September 13, 2004

04-021ANPR
04-021ANPR-74
Jan Lyons

Docket Clerk
Food Safety and Inspection Service
U.S. Department of Agriculture
Room 102, Cotton Annex
300 12th Street SW
Washington, DC 20250

Re: Docket No. 04-021ANPR, "Federal Measures To Mitigate BSE Risks: Considerations for Further Action."

Dear Docket Clerk:

On behalf of the National Cattlemen's Beef Association (NCBA) I want to express our appreciation for the opportunity to comment on the Food Safety and Inspection Service (FSIS) Docket No. 04-021ANPR, "Federal Measures To Mitigate BSE Risks: Considerations for Further Action." Producer-directed and consumer-focused, the National Cattlemen's Beef Association is the trade association of America's cattle farmers and ranchers, and the marketing organization for the largest segment of the nation's food and fiber industry.

NCBA has worked to lead the U.S. beef industry since 1986 on preventative and proactive "firewalls" regarding Bovine Spongiform Encephalopathy (BSE). These firewalls protect animal health and public health. The finding of BSE in an imported cow from Canada in December 2003 has proven why it is so important that these firewalls be in place. NCBA commends the U.S. Department of Agriculture (USDA) for taking further actions, such as the ban on Specified Risk Materials (SRM) to ensure additional protection for the public.

NCBA appreciates the opportunity to provide comment on these additional areas addressed by FSIS in the Advance Notice of Proposed Rulemaking (ANPR). Our comments on the specific questions raised by FSIS are below.

1. Would there be value in establishing a specialized advisory committee or standing subcommittee on BSE? It is our understanding that there has been an interagency BSE committee for many years. The proactive measures taken by government and industry to prevent BSE in the United States since 1989 are the direct result of the existing interagency committee and the respective agencies interactions with the private sector.

Relative to the International Review Team (IRT), we did not and do not agree that this groups contributions in response to the BSE case in December of 2003 were appropriate or meaningful.

The IRT report was not science or fact-based. It ignored our efforts to prevent BSE since 1989 and directly implied that the BSE situation in the United States was equivalent to that of Europe. There were no steps recommended by the IRT that our own government experts were not already fully aware of as possible actions to be taken based upon risk analysis. However, our government experts were clearly more aware of

the proactive steps the U.S. had taken since 1989 than was the IRT. We believe the IRT did not function in an objective science-based manner and that our own government experts are more than capable of handling the review and evaluation or our BSE prevention efforts.

Consequently, we strongly suggest that the existing interagency BSE committee continue to function and that they routinely bring in the private sector to discuss the BSE situation. If there is a need to formalize this interagency activity, we would not be opposed to that occurring but the most important issue is to increase cooperation and collaboration within government agencies and especially with the private sector.

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? NCBA knows of no scientific information that justifies the IRT recommendation to remove brain, spinal cord, skull and vertebral column from cattle over 12 months of age. There also is no scientific information available that justifies removal of the entire intestine.

The BSE agent has been documented to have been found in certain lymph-reticular system tissues called the Peyer's patches, which are concentrated in the distal ileum of the small intestine (Wells et. al., 1994). Current research indicates that the infective agent is not found in other gastro-intestinal tissues other than the distal ileum (Wells et al., 1998). Specifically, research has shown that the infective agent is not present in the duodenum and the jejunum portions of the small intestine even when the agent is found in the ileum (Terry et al., 2003). Additionally, the infective agent for BSE has only been found in the distal ileum of cattle which were inoculated with the BSE infective agent. Due to the increased amount of infective agent the animals were exposed to, the agent has not been reported to have been found in animals which have succumbed to the disease naturally (Wells et al., 1998; Terry et al., 2003).

We believe that a protocol can be developed and implemented that would ensure removal of the distal ileum and allow the remaining portion of the small intestine to be utilized.

26. How can training and educational materials be designed or improved to meet the needs of multiple audiences with variable levels of scientific training? As we have discovered with the Animal and Plant Health Inspection Service (APHIS) initiative to develop educational and promotional information associated with the BSE surveillance program, there MUST be an open dialog with producers BEFORE any of these well intentioned materials are developed. Thus, the most important message for all government agencies is that we need to develop these materials together. Together we can efficiently design materials to reflect the needs and abilities of all segments with a stake in BSE prevention as well as how best to distribute the materials and programs.

32. What measures are necessary to prevent cross contamination between carcasses? NCBA continues to believe that proper cleaning and sanitizing of equipment between carcasses is the proper measure to

prevent cross contamination at this time. While current cleaning and sanitizing procedures in place by establishments will not inactivate prions, it will reduce cross contamination due to multiple risk mitigation measures in place. The procedures outlined in the "Practices Useful for the Removal and Handling of SRM" document are adequate to prevent cross contamination between carcasses. This Beef Industry Food Safety Council document is currently undergoing industry review and will be finalized within 45 days.

There has been a significant amount of research in this area in the last six months. NCBA, on behalf of beef producers and the Cattlemen's Beef Board, are investing checkoff dollars into this important research area. We encourage USDA to make this a research priority as well to answer this question once and for all. If research reveals more adequate measures to prevent cross contamination, then NCBA would encourage the
industry to adopt such practices.

33. In establishments that predominantly slaughter cattle 30 months of age and older. Are additional sanitation requirements necessary to prevent edible portions of carcasses from being contaminated with SRMs? The risk of cross contamination between carcasses is very low due to the extremely low risk of BSE in the U.S., the procedures in place to not allow 4-D cattle in the food supply, and the industry practices to reduce cross contamination between carcasses. NCBA believes that the risk of cross contamination between carcasses of cattle 30 months of age and older is extremely low and therefore, no additional sanitation requirements are necessary. While current cleaning and sanitizing procedures in place by establishments will not inactivate prions, it will reduce cross contamination due to multiple risk mitigation measures in place. The procedures outlined in the "Practices Useful for the Removal and Handling of SRM" document are adequate to prevent cross contamination between carcasses. This Beef Industry Food Safety Council document is currently undergoing industry review and will be finalized within 45 days.

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industry to adopt such practices.

34. Should FSIS provide an exemption for "BSE free" countries or countries with some other low-risk BSE designation? FSIS has stated in the ANPR that countries have requested that their "BSE free" or "provisionally free" status is an "equivalent sanitary measure" to the public health protection requirements in the FSIS interim final rule.

We have learned, after over 15 years of monitoring the BSE situation globally, that dealing with the animal health and public health risks from this disease warrant taking actions before the disease is identified. In this regard, over time, we have taken steps in the U.S., independent of our BSE risk categorization, to eliminate the use of pneumatic stunning equipment, and to regulate the use of Advanced

Meat Recovery (AMR) technology in an effort to reduce the potential for brain and spinal cored from entering the human food supply. In December of 2003 these measures were "codified" and additional measures were taken to reduce the human health risk poised by BSE even though the U.S. has yet to have an indigenous case of BSE.

Consequently, we believe that it is prudent to harmonize globally the steps that should be taken, independent of BSE status, to provide a basic level of risk reduction. Specifically, even in countries that are BSE free of provisionally free, efforts should be taken to prevent brain, spinal cord, and the other SRMs from animals over 30 months from entering the human food supply. NCBA believes that animal health status alone is not an equivalent public health protection to removing SRM tissues and banning nonambulatory cattle from the food supply. Therefore, NCBA does not support such an all out exemption for the countries that can meet a "BSE free" or "provisionally free" designation.

NCBA would support a program where these countries develop verifiable procedures to remove the SRM materials from animals 30 months of age and older from entering the food supply, ban nonambulatory cattle from the food supply. Each country also needs to have in place a BSE surveillance program capable of detecting the disease if it were to exist at a rate of 1in 1 million cattle or more at the 95% confidence interval.

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? NCBA does not support the exemption for "BSE free" countries from the provisions in the SRM rule. NCBA believes that it is prudent to harmonize globally the steps that should be taken, independent of BSE status, to provide a basic level of risk reduction and we urge that the importing country must:

* meet the basic standards developed by the OIE to determine the animal health status; and
* remove the brain, spinal cord, and other SRMs from animals 30 months of age and older from entering the food supply; and
* ban nonambulatory cattle from the food supply; and
* conduct a surveillance program to find the disease if it was present in 1 in 1 million cattle with a 95% confidence interval.

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? Again, NCBA does not support the exemption for "BSE free" countries from the provisions in the SRM rule. If FSIS were to go that way based upon a sound legal and scientific analysis, FSIS should work with APHIS, as the animal health experts, to verify that the country does in fact meet the requirements of the OIE to be "BSE free" or "provisionally free." These aspects include but are not limited to verifying that the surveillance program, import ban, and feed ban are effective. FSIS should then as part of the annual inspection of importing country systems, verify the methods and procedures to remove SRMs and nonambulatory cattle from the food supply are being implemented.

NCBA appreciates the opportunity to provide comments to FSIS on this ANPR. We urge FSIS to consider all comments and scientific information received so that science based decisions are made by the agency.

Sincerely,
<<Picture (Metafile)>>
Jan Lyons
President
National Cattlemen's Beef Association
References

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