

January 13, 2003

138

02N-0273 176

Dockets Management Branch  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20852

Re: Docket No. 02N-0273 – Substances Prohibited From Use In Animal Food Or Feed;  
Animal Proteins Prohibited In Ruminant Feed; Advanced Notice Of Proposed  
Rulemaking

Dear Sir/Madam:

The undersigned organizations representing a coalition of the nation's animal producers, feed and ingredient manufacturers, meat processors and animal care providers offer these comments to the above-referenced notice. Our organizations have and continue to support the current scientifically based animal feeding regulations that restrict the use of certain animal proteins derived from mammalian tissues for use in ruminant feed. A careful analysis of the facts suggests no regulatory changes are warranted at this time.

FDA in 1997 adopted the current feed restrictions based on sound science and review of industry practices. We believe the existing FDA animal feed regulations are appropriate given the low level of risk that BSE will occur in the U.S. Our goal is not to change the regulations, but to achieve 100 percent compliance with the existing regulations. According to FDA, compliance with the BSE feed rule (21 C.F.R. § 589.2000) has been excellent. In fact, the coalition is unaware of any other FDA rule or program even approaching a near 100 percent compliance rate.

BSE prevention in the U.S. involves multiple programs that can best be described as a "triple firewall" strategy. This includes: (1) a ban on the importation of ruminants and ruminant products from countries with BSE; (2) a statistically sound and comprehensive animal surveillance program to continually monitor for the presence of the disease; and (3) ruminant feeding restrictions to prevent the amplification and spread of the infective agent in the unlikely event BSE occurs in our domestic cattle. The current BSE feed rule, as part of this triple firewall strategy, is more than adequate to meet the objectives stated in the preamble to the final rule.

In fact, several scientific studies have confirmed the fundamental soundness of the government's approach and indicated our nation's risk is extremely low. Neither current science nor the current excellent compliance rate supports an expansion of the rule at this time. The

02N-0273

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coalition agrees the rule needs to be reviewed from time-to-time and applauds the agency's efforts to do so by conducting a public hearing on October 30, 2001 and publishing its Advanced Notice of Proposed Rulemaking (ANPR) on November 6, 2002. An occasional review of the rule will serve to strengthen it, if new risks are identified or new, relevant science is brought to light. However, no new risks or science support the proposed changes set forth in the ANPR. In fact, as the Harvard BSE Risk Assessment indicated, if BSE were to occur in the United States, the disease would not be able to sustain itself because of the current measures in place. Not only would the proposed changes have no appreciable effect on the risk of BSE occurring or proliferating in the U.S., the proposed changes would likely take away valuable resources that are needed to ensure full compliance with the current rules in place.

Rigorous enforcement of the current feed rule will result in greater risk reduction than any or all of the proposed changes discussed in the ANPR. To that end, we urge the agency to continue to educate the regulated industries about the rule, continue active surveillance, assure compliance if violations are discovered, take vigorous enforcement actions against violators and continue the agency's cooperation and support of state inspection programs.

The coalition believes FDA has been diligent in carrying out its responsibilities to reduce, as much as possible, the risk of BSE being introduced and amplified in the U.S. Our risk of BSE in domestic cattle is not zero, nor can it ever be, but our risk today is the lowest it has ever been since the disease was first recognized as a threat to the U.S. cattle population. We pledge our continuing commitment to a goal of 100 percent compliance and assuring that federal and state agencies have the necessary resources to achieve that goal.

We thank the agency for the opportunity to submit these comments and for the agency's consideration of them. Individual trade associations will offer additional comments on issues relevant to their members.

Sincerely,

American Farm Bureau Federation  
American Feed Industry Association  
American Meat Institute  
American Sheep Industry Association  
Fats and Proteins Research Foundation  
National Cattlemen's Beef Association  
National Chicken Council  
National Grain and Feed Association  
National Institute for Animal Agriculture  
National Milk Producers Federation  
National Meat Association  
National Pork Producers Council  
National Renderers Association  
National Turkey Federation  
Pet Food Institute