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August 6, 2004

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

Re: Docket No. 2004N-0264

Dear Sir or Madam:

On behalf of its members, the Pet Food Institute (PFI) submits the following comments in response to the above docket number. PFI is the trade association that represents the companies that produce 97 percent of the dog and cat food sold in the United States, a $12.5 billion industry domestically, with an additional $1 billion in export sales in 2003.

Since the identification of this issue, PFI has submitted several statements that support the removal of specified risk materials (SRMs) from all animal feed, including pet food, to the legislative and executive branches of government, including the US Department of Agriculture (USDA) and the Food and Drug Administration (FDA).

These comments, in response to the latest announcement by FDA, reflect PFI's views on the efforts to prevent the spread and amplification of BSE in the United States. PFI has a long history of supporting the government's efforts in this regard and has even gone so far as to create its own education program to inform interested parties about the pet food-specific requirements contained in the original 1997 rule (21 CFR 589.2000). Over 16,000 copies of a brochure developed by PFI to address the proper handling of salvage and distressed pet food products and the requirements for including them in animal feed, and the reasons for excluding them from ruminant feed, have

been distributed. It is also available for downloading from the PFI website www.petfoodinstitute.org and has been used as a training aid by FDA as well as a resource for State regulators, industry and other interested parties.

PFI has called upon FDA to remove SRMs from all animal feed. Since the USDA Food Safety Inspection Service (FSIS) in early January of this year, ordered the removal of an extensive list of SRMs (which includes the brain, skull, eyes, spinal cord, trigeminal ganglia, most of the vertebral column and the dorsal root ganglia from all cattle over 30-months of age and the tonsils and distal ileum from all cattle regardless of age), animal feed has become a *de facto* repository for all potentially infective materials.

Until such time as the FDA orders the removal of these same materials from animal feed, there will exist the risk that a BSE infected cow could, conceivably, be processed into animal feed, either through accidental or intentionally illegal cross contamination. In numerous answers to questions below, PFI sets forth its reasons for urging the Agency to quickly take steps to remove all SRMs from animal feed.

The underlying need for the removal of SRMs from all animal feed was captured in the report delivered to Secretary of Agriculture Ann M. Veneman by the Foreign Animal and Poultry Disease Advisory Committee's Subcommittee on the United States' Response to the Detection of a Case of Bovine Spongiform Encephalopathy (hereinafter referred to as the "Subcommittee Report"). That group stated,

> However, given the epidemiological evidence indicating that BSE agent was already circulating in ruminant feed prior to the feed ban in 1997, and the integration of the North American cattle and feed industries, strong consideration should be given to excluding all SRM from **both the human food and animal feed supplies**. (page 8) [emphasis added]

The Subcommittee Report continues,

> "Considering the BSE situation in North America, the subcommittee believes the partial (ruminant to ruminant) feed ban that is currently in place is insufficient to prevent exposure of cattle to the BSE agent. (page 8)"

SRM removal addresses the concerns contained in the Subcommittee Report and will help to restore international consumer confidence in the health and safety of the US cattle herd and products, including pet food, containing bovine-derived ingredients.
Beyond the recent experience of the United States in dealing with this disease, back in 1996, the World Health Organization (WHO) made similar recommendations when it stated that, "No part or product of any animal which has shown signs of a TSE should enter any food chain (human or animal)." The recommendation was made in that organization's *Consultation on Public Health Issues Related to Human and Animal Transmissible Spongiform Encephalopathies*, issued in April 1996. This would apply to animals that show clinical signs of TSEs, but the WHO report goes further in stating, "Countries should not permit tissues that are likely to contain the BSE agent to enter any food chain (human or animal)." This clearly indicates that experts with the most experience in dealing with this disease, in terms of both animal and human health, advocate the removal of all SRMs from animal feed.

Simply put, removing SRMs from the ingredients used in animal feed will:
1) Exclude the most potentially infective tissues from <u>all</u> feed;
2) Remove the opportunity for the accidental or intentional "contamination" of ruminant feeds with potentially infective materials;
3) Remove concerns regarding the potential contamination of poultry feed with infective material and thus eliminate any need for restricting the use of poultry litter as cattle feed, preserving farm economies in areas of the country where poultry and cattle are raised concurrently and where poultry litter serves as a significant feed resource;
4) Eliminate the need for removing the plate waste exemption, since SRMs have been removed from human food since January; however, if maintained, further clarification of the definition is needed to completely eliminate SRMs from the plate waste stream;

5) Eliminate the need for dedicated facilities and transportation, since the potentially infective material is no longer present;
6) Continue to allow the use of non-ambulatory disabled and dead stock cattle as sources of animal feeds, while removing potentially infective materials;
7) Make enforcement of the rule clear and effective since slaughter, processing and rendering plants, along with any subsequent processor of SRM materials are easily identified, removing any need for FDA or State inspections on farm to enforce this regulation; and
8) Establish animal feeding rules that are much more consistent with those of our trading partners, leading to re-opening of many borders closed to US products, ruminant-based or otherwise.

One issue that will no doubt enter these discussions on possible changes to the Agency's 1997 feed rule, as well as any considerations on the removal of SRMs, will be the existence of the appropriate legal authority for the agency to make these changes. Alterations to the 1997 rules are well within the purview of the agency's long standing legal authority. PFI believes, and has made these views known since April 2004, that the Agency also possesses the legal authority to not only order the removal of all SRMs from animal feed but to do so without any rulemaking requirements. PFI has attached to these comments a copy of its April 29, 2004 communication to the Dr. Stephen Sundlof, Director, FDA Center for Veterinary Medicine, outlining these legal positions.

To answer the questions contained in the agency's recent ANPRM, for ease of reference, these comments adopt the same question numbering scheme as used in the ANPRM.

3. What information, especially scientific data, is available to support or refute the assertion that removing SRMs from all animal feed is necessary to effectively reduce the risks of cross-contamination of ruminant feed or of feeding errors on the farm? What information is available on the occurrence of on-farm feeding errors or cross-contamination of ruminant feed with prohibited material?

The International Review Team cited several studies and made clear recommendations that the removal of SRMs from animal feed was critical to the reduction of the possibility that BSE could occur or be amplified. Therefore, it follows that the removal of SRMs from all feed would also reduce the possibility of cross-contamination of ruminant feed and/or feeding errors on the farm.

4. If SRMs are prohibited from animal feed, should the list of SRMs be the same as the list as for human food? What information is available to support having two different lists?

We believe it would be appropriate to have the same list of SRMs removed from both human food and animal feed. The list of SRMs includes all cattle tissues previously identified by USDA's Food Safety Inspection Service (FSIS) as possible reservoirs of BSE infection. In addition, there are instances where food ingredients and products are later used as feed ingredients. Therefore, synchronization between the agencies responsible for regulating the removal of SRMs would be appropriate. This synchronization would not be possible if there were two lists of SRMs, and would thus be confusing domestically and to our trading partners. In addition re-synchronization/harmonization with NAFTA countries would improve the ability to export products to our trading partners without dealing with artificial borders.

5. What methods are available for verifying that a feed or feed ingredient does not contain SRMs?

PFI believes the documentation currently used to determine compliance with the HACCP programs in place for packers for removing the material from human food would be sufficient to prevent the inadvertent inclusion of these materials in animal feed. It is much easier and cleaner to remove those materials at the "top of the pyramid" than at any lower point in the processing or feeding chains. Further, inspections at facilities downstream from packers or renderers which supply animal feed will be much more straight-forward if the requirements for removal of SRMs from all animal feed are clear. This includes on-farm and local feed manufacturers.

6. If SRMs are prohibited from animal feed, what requirements (labeling, marking, denaturing) should be implemented to prevent cross-contamination between SRM-free rendered material and materials rendered from SRMs?

SRM-derived rendered material would require a specific denaturing to ensure it is not, intentionally or otherwise, included in any animal feed. The ultimate disposition of SRMs may be through energy generation, disposal rendering, or some other effective processing, and these processes must be fully explored. Those processes will, in most cases, require dedicated facilities which should be required to take precautions in marking and labeling to prevent those materials from inclusion in feed and for adequate disposal or industrial use. In addition, PFI would urge the agency to require SRM derived materials be further denatured when they reach their final form. This would reduce the likelihood that these materials would be diverted to inappropriate uses.

7. What would be the economic and environmental impacts of prohibiting SRMs from use in all animal feed?

While recognizing that there will be economic impacts due to this rule, PFI believes that a failure to order the removal of these materials would lead to massive marketplace disruptions. Specifically, many pet food companies which use beef meals have already begun work to source ingredients from suppliers that remove SRMs and/or to change sourcing away from beef meals entirely. This has caused numerous disruptions in ingredient supplies and has had a dramatic financial impact, particularly on smaller companies with limited suppliers. Further, prohibiting SRMs from inclusion in animal feed will relieve the poultry and swine feeding sectors from any need to discontinue the use of ruminant meat and bone meat from their feeding rations, and will maintain a value for beef-based meat meals and meat and bone meal. Avoiding the perception that any feed containing SRMs is, in some way, dangerous or not fit for use in certain species will reduce economic fluctuations in animal feed ingredient prices. Without the removal of SRMs, beef meals and meat and bone meals will likely take an even larger discount in the market than that to which they have already been subjected.

8. What data are available on the extent of direct human exposure (contact, ingestion) to animal feed, including pet food? To the degree that such exposure may occur, is it a relevant concern for supporting SRM removal from all animal feed?

If SRMs are removed, data regarding the exposure to humans to all animal feed is irrelevant. Consumer perception that there is a risk associated with products that contain SRMs will be sufficient to prevent their use.

9. What information, especially scientific data, is available to show that dedicated facilities, equipment, storage and transportation are necessary to ensure that cross contamination is prevented? If FDA were to prohibit SRMs from being used in animal feed, would there be a need to require dedicated facilities, equipment, storage, and transportation? If so, what would be the scientific basis for such a prohibition?

If SRMs are removed there is no need for dedicated facilities or transport. With SRMs removed, the tissues that could potentially contain the BSE infection would no longer be present to contaminate other products, vehicles or systems.

10. What would be the economic and environmental impacts of requiring dedicated facilities, equipment, storage and transportation?

PFI believes the impact would be massive, most likely reaching millions of dollars across many segments of the feed industry, since dedicated systems would require duplication of those that already exist so that materials containing SRMs could be held separate from others. The fact that this duplication would be required would likely remove beef-based meals and meat and bone meal from any significant level of use as animal feed in the marketplace, with a subsequent deleterious effect on the beef market.

11. What information, especially scientific data, is available to demonstrate that clean-out would provide adequate protection against cross contamination if SRMs are excluded from all animal feed?

Clean-out procedures would no longer be essential if SRMs are removed since the tissues that could potentially harbor the BSE infection are no longer present.

12. What information, especially scientific data, supports banning all mammalian and avian MBM in ruminant feed?

There is no need to remove avian or other mammalian (porcine or equine) MBM from ruminant feed since avian and non-ruminant tissues have never been shown to harbor BSE infectivity. The current rule banning the inclusion of ruminant MBM in ruminant rations has been in place since 1997. Once again, removing SRMs at the top of the processing pyramid is the most effective way to minimize inclusion of potentially infective material in animal feed. Regardless of any additional steps taken to further reduce the risk of inclusion on possibly BSE-infected materials in ruminant rations, the prohibition on including ruminant MBM in ruminant feed should be maintained. The maintenance of the prohibition and removal of potentially infective materials found in SRMs, coupled with the record high level of compliance with the current rule should provide safe feed ingredients.

13. If SRMs are required to be removed from all animal feed, what information, especially scientific data, is available to support the necessity to also prohibit all mammalian and avian MBM from ruminant feed, or to otherwise amend the existing ruminant feed rule?

Please see the answer to Question 12. PFI believes that if SRMs are removed there is no need to amend the current ruminant feed rule in any way.

14. What would be the economic and environmental impacts of prohibiting all mammalian and avian MBM from ruminant feed?

PFI believes economic and environmental costs would be quite large, most likely reaching hundreds of millions of dollars across many segments of the feed industry. In short, PFI believes the economic effect would be significantly injurious due to the decline in value to producers of these animal-based proteins, coupled with the upward pressure on non animal-based feed ingredients. As an example of the latter, the USDA's most recent supply-demand estimates predict that US oilseed ending stocks for the 2004/05 marketing year will decline sharply, to the lowest levels since 1976/77, causing undue economic pressure on all users of these ingredients.

15. Is there scientific evidence to show that the use of bovine blood or blood products in feed poses a risk of BSE transmission to cattle and other ruminants?

To our knowledge, bovine blood has never been implicated in bovine-to-bovine transmission of either natural or mechanically induced BSE. Further, when the Harvard Center evaluated the potential for BSE to be transmitted orally to cattle through blood products, it found the opportunity for introduction of BSE to be extremely low. Thus, PFI believes that the rationale used by FDA in its 1997 rule remains valid. In that rule FDA noted:

> FDA excluded these items from the definition because the agency believes that they represent a minimal risk of transmitting TSE's to ruminants through feed. The excluded proteins and other items are materials that the available data suggests do not transmit the TSE agent, or have been inspected by the FSIS or an equivalent State agency at one time and cooked and offered for human food and further heat processed for feed and thus are of lower risk than those products that the agency has determined to be nonGRAS, or current industry practices can provide assurances that certain mammalian products can be produced without becoming commingled with potentially infective materials. (62 Federal Register 30938, June 5, 1997)

In short, the scientific basis for these exemptions has not changed. In addition, if the Agency requires the removal of SRMs, as described in answers to other questions, then the possible Food and Drug Administration BSE transmission concerns over cross contamination raised in the 1997 and other rules will be further reduced if not eliminated.

16. What information is available to show that plate waste poses a risk of BSE transmission in cattle and other ruminants?

Plate waste has never been shown to pose a risk of infectivity to cattle or other ruminants, and since the January announcement by FSIS, there have been no SRMs found in human food, therefore none are found in plate waste, thus no risk of BSE transmission exists. There is no "contamination" issue with plate waste, if plate waste is truly only food that was once offered for human consumption, only a testing issue. If FDA wants to eliminate the inclusion of plate waste as a means to simplify its testing, which would not be necessary if all SRMs were removed, it should indicate that reasoning as a need for removing the plate waste exemption. Without this basis for change, the removal of this exemption is not justified.

17. If FDA were to prohibit SRMs from being used in animal feed, would there be a need to prohibit the use of poultry litter in ruminant feed? If so, what would be the scientific basis for such a prohibition?

If SRMs were prohibited in animal feed, any concerns regarding the potential contamination of poultry feed with infective material would be eliminated and thus any need for restricting the use of poultry litter as cattle feed would be abolished, salvaging farm economies in areas of the country where poultry and cattle run concurrently and poultry litter serves as a significant feed resource.

18. What would be the economic and environmental impact of prohibiting bovine blood or blood products, plate waste, or poultry litter from ruminant feed?

The impact of prohibiting these materials is two-fold. First, as discussed in the answer to Question 15, there is little scientific evidence that any of these products are currently significant risk factors for amplifying BSE, and second, the removal of SRMs from any animal feed would further mitigate the need for exclusion of these materials. Thus a prohibition against their use would be of significant economic impact, again to the beef industry, the food recycling industry and to poultry and pork producers for the loss of a useful feed ingredient, without justification. Finally, if these materials are not fed, the disposal of them will cause significant impact to environmental services such as landfills.

Further, the use of bovine blood and blood fractions is critical to the dairy, beef cattle and feed industries in supplementing the immune systems of young calves. More than 40% of heifer calves raised in the US suffer from a failure of passive immunity transfer due to inadequate intake of Immunoglobulin (Ig) from colostrum. Half of the early (pre-weaning) mortality in heifer calves is a result of inadequate intake of quality colostrums, however, colostrum is also a recognized vector for a number of disease transmitting organisms, including that for Johne's disease. Bovine serum and blood fractions have been shown in several published studies to be the only effective alternatives for colostrum in providing passive immunity and should not be denied to the industry.

19. Is there any information, especially scientific data, showing that tallow derived from the rendering of SRMs, dead stock or non-ambulatory disabled cattle poses a significant risk of BSE transmission if the insoluble impurities level in the tallow is less than 0.15 percent?

Please see the answer to Question 20 for an important distinction between animal tissues used in tallow. Further, the OIE definition of protein-free tallow, no matter the source, is acceptable as a feed ingredient and recognized globally as risk-free for BSE.

20. Can SRMs be effectively removed from dead stock and non-ambulatory disabled cattle so that the remaining materials can be used in animal feed, or is it necessary to prohibit the entire carcass from dead stock and non-ambulatory disabled cattle from use in all animal feed?

PFI would urge the Agency to distinguish between three classes of cattle material: 1) non-ambulatory animals presented for slaughter or those otherwise not allowed for human consumption, 2) dead stock that can have SRMs removed, and 3) dead stock that cannot have SRMs removed.

These distinctions are important for the purposes of determining SRM removal and use in animal feed. Specifically, animals presented for slaughter that, for whatever reason, are not allowed for human consumption by FSIS personnel, should have SRMs removed and be available for use in animal feed, either directly or via normal rendering procedures. The second group, animals that have died prior to slaughter and can have SRMs removed should also continue to be permitted in animal feed. The third group, cattle that present added logistical problems in terms of removing SRMs, should be confined to disposal rendering or other processing and used for non-feed purposes only. This division of animal categories will allow for the continued use of the most valuable materials in feed while adding protections against the inclusion of animals most likely to harbor BSE infections.

PFI believes that SRMs should be removed from all cattle suitable for and processed for inclusion in all animal feed. Further, the product of Automated Meat Recovery Systems which must be labeled Mechanically Separated Meat, should be allowed for pet food production.

21. What methods are available for verifying that a feed or feed ingredient does not contain materials from dead stock and non-ambulatory disabled cattle?

If SRMs are removed from these animals, see answer to question 20, then there is no need to develop testing methods or to conduct inspections to verify that tissues from these animals are or are not included in animal feed, as these materials would continue to be acceptable.

22. What would be the economic and environmental impacts of prohibiting materials from dead stock and non-ambulatory disabled cattle from use in all animal feed?

Again, PFI would refer to its answer to Question 20. If these materials are no longer permitted for use in animal feed, even with SRMs removed, there will be a number of unacceptable consequences to the feed and other industries. For example, if these materials were not allowed, cattle producers would be forced to otherwise dispose of animals that die prior to slaughter.

The materials derived from these animals, when SRMs are removed, present no disease risk and their use in feed allows producers to recoup at least a portion of the costs of producing the animals. FDA currently allows the use of these materials in animal feed production and the

removal of this source would have significant effects on the economics of the animal feed industry.

In addition, these materials provide significant nutritional value for feed. As previously referenced, grains are currently at a premium due to very low supplies, corn and soybean prices have increased and there is insufficient poultry and pork meal produced in the US to compensate for the loss of the protein provided by these materials. Finally, the disposal costs associated with removing an entire carcass versus only SRMs would add additional costs and disposal requirements.

The removal of SRMs, as defined by USDA, from all animal feed addresses many of the issues raised in the ANPRM and makes many of the proposed changes moot. Pet Food Institute again urges the Agency to act to remove SRMs from all animal feed and thanks the Agency for the opportunity to present these comments.

Sincerely,

Duane Ekedahl
Executive Director