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IMMEDIATE PAST PRESIDENT

ROBERT E. FROST

Division of Dockets Management (HFA 305)
Docket #2004N-0264
Food and Drug Administration
5630 Fisher Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 2004N-0264, Federal Measures to Mitigate BSE Risk:
Considerations for Further Action

Dear Sir/Madam:

These comments are submitted on behalf of the United States Animal Health Association (USAHA) in reference to the Food and Drug Administration (FDA) advanced notice of proposed rule making (ANPRM) (Docket No. 2004N-0264) Federal Measures to Mitigate BSE Risks: Consideration for Further Action

USAHA is a 108 year-old science based, dues supported, voluntary national organization of state and federal animal health agencies and other governmental departments, animal agriculture industries, university animal scientists, and veterinary laboratory diagnosticians that addresses issues of food safety, animal health and disease control, homeland security, animal welfare and public health.

The Association serves as a clearinghouse for new information and methods that may be incorporated into laws, regulations, policy and programs. It acts to develop solutions to animal health and food safety issues based on science, new information and methods, public policy, risk/benefits analysis and the ability to develop consensus for changing law, regulations, policies and programs.

The USAHA is concerned that requests by several groups that are members of USAHA for extension of the comment period have been denied. We believe that FDA will not receive in-depth comments on this advanced notice with the limited time allowed especially in areas of concern with our rendering industry, the other providers of service for disabled, downer, diseased or dead cattle (4-D establishments) and the cattle industry, especially dealing with economic and environmental data and with our scientific and diagnostic community dealing with disease surveillance. We urge the agency to allow a 90-day comment period for comments to any proposed complex regulations.

2004N-0264

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The USAHA commends FDA for taking a very aggressive regulatory compliance position towards the current ruminant feed ban. We believe there has been no FDA rule with a higher level of compliance than this feed rule and applaud the agency's continuing education and compliance effort. The USAHA is committed to support the agency's effort to enforce the current ruminant feed ban.

The USAHA strongly supports the effort of USDA's enhanced BSE surveillance plan that started June 1, 2004 and is concerned about FDA's rush to propose changes without the benefit of the 18 month enhanced surveillance study that relies heavily on renderers, 3 D and 4 D establishments for samples. Canada's heightened enhanced BSE surveillance efforts began soon after the discovery of a native born BSE case in Canada in May 2002 and results to date have found no further cases of this disease in that country. **The USAHA believes that any additional mitigation measures must be based on sound science and a clear need determined from a comprehensive risk/benefit analysis before additional FDA actions are proposed.** This action would follow the recommendations of the International Review Team (IRT) commissioned by USDA following the discovery of the Washington State BSE case in a Canadian born dairy cow in December 23, 2003. The IRT stressed the importance of enhanced surveillance in high risk animals (4-D) of the U.S. cattle population to determine what other controls would be necessary based on the enhanced surveillance results. FDA's proposed SRM ban will seriously harm efforts to get that data. The FDA's proposed all-SRM ban looks at reducing an already miniscule risk further at tremendous cost to industry and disease surveillance. It is estimated that over \$2 billion will be lost to revenue of the cattle producer and industry, downstream lost revenue and disposal cost. Both the National Renderers Association's Sparks Companies 2001 report: The Rendering Industry: Economic Impact of Future Feeding Regulations and the Harvard-Tuskegee Risk Model Study have abundant economic and risk analysis data at a fraction of the costs that an all-SRM ban would generate. The approaches include some controls suggested by FDA in the January 26, 2004 announcement, such as dedicated feed mills and equipment, registration of all handlers/distributors of prohibited mammalian protein and third party certification of those farms and consideration for banning poultry litter.

The following USAHA responses are provided to certain specific questions posed in the proposed rule.

1: Would there be value in establishing a specialized advisory committee or standing subcommittee on BSE? The USAHA's structure; representing federal/state government agencies, academia, animal industry organizations, and veterinary diagnostic laboratories and the development of committees to work on several diseases, eg, brucellosis, tuberculosis, pseudorabies, pullorum disease, etc. that constantly advises agencies on programs would be an excellent forum for a BSE committee. The committees work at several levels; technical, producer/management and scientific levels. All regulatory diseases require review and must be dynamic to meet scientific advances and management change.

3. What information, especially scientific data, is available to support or refute the assertion that removing SRM's from all animal feed is necessary to effectively reduce the risks of cross contamination of ruminant feed or of feeding errors on the farm? What information is available on the occurrence of on-farm feeding errors or cross-contamination of ruminant feed with prohibited material? The USAHA is aware that there is on-going review of on-farm practice by USDA's APHIS and the Harvard Center for Risk Analysis. These on farm interviews will provide data to answer these questions. FDA's own inspection data indicates violations are low. Inspections of facilities are limited and the agency needs to increase their field force or use other federal or state or private agencies to increase education, inspection, review and provide data of cross contamination.

7. What would be the economical and environmental impacts of prohibiting SRM's from use in all animal feed? The USAHA feels that FDA must conduct a risk assessment and economic cost/benefit analysis of the impact of removing all Specified Risk Material (SRM) from the animal feed supply. We feel that their action will create significant economic problems throughout the entire feed, rendering, livestock and extended industries. The resulting disposal of SRM's and 4-D animals will pose significant environmental impacts without an extensive government plan and support for safe and significant disposal options and the availability of these animals for diagnostic surveillance of BSE and other diseases. Unless removal of all SRM's can show significant reduction of future BSE infectivity risk to our nation's cattle population from the level of risk now present under the current ruminant protein feed ban, USAHA believes such significant economic disruptions would not be justified. USAHA would encourage FDA to propose a number of the risk reduction alternatives as suggested in the Harvard Risk Assessment Model. Such an approach would permit the industries to comment on what alternatives might provide the greatest risk reduction at the lowest cost. Any mitigations resulting in economic and environmental disruption to the affected industry sections need appropriate government and public support which might be necessary to develop or address various SRM and animal protein utilization alternatives such as bioenergy.

9. What information, especially scientific data, is available to show that dedicated facilities, equipment, storage, and transportation are necessary to ensure that cross contamination is prevented? If FDA were to prohibit SRM's from being used in animal feed, would there be a need to require dedicated facilities, equipment, storage and transportation? If so, what would be the scientific basis for such a prohibition? The USAHA would prefer requiring dedicated facilities and equipment in lieu of a SRM ban. The FDA needs to develop a risk reduction model based on the agency inspection experience on cross contamination. This current data is limited, but indicates very good industry compliance.

12,13,14. Questions concerning banning all mammalian and avian MBM in ruminant feed. USAHA is unaware of any data to justify such a ban. FDA was not concerned in both its 1997 final rule preamble and its 1998 video teleconference proceeding about all mammalian and avian MBM in ruminant feed.

15. Is there scientific evidence to show that the use of bovine blood or blood products in feed poses a risk of BSE transmission in cattle and other ruminants? There is no scientific evidence that demonstrates that the use of bovine blood or blood products in feed poses a risk of BSE transmission on cattle and other ruminants. The USAHA is aware of transmission of BSE in sheep via a large quantity of blood transfused from an experimentally infected sheep; also of the two suspected human cases of vCJD possibly transmitted through blood transfusion. We have not found reported evidence that BSE can be transferred to cattle through transfusion of blood or blood products or through feeding of blood or blood products. The observations of scientists believe there is a difference in the pathogenesis of the disease in different species; sheep infected orally with BSE show widespread deposition of prions in the lymphoreticular system (LRS), similar to vCJD human patients, whereas in cases of human CJD and cattle BSE, peripheral pathogenesis does not appear to involve the LRS (Hunter et al).¹

¹ Hunter N, et al Transmission of prion diseases by blood transfusion, Journal of General Virology (2002): 83,2897-2905

The European Commission Scientific Steering Committee (SSC) has never implicated bovine blood in bovine-to-bovine transmission of either natural or experimental BSE. The Harvard-Tuskegee Risk Assessment demonstrates that feeding bovine blood will not spread BSE in cattle populations. The banning of air injection stunning during slaughter of cattle has eliminated the risk of neural embolic material being disseminated in blood or tissue. Bovine blood products are fed orally and oral consumption is the least effective method of transmission of BSE. Bovine blood products are collected only from cattle that pass USDA antemortem inspection. The Office International Epizootics (OIE) and WHO classify bovine blood and plasma with tissues indicating no detected infectivity. The IRT did not recommend removal of current feeding exemption for bovine blood or blood products. The USAHA believe there is no scientific evidence to show that the use of bovine blood or blood products in feed pose a risk of BSE transmission in cattle and other ruminants. The USAHA is also concerned that blood products utilized in milk and colostrum replacers not lose their current exemption under the Mammalian to Ruminant Feed Ban 21 CFR589.2000. These products play an important role in the control of Johne's disease and other enteric, and neonatal infections in the newborn calf.

22. What would be the economic and environmental impact of prohibiting materials from dead stock and non-ambulatory cattle from use in all animal feed? The USAHA is very concerned that if the above material is banned from all animal feed without a comprehensive plan being developed for the disposal and utilization of both banned SRM's and dead stock, the rendering industry and 3-D and 4-D establishments will have no economic incentive to continue SRM and dead stock processing. **It is paramount that FDA and USDA cooperate with industry to develop a comprehensive national 4-D and SRM disposal and utilization plan that will provide the necessary economic incentive for producers to submit 4-D animals for animal health monitoring and surveillance purposes and provide for the development of alternative market outlets for such rendered material if it is banned in all animal feed.**

24. When and under what circumstances should the recently announced National Animal Identification System (NAIS) transition from voluntary to mandatory? The USAHA support the recommendations of the U.S. Animal Identification Plan (USAIP) Cattle Species Working Group which requested to develop recommendations for implementation of a national animal identification program capable of tracking all animal movement within 48 hours of an animal health event or emergency. A "critical mass" level of participation in order to assure successful trace back of any diseased animal within 48 hours should be set and monitored by state animal health agencies and USDA/APHIS. This will be determined in an initial voluntary phase. USDA should be prepared to fund the implementation of a required animal identification program in 2007.

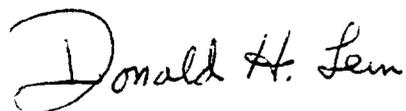
25. What species should be covered, both initially and in the longer term? The USAHA would recommend that all cloven-hoofed species of livestock used for food purposes be included initially in NAIS by 2007. These are species that are most capable of spreading a highly contagious foreign animal disease such as Foot and Mouth Disease. The USAHA would recommend that all species of livestock, including pleasure and recreation species, be required to meet NAIS requirements within the next 5 years.

28. Should FDA include exemptions to any new requirements to take into account the future development of new technologies or test methods that would establish that feed does not present a risk of BSE to ruminants? The USAHA fully supports this approach as is now practiced in the current BSE feed rule. This is an excellent example of use of a standing committee on BSE discussed in Question 1.

34,35,36. Questions related to issues of equivalence. The USAHA recommends that FSIS and FDA not exempt foreign countries from any provisions of the SRM rule that might be adopted in the U.S., regardless of the "BSE Status" claimed by the exporting country. The OIE plan for BSE control and trade issues should be studied and followed.

The USAHA appreciates the opportunity to submit these comments to FDA on this advanced notice of proposed rule making. We offer our service to form a BSE committee similar to several of our other disease committees to work with federal and state agencies, industry and scientific community concerning the national BSE program. If we can be of additional assistance, please contact us.

Sincerely,



Donald H. Lein, DVM, PhD
President, United States Animal Health Association