

# FACT

## FOOD ANIMAL CONCERNS TRUST

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August 12, 2004

Docket No. 2004N-0264  
(RIN) 0910-AF46  
Division of Dockets Management (HFA-305)  
Food And Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20852

Please find the enclosed comments from Food Animal Concerns Trust on the Advance Notice of Proposed Rulemaking (ANPR) *Federal Measures to Mitigate BSE Risks: Considerations for Further Action*. We appreciate the opportunity to comment on this important matter.

Sincerely,



Steven Roach  
Food Safety Program Manager

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Comments from Food Animal Concerns Trust (FACT) in response to the  
Food and Drug Administration's (FDA)  
Advance Notice of Proposed Rulemaking (ANPR)  
Federal Measures to Mitigate BSE Risks: Considerations for Further Action

Comments submitted by  
Richard Wood, Executive Director and Steven Roach, Food Safety Program  
Manager

August 6, 2004

Food Animal Concerns Trust (FACT) is a non-profit organization that advocates better farming practices to improve the safety of meat, milk, and eggs. Since Bovine Spongiform Ecephalopathy (BSE) was first recognized in the mid 1980s, FACT has worked diligently with Federal regulatory agencies to develop an appropriate response to the threat to human and animal health presented by this fatal degenerative disease. This is the third time since October 2001 that FACT has submitted written comments to the FDA addressing the adequacy of the ruminant feed ban. FACT submitted written comments to FDA Docket 01N-0423 in the fall of 2001 and to Docket 02N-0273 in February 2003. While new rules were announced by the agency in January 2004, the FDA never published

these rules and has not taken any other regulatory action in response to its prior requests for comments.

FACT is submitting these new comments in the hope that they will guide the FDA in steps to strengthen the ruminant feed ban with the goal of protecting United States consumers from the risk of disease resulting from the consumption of cattle infected with Bovine Spongiform Encephalopathy (BSE).

The most significant change in the science related to BSE since the original 1997 ruminant feed ban is that we now know that the infectious dose for cattle is much smaller than previously believed. This in itself requires that we carefully reexamine our existing ban.

The 2003 discovery of two indigenous North American cases of BSE is even more troubling than this new scientific information. The United States response to the threat of BSE has always had three aspects 1) protecting the borders from the import of the disease, 2) the ruminant feed ban to limit spread if the disease is introduced, and 3) domestic surveillance. The two indigenous North American BSE cases show that border controls were not put in place quickly enough to keep the disease from being introduced.

Because of this failure of the border controls, the feed ban is now the most important tool to limit the spread of BSE in the United States. The United States Department of Agriculture does have a surveillance program in place but this is a sampling program designed to estimate disease prevalence, and it is not designed to provide human or animal health protection. Given the primary importance of the feed ban in preventing the potentially devastating spread of this disease, FDA needs to act promptly to publish new rules that take into account the fact that BSE is present in the North American cattle herd.

#### General comments

FACT supports the recommendations of the International Review Team (IRT) convened by the Secretary of Agriculture and believes they are consistent with the rules announced by the FDA on January 26, 2004, while at the same time going further than the announced rules. FACT believes that it is inaccurate to describe the IRT's recommendations as "a different set of measures for reducing the risks associated with animal feed risks" as is stated on page 42292 of the ANPR Federal Register notice. For example, the IRT implicitly supports a ban on the feeding of poultry litter when they state that one of the reasons for a ban on the use of avian protein is the concern about "ruminant derived protein contained in the lumen of porcine or avian intestines at slaughter in animal feed that may be used for ruminants." If these proteins in the lumen at slaughter are a

problem, they will continue to be a problem when spilled or excreted into litter. The IRT also clearly supports dedicated facilities for ruminant and non-ruminant feed when it states that the “prevention of cross-contamination at this level is virtually impossible to deliver where mammalian MBM intended for inclusion in pig/poultry feed or pet food is present in feed plants that produce ruminant feed.”

The IRT’s recommendations are also generally consistent with the pathways identified by the Harvard-Tuskegee Study as being most likely to “facilitate human exposure to the BSE agent or the spread of BSE”. These pathways as noted in the ANPR are 1) non-compliance with the feed ban, 2) rendering of animals that die on farm and 3) inclusion of high-risk tissues from cattle in human and animal food. The majority of the recommendations of the IRT with respect to animal feeds are aimed at addressing non-compliance with the feed ban given the difficulty of controlling and monitoring cross-contamination. The third pathway is also specifically considered by the IRT in the recommendation that high-risk tissues be excluded from all animal feeds.

The consistency between the January 2004 FDA interim rule announcement, the IRT report, and the Harvard-Tuskegee study are not surprising. The scientific basis of all three sets of recommendations is the same. Infective materials are concentrated in specific tissues of cattle, and older sick cattle are more likely to

be infected. The IRT report differs from the other two studies because it acknowledges the challenge in maintaining adequate compliance with the feed ban given the dual problems of cross-contamination and the difficulty in distinguishing analytically between allowed and prohibited proteins.

While the level of compliance to the feed ban based on annual inspections by the FDA is commendable, the day to day actions of millions of people from the employees of rendering plants to the cattle feeders are what determine whether the feed ban is working. Each day the feed hauler needs to make sure his truck is adequately cleaned out between loads of pig and cattle feed. There is no way that a regulator can ensure that this will happen. For this reason, the IRT recommends multiple and redundant steps to reduce the risk of cross-contamination. These recommendations are based on experience in Europe where cross-contamination after feed bans were put in place continued to allow the disease to spread. The questions to be answered are not scientific, but regulatory -- what steps are necessary given the inability of regulators to oversee these millions of actions taken each day by such a wide variety of different actors? FACT believes that the IRT has described prudent measures that can be taken to strengthen the feed ban. The FDA should put these measures in place.

FACT supports the recommendation of the IRT that SRMs be removed from all animal feeds and that all MBM be removed from ruminant feed. FACT

interprets all MBM to include poultry litter and plate waste. The IRT report noted that it is impossible to detect through sampling cross-contamination at levels sufficient to preclude the spread of the disease through feed. Therefore, FACT supports the requirement of separate facilities for non-ruminant and ruminant feeds as announced by the FDA in January 2004. FACT also supports the IRT recommendation that a "rigorous audit of compliance with feed controls" be implemented including regulatory sampling of feed and feed ingredients. The FDA has spent years collecting information on what next steps to take. FACT asks the FDA to act swiftly and publish a new interim final rule implementing the recommendations of the IRT.

### Responses to Specific Questions

**Question 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?

**FACT Response:** Clearly the scientific consensus is that the infective agent is concentrated in the tissues considered specified risk materials. Given the small amount of material required to orally infect cattle, (less than 10 mg of infected brain as noted in the ANPR), removing these materials at the outset will unquestionably reduce the risk that they are accidentally or intentionally fed to cattle.

As to the what portion of the intestine should be removed, in the absence of data that slaughterers and renderers can consistently remove the distal ileum when removing only the lower intestine, the whole intestine should be removed.

FACT accepts the conclusion of the IRT that central nervous system tissue, skull, and vertebral column, should be considered specified risk materials when derived from cattle over thirty months old. If surveillance indicates that cattle younger than this are infected in North America, this age limit should be lowered to materials from cattle over 12 months as recommended by the IRT.

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

**FACT Response:** As noted above, removing the tissues likely to contain the major part of the infective material reduces the risk that they will be accidentally mixed into ruminant feeds. The scientific data is based on the historical evidence from Europe and was further supported by the Harvard-Tuskegee Study.

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

**FACT Response:** FACT believes that the list of SRMs should be the same between animal feed and human food. This does not mean that we believe that ruminant feed should have the same ingredients as human food. Further restrictions on ruminant feeding as included in the current feed ban and recommended by the IRT are important given the much higher susceptibility of cattle to the BSE infective agent.

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

**FACT Response:** FACT does not have expertise in analytical methods for sampling animal feeds, but is aware of several techniques for detecting SRMs in feed ingredients. The United States Department of Agriculture's Food Safety and Inspections Service currently has a testing program for spinal tissue in advanced meat recovery systems. This testing program uses both enzyme-linked immunosorbent assay and microscopic examination. It is unclear if these methods would work on MBM that has been rendered. A prohibition on SRMs in animal feeds should include

mandatory process controls that require sampling to evaluate the effectiveness of SRM removal. This should occur before heat treatment of rendered material or other processing steps that reduce the ability to detect SRMs.

**Question 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?

**FACT Response:** FACT does not have a specific recommendation beyond that whatever method used be effective in insuring that SRMs do not enter animal feeds. Whatever method is used to mark SRMs, these high risk materials should be processed on separate equipment from material intended for animal feed.

**Question 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?

**FACT Response.** As noted in the IRT report, the very small quantities of brain tissue required to orally infect a cow combined with difficulties in sampling techniques means the it is "virtually impossible" to avoid cross contamination even in cases where SRMs are removed. Given the difficulty in completely removing all SRMs during carcass processing, requiring dedicated facilities is prudent.

There is a clear consensus among scientists and risk mangers that removing SRMs does not make ruminant derived MBM safe for feeding back to ruminants. If SRM removal did make this material safe, a ban on feeding ruminant MBM would not be necessary. Given the inevitable failures of the SRM removal process, other steps are necessary to insure that the infective material is not fed to cattle. One of these additional steps is requiring dedicated facilities. Further, the historical evidence from Europe where many of the after the ban cases are linked to cross-contamination supports the additional step of requiring dedicated facilities. In the absence of a sampling program sensitive enough to detect cross-contamination at levels low enough to ensure that infective materials are not in ruminant feeds, dedicated facilities should be required.

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

**FACT Response:** Any data showing the effectiveness of clean-out must show its effectiveness in actual field situations where the person doing the cleaning is not aware that a test will occur.

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

**FACT Response:** As noted in the general comments above, the IRT provided the scientific justification for this question in its report. FACT accepts the argument made by the IRT.

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

**FACT Response:** The IRT did not suggest that one or the other of these steps be taken, it recommended a SRM feed ban and a ban on feeding all avian and mammalian protein to ruminants. FACT supports the recommendations of the IRT.

**Question 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?

**FACT Response:** While feeding experiments have not demonstrated that BSE can be transmitted through blood, there are two cases of Variant Creutzfeldt-Jacob Disease in the United Kingdom that are most likely the result of blood transfusion. These two cases show clear evidence that the infective agent is present in blood and must be considered a risk.

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

**FACT Response:** Banning plate waste is consistent with the most basic provision of the current ruminant to ruminant ban, ruminant proteins should not be fed to ruminants. It is inconsistent for the FDA to ban a

feed ingredient for cattle and then allow the exact same ingredient to be used for cattle because it has been offered as human food.

**Question 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?

**FACT Response:** The scientific basis for a prohibition on the use of poultry litter in ruminant feed after the removal of SRMs is the same as the scientific basis for continuing to prohibit the use of ruminant MBM in cattle feed after removing SRMs. Removing SRMs does not render ruminant MBM safe for feeding to ruminants. Spilling ruminant MBM on a poultry house floor is not a step that will reduce the infectivity of the BSE infective agent.

### Conclusion

FACT appreciates this opportunity to provide comments to the FDA on important steps to be taken to strengthen the ruminant to ruminant feed ban. FACT encourages the FDA to quickly move forward in publishing an interim final rule based on the recommendations of the international review team. This final rule should include a prohibition on SRMs in all animal feeds and a prohibition on all mammalian and avian MBM, including poultry litter, in ruminant feeds. The final rule should also include a requirement for dedicated facilities as part of steps to prevent cross-contamination. By heeding the recommendations of the International Review Team, an independent scientific panel, the FDA can strengthen the feed ban to further protect American consumers.