GRIFFIN INDUSTRIES, INC.

Dennis B. Griffin, Chairman

August 10, 2004

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

Regulatory Analysis & Development
PPD,APHIS,Station 3C71
4700 River Road Unit 118
Riverdale, Maryland 20737-1238
Reference: Docket No. 04-047-1

Docket Clerk
U.S. Department of Agriculture
Food Safety and Inspection Service
300 12th St.
S.W. Room 102 Cotton Annex
Washington, DC 20250
Reference: Docket No. 04-021 ANPR

Dear Sir or Madam:

In responding to the above referenced docket numbers, our family owned and operated rendering company, Griffin Industries, headquartered in Northern Kentucky with facilities in 16 southern states, wishes to make an opening statement before attempting to address each of the many questions included in this request for input on possible additional regulations on BSE.

Firstly, the agency's request for such detailed information does not allow enough time for quality responses that need a professional consultant's input, especially where the questions deal with financial and environmental impact. Why doesn't the agency conduct these studies as required by law when such a radical change is being considered?

2004N-0264 C61

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Secondly where is the need to do anything additional in the many efforts put in place by governmental agencies, ruminant protein producers and those that produce and feed all species of animals, especially ruminants? The ruminant to ruminant feed restriction is probably the most compliant FDA Program ever established!

Thirdly, a SRM removal/feeding ban is not warranted in the United States. The IRT Report is so European bias and their recommendations which have no scientific basis for the United States BSE risk. Such references by this group directly conflict the Harvard Study and Risk/Ratio of such possible BSE cases in the United States.

Fourthly, with SRM removed from all ruminants, your action will eliminate all small packer/locker plants/country slaughters, and fallen animal removal service from the animal agriculture industry, especially with separate processing and transportation required in handling such products. With these additional fixed costs as well as the loss of the animal protein value, the economics for the removal and processing cost will be too much of a financial burden for these meat/animal producers. Your possible action is much more costly than you apparently realize and will cause extensive environmental issues on these farms.

Fifthly, the current high risk BSE Testing Program will clearly demonstrate the BSE risk in the United States **once and for all**, so why not wait for the risk/ratios of BSE and then determine if any further action is necessary to reduce our BSE exposure in America?

In summary, please **do not** eliminate SRM and fallen animals from animal feed. It will be disastrous to all involved in beef production and dramatically increase the consumer's prices for U.S. beef, which is the **safest** and highest quality beef in the world. Don't let those in the world that want to hurt the U.S. Economy influence your agency by requiring more regulations that aren't warranted by scientific need!

Based on USDA's (APHIS) requests:

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

Answer: Only if USDA/APHIS keeps science as its basis for actions

FSIS and FDA requests:

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?**

Answer: Removal of any SRMs will not be practical in the areas served by our company. Therefore all SRM removal and fallen stock service will be eliminated if regulations of removal from other species feed are enacted and will create severe disposal problems for our current customers.

FDA seeks comments on:

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 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?**

Answer: There is no scientific evidence to support the removal of SRMs from all animal feed. Compliance has been outstanding in all segments of protein producers, feed manufacturers and users.

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

Answer: Doesn't matter. All raw product service for any product not allowed in feed will stop immediately.

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

Answer: Microscopy inspection, regular compliance inspections at protein producers and feed producers, and review new technology that will soon be on the market.

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 material rendered from SRMs?

Answer: None at our facilities because we will not be able to produce both varieties.

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

Answer: VERY HIGH on both economic and environmental impact. FDA must determine this under the requirements of new regulations. There is not enough time for the private sector to get professional help in developing an accurate response with such short response time and FDA's refusal to grant more time to address such complex issues.

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?

Answer: None from our familiarity with the European BSE problem since the mid 1980's in those who have handled and been exposed with over 220,000 confirmed cases. Also, we **HAVE NOT ONE CASE** of BSE from native animals in the United States which clearly demonstrates that the U.S. **does not** have the same possible exposure as Europe.

9. What information, especially scientific data, is available to show that dedicated facilities, equipment, storage, and transportation are necessary to ensure that cross-contamination s 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?

Answer: Financial feasibility prohibits this option unless FDA mandates rendering as the method of disposal for the restricted materials. The present cleanout procedures are more than adequate with the ruminant to ruminant feed ban in place.

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

Answer: TERRIBLE! Probably would end service for the proposed restricted materials not allowed in animal feeds.

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

Answer: Lack of positive BSE in the U.S. negates any scientific data. The U.S. animal protein producers are much more professional and caring than E.U. producers who could not close the flow of leakage of known BSE proteins being fed to ruminant animals which clearly continued after the protein ban in all feed was put in place in the 1980's. We don't have the same risk as European countries and no scientific need to ban SRM material from animal feed.

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

Answer: None!!!!

13. **If SRMs 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 fee, or to otherwise amend the existing ruminant feed rule?**

Answer: None. If all SRMs are removed, then why would a ruminant to ruminant feed ban be necessary?

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

Answer: Very large. Restricted protein markets would lead to less value to the animal producers and higher prices to consumers through higher ingredient cost for animal feed.

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?**

Answer: Nothing. Only perception which has no scientific facts.

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

Answer: Very little, if any. Very small amount of meat is included in plate waste and only muscle meat and bone which has never been proven to carry BSE agents in all the studies done in Europe. European food waste contained some SRM material due to different eating habits, not prevalent in the United States.

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?**

Answer: Very little, if any. Very small amount of animal proteins from both mammalian and poultry would be inclusive in ruminant diet. With the many dilutions of other feed ingredients, the ruminant protein would be very small.

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

Answer: Unknown and not enough time to conduct a quality response

19. **Is there any information, especially scientific data, showing that tallow derived from the rendering of SRMs, 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%?**

Answer: None, other than common sense about such a small amount of solids in a raw material that is diluted many times and subjected to high temperature/pressures during various processing procedures. Also, extensive research has been conducted in Europe which clearly demonstrates that there is no need of any standard required for food safety issues. Impurity limits should be a commerce issue.

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?**

Answer: SRMs will not be removed from the fallen animals that we remove from animal producers. Warm weather conditions dictates that animals are not skinned so removal of SRMs is not an option. Animal collection service will be stopped, unless rendering is mandated foranimal removal service and processing as is the case in Europe.

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?**

Answer: Full compliance and inspection.

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?**

Answer: Very costly, same as **Question #7**, with no scientific need at this time—we don't have the same situation as Europe who has experienced over 220,000 cases of BSE and we have experienced **none** in a native U.S. animal!

APHIS welcomes comment on the following:

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

Answer: Use common sense, monitoring strong compliance to the ruminant to ruminant feed ban and mandate that all ruminant animals and their by-products be transported, processed and tested when needed by the rendering industry---***THE ONLY METHOD OF DISPOSAL*** that is licensed, permitted, and regulated by FDA and USDA until this BSE window of concern passes.

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

Answer: When BSE is detected higher than the risk/ratio acceptable limit over one case in 10,000,000 ruminants and a creditable animal I.D. system is in place.

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?**

Answer: Initially ruminants only because of life expectancy compared to other species and then other species with a life expectancy of over 30 months.

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

Answer: More participation of the many associations that have an interest in this issue. Their coverage would cover almost all involved and welcome a partnership with governmental agencies to "weather the

BSE storm" which will pass as all storms weaken and others start. The animal agriculture group of industries has much at stake and want to overcome the BSE issue. Keep a steady flow of scientific information flowing through these channels.

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

Answer: Help create scientific based information and don't be afraid to defend science rather than perception

FDA has an interest in the following:

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?

Answer: Hopefully, there will be new developments, especially in live animal testing, which could remove all BSE regulations and stop all the issues past a live test program of suspect animals including "downers".

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?

Answer: Use the BSE panel of experts who use science as their guideline in making such important decisions with the assistance of stakeholders in the meat production industry.

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 SRMs 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 SRMs and other cattle material, or of human exposure to non-ruminant feed (including pet food) provide a basis to ban SRMs and other cattle material from all animal feed?

Answer: We don't think so. Without scientific findings and without any native BSE positives above the 1 in 10,000,000 ratio we would hope that common sense prevails instead of legal challenges but that decision will be made by FDA. Our industry clearly has demonstrated our cooperation in helping to build firewalls against BSE entering our country's cattle population as well as the feed producers who want to do the best compliance possible. We are all in this together and as long as decisions are made based on science and full cooperation, we will get through this challenge. Actions created by perception or political pressure from non-scientific based demands will hurt cooperation and create a more negative environment. What reasoning could possibly be offered that there is immediate need to do more removal of animals and SRMs when the U.S. does not have the same risk/ratio of European countries?

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

Answer: None other than possible mandating rendering for ruminant animals and their by-products as the only means of disposal which is regulated by FDA/USDA, and have many years of experience already of handling these difficult raw materials with its specialized fleet and HACCP operated plants.

FSIS welcomes comments on the following:

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

Answer: None. All restricted parts are inside the hide envelope

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 SRMs?

Answer: No. Keep using same procedures as used in separation of edible and inedible products.

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

Answer: No, BSE designation should never be the same as our country's classification. Using our country's criteria is much more desirable compared to E.U. criteria.

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

Answer: Never give any country BSE free status. We could not trust others to be as thorough as our country's effort. Such action would give away economic edge for our domestic production.

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?**

Answer: DON'T DO IT---you could not control compliance. OIE recommendations are European slanted and protect the EU which has experienced over 96% of all BSE cases worldwide with many cases occurring after feed ban due to non-compliance.

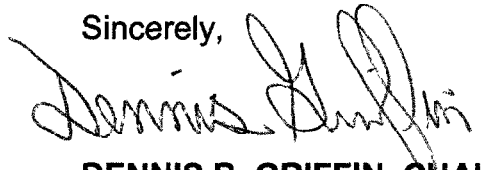
CLOSING STATEMENT:

The need for additional BSE restrictions are not warranted at this time. Finish the current testing program of high risk animals which now totals over 100,000 since 1986, and which is many times more than OIE recommends for the U.S., and then determine if any further action is warranted.

The BSE "window", from a time standpoint, is starting to close and if FDA will keep its focus on science based needs, the United States will demonstrate to the world we are capable of protecting our consumers from this European disease known as BSE, while maintaining general commerce in the U.S. Meat Industry.

Please use **common sense**, **stay the existing course**, and **keep your decisions based on science.**

Sincerely,



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