for other animals.”
- “I won’t buy it if I don’t understand what it says! And I don’t understand, so I will be on the look out for that message.”
- “What is a ruminant?”

In summary, these survey results clearly indicate that the presence of the caution statement “Do not feed to cattle or other ruminants” on retail pet food causes an unfounded increase in food safety concerns, a dramatic decline in pet food sales and may inadvertently lead to consumers questioning the safety of beef and other products for human consumption. A majority of pet owners and pet food purchasers do not understand the text of the label and are unable to place it into context as it relates to disease prevention. All of these consequences occur when the caution statement is placed on pet food though the United States, as often stated by agency officials, remains free of BSE.<sup>4</sup>

In addition to having a damaging effect on consumer confidence in the safety and nutrition of pet food products, this proposed cautionary statement, should it be placed on pet food sold at retail, would also have a direct effect on pet food exports.

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<sup>4</sup> See Exhibit C for graphic presentation of consumer responses.

As previously stated and agreed to by the FDA, the US remains free of BSE. This is not the case with a number of US trading partners, particularly many members of the European Union, Israel, Japan and others. In each and every case, these countries with BSE in their domestic cattle herds do not require a cautionary label on pet food products.

In its summary, the Harvard Report states that even a single case of BSE in the United States would have "important ramifications for public opinion, trade and other areas."<sup>5</sup> This is also true for BSE prevention efforts that are not based on any real risk of transmission and would alarm not only US consumers, as illustrated above, but would also undermine efforts to increase US pet food exports and advances in pet nutrition.

### **PFI's Salvage and Distressed Program**

In an effort to supplement the information available to pet food manufacturers, shippers, retailers, government agencies and others about their responsibilities to handle salvage and distressed pet food in compliance with 21 CFR §589.2000, the Pet Food Institute undertook a comprehensive education program. With its efforts centered on the development and distribution of a brochure titled "Handling Salvage and Distressed Pet Food," PFI has worked to prevent the inclusion of salvage and distressed pet food products in ruminant feed.<sup>6</sup>

To date, PFI has distributed over 10,000 of these educational brochures. The range of recipients has been varied and includes any individuals or firms that may handle salvage or distressed pet food products. Recipients include PFI members, state and federal government agencies, agricultural and consumer product trade associations, retailers, distributors, reclamation centers, pet stores, feed manufacturers, veterinarians, educators and agricultural extension agents. The Food and Drug Administration has used the brochure as a training aid

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<sup>5</sup> Harvard Center for Risk Analysis, "Evaluation of the Potential for BSE in the United States," p. 97.

<sup>6</sup> The complete text of the "Handling Salvage and Distressed Pet Food" is attached to these comments as Exhibit A. For these comments, "salvage pet food" is defined as product that is still under the control of the original manufacturer and will not be offered for sale at retail, including start-up and over-run product. "Distressed pet food" is defined as a product in distribution or at retail that is not longer available for retail sale, including product past its sell-by date or with damaged packaging. (See page 5 of Exhibit A).

for its staff and the state of Florida, for example, has distributed the brochure to every food and pet food retail outlet in the state. A complete list of recipients is attached to these comments as Exhibit B.

In addition to the distribution of this brochure, PFI members have all informed their customers, suppliers and transport agents of the importance of proper handling and labeling of salvage and distressed pet food. In order to gauge the amount of product that could conceivably be diverted into ruminant feed, PFI surveyed its members and found that, on average, less than one percent of all pet food results in distressed product. This small percentage, coupled with the industry's requirements that all portions of the distribution chain for pet food products comply with the salvage and distressed labeling requirements, means that a negligible amount of any pet food product could ever be used in a prohibited manner. If pet food products were improperly used by a cattle feeder (beef or dairy), the use of the product would be the responsibility of the feeder and not the manufacturer. It is highly unlikely that the addition of the proposed caution statement to retail labels would have any effect on the purchase of product designated as salvage or distressed pet food.

### **Conclusion**

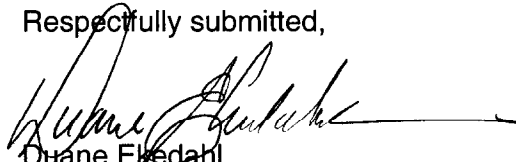
Members of the Pet Food Institute support the FDA's ongoing efforts to prevent the introduction and amplification of BSE into the United States. Under the current rules, according to the Harvard Study, even if BSE were to be found in the US, it would not spread as it has in other nations with the disease because of the effectiveness of the rule and its enforcement. As PFI's consumer survey shows, changes to the rule that would require cautionary statements on retail pet food products would have the unintended effect of alarming consumers who purchase pet food, as well as beef and other meat products.

The economic damage caused by the imposition of a cautionary labeling scheme would be enormous and unnecessary since, as all government agencies recognize, BSE is not present in the United States. Therefore, PFI would urge the agency to abandon its proposal to place



such a damaging cautionary statement on retail pet food and use its resources to attain its goal of 100 percent compliance with the current rule.

Respectfully submitted,



Duane Ekedahl  
Executive Director

Attachments:

- Exhibit A – Complete text of PFI brochure “Handling Salvage and Distressed Pet Food”
- Exhibit B – List to Date of “Handling Salvage and Distressed Pet Food” brochure recipients
- Exhibit C - Survey slides