



August 13, 2004

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

Re: Docket # 2004N-0264

Dear Sirs,

This letter is to provide some comments on your advanced notice of proposed rulemaking. I am writing this as a representative of the American Association of Bovine Practitioners and the chair of the organization's Food Quality, Safety and Security Committee. The AABP would like the FDA and USDA to continue to consider scientific evidence in rulemaking decisions. While adding new rules as needed is laborious, it is easier than revoking/rescinding rules later. As there have currently been no indigenous cattle identified with BSE in the United States and the USDA has heavily intensified surveillance for the next 16 months, it seems premature to invoke major changes to a system that has kept us BSE free for over a decade.

In addition to the specific comments below, I have enclosed a copy of our organization's position statement on Bovine Spongiform Encephalopathy (BSE).

Section V, Part B, Question 2:

Research has shown that infective material can be isolated from the distal ileum, not the entire small intestine. Removal of the caudal third to half of the small intestine and proximal large intestine should be sufficient to supply the "abundance of caution" principle to protecting public and animal health. As the juncture of the small and large intestine is easily identifiable, it should not be difficult to remove this material from the human and animal feed chain. Allowing the remainder of the intestine to be utilized will decrease disposal issues. While packing plants may opt not to separate out this material because of value/costs issues, the entire intestine is not considered risk material and, in following science-based decision making, should not be banned.

Section V, Part C, Question 5:

There is a commercially available test kit from Neogen[®] Corp. (Reveal[®]) that can identify the presence of ruminant protein in feed. While it does not specifically identify neural tissue, it is useful in ruling out the

AMERICAN ASSOCIATION OF BOVINE PRACTITIONERS

PO Box 1755 Rome, Georgia 30162-1755 phone - 706 232 2220 fax - 706 232 2232 e-mail - aabphq@aabp.org

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presence of ruminant-derived protein. Tests performed in my laboratory show that it can also be used for recycled poultry bedding (AKA poultry litter) contaminated at a concentration of 2.5% (unpublished).

Section 5, Part C, Question 15:

While there has been data showing transmission of BSE in sheep receiving transfusions of blood from infected sheep, there is not data available currently that indicates oral transmission of BSE via blood. It is believed that the removal of the cellular fraction of the blood removes any risk of transmission. Based on this, a more prudent move might be to allow the use of acellular blood products. From the standpoint of cattle, plasma is an important product in colostrum supplements. These supplements have been shown to be beneficial for health maintenance in calves that did not receive adequate colostrum. Based on what would have to be a very low risk of transmission BSE (if it is any risk at all) by feeding plasma and the demonstrated positive effects on animal health, it seems premature to ban this practice without definitive data that it is a danger.

Section V, Part C, Question 17:

If ruminant derived protein is removed from poultry diets, there would be no "BSE-related" basis for a ban on feeding recycled poultry bedding (AKA poultry litter) to cattle. While there are many that will argue against feeding the product, it would not be a risk factor for the spread of BSE.

Section VI, Part A, Questions 28 and 29:

It would be a prudent move by the FDA to include some mechanism in the rulemaking process to account for changes in technology and proof that a particular feed is not a risk factor in the spread of BSE. Better yet, not instituting new rules without scientific evidence of risk, would be preferable. Validation that the technology is accurate should be carried out by independent laboratories with no monetary interest in the outcome.

In summary, we encourage you to base your rulemaking on confirmed science and not on unsubstantiated opinion. Remember, we have not (as of this writing) identified BSE in our indigenous cattle population. Blanket bans of minimal risk materials will create waste management issues that may be of more concern in the long term.

If you would like further information or clarification of points discussed above, please feel free to contact me at (919) 513-6244 or dawn_capucille@ncsu.edu.

Regards,



Dawn J. Capucille, DVM, MS
Diplomate - Am. Board of Vet. Practitioners
Chair - Food Quality, Safety and Security
Committee of AABP

Enclosure

Cc: Dr. Mark Spire
Dr. Richard Meiring
Dr. James Jarrett
Dr. Reny Lothrop



AABP position statement regarding Bovine Spongiform Encephalopathy

The American Association of Bovine Practitioners is committed to protecting animal health and promoting public food safety by facilitating production of meat, milk and other dairy foods which are safe, secure, and abundant. Bovine spongiform encephalopathy (BSE) exposure has been demonstrated in North America with the identification of a case in Canada in May of 2003 and a case in the United States in December of 2003. This disease affects cattle and has been associated with a slight risk to human health. Its diagnosis in the United States cattle herd may reduce consumer confidence in the safety of beef and milk. To mitigate the impact of BSE, AABP supports that further actions be taken in North America to protect cattle from exposure to the agent of BSE and to demonstrate that proactive incremental BSE prevention strategies continue to be implemented as new epidemiologic information becomes available.

As an organization, AABP recommends that further actions should:

- 1) Provide for the early detection and removal of the disease through continued diagnostic surveillance targeted toward cattle exhibiting signs consistent with BSE.
- 2) Promote a national cattle identification system which allows retrospective investigation and rapid removal if exposed to contaminated feed material.
- 3) Protect cattle and other animals from exposure to the BSE agent by removing ruminant brain and spinal cord from animal feed, by developing methods to readily identify feed sources as safe and legal to feed to cattle, and by developing strategies for the safe removal and destruction or use of potential risk materials.
- 4) Support the USDA's additional BSE prevention measures to demonstrate that the food supply is safe from contamination with the BSE agent, e.g., removing specified risk materials from human food, banning mechanical recovery of meat from the carcass of cattle greater than 30 months of age, banning the use of compressed air stunning tools, and removing downer cattle from the human food supply.
- 5) Promote the removal of bovine whole blood products from the cattle feed supply, as its presence confounds feedstuff compliance testing.

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6) Support the continued use of purified protein products in calf colostrum supplements and milk replacers, including bovine plasma, serum and fractions thereof, as they have a demonstrated positive effect on calf health and disease control and no evidence of transmissible spongiform encephalopathy (TSE) infectivity.

7) Promote the use of more resources for research and for educating the public on:

- The actual risk of cattle developing BSE.
- The further risk of the development of variant Creutzfeldt-Jakob Disease in the human population.
- Provide science and risk-based information for changes in regulations surrounding BSE and protection of the food supply.

8) Use science-based information to normalize agricultural commodity commerce between the United States and Canada as quickly as possible.