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Docket No. 2004N-0264
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061 Rockville, MD 20852

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

To Whom It May Concern:

The undersigned organizations, representing U.S. poultry and egg producers, and food, feed and ingredient processors and manufacturers, offer the following comments regarding the Federal Measures to Mitigate BSE Risks: Considerations for Further Action, Docket No. 2004N-0264.

Our organizations have worked, in conjunction with federal agencies, to ensure this country's animal feeding regulations are based upon the best scientific research that has been conducted. Over the years, numerous firewalls have been created to prevent the introduction and spread of the BSE infective agent into both the animal and human food chains, providing redundant levels of protection for both animal and public health.

FDA SHOULD USE APPROPRIATE AND CONCLUSIVE SCIENTIFIC DATA FOR POLICY DECISIONS

The FDA advance notice of proposed rulemaking (ANPR) indicates a significant shift in philosophy, from a policy based on comprehensive scientific research, to one that is precautionary and not based exclusively on science. Although we have and will continue to share FDA's goal of controlling the BSE risk within the US, we are concerned by the lack of supporting information for the proposed BSE mitigation measures in the ANPR. This lack of scientific justification is evidenced by the broad range and number of questions posed in the ANPR. Prior to enacting any additional control policies, FDA should gather the appropriate data through research, expert panels/advisory committees, and surveillance programs.

ANY FUTURE POLICY ACTIONS SHOULD CONSIDER THE CURRENT FEED BAN AND ITS COMPLIANCE STATUS

The current feed restrictions, adopted by FDA in 1997, restrict the feeding of ruminant products back to ruminants to prevent the spread and replication of the BSE infective agent in the U.S. herd. This firewall has been a success, as feed mills and renderers have overwhelmingly adhered to this scientifically justified restriction, which has been demonstrated in FDACVM updates. The most recent report, published July 29, 2004, indicates that 99.4% of all firms inspected by FDA received either a Voluntary Action Indicated (VAI) or No Action Indicated (NAI). The inspection reports demonstrate industry's commitment to comply with justifiable

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regulation. More importantly, they display the strong partnership between industry and regulatory agencies to prevent and control the introduction and spread of BSE in the US domestic herd.

The agency's ANPR refers to the risk-reduction level found by the Harvard-Tuskegee "Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States." The risk assessment demonstrates an 88% risk-reduction when SRM's are removed *if* 10 BSE-infected cattle were to be introduced. However, it does not appear that the risk assessment gives full consideration to the high compliance rate with the 1997 feed ban. This fact is iterated in the "Review of the Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States" prepared by RTI International.

With regard to the 1997 feed ban, it should be noted that the International Review Team (IRT) indicated in their report that it may be found that no additional restrictions are necessary if, in fact, compliance with the 1997 feed ban proves to be successful at preventing ruminant protein from being introduced in ruminant feed. As a systematic mitigation process, the IRT also suggested that an extensive surveillance program should be implemented to determine the prevalence of BSE within the U.S. domestic herd prior to the creation of additional policies.

FDA SHOULD BASE ANY ACTIONS ON THE USDA AGGRESSIVE SURVEILLANCE PROGRAM RESULTS

USDA is currently conducting an enhanced surveillance program to determine if BSE exists in the U.S. herd. This measure, as indicated by the IRT, serves as another important firewall and should be used as an important tool by governmental agencies in determining policy changes. To date, over 32,698 cattle have been tested without finding a single case of BSE. FDA should appropriately consider this fact as it determines any policy changes. The Agency should allow USDA to continue its program and issue a report prior to proposing any additional policies. In fact, the IRT indicated in their report that if the surveillance indicates a minimal risk of BSE according to OIE standards, no policies other than the 1997 feed ban may be necessary. The IRT also recommended that until such aggressive surveillance is used to establish the risk, the current ban is a "reasonable temporary compromise." Therefore, we stress that FDA should not act preemptively, and should allow sufficient time for the USDA surveillance program to accomplish its goal.

TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES (TSEs) ARE NOT A CONCERN FOR POULTRY

As mentioned in the Harvard-Tuskegee Risk Assessment, poultry species are not susceptible to TSEs. There have been numerous studies conducted in the U.K that demonstrate that poultry species are not susceptible to prion diseases even when the infectious agent is injected intracranially. Therefore, if the etiological agent were possibly presented to the poultry via feed or other means, the poultry would be unaffected by the BSE prion and such an occurrence would represent little epidemiologic significance given the virtually negative level of BSE in American livestock.

CONCLUSION

Our organizations strongly recommend FDA follow a policy of adhering to sound scientific research when formulating regulatory policies. The agency should not act on precautionary principle when determining policy direction, and instead should rely only on sound scientific data to justify its actions.

We commend the agency for taking a proactive stance with issuance of the 1997 feed ban. This policy decision, as well as the high compliance rate by the industry, has ultimately resulted in preventing the possible replication and spread of the prions. This policy action reflects the appropriate direction FDA should take when developing future policies.

Thank you for this opportunity to submit our comments for the public record.

National Chicken Council
National Turkey Federation
Poultry Protein and Fat Council
United Egg Producers
US Poultry and Egg Association