


VALLEY PROTEINS, INC.

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December 19, 2005

VIA FAX AND EMAIL

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

RE: Food and Drug Administration
Docket Number 2002N-0273
Proposed Rule: 21 CFR Part 589
Substances Prohibited from Use in Animal Food or Feed

To Whom It May Concern:

Valley Proteins and Carolina By-Products (hereinafter, "Valley Proteins") have been in the rendering business for over fifty years. We are the nation's third largest independent renderer, with facilities in ten states in the Mid-Atlantic, Southeastern, and Southwestern United States. We have over 1300 employees and provide service to approximately 50,000 customers in fifteen states. One of the invaluable and under-appreciated services we provide is the collection of dead animal carcasses from producers and livestock slaughter/process facilities. The ability to handle these animals in a safe, economically and environmentally sound manner is being put at risk due to provisions of the FDA's proposed Feed rule.

It seemed that FDA had always prided itself in utilizing sound science in the decision making process. FDA should be commended on taking immediate action in 1997, in collaboration with the rendering industry, to develop a rule that prohibits feeding ruminant materials to ruminants. This "feed ban" has been very effective, as discussed below. However, the proposal discussed herein leads one to believe that politics is winning out over science. There is no sound scientific basis to institute these new requirements, for the following reasons:

- The feed ban put in place in 1997 is working. FDA's own inspections indicate a compliance rate of over 99%.
- USDA's BSE surveillance program that has tested nearly 600,000 high-risk animals has detected only one positive animal. This particular animal was born four years before the feed ban was instituted. Careful investigation has failed to uncover the cause of this cow's infection. Further, it is our understanding that this animal did not test positive as a typical case of BSE.
- During USDA's BSE testing of 21,216 healthy animals, none tested positive.
- The specified risk materials (SRMs) on which this rule is focused are already banned from the human food chain, so the risk to human health is negligible at best.
- The report of the Harvard Center for Risk Analysis demonstrated that the potential for spread of BSE in the United States is extremely low. It is our understanding that this Risk Analysis is being updated with current surveillance data, and we would hope that FDA takes this new risk analysis into account before making this proposed rule final.

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The existing programs are working and will continue to work. There is no rational reason to add these new restrictions to the existing rule. We believe that FDA should take the following matters and consequences into account before making this proposed new rule final:

- The European experience is referenced numerous times in the document. There is no basis for comparison with Europe, as the United States government and industry took prompt action to eliminate the potential for spread of BSE to the United States.
- The implementation of this proposed rule will greatly reduce the supply of "high risk" animals available for USDA's BSE surveillance program. In recent years, Valley Proteins has charged \$35 per head to pick up and process dead cows from dairy and other operations. Since June 2004, when the USDA testing protocol went into effect, we have seen a significant increase – almost 50% in Pennsylvania alone – in the numbers of dead cows picked up by or delivered to our plants. This increase was a direct result of our ability to waive the \$35/head charge to accept these animal carcasses.
- Valley Proteins projects that the cost to pick up and process dead stock will increase to approximately \$150-\$175 per animal if the proposed rule goes into effect. Based on experience in this market for decades, we do not believe that farmers and dairymen will pay that much to dispose of their dead stock. Many remember years past when we actually paid for such carcasses because of the value of the hide and meat. We expect that, when fees go up to cover the separate processing required, most of these animals will be buried or otherwise disposed of in an environmentally unsound manner.
- As to the feasibility of handling dead stock under the proposed rule, we estimate that 65% of the dead ruminant animals we collect would not be of a quality that would allow for the effective removal of the brain and spinal column. In other words, these carcasses would be decomposing to the point that they could not be hand-processed to remove these materials.
- Valley Proteins collects and processes over 67 million pounds of ruminant dead stock per year. We project that 80% of ruminant dead stock would no longer be received due to the higher fees we would need to charge to cover the cost of separate processing lines and loss of protein sales value. Accordingly, we believe that farmers and dairymen will bury this material on the farm instead of paying such charges.
- If Valley Proteins stops running its dead stock pickup routes because it can no longer handle dead cows, we will also stop picking up other dead animals, e.g., horses, pigs, deer, etc. Our route trucks pick up more than 17 million pounds each year of these other animals as dead stock. We expect that farmers and others will simply bury all or most of these animals.
- There would be a significant disposal issue for the small packers/abattoirs we service. Spinal columns and brains from animals over 30 months of age would have to be handled and transported separately. We believe the cost of this separate service would force the supplier to dispose of this material in a landfill or other less desirable disposal method. Our survey shows landfill fees of between \$50 and \$135 per ton in our service area, if this material can be accepted at all.

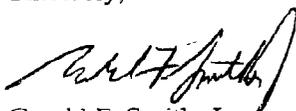
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- Our survey indicated that landfills in a number of States in our service area are unwilling or unable to accept dead cattle for disposal in any significant quantities. We found no incinerators in our service area that would accept dead cattle. Composting is not a viable option due to the nature of the material and attendant concerns over odor and disease. Thus, absent rendering, the likely disposal of dead cattle would be by on-the-farm burial or landfilling, where available. Disposal of dead cattle by rendering is the best option, although an option that effectively would be foreclosed by the proposed rule.
- Landfilling and on-the-farm burial create numerous environmental and public health concerns including odor, water contamination, and spread of disease. Landfill operators and State solid waste regulators simply are not prepared to deal with the magnitude of the disposal problem and associated adverse environmental and health problems that would be created by this proposed rule.
- We believe the burial or other improper disposal of these carcasses will lead to a broader spread of animal disease, and therefore present a much more significant animal/human health risk than BSE ever could be.

Valley Proteins believes that there is no scientific basis for putting this proposed rule into effect. There are numerous regulatory firewalls in place that adequately protect our food and feed supply from BSE. The risk of BSE in the United States is essentially zero, and the Harvard Risk Assessment demonstrates that it would not spread significantly, even if it were present. Our experience in handling large quantities of dead stock for decades tells us that farmers and dairymen will not pay fees high enough to cover our costs to process this product if the proposed rule goes into effect. Instead, these farmers and dairymen will bury all or most of their dead stock, at great cost to the environment. We believe that the environmental and economic impacts of the proposed rule greatly exceed any potential risk reduction. The United States has a system that is WORKING; let's keep it.

Sincerely,



Gerald F. Smith, Jr.
President

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