



1014 10 10 11 11 11
January 28, 2003

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

Dear Sir or Madam:

Baker Commodities Inc., is a family owned and operated business, and a recognized leader in the production of top quality fats and proteins for over 50 years. The company is a diversified rendering company with multiple locations throughout the United States, serving both the domestic and international markets. The company has an inherent interest in biosecurity and food safety, supports research, and has a progressive agenda to assist sustainable agriculture in the country, an objective of the incumbent administration. As such, the company has a definite interest in any proposed regulatory initiatives that could impact the rendering industry, and takes the opportunity to address Docket No. 02N-0273, an Advance Notice of Proposed Rulemaking (ANPR), in which the agency is soliciting information, comments and opinions on potential changes to its existing rule: "Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed" with special pertinence to five specific questions posed by the agency.

The agency identified the five issues in a question format as of special relevance to the ANPR:

1. Excluding Brain and Spinal Cord From Rendered Animal Products
2. Use of Poultry Litter in Cattle feed
3. Use of Pet Food in Ruminant Feed
4. Preventing Cross Contamination
5. Eliminating the Plate Waste Exemption

Baker Commodities has and continues to support the current scientifically based animal feeding regulations that restrict the use of certain animal proteins derived from mammalian tissues (with the current exemptions) for use in ruminant feed. The company has, by tradition and practice, pursued conservative measures to preclude hazards that could contribute to any potential for disease transmission from the production cycle, and has spent considerable sums of money in training and education of personnel to enhance these objectives. But, a careful scientific analysis of the facts suggests that no regulatory changes or modifications are warranted at this time. The following reasons support the company's recommendations:

02N-0273

C 37

1. The Food and Drug Administration (FDA) in 1997 adopted the current feed restrictions based on a review of industry practices and sound science. Baker Commodities is of the opinion that the existing animal feed regulations are appropriate given the minute level of potential risk for an outbreak of BSE in the United States.
2. All the current indications, based on the government's own inspection audits and monitoring programs, demonstrate that in spite of extensive testing that exceeds the international standards recommended by the Office Internationale des Epizooties (OIE), the world organization for animal health, the United States is still free of bovine spongiform encephalopathy (BSE). To heighten this analogy, be advised, under the international standard, a BSE-free country like the United States would be required to test only 433 head of cattle per year. The USDA is now testing 41 times that amount.
3. FDA's oversight of the BSE feed rule (21 CFR 589.2000) indicates a 99.2 percent compliance rate. This is most likely the highest conformance for compliance in the history of the agency.
4. The U.S. BSE prevention strategy has been developed to include multiple programs commonly described as a "triple firewall" approach with the major goals of (a) a ban on the importation of cattle and beef products from countries with BSE; (b) a statistically sound program to monitor for the presence of the disease, heightening risk-based epidemiology in the process; and (c) ruminant feeding restrictions that are in place and constitute the core of the feed rule.
5. Prior to the Harvard University Center for Risk Analysis findings that the "U.S. is highly resistant to an introduction of BSE or a similar disease," the agency's own internal risk assessment audits done as early as 1997, parallels the findings of the Harvard analysts. Be informed, many reputable epidemiologists in this country and extern to the country, consider the Harvard BSE risk assessment, the "gold standard" and probably the most comprehensive study of an animal disease and the risk factors associated with it, ever studied.
6. Baker Commodities is equally convinced that in the absence of any changes in the present risk factors that could contribute to a disease outbreak, the rigorous enforcement of the existing rule, including the excellent compliance by the industry, will result in a far greater reduction of risk than all of the proposed changes in the ANPR.
7. Change or modification of an existing rule/regulation should only be considered when there is convincing new evidence, validated and affirmed by science, that a change is definitely indicated.

While as a company, we commend the government's proactive preventive approach to control this serious and enigmatic disease, nonetheless, it must be clearly recognized that the success of our country's prevention and control initiatives was a clear demonstration of all involved sectors working together collaboratively to keep this complex disease, with its public health implications, from gaining a foothold in the United States. In reality, we have been doing this successfully for over 16 years, and currently, with all the instituted controls, we can safely say that the country today has the lowest level of risk

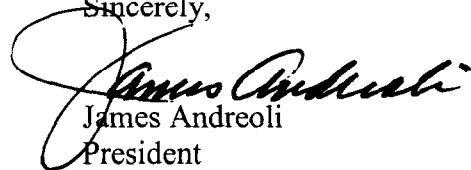
factors since the disease was first reported in the United Kingdom in 1986. This fact should be celebrated as a great achievement by the government to counter the constant doubts and lingering concerns of those that seek zero risk.

Baker Commodities, nonetheless, recognizes that BSE is a challenging disease, and complements the agency for its continuing examination of options, however, as a company, we feel that approximately 6 years since the rule has been in place, the process is working well based on the agency's own official compliance findings, and the rendering industry's own third party inspection audits. We recommit our resources to work diligently with the agency to ensure compliance, but see absolutely no need for any modifications or changes of the present rule, unless as alluded to earlier, new risk factors are clearly identified that will dictate otherwise. In fact, we feel that change of the rule in any manner will serve to create unnecessary uncertainty in a country that has no evidence of the disease.

We appreciate this opportunity to comment as a company, and summarize by stating for emphasis, that all the instituted controls in our country since 1987, and a rule in place since 1997, there is a time for the government to consider closure.

If our company can be a resource, or serve in any way to assist in the examination of objective options to heighten biosecurity of feed ingredients and feed, you can be assured of our commitment to be actively involved.

Sincerely,



James Andreoli
President