TAB 34

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Ag Innovations LLC

Statement before the

Food and Drug Administration Public Hearing

On BSE Prevention Strategies

Substances Prohibited From Use In Animal Food or Feed
Animal Proteins Prohibited in Ruminant Feed

October 30, 2001

Westin Crown Center Hotel, Kansas City, MO

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We appreciate the opportunity to present this statement regarding the Food and Drug Administration's regulations on animal feeding that were established to prevent the entry of bovine spongiform encephalopathy (BSE) in the United States.

I am Mike Malecha, President of Ag Innovations LLC in Madison, WI. As consultants to the Food, Feed, and Industrial Agricultural industry, our main focus is to work with client Companies to effectively manage their coproducts to greater value, both economically and environmentally. Maintaining feed and food safety is paramount in the fulfillment of our responsibilities. As an active member of the Feed Industry, I currently serve on the Board of Directors, chair the Feed Trade Rules Subcommittee, and serve on the Feed Industry Committee, of the National Grain and Feed Association. I recently served as a member of the Liquid Feed Committee of the AFIA. During my 26 years in the Food and Feed Industry, I have most recently spent over eleven years at Kraft Foods, North America as Manager of Byproducts and Feed ingredients. Prior to Kraft I managed ingredient purchasing for Ralston Purina Company in their Petfood and Grain Divisions for nearly ten years.

To start out, it is important to reiterate that there has not been a single case of BSE found in the United States. Due to active surveillance by the FDA and USDA and strong industry support by the feed manufacturers, livestock producers, meat processors, transportation industry, food manufacturers and purveyors, veterinarians, and trade groups, the science based regulations currently in force have facilitated the goal of keeping BSE from entering our country.

The FDA should be commended for their leadership in the prevention of BSE and for being the linchpin in the protection of our food and feed supply. The establishment and enforcement of the three firewalls- the import ban, the prohibition on feeding specified mammalian proteins to ruminants, and an aggressive inspection and surveillance system- has provided a sound strategy in that effort.

We strongly believe that the FDA must continue to base its position on sound science as

We move forward. As new scientific information is confirmed, the strategy should be adjusted to accommodate it. It is vitally important that the FDA maintains its high standards and the reputation as the lead agency in food safety in the United States and the entire world. Because of that leadership and the support of the entire food industry, the public will continue to enjoy the safest food supply possible. To continue in those efforts, we recommend that the FDA should maintain the program of direct inspection. By providing the necessary resources and enlisting the support of the State Feed Control Agencies to inspect feed facilities and transportation concerns the regulatory task can be accomplished. It is our view that affidavits of compliance, and bonified third party inspections, as APPI has undertaken, are affective measures as long as there is definite periodic inspection by FDA or their State designate. To allow certification by not-so independent arms of organizations, take the place of FDA driven inspection would undermine the confidence and support of the Food Industry and the public at large, and would damage the reputation that the FDA currently enjoys. These latter certifications, while certainly providing augmentation to company best management practices, are viewed by much of the food industry as not independent enough, and as possibly anti-competitive in nature due to their cost. The entire Food and Feed industry must be unified and stand behind the FDA in the BSE prevention effort. A strong science based FDA ads credibility to the Food And Feed industry in the global economy as well.

In response to the questions that were posed by FDA in the Federal Register on October 5, 2001, we have the following responses.

Question 1,

To improve compliance with the rule we recommend that the FDA and the State Agencies forge a strong inspection and compliance program that is driven by a tracking system from initial source to the ultimate user. By using the trace-forward approach, a targeted inspection program can be implemented in an effective and efficient manner to best deliver the necessary feed safety. It is vitally important that adequate funding be provided by congress to carryout the strategies to meet full compliance with the rule!

Question 2,

Regarding the present rule and its objectives, we believe that the current rule is satisfactory as written.

Question 4,

The issue of dedicated facilities should be left to the individual companies to decide, based on their ability to manage the process. As a recommended best management practice, separate facilities, or fully separate systems would be preferred, but the ultimate decision should rest with the individual business. To require separate facilities would be anti-competitive and could be financially detrimental for some concerns.

Question 5,

The transportation method should be left up to the shipper and receiver to decide, provided best management practices are employed to comply with the rule. To restrict shipments to dedicated conveyances would be extremely costly, and lead to unnecessary overcapacity, and/or significant delays in service.

Questions 7&8,

We do not believe that the FDA should change or revoke any of the exclusions to the current rule nor should the agency add to the list of prohibitive materials, unless there is compelling science-based evidence to do so.

Question 10,

The record-keeping requirement is satisfactory at one year, provided a complete trace-back process is in place.

Questions 11&12,

Regarding labeling, the protein-containing feed label should not be required to list the specific type of mammal that the feed is from, nor include in the caution statement the additional names of specific species of animals that it should be restricted from. There is