

P.O. Box 3588
Winchester, VA 22604-2586



Tele: (540) 877-2590
Fax: (540) 877-3215

December 15, 2005

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

Reference Docket Number 2002N-0273

To whom it may concern:

Valley Proteins and Carolina by Products have been in the rendering business for over fifty years. One of the invaluable and under appreciated services we provide is the pick up of dead animals from producers as well as 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 proposed rule 21 CFR part 589.

It seemed that FDA had always prided itself in utilizing sound science in the decision making process. FDA should be commended on taking a proactive stance in 1997 in collaboration with members of industry to develop a sound rule regarding feeding of ruminant materials to ruminants. This current proposed rule, which would amend the existing rule, would lead one to believe that politics is winning out over science as there is no sound scientific basis to make the proposals. For example:

- 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 4 years prior to the implementation of the existing feed ban. To our knowledge there is no evidence that this animal ever consumed feed containing ruminant proteins.

O2N-0273



C 416

- It is our understanding that this animal in question did not test as a typical positive using multiple testing methods.
- USDA's BSE testing of 21,216 healthy animals all tested negative.
- SRM's are restricted from the human food chain therefore risk to human health is negligible at best.
- Harvard Risk Analysis shows the potential for four additional BSE positive animals over a 20 year span if 10 infected animals were introduced into the market place. As this number is significantly higher than the prevailing rate in the United States one would think the actual BSE risk is virtually non-existent. It is our understanding that this Harvard Risk Analysis is being updated with current surveillance data and we would hope that FDA takes this new risk analysis into account.

In reality the existing program is working and will continue to work. There is no rational reason to add these new restrictions to the existing rule. Following are comments about this proposed rule as well as consequences we foresee if this proposed rule were to go into effect:

- The European experience is referenced numerous times in the document. There is no real comparison between Europe and US given the prevalence of BSE in the EU. There was also compensation to the rendering industry to keep processing this material to eliminate any potential environmental issues.
- The implementation of this proposed rule will greatly reduce the supply of "high risk" animals available for USDA's BSE surveillance program.
- The implementation of this new rule could significantly impact the credibility of a national animal ID system when said program is finally put into place.
- The cost to pick up dead animals would increase significantly if the current proposed rule were to go into effect. We believe that our charges would increase to approximately \$150-\$175 per animal to be able to economically pick up and process these animals. It is our belief that the producer would not pay such a charge and most of these animals would be disposed of in an environmentally unsound manner.
- It is our belief 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.
- Valley Proteins/Carolina By Products collects over 67 million pounds of ruminant dead stock per year. We believe that over 80% of this material would no longer be processed due to fees we would need to charge due to the loss of protein sales value. We believe this material would be buried on site or land filled. What will the environmental impact be?

- There is over 17 million pounds of non ruminant dead stock that might not be collected due to the expected poor economic returns for our routes if we experience the expected loss of ruminant material on these routes.
- 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 proposed rule is implemented it is highly likely that 2 of our existing plants would close. Close to 100 jobs could be at risk. A third plant would be significantly impacted and could loose over 30 jobs.
- We feel that we would loose over 4 million dollars of product value from no longer processing these animals.
- There is no scientific reason to remove the spinal column or brain from an animal under 30 months of age.
- We believe the improper disposal of these carcasses will lead to a broader spread of animal disease and therefore be a much more significant animal/human health risk than BSE ever could be.

We believe there is no scientific reason to put the proposed rule into effect. There are numerous firewalls in place that adequately protect our food and feed supply from BSE. The risk of BSE is currently miniscule. We believe that the environmental and economic impacts of the proposed rule would greatly exceed any potential risk reduction. We have a system that is WORKING; let's keep it.

Thank you



Mike Reiser
Director of Marketing
Valley Proteins
540-877-3224