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August 12, 2004

04-021ANPR
04-021ANPR-18
Gerald F. Smith, Jr.

Docket Clerk
U.S. Department of Agriculture
Food Safety and Inspection Service
300 12th Street
S.E., Room 102 Cotton Annex
Washington, DC 20250

Re: Docket No. 04-021 ANPR
Federal Measures to Mitigate BSE Risks: Considerations for Further Action

To Whom It May Concern:

This letter is in reference to Docket No. 04-021 ANPR the agency's advance notice of proposed rulemaking (ANPR) and the invitation to comment on federal measures to mitigate BSE risks: Considerations for further action.

Valley Proteins, Inc. is one of the nation's largest non-captive recyclers of animal by-products and waste cooking oils with facilities located in 10 states. We process approximately 65 million pounds per week of these waste materials or about 7% of the total U.S. supply, and we provide service to over 40,000 meat and poultry processing plants, supermarkets, restaurants and farmers located in 17 states.

Before addressing the individual questions posed by the various agencies, we wish to first point out that animal by-products have been recycled into feed ingredients in the United States on a commercial basis for over 100 years. These recycled by-products were fed legally to ruminant animals throughout those 100 years until June 5, 1997 when the current feed rule was enacted by the FDA on June 5, 1997 with the full support of the U.S. Rendering Industry. We further wish to point out that it has been illegal to feed ruminant animals any ruminant based by-products including Specified Risk Materials (SRMs) for the past seven years, and that FDA's own inspection efforts in this regard indicate a compliance rate of over 99% by the rendering and feed industries. The underlining concept of the majority of these questions is whether SRMs should be removed from any or all animal feeds in the United States. The apparent reason for addressing SRM removal from feeds relates to two incidences of BSE in North America over the past 15 months. There has been no scientific evidence, only conjecture, to prove that either of these animals was ever fed prion infected animal by-products either legally prior to June 5, 1997 or illegally subsequent to that date. In fact, in order for these animals to have been exposed to BSE infectivity through animal feed, such disease would have had to exist in Canada in the first half of 1997 and prior. If this were the case, it is very difficult to believe that surveillance testing in both the U.S. and Canada would not have detected this disease much earlier than the year 2003.

USDA's International Review Team (IRT) formed in response to the U.S. BSE incident suggested a significantly increased surveillance effort to determine the underlining level of BSE within the U.S. cattle population. Starting June 1, 2004, USDA-APHIS commenced such a plan. We feel that based on the test results received thus far that no changes to June 5, 1997 feed rule are scientifically justified at this time. **We ask FDA and USDA to delay any contemplated changes to existing U.S. regulations in this regard until this enhanced BSE surveillance plan is completed proving whether BSE is in our cattle population or not and, if so, at what level.** The removal of SRM's and the significant cost

burden on all members of animal agriculture cannot be justified unless there is a significant level of BSE in the U.S. cattle population.

The following are our responses to each of the questions addressed by agencies:

2. What data or scientific information is available to evaluate the IRT recommendation described above, including that aspect of the recommendation concerning what portion of the intestines should be removed to prevent potentially infective material from entering the human food and animal feed chains?

There is no scientific basis for removing the brain, spinal cord, scull and vertebral column of cattle under the age of 30 months or more than the distal ileum from cattle over six months of age. While it is important to err on the side of caution, such regulations in this regard need to be based on the best scientific evidence available. BSE surveillance testing to date indicates virtually no BSE infectivity exists in the U.S. so removal of even the distal ileum does not appear warranted since rendered animal proteins containing this material cannot legally be fed to cattle and other ruminants. The cost of producing all meats in the United States will be increased substantially if these additional by-products are removed from the animal feed chains with only a slight reduction in risk exposure.

26. How can training and educational materials be designed or improved to meet the needs of multiple audiences with variable levels of scientific training?

No comment.

27. How can the Federal Government increase access to these materials?

No Comment

32. What measures are necessary to prevent cross contamination between carcasses?

No comment

33. In establishments that predominantly slaughter cattle 30 months of age and older. Are additional sanitation requirements necessary to prevent edible portions of carcasses from being contaminated with SRMs?

No comment.

34. Should FSIS provide an exemption for "BSE free" countries or countries with some other low-risk BSE designation?

So long as such designation was determined on a scientifically defensible basis consistent with the classification of the United States in the framework of the OIE guidelines, it would be acceptable to provide such designations. We believe that trade will only resume between countries which have experienced BSE incidences if all countries base their regulations on scientifically determined parameters and discontinue using BSE as an economically driven trade barrier.

35. If FSIS were to exempt "BSE free" countries from the provisions of the SRM rule, what standards should the Agency apply to determine a country's BSE status?

The agency should reference both OIE guidelines and U.S. regulations in determining internal classifications of BSE status. Countries granted "BSE Free" status by the U.S. must have acceptable and adequately enforced animal feed regulations, BSE surveillance programs and BSE reporting requirements. Obviously, the US government needs to lobby the OIE to be certain that OIE's BSE classification standards are determined by scientific based parameters.

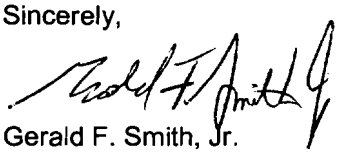
36. How would FSIS determine that country meets such standards? For example, should it rely on third party evaluations, such as the OIE, or conduct its own evaluation?

FSIS would need to make these determinations for countries which wish to export to the United States. Such determination would need to be made by indexing scientifically determined parameters based on OIE guidelines and U.S. regulations. Third party firms contracted for by FSIS could be used for this purpose.

In closing, we wish to thank the Agency for the opportunity to provide comments in this regard and for the responsible manner in which the agencies have dealt with the recent BSE incident in the United States. We believe that these efforts have provided adequate and reassuring information to the U.S. consumer and to our overseas trading partners. We, however, encourage the agencies to delay any further regulations until we have a clearer picture of whether or not we have BSE in the United States and at what level, and we are certain the agencies can comfortably wait for these results since we have an excellent program for keeping potentially prion infected by-products from our ruminant animals.

On behalf of our over 1,300 employees and 40,000 by-products suppliers we thank you for this opportunity to comment on the ANPR.

Sincerely,



Gerald F. Smith, Jr.
President

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