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Processors of Animal By-Products

December 19, 2005

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

***Re: Docket No. 2002N-0273, Substances Prohibited From use in Animal Food or Feed***

To Whom It May Concern:

We appreciate the opportunity to provide FDA with comments on the proposed rule. It is our sincere hope that FDA review the comments submitted by livestock producers and the rendering industry and consider the severity of the impacts, both environmental and economic, that would be created if the proposed rule were implemented. We cannot emphasize strongly enough that no new feed rules are needed and hope to clearly outline in this document the data to support this position while bringing to light the actual economic and environmental impacts of such a rule.

### **History of BSE Surveillance in the United States**

Since 1990 USDA/APHIS has conducted testing for BSE in the United States cattle population. Prior to 2003 this testing program focused on those animals exhibiting symptoms of a central nervous system disorder and/or cattle that could not rise from a recumbent position. From the time this testing program began in 1990 through the end of 2002 approximately 36,819 cattle were tested for BSE and *none* were found to be positive.

In 2003 approximately 20,543 cattle were tested for BSE and only one was found to be positive for the disease. The investigation into the origin of this animal later revealed that it had been imported from Canada, and was born prior to the implementation of the 1997 feed rule prohibiting the feeding of ruminant derived proteins to ruminant animals.

On June 01, 2004 USDA/APHIS began its enhanced BSE surveillance program targeting the “highest risk population”. These were cattle that statistical data has shown to have the highest incidence of testing positive for BSE and include not only those animals that are exhibiting CNS symptoms, but also those animals 30 months of age or older that have died for reasons other than slaughter.

Since the enhanced surveillance program began in June 2004, nearly 550,000 cattle have been tested. Of those 550,000 only *one* animal has tested positive for the disease. It is important to note that, although this animal was born prior to implementation of the 1997 ruminant feed ban, the epidemiological investigation into this animal’s life history showed no link between ruminant-derived feed and infection with the disease.

These statistics *do not* provide the basis for further feed restrictions. What these statistics *do provide* is supporting scientific evidence that the current ruminant-to-ruminant ban *has* been effective, *continues* to be effective and *does* provide a level of protection sufficient to not only prevent the establishment, amplification and spread of BSE in the United States but also to eradicate the disease if it were found to be present in a greater percentage of the cattle population.

### **Effect of SRM removal on processing capacity**

While the removal of brains and spinal cords from fallen cattle is not impossible, it is a daunting task. Several factors must be taken into consideration when contemplating the ability to remove these materials from cattle. Weather, for example, plays a crucial role in the ability to remove SRMs. Rapid decomposition during summer months as well as freezing of the spinal column and brain cavity in winter months create significant challenges in effectively removing these materials.

Handling of the animal post-mortem also plays a role in the ability to remove SRM from the vertebral column. If the animal is scooped out of the pen with a loader or drug out of the pen with another vehicle significant damage is usually done to the vertebral column. That being the case, the only feasible way to remove the spinal cord is by splitting the carcass. While carcass splitting is part of the slaughter process, it is not typically part of the process in plants that process 4D material.

This additional step in the process chain would negatively impact the processing capacity of 4D processing plants. We estimate that our total processing ability would be diminished by 40% to 50%. This reduction in processing capacity would in turn have a negative effect on the cost of operations due to efficiency losses brought about by reduced processing capacity. In order to maintain current processing capacities it would be necessary for our company to increase the size of our processing area by approximately 60% to accommodate the additional equipment and personnel required to remove these materials.

### **Ability to remove SRM from cattle and calves**

As mentioned earlier weather conditions have a significant impact on the ability, or lack thereof, to remove SRMs from fallen cattle. Rapid decomposition of the carcass in warmer seasons as well as freezing conditions in winter months can make it unusually difficult to accomplish this task. In many cases removal and disposal of the entire vertebral column and removal and disposal of the whole head will be required. In approximately 15% of the carcasses neither of these options will be viable due to extreme decomposition which will force disposal of the entire animal.

These circumstances will result in a far greater volume of CMPFAF requiring disposal than FDA has acknowledged in the proposed rule. Disposal in landfills, where permitted, appears to be the disposal option of choice given that it currently appears to be the least-cost option. Burial, composting, incineration and chemical digestion are all much higher in cost and require much more time, equipment and personnel than disposal in a landfill.

### **Effect on dead stock removal service**

The combined effect of increased labor, equipment and disposal costs coupled with a decrease in revenue from loss of saleable finished product will force renderers and other dead stock collection operations to impose significant charges to producers for the removal and proper disposal of cattle mortalities. With operational costs of livestock production increasing on nearly every front, many livestock producers will turn to less appropriate methods of mortality disposal as a matter of continued survival amidst the many adverse conditions facing their industry.

Serious environmental as well as human and animal health issues will emerge as a result of inappropriate disposal practices. The incidence of human and animal diseases will almost certainly increase and a perfect environment will be created for the amplification and enhanced natural evolution of viral and bacterial diseases.

We strongly encourage FDA to examine and evaluate the data provided by the National Renderers Association in their comments as well as the data provided by Informa Economics in their report which was commissioned by NRA..

### **Summary**

FDA has been provided more than enough scientific data through the enhanced surveillance program, the Harvard Study and the National Renderers Association, among others, to assess the BSE situation as it pertains to both the United States and North America. In analyzing the information provided it is clear, based on the scientific and statistical data provided that no further regulation is required nor justified relative to the manufacturing of animal feed in the United States.

It is of the utmost importance that FDA realize the finality of the impacts that would result from the implementation of the proposed rule. When rendering service becomes unavailable in areas currently being serviced and plants cease operation in those areas as a result of the proposed rule there will be no turning back. As we witnessed in the recent Midwest blizzard, literally thousands of cattle were lost solely as a result of severe weather changes and significant snowfall. Without the rendering industry to collect and dispose of these mortalities the environmental and human health impacts, as well as the disposal challenges, of the weather related death loss in the Midwest in just the past few weeks would be disastrous.

We strongly urge FDA to reconsider its position on implementing any further changes to the current feed rule. To implement the proposed rule without a full assessment of these environmental, economic and human and animal health impacts would be disastrous.

Sincerely,

Tom L. Johnson  
General Manager