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

**Re: Docket No. 2004N-0264, Federal Measures to Mitigate BSE Risks:
Considerations for Further Action**

To Whom It May Concern:

The National Renderers Association (NRA) and the Animal Protein Producers Industry (APPI) reference FDA's Docket No. 2004N-0264, the agency's advance notice of proposed rulemaking (ANPR) and the invitation to comment on federal measures to mitigate BSE risks: Considerations for further action.

NRA is the international trade association for the industry that safely and efficiently recycles animal agriculture by-products into valuable ingredients for the livestock, pet food, chemical and consumer product industries. NRA represents its members' interests to Congress, regulatory and other government agencies, promotes greater use of rendered products, and fosters the opening and expansion of trade between North American exporters and foreign buyers.

The APPI association was established by the rendering industry in 1980 to address biosecurity issues. APPI also developed a voluntary Salmonella education and monitoring program. In 2001, APPI created an industry-wide third party certification program to specifically address compliance with the FDA restricted use protein feed rule (21 CFR 589.2000).

NRA and APPI continue to support scientifically based animal feeding regulations to restrict the use of certain animal proteins derived from mammalian tissues used in ruminant feeds. We agree animal feed regulations need to be reviewed from time-to-time

2004N-0264

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if new risks are identified or new, relevant science is brought to light. However, our analysis of the facts make us believe FDA's preliminary conclusion to remove specified risk material (SRM) from all animal feed and pet food is not warranted and that this and other BSE prevention measures proposed by FDA are not scientifically or economically justified.

NRA commissioned Informa Economics to conduct a detailed economic study of the impacts of the proposals in the July 14, 2004 ANPR, and that study is offered as an attachment to this document. NRA and APPI provide the following comment on each of the questions posed by FDA in the ANPR:

- 2. What data or scientific information is available to evaluate the International Review Team (IRT) recommendation described above, including that aspect of the recommendation concerning what portion of the intestine should be removed to prevent potentially infective material from entering the human food and animal feed chains?***

There is no need to remove these tissues from the entire animal feed chain. Scientific information reports that the distal ileum is a primary infection site in cattle with the infective agent detected as early as 6 months (Ref: Bovine spongiform encephalopathy, M.J.Prince et al. Rev. sci. tech. Off. Int. Epiz. 2003, 22, (1), 37-60.). This conclusion was confirmed by a bioassay infectivity study demonstrating that pathogenesis of BSE is initiated in the distal ileum. The current prohibitions in the 1997 FDA Feed Rule (defined in 62FR303936; June 5, 1997: codified at 21CFR 589.2000) are specifically directed at preventing infectious tissue presence in ingredients to be fed to ruminants.

If a processor can develop a procedure to remove only the infectious tissue, the agency should allow that process so as to minimize the amount of material requiring special disposal.

- 3. What information, especially scientific data, is available to support or refute the assertion that removing SRM's from all animal feed is necessary to effectively reduce the risks of cross-contamination of ruminant feed or 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?***

There is no scientific evidence to support the removal of SRM's from all animal feed. If the 1997 FDA Feed Rule banning ruminant materials fed back to ruminants was a failure, removal of SRM's from all animal feed may be necessary. However, preventive measures have been adopted by the feed and rendering industries extending from the origin of ingredients to feeding that minimize the occurrence of feeding errors and cross contamination. Inspections and audits by FDA concluded there is 99%+ compliance with the 1997 Feed Rule.

The removal of SRM's from cattle feed has been accepted internationally as central to the control of BSE. This has been referenced in the published literature and recommended by various regulatory agencies, including the World Health Organization (WHO), as mandatory to prevent transmission and amplification of the disease.

The IRT, in part, bases its evaluation and recommendations on the European experience of significant cross-contamination and the concern that a relatively low infectious dose of the agent can transmit disease. Their concern was based on the risk in Europe which has 99.6 percent of all BSE cases. The United States has had only one reported case in an imported cow and has a much lower risk. Further, animal agriculture in the United States is much more specialized than in Europe in general and the United Kingdom specifically. Nearly all poultry and swine in the United States are grown in controlled facilities and fed concentrated diets specifically formulated for these species. Likewise, many dairy farms have consolidated into larger units which concentrate on dairy only. Beef cattle production is likewise concentrated into feedlots specializing in these animals. Therefore, the risk of cross contamination at the farm level is very small.

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

The list of SRM's should not be the same as for human food. The Harvard Risk Study notes that the level of potential infectivity varies considerably across these materials, with nearly 90% of total infectivity limited to the brain and spinal cord (Table 1). Importantly, rendering reduces the infectivity rate of the tissues by at least two logarithms. The "ruminant-to-ruminant" feed rule, the established validation for compliance, the minimal potential for any transmission via cross contamination or feeding errors, and the low inclusion of animal protein in livestock and poultry rations all minimize potential risk.

Table 1: Relative BSE Infectivity Associated with Cattle Tissues

Tissue	% Total Infectivity
Brain	64.1%
Spinal cord	25.6%
Dorsal root ganglia	3.8%
Trigeminal ganglia	2.6%
Distal ileum	3.3%
Tonsil	< 0.1%
Eyes	< 0.1%

Accounting for the fact that material designated as SRM is restricted from human diets, the potential human exposure to BSE resulting from a ban on rendering dead cattle is effectively reduced from only 4.922 to 1.997 new cattle infected over a 20-year period (the NRA-commissioned Informa Economics study of August 2004 shows detailed

calculations on risk of various scenarios using assumptions from the Harvard Risk Study). Given the enormous volume of beef produced in the United States, this decrease in potential human exposure is, essentially, too small to be considered meaningfully significant. The decrease in potential human exposure by prohibiting SRM's from animal feed is extremely small and should be viewed in the larger context of the costs and environmental harm that is likely to result from these types of feeding restrictions.

Simply eliminating SRM's from the human diet appears to have reduced the risk of human exposure to BSE nearly as much as would be expected from a complete ban on rendering this material, and certainly to levels that are far below risks to human health associated with any number of daily activities.

5. *What methods are available for verifying that a feed or feed ingredient does not contain SRM's?*

Currently, analytical methods for detecting individual species or specific tissues from any given species are lacking. The official method for differentiating mammalian meat and bone meal (MBM) in animal feed in both the U.S. and the U.K is a microscopy technique requiring significant operator expertise subject to interpretation. The method depends largely on the presence of bones and allows differentiation between bones of terrestrial animals. The method can distinguish between mammalian bones and poultry bones. There are no detectable differences in mammalian bone or muscle fibers among species. Soft tissues such as brain, spinal cord, lymph nodes, and even smooth muscle tissue (distal ileum) are not detectable following post rendering procedures or even after limited autolysis. The method is time consuming, laborious, and costly. The number of people trained to use the microscopy technique to test feed in the U.S. is extremely small.

Other analytical procedures include various adaptations of the enzyme-linked immunosorbent assay (ELISA) and polymerase chain reaction (PCR). Both have limitations in specificity and sensitivity. An ELISA analysis is commercially available for detecting ruminant tissue in both animal protein meal and formulated feeds. These (Reveal® Test Kits – Neogen Corporation, 620 Leshar Place, Lansing, Michigan 48912) analytical products have received AOAC validation and have been shown to be assets in monitoring errors in labeling or cross-contamination should they occur. (Ref: An overview of tests for animal tissues in feeds applied in response to public health concerns regarding bovine spongiform encephalopathy, Gizzi, G. et al. Rev. sci. tech. Off. Int. Epiz. 2003, 22 (1) 311-331.)

The agencies are encouraged to be much more supportive to initiatives in industry research and development of analytic methods necessary for compliance with new regulations.

The rendering industry has demonstrated it keeps good records, conducts HACCP-like good manufacturing processes, and can screen raw materials that are rendered. These methods are currently more effective than testing.

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

Methods such as labeling, marking, dyeing, denaturing, and good record keeping would be effective in keeping feed materials from being cross contaminated. Any prohibition of SRM's must be accompanied by specific processing and disposal regulations. If proper disposal methods are not regulated, SRM prohibition from animal feed could lead to environmental, human, and animal health hazards unrelated to BSE.

The rendering process and infrastructure is currently the only regulated entity meeting necessary requirements in collection, transport, and proper processing of otherwise unwanted carcass components in a way to minimize health and environmental risks. The prohibition of SRM's would require licensing of facilities to handle SRM's, along with required documentation of origin and ultimate disposition of the finished products derived from processing SRM material.

7. *What would be the economic and environmental impacts of prohibiting SRM's from use in animal feed?*

Removing all SRM from animal feed will cause real and significant economic dislocations throughout the livestock industry. It will require costly redesign of facilities and processes, significantly increase disposal costs, reduce the value of livestock and necessitate closure of certain rendering facilities that cannot feasibly exclude SRM from their raw material supply. The disposal of SRM and all dead stock will also create significant environmental concerns that are unresolved.

The NRA commissioned Informa Economics study of August 2004 (provided as an attachment to these comments) provides data and supporting documentation that the annual economic loss to renderers would be \$32.4 million from lost MBM sales and \$59.2 million in lost sales of tallow, for a total product loss of \$91.6 million. In addition, the total cost to dispose of the 1.423 billion pounds of SRM by-products currently produced in the U.S. would be \$74.7 million per year. This estimate is consistent with a recent report published by the European Association for Animal Production showing *the cost of MBM disposal is nearly twice the value of MBM.*

In addition to the \$166.3-million annual economic impact, the disposal of non-rendered dead stock cattle, non-ambulatory disabled cattle, and SRM's removed at slaughter would create a major environmental impact. Placing these infectious tissues in landfills would greatly increase the amount of infectious waste in the environment. Haas (1996) estimated the primary load of infectious waste received in landfills was 126,500 tons per year, composed primarily of human feces from disposal diapers and pet feces. Restricting SRM from animal feed would likely lead to no pickup of dead stock by renderers. There is a high probability more dead animals would be disposed of

improperly with detrimental environmental effects as well as preventing APHIS' testing of high risk animals for BSE. If SRM and dead and downer cattle were all disposed of in landfills this would amount to 7 billion pounds or 3.5 million tons annually, increasing the load of infectious waste by over 27 times. Disposal costs would be very high, as it is in Europe where the government subsidizes the collection and rendering of SRM's before taking responsibility for incinerating the rendered products. Prohibiting SRM's from use in animal feed may be necessary in Europe where incidence of BSE is high, but it is not necessary in the U.S. Without government subsidies for the pickup and disposal of SRM's and dead animals, more dead animals would probably be disposed of improperly and the most important high risk animals for BSE would not be available for APHIS surveillance.

In actuality, the number of landfills capable of handling this material would be limited since they would have to be compliant with 40 CFR Part 258 requirements. This includes requirements to construct disposal cells separated by heavy poly liners and leachate collection systems. More recently, the EPA published recommendations for the disposal of CWD carcasses and wastes (April 6, 2004), recommending the leachate be recycled where practical, and that a foot of absorbent material be used to cover every layer that is two carcasses deep. EPA can be reasonably expected to require similar procedures for dead cattle.

Other disposal methods, such as carcass abandonment, are not attractive, and in most states illegal for obvious human and animal health reasons. On-farm burial is limited in most states by the number of animals buried per acre, as well as the depth and location in relation to surface and ground water sources. While a well-controlled composting process may destroy many of the pathogens present in these materials, conditions are not extreme enough to eliminate spore-forming bacteria, and there is little information to suggest composting reduces the level of the BSE infective agent. Many composting operations can't control seepage or run-off from the piles or access by scavengers. In addition, the volume of compost created is much more than the original volume due to the amount of carbon material that is added. Incineration and chemical digestion have been shown to eliminate conventional pathogens and TSE's, but current capacity does not exist to handle the volumes anticipated. Burial and composting are expensive in relation to rendering, and both create waste streams requiring disposal.

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

There are no data known to implicate any transmission of TSE's to humans via animal feed—including pet food—whether exposed via ingestion or contact. Animal feeds and pet foods are both packaged to make it obvious they are not intended for human consumption.

Demographic data have not differentiated a higher incidence of CJD or vCJD cases by occupation or incidence of exposure to known infected bovine or slaughter house environments such as farmers, dairy employees, or meat processors. The inference of oral transmission of CJD or vCJD from BSE infected beef still remains to be scientifically confirmed other than by empirical association. There is no scientific data indicating removal of SRM's from animal feed is necessary.

The concern is based on the over-cautious assumption that BSE exists in the United States. Even if enhanced testing proves incidence is at a low level in the U.S., risk would still be near zero. However, it is likely there are no infectious agents or infectious dose in U.S. cattle, and no likelihood of disease transmission.

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 SRM's 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?

The current USDA surveillance program substantiates there may be at most minimal BSE in the United States, and no scientific reason for prohibiting SRM's in animal feed other than cattle feed. Preventive measures have been adopted by the feed industry extending from the origin of ingredients to feeding that minimize the occurrence of feeding errors and cross contamination. Inspections and audits by FDA concluded there is 99%+ compliance with the MBM feed ban for ruminant animals. Thus, dedicated facilities, equipment, storage, and transportation to prevent cross-contamination are unnecessary.

If FDA were to prohibit SRM's from animal feed and feed ingredients, there would be no need to require the handling of these materials through dedicated facilities, equipment, storage, and transportation. The current FDA "feed rule" (CFR21 589.2000) allows renderers to use an approved clean-out procedure for rendering lines used to produce both prohibited and non-prohibited materials. Most independent rendering facilities in the U.S. employ single processing lines.

An approved clean-out procedure allowing facilities to safely process both categories of materials is necessary or few facilities will handle prohibited materials, further eroding APHIS access to targeted cattle populations for surveillance. Lack of an approved clean-out procedure would also encourage further expansion of improper and illegal disposal of prohibited materials. In order for renderers to participate in government-sponsored disease mitigation effort, they must be able to convert back to non-prohibited material after processing prohibited materials (as in the example of renderers to participating in the seasonal disposal of deer harvested in Wisconsin as a part of that state's strategy to control CWD in its deer population). In the event a rendering facility wishes to convert to all SRM-free material or processes material it later learns contains TSE infective material, an approved clean-out procedure is needed to resume production (as in the

example of the recent BSE event in Washington State where two rendering companies required such government approval).

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

If the FDA requires dedicated facilities, equipment, storage, and transportation equipment to insure cross contamination is prevented, it may not be economically feasible for industry to continue processing SRM material. It would be more likely for this material to be deposited in landfills, resulting in increased environmental exposure because of the high biological load of this material in its unprocessed state.

Dedicated trucks for the transport of SRM-containing finished proteins are not economically feasible, logistically practical, or environmentally sound. The cost of transporting prohibited proteins would more than double if dedicated trucks are required. The agricultural commodity industries use a network of independent trucking firms to transport a variety of bulk commodities throughout North America. The efficiency of this system depends upon the ability to arrange backhauls in close proximity to prior delivery points or even between two plants owned by the same company. The operation of this network is based upon the ability to haul a wide variety of commodities in each truck. This is an efficient use of resources and reduces the number of trucks on the roadways. The unintended expenses and consequences of requiring dedicated vehicles and creating a new category of "toxic waste" could include expensive or unavailable insurance, unnecessarily expensive spill clean-up regulations, and special DOT placards. Independent renderers without their own truck fleets would be burdened with the cost of establishing their own private truck fleets in order to have dedicated transportation for SRM-containing material.

11. *What information, especially scientific data, is available to demonstrate that cleanout would provide adequate protection against cross-contamination if SRM's are excluded from all animal feed?*

In its initial final rule, published June 5, 1997, FDA explained the need for regulatory action was based on the risk BSE will be established and proliferate in the United States. Fortunately, seven years later this has not occurred. The agency also defined applicable and appropriate cleanout procedures and a comprehensive set of guidance documents describing the procedures. The regulated industries have made management and equipment modifications and have achieved excellent compliance. There is no reason to believe the same procedures can not be employed to eliminate cross-contamination from SRM's under revised regulations.

The feed and ingredient have historically high compliance with stringent requirements preventing cross-contamination of medicated feed. The extremely rare possibility of infected tissue ending up in animal feed combined with high dilution factors make an infectious dose nearly impossible even if SRM's are not excluded from all animal feed.

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

There is no scientific data available supporting a ban of non-ruminant mammalian and avian MBM from being fed to ruminants. Cross contamination is prevented with good manufacturing programs in place and compliance is verified by government surveillance. Experimental evidence has shown pigs to be resistant to oral exposure with BSE-infected cattle brain. Studies in domestic chickens indicate they are resistant to both parenteral and oral challenge. (Ref: The potential for transmissible spongiform encephalopathies in non-ruminant livestock and fish. Matthews, D., and Cooke, BC; Rev. sci. tech. Off. Int. Epiz. 2003, (22 (1), 283-296).

In the United States, less than five percent of the feed fed to poultry and swine is derived from animal by-products. The volume of undigested feed in material going to rendering when an animal is slaughtered for human consumption is minuscule. Since BSE surveillance in the U.S. shows there is virtually no BSE risk in our cattle population, the volume of potentially infected material which could pass through rendering channels would likely be insufficient to cause a problem in ruminant animals.

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

There has been no scientific data published to support the removal of SRM's from all animal feed. There is no scientific data to imply a risk of feeding MBM other than ruminant-derived proteins to ruminants.

If potentially infectious tissues in the form of SRM's are removed from all animal feed, the resulting SRM-free MBM will replace the current SRM-containing MBM in the diets of pigs and chickens. With no potential exposure of these animals to the BSE infective agent, the pork or poultry meals created from the rendering of by-products from these animals would also be SRM-free. There would be no risk in continuing the practice of feeding pork or poultry meals to ruminants. To ban the feeding of these meals to ruminants would not be necessary.

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

Prohibiting all mammalian and avian MBM from ruminant feed would cause real and significant economic dislocations throughout the livestock industry. It would increase the cost of production for beef producers, lower the value of by-products, and cause environmental damage.

Past economic analyses conducted for the NRA by the Sparks Company document severe economic, environmental and negative animal health impacts that would occur upon prohibition of various mammalian or avian derived protein meals or fat from animal feed. Restricted protein markets would lead to less value to animal producers and higher prices to consumers through higher ingredient costs for animal feed.

The current average annual slaughter and processing of approximately 100 million hogs, 35 million cattle, 280 million turkeys, and 8 billion chickens yields more than 50 billion pounds of inedible (for humans) raw animal material that is highly perishable. This raw material contains microorganisms, many of which are pathogenic to humans and animals unless destroyed by the rendering process. The amount of raw material for rendering continues to increase as further processing and table-ready entrees are developed and more inedible material is captured. The products produced from this inedible raw material make significant economic, environmental, human and animal health contributions to allied industries and society. These by-product materials have been used for animal feed for about 100 years, with volumes of scientific references validating their nutritional qualities and safety. The economic impacts should be fully assessed for each of the respective impact segments should these materials not be used in ruminant feed, mammalian feed, or avian feed.

The environmental impacts would be great because the increased cost for the disposal of this material in landfills would encourage improper disposal instead of the current responsible uses of it through rendering.

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

There is no scientific or peer reviewed literature that links the feeding of bovine blood in the form of blood meal or other blood products in feed to any risk of BSE transmission in cattle and other ruminants. Bovine blood has never been implicated in bovine-to-bovine transmission of either natural or experimental BSE (European Commission Scientific Steering Committee (SSC), April 2000; SSC, October 2000). Despite intensive research trials and detailed epidemiological evidence, no BSE infectivity has been detected in bovine blood in either natural or experimental cases (Bradley, 1999, 2000; Fraser et al., 1992; Kimberlin and Wilesmith, 1994; Middleton and Barlow, 1993; Moon, 1996). Blood and plasma products are included in Category IV, i.e.; tissues with no detected infectivity (DEFRA, 2001; OIE, 1998; SSC, 1997; WHO, 1997).

BSE infectivity has not been detected in the buffy coat, spleen, or lymph nodes from naturally or experimentally infected cattle when bioassayed in susceptible mice or directly in calves (Wells, et al., 1994; 1998; 1999). In an experiment initiated in 1996, buffy coat from a BSE-infected cow (experimentally infected, 32 months post exposure) was injected i/c into a recipient calf. To date (over seven years post exposure) the recipient calf has not developed BSE (Dr. Ray Bradley, 2004, personal communication).

Based on these data, if BSE infectivity is present in the blood of BSE infected cattle then it is present at very low levels, below the level of detection of these tests.

The Harvard-Tuskegee Study was extensive and evaluated numerous risk factors associated with the introduction and transmission of BSE. The potential for orally consumed blood to contribute to the transmission and amplification of BSE was evaluated. The authors recognize infectivity has not been found in BSE-infected cattle. However, the authors did consider BSE infectivity in bovine blood could exist at a level below the limit of detection in the bioassays used (10 ID₅₀ / kg tissue; SSC 2000). In addition, the effects of stunning were included as the authors allowed for neural emboli and for leakage of neural tissue from the stun wound. It was assumed heifer calves consumed blood from birth, while bull calves consumed blood from seven months to market age. Finally, it was assumed BSE infected cattle exist in the U.S. cattle population. When these assumptions were included in the model blood contributed on average 0.11 new cases over a 20-year period. Based on assumptions included in this model the use of blood as a feed ingredient for ruminants does not amplify BSE in the U.S. cattle population.

The recent reports of BSE transmission by blood transfusion in sheep (Hunter et al., 2002; Houston et al., 2000) or human patients (Llewelyn et al., 2004) does not change the outcome of the Harvard Risk Assessment. Transfusion data do not change the estimated level of potential BSE infectivity in bovine blood used in the Harvard Risk Assessment. In addition, there is considerable data demonstrating pathology of TSE diseases differs significantly depending on the disease and on the animal model being studied, especially with respect to involvement of the lymphoreticular system (Barclay et al., 2002, Foster et al., 1996, 2001; Wells et al., 1998; Wells, 2003). Finally, direct transfusion of blood is a much more efficient method of transmission than is oral consumption (Kimberlin, 1991). Therefore, the transmission of BSE between sheep or between humans via blood transfusion does not alter the outcome of the simulations reported in the Harvard Risk Assessment. The conclusion is still valid, bovine blood used in ruminant feeds will not contribute to amplification of BSE.

These data support the conclusion that oral consumption of bovine blood or blood products will not transmit BSE and that these feed ingredients should not be banned from ruminant feed. Further, recommendations recently received by USDA's IRT did not include references to further actions to restrict blood or blood product feeding to ruminants.

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

Plate waste consists of predominantly non-meat products, and with current FDA regulations, infective tissues of ruminant origin are extremely unlikely to be included. A conclusion in the 2001 Harvard Risk Assessment states: "Plate waste consists of little mammalian protein, and the tissues that are included in this waste are unlikely to contain

BSE infectivity. Moreover, plate waste undergoes a substantial amount of heat treatment, which would further reduce the level of infectivity in this material.”

Sanitary collection, processing and regulations that prohibit its use and inclusion in ruminant rations, as with other ruminant raw material, is the most effective method for handling and processing plate waste.

It is important to note used cooking oils collected from restaurants and snack food manufactures are not plate waste. There are no risks associated with this product since it does not contain any SRM's.

17. *If FDA were to prohibit SRM's 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?*

Renderers maintain there is no scientific justification to prohibit SRM's from all animal feed. Even if the agency does not prohibit SRM's from all animal feed, there is no scientific basis for the prohibition of poultry litter in ruminant feed. The policy statement made by the CVM in 1998 is still applicable today, “FDA has no evidence that the agent that causes BSE would survive the chicken intestinal tract.”

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

Many studies from the involved sectors have been shared with FDA on the economic and environmental impacts, especially representatives from blood processors and the poultry industry. Collectively, the dual impacts (economic and environmental) could be very great on the industries. If these products are prohibited from ruminant feed, there is reduced market for such products and their disposal costs increase. This could lead to improper disposal, disposal in landfills, or by land application on farms. If feeding of blood meal were prohibited for cows, farmers would either feed higher protein levels and/or milk additional cows to maintain milk production. Either course of action would result in increased nitrogen and methane release into the environment.

Bovine blood meal represents a very valuable feed ingredient especially for the rations of the lactating dairy cow. It provides high levels of lysine that does not degrade in the rumen. High levels of lysine are necessary to maintain optimum levels of milk production. Over the past 12 months, the value of ruminant blood meal has ranged from \$357/ton to \$585/ton. Porcine blood meal has ranged from \$377/ton to \$950/ton, with most of the increase occurring following Washington State BSE incident in December of 2003. It is obvious if bovine blood meal were removed from use in mammalian rations, the price of porcine blood meal will continue to increase, placing an additional financial burden on the dairy industry.

In 2001, the Sparks Company evaluated the impact of prohibiting cattle derived blood meal in ruminant diets on behalf of the NRA. In 2000, 1.48 billion pounds of blood were generated from the slaughter of cattle. A resulting 121.9 million pounds of cattle blood meal and 49.8 million pounds of mixed species blood meal were manufactured. Total ruminant containing blood meal produced was 171.7 million pounds, 70% of which was utilized in ruminant diets. The study determined if the use of blood meal were prohibited in cattle diets, *a product loss of \$45.3 million would be realized by the cattle sector.* Additional indirect losses from reduced animal productivity at the farm level were not considered by the report and are estimated below.

[http://www.renderers.org/economic_impact/index.htm]

The unique nutritional properties of blood meal, primarily a high level of non-degradable lysine, provide a high return when used by dairy producers. Lysine is considered the first limiting amino acid vital to high milk production. Unlike poultry and swine, high producing dairy cows can't utilize synthetic lysine, thus milk production will drop if this ingredient is removed. Typically 0.5 pounds/day of dried blood meal is fed to a dairy cow. A reduction of 4 pounds of milk/cow/day would be expected if blood meal were no longer utilized in these diets. Using the figure from the Sparks report that 70% of ruminant blood meal was utilized in dairy rations, an overall drop in milk production of 9.6 million hundredweight would occur. At \$12/cwt this loss in milk production would reduce dairy farm income by \$115.4 million. *Thus, combined losses to the U.S. beef cattle and dairy sectors would total \$160.7 million.*

It is critical the dairy industry continues to have access to bovine blood and bovine blood fractions. Over 41% of the heifer calves raised in the U.S. suffer from failure of passive transfer due to inadequate colostrum Ig intake. Approximately 11% of heifer calves died before weaning, and half of this mortality can be attributed to inadequate supply of quality colostrum (NAHMS, 1992, 1996). Colostrum is also recognized as a vector for transmission of a number of disease-causing organisms, including *Mycobacterium paratuberculosis* (Johne's disease). Published studies indicate bovine serum and fractions thereof are the only effective alternatives for colostrum (Arthington, et al., 2000 a,b; Quigley et al., 1998, 2000, 2001; McCoy et al, 1997; Holloway et al, 2002; Poulsen et al, 2003). If access to these proteins is restricted, there is no effective alternative to reduce calf mortality or to break these disease cycles. For a more complete review see the review of Quigley et al. (2004).

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

Tallow with impurities of less than 0.15% insoluble impurities do not pose any risk of BSE transmission, regardless of the source of the raw material. The OIE categorizes tallow with insoluble impurities of no more than 0.15% to be protein-free tallow and indicates tallow meeting this standard can be safely consumed by animals, regardless of

the source raw materials. The agency must reconsider the method required for measuring insoluble impurities (details follow, after the comments on question 19).

There are extensive research findings to indicate the safety of tallow with respect to BSE transmission. In 1991, the WHO assembled specialists in TSE's and determined tallow is not a risk to animal or human health. The organization concluded in 2001 that because of the proteinaceous nature of the TSE agents, these agents tend to remain with the cellular residues of meat and bone meal (MBM) during the extraction process, rather than being extracted with the lipids of the tallow (Ref: World Health Organization, Geneva, Switzerland, 2001.)

A rendering study funded jointly by the EU and the UK Ministry of Agriculture, Fisheries, and Foods in 1997, showed tallow can be considered safe even if its treatment does not achieve the 133C/20 minutes/3 bars of pressure minimum treatment standard. The Harvard Risk Assessment referenced this study, determining that recycling this material poses little risk of exposing cattle to BSE.

Work done by Taylor and associates at the Animal Health Institute in Edinburgh, Scotland, the premier reference on the safety of tallow indicates (1) epidemiological studies failed to find any association between the occurrence of BSE and the consumption of tallow by cattle, and (2) in BSE-spiked rendering studies, no infectivity was detected in crude, unfiltered tallow produced by a traditional rendering procedure.

The research findings were validated by injecting homogenates of spiked-BSE infected tallow into-cerebrally (IC) into experimental mice and could not demonstrate the classical spongiform changes associated with TSE, even after a prolonged period of observation. Ref: Taylor, DM, Woodgate, SL: Rendering Practices and Inactivation of Transmissible Spongiform Encephalopathy Agents, In Risk analysis of prion diseases in animals. World Organization for Animal Health (OIE), Vol. 22 (1), 2003.

Insoluble impurities are defined as the small amount of sediment included as a routine analysis for all fats and oils, including tallow referred to as MIU analysis. The moisture, impurities, and unsaponifiables (MIU) are commercial trading specifications established for fats and oils. The impurities characterize the small amount of sediment that are of nonglyceride content. The impurities consist principally of free fatty acids and sterol glucosides, which are colorless and heat stable but for all practical purposes inert. Phosphatides, mucilaginous material, precipitates from processing and transport equipment and fragments of the refining and bleaching processes are all inconsequential components of the impurities. Protein is a miniscule component of the impurity fraction.

A major issue that must be addressed is the method for measuring the "hexane-insoluble matter" as stipulated in the FDA interim final rule (IFR) for the "Use of Materials Derived From Cattle in Human Food and Cosmetics." The method cited from "Food Chemicals Codes," 5th Edition (2004) is not the method used by the laboratories that service the animal production, rendering, feed production, or oleochemical industries in

the U.S. In a survey of commercial laboratories, there were no facilities equipped to perform the hexane-insoluble matter assay. These labs commonly use the American Oil Chemist Society (AOCS) method Ca 3a-46.

The differences between the two methods are substantial. An initial estimate of per assay costs are \$275- \$300 for the referenced assay, compared to \$10-\$20 for the AOCS procedure. In addition, the method stipulated by the FDA would be burdensome to perform. The FDA-stipulated method uses a sample size of 100gm, 1500ml of hexane per sample, and a fritted porcelain filter funnel. The AOCS method requires 2 grams of sample, 100ml of kerosene and a small amount of pet ether, and uses glass-fiber filter paper. Keeping the pores in the porcelain filter funnels from plugging and changing the filtering dynamics from sample to sample is problematic. Commercial labs would be reluctant to use these filters as they would either have to discard and replace them at \$120 each, or invest the labor to clean and verify their efficiency from sample to sample. In addition, the volume of hexane required per sample is also economically and environmental unsound compared with the volume of solvents required by AOCS method. The increase in the cost of the solvents used in the FDA stipulated method is roughly four times higher. The cost of properly disposing of the solvent wastes is about 15 times higher.

In summary, the need for the establishment of a maximum level of insoluble impurities is not supported by science based on the available data of BSE transmission failure via tallow or BSE-spiked tallow. Also, there are extremely low amounts of residues present in tallow. Further, the analytical procedures for determining the content of insoluble impurities should not be altered from the commercially used procedure now readily available, economic, safe to perform, and certified/approved by a highly recognized scientific society. We strongly recommend FDA reconsider the method approved for measuring insoluble impurities.

20. Can SRM's 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?

We do not believe that entire carcasses from dead stock and non-ambulatory/disabled cattle should be prohibited from animal feed. Cattle under 30 months of age should be allowed to be processed into MBM approved for animal feed. While in many cases it would not be economically feasible or practical to remove SRM's from cattle over 30 months of age, it should be allowed if renderers found it to be economically feasible.

Prohibiting entire carcasses from dead stock, non-ambulatory cattle, or SRM's thereof would have the effect of increasing more hazardous practices of animal disposal. The human and animal health risks associated with these practices are greater than the risks of transmission and amplification of BSE in the U.S. under current conditions, rules, and compliance records.

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?*

It is unlikely that any test method could distinguish MBM containing materials from dead stock and non-ambulatory disabled cattle from MBM containing materials from cattle that have passed inspection for human consumption. Rendering plants are capable of keeping products from various different sources separate and using production, inventory, and shipping records to document the movement of both SRM and SRM-free materials. Such management practice can be verified by inspection, much like those conducted at USDA-inspected cattle slaughter facilities.

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

The NRA commissioned Informa Economics study of August 2004 (provided as an attachment to these comments) provides data and supporting documentation that the annual economic loss to renderers caused by a ban on the use of cattle and calf mortalities and SMRs in livestock feed would be in excess of \$190 million annually. This accounts only for the loss of rendered products and collection fees for dead animals, and does not include the costs of alternative disposal methods, impact on livestock feed costs, lost economies of scale in by-product rendering, and other costs.

The loss of this MBM product would substantially diminish the amount of animal protein available for the feed industry and cause higher feed prices. Feed studies have shown animal protein has distinct advantages over vegetable proteins in providing essential amino acids and minerals not available in an all-vegetable protein diet.

The environmental impact would have long-range effects. Without dead stock collection service by renderers, the owners of these carcasses must find alternative methods of disposal. Landfill options are expensive, and if used for all dead and downer livestock, capacities would be reached prematurely. Alternatives such as carcass abandonment, on-farm burial, composting, and incineration may appear to offer lower cost means of disposal, but they do not offer the same high level of biosecurity, environmental protection and traceability that rendering disposal does. Regulations shifting disposal of these infectious tissues away from the rendering industry to unregulated alternatives are a serious threat to animal and human health and the environment. There would be a need for federal regulation of the safe collection, processing, and final disposition of cattle materials if they are prohibited from animal feed to prevent their indiscriminant disposal throughout the environment.

26. *How can training and educational materials be designed or improved to meet the needs of multiple audiences with variable levels of scientific training?*

Renderers believe BSE educational programs must be designed to cover a broad spectrum of the population with different levels of scientific training or knowledge. Every stakeholder in the meat production and supply chain has an important role to play. The educational materials should address the major aspects of risk in detail and what the government and industry have done to prevent the disease. It is critical to foster public trust and confidence in government policies and the safety of the food chain.

27. How can the Federal Government increase access to these materials?

Make as many resources available as possible through all forms of communication, including the Internet. Give the facts – not sensationalism.

28. Should FDA include exemptions to any new requirements to take into account the future development of new technologies or test methods that would establish that feed does not present a risk of BSE to ruminants?

Research is currently underway to establish methods to detect BSE in live cattle, as well as to prevent and eradicate BSE. If new technologies are developed, establishing MBM does not present a risk of BSE, then the FDA must modify or rescind regulations that are no longer applicable. Caution and objectivity, including ongoing risk assessments, should be encouraged.

The 1997 feed rule and other regulations were developed and implemented based on science while incorporating numerous cautionary principles. New knowledge from science or more appropriate risk parameters from analysis may diminish the need to act out of “an abundance of caution.” Provisions to alter the regulatory process should be progressively implemented as more is known about the risk from BSE.

29. If so, what process should FDA use to determine that the technologies or test methods are practical for use by the feed industry and ruminant feeders and provide scientifically valid and reliable results?

The process for determining the practicality of any new technologies or test methods should be evaluated in cooperation with the scientific community and industries that would be expected to perform and/or live by the tests. A list of parameters for approval should be established, as well as review processes to determine whether the criteria for approval have been met. Often, technology and analytical validation procedures are not developed for the purpose of assessment of regulatory compliance, and procedures should include the record keeping and other processes that would be helpful.

30. Do FDA's existing authorities under the Federal, Drug, and Cosmetic Act (that address food adulteration and misbranding) and under the Public Health Service Act (that address the prevention and spread of communicable diseases) provide a legal basis to ban the use of SRM's and other cattle material in non-

ruminant animal feed (e.g. feed for horses, pigs, poultry etc.) notwithstanding that such materials have not been shown to pose a direct risk to non-ruminant animals? More specifically, under FDA's existing authorities, would the potential occurrence of on-farm feeding errors of cross-contamination of ruminant feed with SRM's and other cattle material, or of human exposure to non-ruminant feed (including pet food) provide a basis to ban SRM's and other cattle material from all animal feed?

The FDA does not have a legal basis to ban the use of SRM's and other cattle material in non-ruminant animal feed because such materials have not been shown to pose a direct risk to non-ruminant animals. The agency has enough authority to protect animal and human health based on the existing science without resorting to an embrace of an extreme approach, even in an environment of "an abundance of caution."

The rendering industry made a commitment to its role in preventive controls in 1996, and it fully supported the 1997 FDA Feed Rule banning ruminant material from being fed to ruminants. The industry's subsequent efforts have been reflected in the FDA's compliance findings over the past three years. This coordination of effort and cooperation between the regulated industry and government for the common good should be continued and would be enhanced by strictly adhering to scientific principles. The agency should not promulgate regulations based on the "potential occurrence" of errors to include human exposure to non-ruminant feed (including pet food), and other elements of cross-contamination when risk caused by such occurrences is practically non-existent.

31. *Are there other related legal issues on which FDA should focus?*

We have sufficient regulations in place now. However, if some of the proposed regulations are enacted, disposal of dead and downer animals and SRM's may require additional regulation to prevent negative unintended consequences previously described. Rendering is the only means of disposal which is regulated by FDA/USDA.

Summary

Renderers recognize the importance of BSE prevention measures to protect both cattle and public health. NRA has actively promoted initiatives to manage the potential risk and we have worked closely with the federal government to ensure this country's BSE mitigation efforts include successful, scientifically based animal feeding regulations. Renderers have an excellent record of compliance with the 1997 FDA feed rule which, with the other BSE-prevention firewalls, has provided redundant layers of protection of public and animal health. The success of these measures is illustrated by the continued absence of any indigenous BSE cases in the U.S.

Renderers continue to share FDA's commitment to a strong BSE risk control program based on scientific facts and practical justification that can be implemented effectively and consistently. However, NRA is concerned control measures proposed in FDA's

ANPR (Docket No. 2004N-0264) may cause significant unintended consequences adversely impacting animal health. There may be alternative actions that enable the agency, in concert with industry, to create a system of enhanced feed controls providing equivalent risk mitigation than would be accomplished by the removal of all SRM's from all animal foods.

FDA should look beyond the feed mill and rendering plant when enhancing risk mitigation, and such measures must be considered in the context of the U.S. experience where prudent BSE-prevention firewalls were implemented seven years or more prior to the first diagnosed case of BSE in North America.

Removing all SRM's from animal feed will cause economic dislocation throughout the rendering and livestock industry. Such action will likely require redesign of facilities and processes, increase disposal costs, may reduce the value of livestock and may necessitate closure of some facilities that cannot feasibly exclude SRM from their raw material supply. The disposal of SRM and all dead stock will also create significant environmental concerns that are unresolved.

The failure of European countries to define an effective SRM disposal system complicated their implementation of feed controls and their prevention of BSE. We believe multiple steps throughout the feed chain should be considered as part of an integrated systems approach before the agency's proposed rule to ban all SRM's from all animal foods is published.

FDA must base any prospective actions on the information gathered in USDA's enhanced BSE surveillance program. As of August 9, 2004, no positive BSE test results have occurred in the 32,698 tests completed. As recommended by the IRT, an aggressive surveillance program will yield information to determine which, if any, additional policy actions are necessary and appropriate.

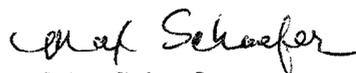
FDA is to be commended for its diligence in carrying out its responsibilities to reduce the risk of BSE in the U.S. with the scientifically based 1997 Feed Rule. Additional regulation is not needed. Renderers pledge their continued commitment to reduce the risk of BSE through compliance to regulatory actions based on the best available scientific evidence.

Thank you for consideration of our views.

Sincerely,



Doug Anderson
Chairman
National Renderers Association



Max Schaefer
Chairman
Animal Protein Producers Industry