



December 20, 2005

Docket No. 2002N-0273 (formerly Docket No. 02N-0273)  
Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane  
Room. 1061  
Rockville, MD 20852

*Re: Proposed Rule - Docket No. 2002N-0273, CVM 2005. Substances  
Prohibited From Use in Animal Food or Feed*

To Whom It May Concern:

The American Meat Institute (AMI) is the national association representing meat and poultry slaughters and processors. Our members slaughter most of the cattle raised in the U.S. and process most of the rendered products produced in the U.S. Therefore, the above referenced proposed rule directly and substantially affects our members.

AMI has and continues to support scientifically based animal feeding regulations to prevent the introduction, amplification and spread of bovine spongiform encephalopathy (BSE) in North America. We support the Food and Drug Administration's (FDA) decision to abandon its earlier efforts to prohibit all know specified risk material (SRM) from animal feed and pursue a more rational course of action to remove the potentially most infectious materials. The measures prescribed in the proposed rule will further strengthen existing safeguards while minimizing the economic and environmental concerns associated with the disposal of the complete list of SRM.

AMI's support for the proposed rule is predicated on the industry's strong desire to maintain uniform, harmonized feed regulations in North America to address the threat of BSE. During the past decade, both the U. S. and Canada have developed, implemented and enforced nearly identical feed regulations. This history of cooperative and harmonized BSE risk mitigation programs has benefited the industry and government of both countries. Full harmonization of our respective feed regulations is by far the best approach to maintain the viability and strengthen the North American beef industry. We strongly urge FDA and other governmental entities to work closely with the Canadian government to maintain a harmonized approach in promulgating future feed regulations.

### **Feed Rules Should Recognize the Very Low Risk of BSE in North America**

The U.S. and Canada remain very low risk countries for BSE because multiple risk mitigation measures have been implemented over the past two decades. Firewalls have been constructed to protect the cattle herd. Import restrictions on countries that have BSE were first put in place in 1989 in both Canada and the U.S. In 1990, the U.S. was the first country in the world to implement an animal disease surveillance program when the disease was not known to exist in this country. Canada has implemented a similar surveillance program. And a precautionary mammalian-to-ruminant feed ban was implemented in 1997 in both countries to prevent the amplification and spread of the disease in North America.

As a result, only one indigenous case of BSE has been diagnosed in the U.S. during an intensive surveillance program that has tested more than 550,000 high risk cattle since June 1, 2004. Only four indigenous cases of BSE have been diagnosed in cattle of Canadian origin. In comparison, more than 189,000 cases of BSE have been diagnosed in cattle since the disease was first discovered in the United Kingdom in 1986. More than 96 percent of the cases worldwide have occurred in the U.K. At the height of the epidemic in 1992 more than 1,000 cases per week were being diagnosed. In 1992 alone, more than 37,000 cases were diagnosed. Experts have estimated that between 3 and 4 million undiagnosed cases actually occurred. That is compared to five native cases of BSE detected in North America that were born before, or shortly after, implementation of feed restrictions in both the U.S. and Canada.

Therefore, it is appropriate for FDA to promulgate additional rules that recognize that the North American cattle population has been exposed to the BSE agent, but also takes into account that the risk is extremely low. AMI agrees with the agency that the recent cases of BSE are an indication that additional animal feed protections are needed to remove potential residual infectivity.

### **Full Compliance With the Existing Feed Rule Must Be Maintained**

The effect of any enhancements in the existing feed rules will not be known for several years due to the long incubation period before clinical disease onset occurs. For example, if a six-month old calf becomes infected today, the disease would not likely manifest itself until the animal is several years old. Therefore, it is imperative that full and complete compliance with the existing feed rules be maintained.

FDA has successfully implemented feed restrictions that prohibit mammalian-derived proteins from being fed to cattle and other ruminants. The Harvard-Tuskegee study confirms that achieving full and complete compliance with the existing regulations provides the greatest level of protection against the spread of BSE. AMI urges FDA to maintain its objective to achieve 100 percent compliance with the existing regulations.

Some proponents for banning risk materials in animal feed have argued that additional requirements to achieve 100 percent compliance with the existing mammalian-to-ruminant feed regulations are not necessary and that FDA can conserve limited resources by reducing inspection and enforcement activities if the subject proposal is finalized. AMI adamantly opposes any diminution of effort to achieve full and complete compliance with the regulations that provide a high level of protection against the spread of BSE in the U.S. Further, FDA has a legal obligation to enforce the regulation. Enforcement discretion is not an option when it comes to protecting the health of the U.S. cattle herd.

### **Prohibiting Brain and Spinal Cord in Animal Feed Reduces Potential Infectivity**

The purpose of any feed regulation is to prevent the BSE agent that is present in an infected animal from being re-introduced into the cattle herd. BSE risk mitigation measures must be considered in combination, not singularly, when evaluating their risk reduction potential. A combination of risk mitigations measures as proposed by FDA will be effective and less costly than banning all SRM from all animal feed.

Almost 90 percent of the infectivity present in an infected animal nearing clinical onset is contained in the brain and spinal cord as shown in Table 1. AMI supports FDA's conclusion that removal of the brain and spinal cord represents a secondary level of protection to address potential failures in compliance that may occur with the existing ruminant feed ban. Removal of these highest risk tissues from animal feed will address noncompliance that could result in cattle exposure to prohibited material through cross-contamination, mislabeling or misfeeding.

Table 1: Relative BSE Infectivity Associated with Cattle Tissues

Tissue	% Total Infectivity
Brain	64.1%
Spinal cord	25.6%
Dorsal root ganglia	3.8%
Trigeminal ganglia	2.6%
Distal ileum	3.3%
Tonsil	< 0.1%

Source: Harvard-Tuskegee Study

It is important to recognize that the objective of any proposal to enhance the existing feed regulations is to reduce the risk that the cattle herd is exposed to BSE infectivity. The absolute elimination of all risk is neither a rational public policy position nor is it feasible. The effectiveness of removing the brain and spinal cord from slaughter cattle will approach, but not be 100 percent, based on best practices and available technology. Before a final rule is published, we strongly urge FDA to clearly define what constitutes an acceptable level of brain and spinal cord removal. A quantitative risk analysis using the Harvard model could be used to establish an acceptable level of

residual brain and spinal cord remaining in materials destined for animal feed from cattle that have passed ante-mortem inspection.

### **A Comprehensive Disposal Plan Must be Developed**

Table 2 shows the quantity of SRM produced each year from the slaughter of 35 million cattle. The table is separated into cattle older than 30 months of age and cattle younger than 30 months of age to replicate the current SRM removal policy now in effect for the human food supply. However, it is important to recognize, as FDA has done, that animal feed regulations do not have to mimic human food protections.

Table 2: Estimated Weight of Specified Risk Material (SRM) In Cattle

Specified Risk Material (SRM)	Cattle >30 Months (Pounds)	Cattle <30 Months (Pounds)
Spinal Cord	0.3	
Brain	1.0	
Skull	14.2	
Vertebra	34.5	
Distal Ileum	6.5	6.5
Tonsil	0.3	0.3
Total Pounds per Head	56.8	6.8
Annual cattle slaughter	7 million	28 million cattle
Total Pounds Per Annum	398 million	190 million

Source: American Meat Institute

The removal of only the brain and spinal cord from cattle 30 months of age and older significantly reduces the amount of risk material that must be removed from animal feed. If full SRM removal was required, nearly 600 million pounds of slaughter waste would require disposal versus less than 10 million pounds if only the brain and spinal cord is removed. AMI agrees with FDA's conclusion that the infrastructure does not currently exist to handle the volume of material from slaughter that would require non-feed disposal if the full list of SRM were diverted from animal feed use. The rule also greatly affects the disposal of dead and non-ambulatory cattle. Therefore, AMI strongly suggests that all affected agencies, in cooperation with the industry, develop a comprehensive yet flexible plan to safely dispose of SRM and dead stock before the subject proposal is implemented.

### **Regulations Must Be Cost Effective**

The cost effectiveness of the subject proposal depends on a wide array of assumptions ranging from the cost of dead stock and SRM disposal to the lost revenue associated with the elimination of certain raw materials that currently are rendered for animal feed. If however, we accept FDA's annual cost estimates shown in Table 3 are generally correct, it becomes abundantly clear that if enhancements to the feed are

implemented, the proposed rule provides the most risk reduction per unit of cost expended.

Table 3: Cost-Effectiveness of Alternative Policies

Option (Description of Banned Tissues/Materials)	Infectivity Reduction <sup>1</sup>	Annual Cost (\$ millions)
Brain and spinal cord from cattle 30 months or older, brains and spinal cord from cattle of any age not passed for human consumption and carcasses of cattle not passed for human consumption if the brains and spinal cords have not been removed (proposed rule)	90%	\$14—\$24
Brain and spinal cord from cattle 30 months or older and carcasses of all dead stock and downers	>90%	\$115—\$135 <sup>2</sup>
Full SRM list from cattle 30 months or older, tonsils and distal ileum from cattle of all ages and carcasses of all dead stock and downers	>99%	\$195—\$240

<sup>1</sup> Percent of ID<sub>50</sub>s from an infected animal that would be banned from use in animal feed.

<sup>2</sup> Detailed cost estimate of this alternative is not included in the regulatory flexibility analysis section of this document.

Source: U.S. Food and Drug Administration

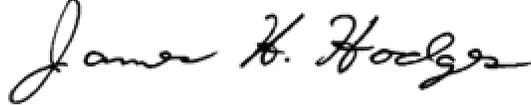
### **Definition of Cattle Not Inspected and Passed Needs Clarification**

FDA has defined cattle not inspected and passed for human consumption as cattle of any age that were not inspected and passed for human consumption by the appropriate regulatory authority. AMI suggests that the definition be clarified to include only cattle that do not pass ante-mortem inspection.

All slaughter cattle must pass both an ante-mortem and post-mortem examination before they are deemed fit for human consumption. All conditions that are related to BSE are readily observable in the live animal before it is slaughtered. Animals can pass ante-mortem inspection, yet be condemned during post-mortem inspection for a variety of reasons totally unrelated to BSE. Prior to final carcass disposition, however, slaughter waste will have already entered the inedible rendering process. A literal interpretation of the rule would require all rendered products to be diverted from the animal feed supply because parts of cattle not inspected and passed would be commingled with parts of cattle that were inspected and passed.

Thank you for the opportunity to comment on this important rule. AMI supports FDA's efforts to reduce the risk of BSE in the U.S. We pledge our continued support for regulatory actions that are technically sound and based on scientific facts and analysis.

Sincerely,

A handwritten signature in black ink that reads "James H. Hodges". The signature is written in a cursive style with a large initial 'J' and a long, sweeping underline.

James H. Hodges  
President, AMI Foundation