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August 11, 2004

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

Dear Sir or Madam:

The Anamax Group of companies, headquartered in Green Bay, Wisconsin, has three rendering facilities, a gelatin bone facility, a grease processing facility, and a hide and skin processing facility. We employ over 350 people and service five states in the upper Midwest.

We are concerned with the limited time given to prepare comments on such a complicated issue and 36 questions to respond to, especially in areas relating to economic and environmental impacts. We would request a minimum of 90 days for a comment period for any proposed rules so that appropriate background information can be collected.

We as a company and an industry have strongly supported all previous and current controls developed as a "fire-wall" against the introduction or spread of BSE in the U.S. We eliminated ovine products from our rendering raw materials in 1992 and promoted the voluntary ruminant protein to ruminant ban in 1996, and we supported the 1997 FDA feed rule, 21CFR 589.2000. In fact, as you know, the industry continues to exceed 99% compliance with the feed rule.

All avenues of precaution regarding BSE must be considered, but at this time making any major changes to the current rule is not justified, either scientifically or financially.

The current surveillance program should have the opportunity to be analyzed after appropriate samples are collected to determine the extent of BSE in the U.S. To implement new regulation now, and try to change in the future when more is known would, as you know, be almost impossible.

Cost/Benefit analysis also needs to be completed to determine appropriate mitigation steps for strengthening the current rule if needed. An all-out SRM ban may sound good or feel good, but the actual risk reduction is miniscule when compared with other options. The 2001 Harvard Risk Analysis stated that if 10 infected cattle with BSE were imported into the U.S., on average only 3 new cases of BSE would occur. This assumed a much higher rate of non-compliance with the feed ban. To make a statement that 98% of risk can be eliminated by removing SRMs from animal feed needs to be taken in context. There is very little difference between 98% of 3

2004N-0264

C 119

animals over 20 years and 50% of 3 animals over 20 years as compared to the entire population of cattle in the U.S.

All options of partial SRM removal should be considered if the agency is determined to have an SRM ban; i.e. removal of heads from all cattle over 30 months and all dead stock.

The situation in North America is dramatically different than the situation that occurred in the E.U. To use the E.U. as a template is not warranted. We will try now to address the specific questions of the A.N.P.R.

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

Yes, a format similar to the Beef Roundtable which seems to have worked well in Canada. It includes academia, government and affected industries.

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?

a) We continue to hear about the large percentage of risk reduction by removing SRM's from animal feed. It would be interesting to utilize the Harvard Risk Assessment to establish the baseline level with 10 positive animals that were introduced into the rendering process and calculate the projected numbers with and without removal of SRM's. i.e. If the projected number of animals that may develop BSE over the next 20 years is 3 without removal of SRM's, there is very little difference removing 60% or 98% of the potential infectivity. A cost benefit analysis could then be done to analyze different levels of "SRM" removal.

b) Refer to audits of the compliance with the current rule.

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?

Refer to #3

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

Glyceroltriheptanoate (GHT – C7 fatty acid) This is a synthetic fatty acid not found in nature. The EU is studying this as a potential marker for rendered products. This could be added to the raw material of prohibited material. After processing it would be a part of the fat fraction and show up in the finished tallow and meat and bone meal. To test for its presence in finished product, the extracted fat would be run through a GC and analyzed for its presence. (See addendum 1.)

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?

- a) Packing House – Physical denaturent for SRM (packers responsibility)
- b) Transportation – Physical denaturent for SRM
- c) Renderer – Physical denaturent for SRM in raw material, add GHT in process

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

Economic:

Utilize the new Informa (Sparks) Study.

Environmental:

“Certified disposal” options would need to be established. Without these in place there would be multiple health and safety issues that would develop.

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?

This is a question that would be best answered by PFI. Utilize EU/UK information and see if any correlation between farmers, packing houses, renderers, feed mill operators and vCJD.

Something to keep in mind is that in the UK where BSE and vCJD are prevalent, the incidence of vCJD was about 1 case for every 8,000 BSE positive cattle that were slaughtered and entered the food chain.

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

- a) Scientific analysis needs to be done.
- b) Should FDA prohibit SRMs from being used in animal feeds, and if appropriate markers or detection systems could be developed, there would not be a need for totally separate facilities. A “certified” clean-out/flush-out procedure could be developed to allow this option with separated storage facilities for the finished products. Raw material transportation equipment should be able to have separation on the same vehicle; i.e., compartments and also a clean-out procedure needs to be approved to allow the back-haul of non-prohibited material.

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

Economic – The costs would be high. The Informa (Sparks) Study of 2001 gives some estimates for the economic impacts of a regulation requiring dedicated facilities, equipment, storage, and transportation, but it should be updated to reflect 2004 costs.

Environmental – Necessity to require dedicated “certified disposal” options

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?

This would need to be tested to develop certified processes. The major concern I have regarding the ability to clean out is related to raw material handling. Equipment utilized to haul SRM and non-SRM material needs to have an approved method of cleaning to allow this option. Again the issue of risk needs to be analyzed.

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

There is no scientific data to support banning all mammalian and avian MBM from ruminant feeds. To utilize the EU approach because of the history of what happened in Europe would be ludicrous, the circumstances are totally different.

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 feed, or to otherwise amend the existing ruminant feed rule?

There is no scientific data to support the removal of mammalian and avian MBM from ruminant feed.

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

Utilize the Informa (Sparks) Report - 51 billion pounds per year would fill landfills in 4 years. A large portion would be disposed of outside of the acceptable, environmentally friendly options.

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?

At this time there has been no information to link the feeding of blood meal or blood products to any transmission of BSE. In fact, eliminating blood and blood products would be a major detriment to the cattle industry.

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

There is no information to show that plate waste is a risk in the transmission of BSE. If there need to be tests to determine "species" of animal proteins it may be necessary to prohibit plate waste from non-ruminant proteins to eliminate "false positives".

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

There is no scientific data that supports any risk of BSE transmission in tallow that is below 0.15% impurity. The industry has successfully defended this position in 1997 in the EU and there is much research that supports this position.

20. Can SRMs be effectively removed from dead stock and non-ambulatory disable 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 disable cattle from use in all animal feed?

To answer this question there first needs to be a definition of what is dead stock and what is SRM. Will the species be an issue? Will the age be an issue? The ability to remove SRM's is dependent on the definition. If removal of the head satisfies the need, that could be accomplished easily. If it is more than that, removal of SRM's is impractical. Another issue to keep in mind is that weather will also have a major affect on the ability of processors to remove SRMs, hot weather will cause deterioration and freezing weather could preclude the ability to process correctly.

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 know of no method to verify the presence of dead stock or non-ambulatory material in feed.

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?

Utilize Informa (Sparks) Study

23. What other innovative solutions could be explored?

With current technology and knowledge it would seem that energy generation would be the preferred alternative for the use of rendered by-products. A major concern is that government regulatory agencies are not in agreement as to the use of products for combustion in energy producing applications. EPA needs to approve various methods of incorporating the use of animal proteins as an acceptable fuel.

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

A national identity system should be implemented as soon as possible. An issue to keep in mind is that for this system to work it must close the loop and mandatory disposal options need to be part of the system.

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?

Definitely start with cattle and see what the costs/benefits are. Take some time to analyze benefits for other species.

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

The first concern is to make sure that whatever programs or rules come into affect, that proper training occurs with all of the stake holders involved, especially the regulatory groups. Information should be disseminated so that a low level of knowledge can understand the

procedures. It is also critical that the general public be educated. A proactive message that we have BSE in the U.S. but it is not a human health issue needs to be disseminated.

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

Make the information understandable and utilize the internet.

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, the door must always be part way open to utilize new technology or information regarding TSE's.

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

None that we know of.

Thank you for the opportunity to comment on this A.N.P.R. It is a very complicated and intertwined issue that needs to be handled in a logical, science-based approach.

Sincerely,



Michael J Langenhorst  
President  
Anamax Corporation