February 4, 2003

Dockets and Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: *Docket No. 02N-0273 - Substances Prohibited From Use In Animal Food or Feed; Animal Proteins Prohibited In Ruminant Feed; Advance Notice of Proposed Rulemaking*

To Whom It May Concern:

The American Meat Institute (AMI) is the national association representing meat and poultry slaughterers and processors. Our members slaughter more than 90 percent of the cattle raised in the U.S. and process most of the rendered products produced in the U.S. Therefore, the above referenced Advanced Notice of Proposed Rulemaking (ANPR) substantially affects our members.

AMI supports the existing animal feeding regulations that restrict the use of certain animal proteins derived from mammalian tissues for use in ruminant feed. However, we oppose additional regulations as contemplated in the ANPR because no scientific justification exists to warrant regulatory changes at this time. AMI and a coalition of 14 other trade associations submitted comments (Attachment 1) to the public record on January 13, 2003, that provide more details regarding our collective opposition to the proposed changes.

AMI is particularly concerned and troubled by FDA's suggestion that brains and spinal cords from ruminants two years of age and older be excluded from all rendered products. Our objections and scientific rationale are outlined below.

Brains and Spinal Cords Produced In The U. S. Pose No BSE Risk

AMI objects to FDA using the terms "high risk tissues" and "specified risk materials" in reference to brains and spinal cords. These terms were first used to describe certain bovine tissues that are produced in countries with endemic BSE in their cattle population. Brains and spinal cords that are produced in the U.S. are not "high risk

tissues" or "specified risk materials" because BSE is not present in the U.S. No evidence exists that brains, spinal cords or other bovine tissues that are derived from U.S. cattle slaughter operations contain the infective agent that causes BSE. Furthermore, brains and spinal cords are inspected and passed for human consumption by USDA's Food Safety and Inspection Service. For these reasons it is inappropriate and plain wrong to classify domestically produced brains and spinal cords as "high risk tissues" or "specified risk materials."

Duplicative Regulations Will Not Reduce BSE Risk

The removal of brains and spinal cords from rendered products would be redundant to existing animal feed regulations that are designed to prevent the amplification and spread of BSE in the unlikely event the disease is ever introduced into the U.S. FDA's current animal feed regulations prevent bovine tissues, such as rendered products containing beef brains and spinal cords, from being fed to ruminants. Furthermore, certain conditions must be simultaneously present to achieve any level of risk reduction by excluding brains and spinal cords from rendered products. The BSE infective agent must be present in the brain or spinal cord, the infective agent must be present in sufficient quantities to cause the disease by oral ingestion and a significant level of non-compliance with the current regulations must exit. These conditions simply do not exist in the U.S.

Effective Regulations Are Already In Place to Control Spread Of BSE

The Harvard Center for Risk Analysis study that was commissioned by USDA to characterize the potential for BSE to be introduced and spread in the U.S. provides clear evidence that existing government regulations provide extraordinary protection to the U.S. beef industry. The Harvard study concluded (1) that the U.S. is highly resistant to any introduction of BSE, (2) that BSE is extremely unlikely to become established in the U.S. and (3) that if BSE is introduced into the U.S. it is likely to be eliminated quickly. Based on the Harvard risk assessment conclusions, AMI believes changes in the animal feed regulations are not warranted at this time.

Compliance with Current Regulations Will Provide Greatest Protection

The Harvard study provides incomplete information in order to properly evaluate the effectiveness of any additional regulations. The study did not quantify the probability that BSE would be introduced into the U.S. through the illegal importation of infected cattle, bovine tissues or feed ingredients. If BSE is never introduced into the U.S., which is a likely scenario given the breath and scope of import restrictions now in place, additional regulations to require the removal of brains and spinal cords from rendered products will prove worthless. The Harvard study confirms that achieving full and

complete compliance with the existing regulations provides the greatest level of protection against the spread of BSE in the unlikely event that the disease is introduced into the U.S.

Additional Regulations Could Adversely Affect International Trade

Excluding brains and spinal cords from rendered products could negatively affect international trade by sending the wrong signal to the world trading community. The World Organization for Animal Health (Office International des Epizooties) and various governments such as the European Union require removal of brains, spinal cords and other tissues from bovine products if a country falls within certain higher BSE risk categories. USDA has consistently presented factual evidence to these organizations and other trading partners that BSE is not present in the U.S.; therefore, removal of these so-called specified risk materials is unnecessary. If FDA proceeds to exclude brains and spinal cords from rendered materials, it would send an erroneous message to these organizations and other trading partners that additional control measures are needed because the U.S. is uncertain of its BSE status. The promulgation of additional regulations to control BSE could undermine international trade negotiations and adversely affect trade with several countries.

Severe Economic Burden is Unjustified

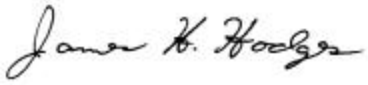
Excluding brains and spinal cords from ruminants two years of age and older from rendered products will cause real and significant economic dislocations throughout the livestock industry. It will require costly redesign of facilities and processes, significantly increase disposal costs and necessitate closure of certain rendering operations that cannot feasibly exclude brains and spinal cords from their raw material supply. An additional complicating factor is no reliable and precise method is available to determine the age of cattle at the time of slaughter. Without the ability to determine age, segregation of cattle two years of age and older becomes a practical concern that could result in brains and spinal cords being removed from all cattle.

Recently, AMI commissioned an economic analysis of regulatory options that have been proposed by USDA's Food Safety and Inspection Service. The study (Attachment 2) contains data that FDA can use to estimate the economic impact of removing brains and spinal cords from rendered products. The study shows that the proportion of cattle slaughtered at or beyond 24 months could be as high as 45 percent. This is a significantly larger share of commercial slaughter than previously estimated by governmental agencies. The study also conservatively estimates that the disposal of brains and spinal cords for only the beef slaughter industry could exceed $50 million annually and that significant economic shocks and reduced profitability will be felt throughout the livestock complex.

Conclusion

AMI appreciates the opportunity to comment on this important rulemaking. We believe adequate safeguards are currently in place to protect the U.S. livestock industry from the threat of BSE. Therefore, we respectfully request that FDA not promulgate additional animal feed regulations at this time and withdraw the ANPR that is the subject of these public comments.

Sincerely,



James H. Hodges
President, AMI Foundation

Attachments

cc: J. Patrick Boyle