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Dec 14, 2005

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

Re: Docket No. 2002N-0273, Substances Prohibited From use in Animal Food or Feed

To Whom It May Concern:

This letter is in reference to FDA's Docket No. 2002N-0273, the agency's proposed rule and the invitation to comment on substances prohibited from use in animal food or feed.

Central Bi-Products is the largest rendering company in the State of Minnesota with plants located in Redwood Falls and Long Prairie. We provide rendering service to three cow slaughtering plants, killing animals over 30 months of age, over a thousand locker plants that are not USDA inspected, and farm pick-up of mortalities. The FDA proposed rule 21 CFR Part 589 will create an extreme hardship for these customers and Central Bi-Products.

Cow Slaughter plants will have 3,500,000 pounds of brains and spinal cords that we will not allow into our rendering plants based upon current understanding of the proposed rule and facility compliance. This material will most likely go to land fills.

Locker plants in our service area will have over 20 million pounds of material that could potentially be land filled.

On farm mortalities create the largest problem. Central Bi-Products provides removal service to Minnesota, Eastern South Dakota and SE North Dakota. If the rule becomes law, Central Bi-Products will be forced to discontinue dead stock pick-up of all bovine animals leaving the farmers and ranchers in excess of 35,000,000 pound of animals that will be disposed of by land fills, burial, dumping into creeks and rivers, or what ever means can be used to make these animals disappear. In addition this loss of material and revenue to contract haulers would most likely eliminate economic pick-up for porcine mortalities as well. Our analysis shows that the only routes that would continue to exist would be those serving commercial feedlots. This would result in the elimination of 24 contract hauler positions and present another financial burden to the family farm. Central Bi-Products would become an independent packer/renderer with this law.

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The states served by our company would lose the important disease control and monitoring service that we have provided to state and federal agencies over the past twenty-six years. We have served USDA and state veterinary services with disease reporting and control, including the service our company provided as part of the BSE surveillance program.

The USDA has tested 530,000 animals for BSE with only one positive case. We do not have a health concern from BSE. Firewalls are in place to assure that ruminant by-products are not feed back to ruminants. The FDA rule is not needed to protect our beef supply, moreover it will create a large economic loss to the industry and create a situation with dead rotting animals and animal parts be disposed of in unsafe ways. We could potentially be creating a breeding ground for many other diseases that are more deadly than BSE. Furthermore, if we do have a positive BSE animal that is buried or allowed to rot and be scavenged be wild animals do we not provide a path for unwanted spread of the prion. What will future generations think of the FDA if we allow this to happen. We disagree with the conclusion that further action proposed in the rule is necessary, urge the FDA to seriously consider comments from the National Renderers Association (NRA) and the 2005 Rendering Industry Study by Informa Economics, and urge the agency to do in-depth economic and environmental impact studies, based on current and representative data, before formalizing the proposed rule.

We continue to support scientifically based animal feeding regulations to restrict the use of certain animal proteins derived from mammalian tissues used in ruminant feeds. We agree that animal feed regulations need to be reviewed from time-to-time if new risks are identified or new, relevant science is brought to light. However, we agree with the NRA analysis of the facts and believe FDA's preliminary conclusion to remove cattle brains and spinal cord and rendered dead animals from all animal feed is not warranted and this action aimed at removing a very minute risk from BSE will increase risks from other diseases, cause environmental degradation, and cost much more than can be justified.

The 1997 feed rule is working and compliance is extremely high. The USDA enhanced surveillance testing program found only one indigenous cow tested positive for BSE out of more than 534,879 surveillance samples from high risk groups over the past 15 months showing the incidence of BSE in the U.S. to be near zero. The National Cattleman's Beef Association estimates an infection rate in the U.S. of one in more than 18 million cattle over 30 months of age—for all practical purposes it is statistically zero.

Applying the same rules as recommended in Europe is nonsense. The incidence in the U.S. is at least 500 fold lower than in the EU. The U.S. instituted preventive measures long before Europe, and the early action assured the infection was never established here. It is also worth noting that the rendering industry in Europe is heavily subsidized so that prohibited materials are picked up and processed avoiding a massive disposal problem.

We agree with NRA's statement that the feasibility of removing brains and spinal cords from dead stock is very low except under the best conditions of weather, climate, distance between production and rendering locations, age, size, and condition of cattle, worker

skill, and equipment and technology. Renderers will be forced to charge higher collection fees to cover the increased costs of material disposal, processing, and lost product revenues or end the practice of collecting dead cattle altogether. The magnitude of the disposal problem the proposed rule would cause is much larger than FDA estimates.

FDA describes the primary benefit of the proposed rule as "elimination of the vast majority of the risk of spreading BSE to other cattle from intentional or unintentional use of non-ruminant feed for ruminants or cross-contamination of ruminant feed with non-ruminant feed or ingredients intended for non-ruminant feed." The risks eliminated by the proposal are likely much smaller than the future risks of burying carcasses and disease agents on the farm at best, and more inappropriate methods at worse.

If the FDA requires dedicated facilities, equipment, storage, and transportation equipment to handle prohibited cattle materials, it may not be economically feasible for renderers to continue processing such material. It would be more likely for this material to be deposited in landfills, resulting in increased environmental exposure because of the high biological load of this material in its unprocessed state.

In summary, we believe this action aimed at removing a very minute risk from BSE will increase risks from other diseases, cause environmental degradation, and cost much more than can be justified—for renderers, producers, processors, and society. We urge the FDA to take no further action to add restrictions to the 1997 feed rule.

Respectfully submitted by:

Charles Neece
Director: Research and Development
Farmers Union Industries
Central Bi-Products, div.