



2004N-0264
August 5, 2004

Docket No. 2004N-0264
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket No. 2004N90264, Federal Measures to Mitigate
BSE Risks: Considerations for Further Action

Ladies and Gentlemen:

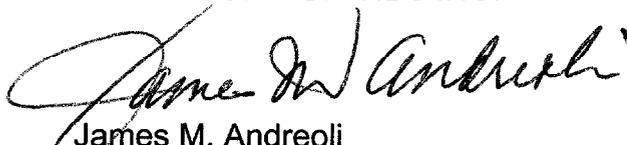
Enclosed herewith please find our written response to the 36 questions posed in
the above referenced Docket.

In summary we believe that:

- A combination of risk mitigations options should be considered.
- A risk/benefit analysis should be conducted to evaluate various options.
- A cost/benefit analysis should be conducted to evaluate various options.
- FDA actions should be based on findings of the USDA enhanced surveillance program.
- All options should be based upon scientific findings, not emotion.
- We should formulate a North American solution, not adopt a European solution for problems we do not have.

Very truly yours,

BAKER COMMODITIES INC.


James M. Andreoli
President

2004N-0264

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July 27, 2004

**USDA and HHS, ANPRM Questions Responses
Baker Commodities Inc., Los Angeles Division**

1. *Would there be value in establishing a specialized advisory committee or standing subcommittee on BSE?*

Yes, we should have a specialized advisory committee or standing subcommittee on BSE with representatives from all industries associated with cattle, pork, poultry, and the scientific and government communities. We need to have information disseminated to all interested parties on testing and preventative measures for BSE. There is much to be learned about the economic consequences of establishing regulations on BSE issues.

2. *What data or scientific information is available to evaluate the 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?*

Data from the scientific community citing studies such as “Harvard-Tuskegee Study”, is available. As to the small intestine, we believe only the distal ileum should be removed for human consumption, but for animal feed it should not be removed until scientific data proves there is a risk with it being included in animal feeds.

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?*

Inspections and audits by USDA, State Departments of Agriculture, APPI, and Cook & Thurber L.L.C. concluded there is a 99% compliance with the MBM feed ban for ruminant animals. The 1% non-compliance was attributed to record keeping problems. Therefore, current regulations are sufficient and removal of SRM's from all animal feed is not necessary.

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 should not be the same as for human food. There has been shown a differing infectivity rate for the various SRM suspect tissues as stated in a report by Dr. Danny Mathews – The Veterinary Laboratories Agency, Weybridge, UK, as reported (USDA/ARS) – March 15, 2001. In addition, rendering reduces the infectivity rate of the tissues by several logarithms.

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

None, other than good record keeping, HACCP, and SRM screening of raw material that is rendered. No specific test, to detect SRM's, is currently available for the rendered meal.

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?*

All of the methods such as labeling, marking, denaturing, and good record keeping (HACCP) would be effective in keeping the materials from being cross contaminated.

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

The impact would be severe. A detailed study would have to be made to determine the total economic and environmental impact. Just using an estimate of 100 pounds of SRM tissue collected from each slaughtered bovine, times 35,500,000 animals slaughtered in the United States for human consumption equals 1,775,000 tons of raw material that is lost to the rendering and animal feed industry, and has to be disposed of in some other way. If the 1,775,000 tons are rendered with a 25% yield at a current market value of \$230 per ton this would be an economic loss of approximately \$102,000,000 dollars to the industry just on SRM materials from human consumption slaughtered animals. These values described above do not include whole dead stock animals rendered, if included in future regulations. This significantly increases the market loss on the rendered product, and the tonnage to be disposed of. The values computed above do not reflect the additional costs that will be incurred to comply with the SRM removal program. Nor do they include the additional cost of replacing MBM in feed rations.

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?*

Currently we know of no existing data, but it is our opinion that the risk of human exposure would be nil. We have heard that pet food has been consumed, and may still be, without any health problems. There is no scientific data indicating that we should remove SRM's from animal feed.

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?*

Based on inspections and audits by USDA, State Departments of Agriculture, APPI, and Cook & Thurber L.L.C. has determined that cross contamination is not an issue. If FDA were to prohibit SRM's from being used in animal feed, dedicated equipment for

transportation, processing, and storage for SRM raw material would be required. In addition, dedicated equipment for storage and transportation would be required for the disposal of the processed SRM material. Special handling and disposal of SRM material will add a significant cost to industry. At present, we see no scientific reason for a prohibition until the current USDA surveillance program substantiates there is more than minimal BSE existing in the United States.

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

Further study is needed to determine the extent of these economic costs and environmental consequences. Because of these additional costs renderers may be prohibited from processing SRM's, and disposing of a greater volume of raw material in landfills, which may create environmental problems such as methane gas, and would greatly tax the capacities of landfills. If the FDA requires dedicated facilities, equipment, storage, and transportation equipment, to insure that cross contamination is prevented, it may not be economically feasible for industry to continue processing material. Therefore, it would require government subsidies that would have a substantial negative impact on the federal budget.

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?*

Based on current cleanout procedures used for edible food transportation, a cleanout of transportation equipment is feasible. When applied to production facilities, a cleanout would pose an economic hardship, and would create difficult situations to manage. It would be very costly, reduce production availability, and would be an economical hardship.

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

There is no scientific data available that supports banning non-ruminant mammalian and avian MBM from being fed to ruminants. With HACCP programs in place and government surveillance, cross contamination is prevented. There are tests available, such as PCR and Elisa methods that allow differentiation between some animal species.

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?*

None. If SRM's are eliminated then the risks are removed and the existing Feed Rule could be eliminated.

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

A further study would be needed to determine the economic and environmental impacts of such a prohibition on all mammalian and avian MBM from ruminant feeds.

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?*

No. There is no scientific data available. Please refer to the North American Rendering Industry (NRA) letter to Dr. Lester Crawford, acting commissioner, FDA, dated February 26, 2004, for blood.

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 little mammalian protein. Based on current FDA regulations, there are no SRM's left in human consumed foods, thus posing no risk of BSE transmission in plate wastes. Please refer to NRA's letter in #15 above, which addresses this issue.

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?*

No. There is no scientific justification to do so. Please refer to NRA's letter in #15 above, which addresses this issue.

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

A study would be needed to determine the economic and environmental impacts.

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 with no more than 0.15% as protein-free tallow and indicates that tallow meeting this standard can be safely consumed by animals, regardless of the source raw materials. The test for insoluble impurities should be the AOCS method, which is the standard recognized worldwide.

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?*

An economic study has to be made to determine what value the animal may have at the time it is being processed. The removal of SRM's from dead stock and non-ambulatory

disabled cattle would not be effective due to decomposition that cannot be controlled by the renderer. Bovine that have been tested and found negative for BSE agents and calves due to their age should be allowed to be placed in the MBM approved for animal feed. Animals, under 30 months, should be used for animal feed.

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?*

We are unaware of any known scientific methods to accomplish this task.

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 economic impact, just in California, would mean the loss of approximately 222,400,000 pounds of material rendered for feed products. At current market value of \$230 per ton using a 25% yield there would be a loss of approximately \$6,400,000 in revenue and an additional cost of \$11,100,000 in disposal costs as well as the cost of \$3,100,000 in transportation. The national economic impact, including the remaining 49 states, would be substantially larger. The loss of this MBM product would substantially diminish the amount of animal protein available for the feed industry. Feed studies have shown that 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 such as landfill capacities being reached prematurely; resulting in additional landfills being created at an additional cost to the taxpayer. One could expect an increase in the illegal disposal and dumping of animals, creating additional environmental and health risks to the public that are greater than if the materials were being used in animal feed.

23. *What other innovative solutions could be explored?*

The Fats and Protein Research Foundation (FPRF) with funding from the National Renderers Association (NRA), Animal Protein Producers Industry (APPI), and others has for many years sponsored research for new and innovative uses for animal proteins. At this time, there are no new uses that would replace the current use of MBM. New innovative solutions are many years in the future. The world currently has a deficiency of proteins for use in animal feed formulas. Any increase in production of animal protein is limited, because it is a by-product of meat and dairy production, therefore unnecessary or non-scientifically based regulations will severely reduce the amount of animal protein available for the feed industry. Any requirement to replace MBM in feed will result in significantly increased costs.

24. *When and under what circumstances should the program transition from voluntary to mandatory?*

If there is going to be an animal identification system, then it should be mandatory so that there is 100% effective tracking of all animals.

25. *What species should be covered, both initially and in the longer term? Specifically, should the initial emphasis be on cattle, or also cover other species? If so which? Which species should be covered by the program when it is fully implemented? What priority should be given to including different species?*

Initially, the program should be for bovine and, because of scrappie, also sheep. If the bovine program proves to be successful, it could be expanded to include porcine. Because of the sheer number and rapid turnover of poultry, an identification program would be difficult and cost prohibitive to implement and maintain.

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

APHIS should develop informational fact sheets targeting the general public for distribution at county fairs, public gatherings, and point of purchase. Develop a mandatory standard training procedure and certification to all farm, slaughter, rendering, feed facilities, and inspection agencies. All states should have a standard program that they should have to follow.

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?*

Yes. Currently, research is underway to establish methods to detect BSE in live cattle, as well as to prevent and eradicate BSE. If new technologies are developed establishing that MBM does not present a risk of BSE, then the FDA must eliminate current and additional regulations.

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 through responses from the scientific community and all related industries who have done research and performed tests. .

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?

No. Unless the current BSE surveillance program substantiates the significant presence of indigenous BSE in the United States. The FDA does not have a legal basis to ban the use of SRM's and other cattle material in non-ruminant animal feed and could be subject to a lawsuit. Over 90 years of feeding this material should be enough of a test period.

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

No. We have sufficient regulations in place now.

32. *What measures are necessary to prevent cross-contamination between carcasses?*

None. In our opinion, this question would be better answered by the meat packing industry.

33. *In establishments that predominantly slaughter cattle 30 months of age or older, are additional sanitation requirements necessary to prevent edible portions of carcasses from being contaminated with SRM's?*

Yes. Dedicated equipment and a more stringent HACCP plan to control bone saw dust and other materials from being transferred to other carcasses are necessary.

34. *Should FSIS provide an exemption for "BSE free" countries or countries with some other low-risk BSE designation?*

No. The other countries need to meet or exceed the established programs set forth in the United States regardless of their BSE status.

35. *If FSIS were to exempt "BSE free" countries from the provisions of the SRM rule, what standards should the agency apply to determine a country's BSE status?*

Any country exporting to the United States should be required to adhere to the same standards that any US company must meet with regard to the SRM rule.

36. *How would FSIS determine that country meets such standards? For example, should it rely on third party evaluations, such as the OIE, or conduct its own evaluation?*

Any country exporting to the United States should be required to adhere to the same standards that any US company must meet with regard to the SRM rule. We should conduct our own evaluation.

CONCLUSION

Why is the industry, which has fed MBM for many years without any problems, being placed under undue economic hardship and regulations for a program that yields no scientific basis for a disease that has yet to be proven to exist in the United States? In our opinion, the current proposed regulations are a reaction to the comments and suggestions of the IRT. Based on the findings of the Harvard-Tuskegee Study, the ruminant ban put in place in 1997 has been sufficient to prevent amplification of BSE in the United States should any BSE have existed prior to the ban. Federal, State and industry audits have substantiated that the industry has been in compliance with the ban since its inception. Therefore, considering the epidemiology of BSE, the US should be crossing the threshold of when absolutely no indigenous BSE is present in the US cattle population. The FDA should allow the current USDA surveillance program to prove this conclusion.

Because we do not have a BSE problem, the U.S. should develop its own regulations and not institute European model regulations where they do have a major problem.

After testing 200,000 to 300,000 animals, and if we do not find a significant number of BSE animals our government will finally have the guts to tell the E.U., R.T.I. and the O.I.E., that we are fed up with their attempt to restrict the trade of our products throughout the world with their regulations, and now, they should tell them to **“kiss our ass.”**